

Pharmacy Ethics and Decision Making

Joy Wingfield and David Badcott

Foreword by Gordon E Appelbe

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Preface

‘A primer in professional ethics and accountability for practising pharmacists.’

This was a shorthand description for this book and we should stress it is indeed a primer, a first step in introducing the reader to this topic. Nevertheless, we recognise that the content may seem a little daunting to student pharmacists and even to those already in practice. We have pitched the content principally with students, preregistration graduates and new pharmacists in mind. We hope that this is, therefore, not too elementary a level for those who are seasoned pharmacy practitioners or for those who have already undertaken additional studies in healthcare ethics or law. Moreover, we hope that many outside the profession may find the book provides a useful insight into the ethical landscape in which pharmacists practise and that it will promote recognition that pharmacists, as well as doctors and nurses (and indeed all those who work in healthcare) daily experience ethical anxiety about whether they are doing the right thing and behaving in the right way.

This book attempts to convey the scope of professional ethics as it applies to pharmacy. In doing so, we have drawn on a substantial body of discourse and writing about healthcare ethics: in many respects the principles are constant, only the application changes. In addition, we have widened our scope beyond the traditional healthcare arena to include, for example, maintenance of professional ethics in business and commercial environments and the global aspects of the pharmaceutical industry and availability of medicines worldwide. Given this scope, this book should only be regarded as a primer for the interested pharmacist. We have provided an extensive bibliography for further consideration of each topic, particularly with respect to the body of case and statute law that is relevant. We have only had space to give an overview of the key legal rulings to date; later cases may change the law and readers should always consult specialist healthcare law textbooks or websites for the latest position.

As a foundation for understanding the scope of pharmacy ethics, we have included a broad grounding in healthcare philosophy. Again,

this material can only be considered an introduction to the topic, but we have provided an extensive bibliography on which to draw. Some might argue that pharmacists and indeed most healthcare practitioners have managed reasonably well without such insight. However, we believe an understanding of the main schools of thought in philosophy helps us to understand why there is rarely one right answer to every ethical question and to appreciate the differing ways in which people reach decisions about how to deal with them.

Finally, a substantial part of our book covers some practical considerations for pharmacists. As pharmacists expand their clinical roles, their accountabilities grow and the need for ‘professionalism’ becomes more challenging. Health professionals are increasingly required to answer for their actions and we provide both an indication of where these accountabilities may arise and a review of techniques that have become accepted approaches to dealing with those associated with decision-making. We have then incorporated exemplar material from an earlier textbook, *Practical Exercises in Pharmacy Law and Ethics*, to complete the picture.

We recognise that few of us have the time or inclination to absorb a textbook at one sitting. We, therefore, suggest that perusal of Chapter 6 might be a useful first step to get an idea of what this book is about in practical terms. This chapter covers ethical principles, common applications to practice and short notes on relevant law (if any) in the same topic areas. It also uses some philosophical terms that may properly be understood by reading the first three chapters, which provide an account of healthcare philosophy. For a sobering account of how the inexorable rise in accountability manifests itself in pharmacy practice, you should read Chapter 4. Armed with this information, you will then be equipped to consider the decision-making processes discussed in Chapter 5, revisit Chapter 6 for detailed consideration of ethical issues and then move to the worked examples of problem solving in Chapter 7.

We gratefully acknowledge the help and advice we have received from many sources. Valuable oversight and review was provided by Dr Gordon Appelbe, whose name (along with that of Joy Wingfield, she hopes) is readily associated with the standard textbook for students and practitioners, *Pharmacy Law and Ethics*. Further overview and valuable suggestions for improvement were given by Dr Richard O’Neill, Associate Head of the Hertfordshire School of Pharmacy and a well-established specialist teacher on pharmacy law and ethics. Postgraduate study into pharmacy ethics is scarce, so an input from Richard Cooper (soon to be Dr), a PhD student at Nottingham School of Pharmacy, was

most welcome. Thanks are due to our ‘supporters’ for the concept and need for this book: Professors Keith Wilson, Tony Hope and Margot Brazier. Generalised thanks are due to the teachers across the UK Schools of Pharmacy, who provided feedback and suggestions through the APPLETT teaching project on the scope of this textbook; and to my students who constantly asked why there wasn’t such a book to provide all the answers to my searching examination questions! Lastly, and perhaps because I (JW) have never had the opportunity to record my gratitude elsewhere, thanks are due to Digby Emson and Barry Bycroft, who jointly created my Boots Special Chair at Nottingham School of Pharmacy and gave me a platform from which to drive forward a proper awareness and regard for pharmacy ethics.

Joy Wingfield
David Badcott
January 2007

Foreword

Preparing a new book from scratch is a daunting task. To write an original one on ethics for pharmacists is even greater, but these two authors have produced a fascinating account of theoretical ethics together with its application to pharmacy practice and present some challenging dilemmas to solve.

Both Joy Wingfield and David Badcott, who are pharmacists, have considerable experience and expertise in this topic. Joy, who is now Professor of Pharmacy Law and Ethics in the School of Pharmacy at Nottingham University, commenced her career in community practice before becoming an inspector for the Royal Pharmaceutical Society and subsequently spent several years as Head of the Ethics Division of its Law Department. David has spent many years as a philosopher in healthcare.

There are accepted standards of conduct known throughout the pharmaceutical profession. Many of these are expressed in the Code of Ethics, a document which represents the collective views of members of the Royal Pharmaceutical Society and which has been approved at a general meeting of members. The Council of the Society, through its Law and Ethics Committee and its Investigation Committee, interprets the Code and gives guidance on any matter concerning professional conduct.

Disreputable behaviour, a breach of professional responsibility or requirement identified in the Code could form the basis of a complaint of misconduct. The Council and the Statutory Committee, in considering whether or not action should follow, take into consideration the circumstances of an individual case but do not regard themselves as being limited or bound to those matters that are mentioned in the Code.

Ethics is not a new concept but until recently has been poorly taught in schools of pharmacy. A copy of the Society's Code of Ethics has been used on the basis that this was the be all and end all of ethics. However the Code of Ethics falls far short of being such, although it provides a simple guide to some of the practical applications. Fortunately, this academic attitude is changing and the pharmacy

schools have been introducing more detailed aspects of the topic. This has been partly driven by the establishment of APPLET, a project initiated and driven by Professor Wingfield, in response to the need to improve teaching of the subject. The next logical step was the production of a book on ethics aimed at pharmacists, pharmacy undergraduates and teachers to help them to understand and appreciate what ethics is all about.

Ethics is the science of morals, or moral philosophy. The principles, written or unwritten, which are accepted in any profession as the basis for proper behaviour are the ethics of the profession. Rules of law and rules of ethics are commonly held to differ mainly because the law is enforced by the state while ethics are generally only morally binding. However, they are not opposites and moral philosophy forms the basis of much of our law and reflects the moral standards of the public at large.

One of the major approaches to healthcare ethics was that embracing the four principles propounded by Beauchamp and Childress in 1989. Historically, these four principles of beneficence, non-maleficence, autonomy and justice, although subject to recent criticism by Clauser and Gert and others, have played an important role in the discussion of moral responsibility and healthcare ethics. The medical profession has for several years now been teaching the theory and concepts of ethics to its undergraduates and departments of medical bio-ethics have been established in several universities. Pharmacy has only recently engaged with the subject, but that is rapidly changing.

The practices of health professionals are now scrutinised more closely by commentators outside the professions, and the expectation of the public embraces many ethical and professional aspects of practice, thus leading to fears of potential litigation. Doctors and dentists are particularly prone to such fears following the Shipman Inquiry, and pharmacists are not immune in this regard. The media also plays its part in such tragic cases as those of Terry Schiavo, Charlotte Wyatt, Diane Pretty and others. Society had grown to believe and trust in the ethical behaviour of doctors and members of other health professions.

The lay public relies on pharmacists to ensure its welfare and the public are encouraged to seek advice from them. In addition, the pharmacy profession has long sought to enhance the standards, image and status of the profession. With their enlarged and potential new powers and enhanced status come added responsibilities and liabilities. Undertaking a more advisory role and taking added responsibilities increases the possibility of error and consequent litigation or disciplinary

action. Pharmacists must appreciate the importance and fundamental nature of professional ethics in order to avoid some of the pitfalls that may occur. In all sectors of pharmacy, it is becoming more and more important to understand the concepts of ethics and the need to comply with its principles in order to protect society at large and to enhance the status of the profession.

Pharmacists regularly face ethical dilemmas in their daily lives, and it is important that they realise the varied aspects of practice that can cause concern. This book fulfils the needs of all pharmacists and pharmacy students in this regard. An example of this is the question of confidentiality – not only when dispensing a patient's medication but in other areas where the patient has confided information relating to their private affairs. Another issue is how to respond to a request for medication details from the police or lawyers.

This book deals clearly and concisely with all aspects of ethics, whether in community, hospital, industry, business or other areas of practice. Topics include defining and discussing what ethics actually is, examining the different types of ethical approach, plus moral reasoning, professionalism, accountability and much more. These issues are all covered as both theory and as practical examples of the application of ethics in the decision-making process.

Every pharmacist and pharmacy student needs to read and inwardly digest this book with its comprehensive coverage of this vast subject, which will become more and more important in the future practice of pharmacy. The book is substantially referenced and is essential for the practicing pharmacist. It makes complementary reading to Dale and Appelbe's *Pharmacy Law and Ethics*, 8th edition, published by the Pharmaceutical Press.

Dr Gordon E. Appelbe
Independent Pharmaceutical and Legal Consultant
London January 2007

Introduction

‘The course of training...shall comprise as a minimum, theoretical and practical training in the following subjects: ...legislation and, where appropriate, professional ethics.’

So states the European Directive of 1985 (still current) that prescribes the content of the training required to become a pharmacist. When precisely, one is tempted to ask, would knowledge of professional ethics *not* be appropriate?

Like politics, ethics pervades our lives: it affects what we think, how we behave, what we believe, how we treat others, our choices of occupation and the values we choose to uphold. There are ethical issues to be considered when studying pharmaceutical practice *and* science; still more will arise in the course of practical application to our complex healthcare system; yet more when trying to accommodate the diversity of those who deliver and those who receive its ministrations.

Ethics is the business of all pharmacists to a greater or lesser degree. It is not just the concern of the few as typified by the immortal comment ‘we leave ethics to the Pharmacy Superintendent’s Office’. Nor is the Code of Ethics an additional set of rules to be mastered along with legislation, like a professional sticking plaster to cover over any gaps in the thinking of our political masters.

Pharmacy has come somewhat late to the party in relation to academic study and discourse on healthcare ethics. True, the profession has had a disciplinary tribunal since the 1930s and a form of ethical code shortly afterwards, but until relatively recently, the Code of Ethics has been rather similar to the Highway Code for drivers – read well before examination and discarded thereafter. Whereas medical ethics became a substantial discipline from the 1980s onwards and the nursing profession rapidly followed suit, there has been little recognition that pharmacy ethics might of itself warrant study. The scope of this study, suggested by Wingfield *et al.* (2004), encompasses both similarities and disparities with the standard range of healthcare ethics topics and those aspects peculiar to the profession and practice of pharmacy.

Similarly, the indicative syllabus for pharmacy could be much more explicitly defined in the area of professional ethics. The APPLET (Advancing the Provision of Pharmacy Law and Ethics Teaching) project, funded by government across UK Schools of Pharmacy, was an attempt to raise awareness amongst teachers of the possible scope of ethics teaching and to collate examples of teaching material for their use. That project and this book, particularly Chapter 6, have been informed by the consensus curriculum for medical undergraduate education, which was established in 1988. We are hopeful that work undertaken by APPLET to establish a similar curriculum for pharmacy ethics will eventually be incorporated in the procedures for MPharm accreditation by the Royal Pharmaceutical Society.

We have restrained ourselves from giving a detailed account of the history of the Code of Ethics – because Rodgers and John (2006) have already done that in the pages of the *Pharmaceutical Journal* recently. Suffice to say that the ethical norms of the profession are constantly changing and our text has been written against the background of a wholesale review of the Code between 2005 and 2007. The majority of our text was completed by late Autumn 2006, when not only was the Code itself in a state of flux but some major legal provisions covering the regulation of the profession and the operation of community pharmacies were in the process of change. This has affected the currency of some parts of Chapter 6 and the exemplars in Chapter 7. We have endeavoured to indicate where this occurs and attention is drawn to our Appendix in which we have included the latest text of the Code of Ethics, which became available as we went to press.

Finally, if you have any suggestions for improvement or complaints about our treatment of, at times, some very complex concepts, please let us know via our publishers. We think this book has the right content at the right level; let us know if you agree or think otherwise.

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Joy Wingfield, LLM, MPhil, BPharm, FRPharmS, Dip Ag Vet Pharm, FCPP, is Boots Special Professor of Pharmacy Law and Ethics at the University of Nottingham. She qualified as a pharmacist in 1971 and then worked for five years in community pharmacy. She joined the staff of the Pharmaceutical Society in 1976 as an inspector under the Pharmacy Acts. From 1986 to 1991 she was the senior administrator, and later Head of the Ethics Division in the Law Department, responsible for professional and registration matters. This was followed by nine years as assistant pharmacy superintendent for Boots. In 1977, she formed the Pharmacy Law and Ethics Association (PLEA), a special interest group for pharmacists and lawyers. From 2002, she was director of APPLET, a government-funded project to develop expertise and resources for teachers of pharmacy law and ethics across UK Schools of Pharmacy.

David Badcott, PhD, MA, BPharm, MRPharmS, is a philosopher of healthcare with a research base in the Centre for Applied Ethics of Cardiff University. A non-practising pharmacist, he worked for over 30 years in R&D in the international pharmaceutical industry, taking early retirement from a senior management post in 1994. Holder of an MA in philosophy of healthcare and a PhD in philosophy, he has a long-standing interest in the application of moral philosophy and philosophy of science to various aspects of the development, use and marketing of medicines.

From 2002 to 2004, he was a member of a project funded by the European Commission on Dignity and Older Europeans. He is a regular presenter at the annual conference of the European Society for Philosophy of Medicine and Health Care, has published several papers in the field of philosophy of healthcare and is currently a member of a Cardiff University study group on professional values.

Cases

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Chapter 6

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Re C (adult: refusal of treatment) [1994] 1 All ER 819 (Fam Div); [1994] 1 FLR 31 at 33E; [1994] 1 WLR 290.
Re F v West Berkshire Health Authority ref [1990] 2 AC 1.
Re R (a minor) (wardship: medical treatment) [1991] 4 All ER 177.
Re T (adult: refusal of treatment) [1992] 4 All ER 649 at 661 (CA).
Smeaton v Secretary of State [EWHC] 610, 18th April 2002.
W v Egdell [1989] 1 All ER 1085; [1990] 2 WLR 471; Ch 359 (CA); (1990) 1 Med LR 272.

Chapter 7

R v Bateman (1925) 94 LJKB 791 at 794, CCA.

Legislation

Chapter 6

Abortion Act 1967

Abortion Act 1990

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Age of Legal Capacity (Scotland) Act 1991

Section 1(1)(b)

Animals (Scientific Procedures) Act 1986

Births and Deaths Registration Act 1953

Family Law Reform Act Section 8(1)

Health Act 1999 Section 18

Human Fertilisation and Embryology Act 1990

Human Fertilisation and Embryology Act

(Research Purposes) Regulations 2001 SI No 188

Human Tissue Act 2004

Human Tissue (Scotland) Act 2006

Medicines (Advertising) Regulations (1994)

SI No.1932 (as amended)

Medicines Act 1968

Medicines for Human Use (Clinical Trials Regulations) 2004

SI 1031

Medicines for Human Use (Marketing Authorisations etc.) Regulations
1994

SI No.3144

Mental Health (Scotland) Act 1994 (as amended)

Mental Health Act 1983

(significant amendments were in progress at the time of writing)

NHS (General Medical Services Contracts) (Prescription Drugs)
Regulations 2004 (SI 2004 No.629)

Offences Against the Person Act 1837 and its 1861 revision

Protection of Animals Act 1911 (1912 in Scotland)

Public Health (Control of Diseases) Act 1984

Road Traffic Act 1988

Sexual Offences Act 2003

Suicide Act 1961

Chapter 7

Access to Health Records Act 1990

Data Protection Act 1998

Freedom of Information Act 2001

Health Act 2006-08-06

Human Rights Act 1998

Medicines Act 1968

NHS (Pharmaceutical Services) Regulations 2005

SI 2005 No. 641

NHS Act 1977

Pharmacists and Pharmacy Technicians Order 2006

Pharmacy Act 1954

Abbreviations

AIDS	autoimmune deficiency syndrome
EMA	European Medicines Evaluation Agency
FIP	Federation Internationale Pharmaceutique (International Pharmaceutical Federation)
GP	general practitioner
GPEU	Groupement Pharmaceutique de l'Union Europeane
MEP	<i>Medicines, Ethics and Practice</i> Guide of the RPSGB
NICE	National Institute for Health and Clinical Excellence
NHS	National Health Service
NPA	National Pharmacy Association
PCO	Primary Care Organisation
PIP	Paediatric Investigation Plan
QALY	quality adjusted life years
RCP	Royal College of Physicians
RPSGB	Royal Pharmaceutical Society of Great Britain
TRIPS	Trade Related Aspects of Property Rights
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

1

Ethical theory

Why do we need a focus on pharmacy ethics?

Most people don't appear to give a great deal of thought to their own behaviour whether concerning domestic affairs or work-related activities unless there are special circumstances. If we do take time to reflect, many of our actions appear to be instinctive or virtually automatic: just plain routine or common sense. We seem to know how to behave and simply get on with it. For experienced practitioners, a great deal of their professional lives is devoted to dealing with relatively routine matters – transactions that are not markedly different from one client to another – and in these we tend to follow regular sequences or informal algorithms. Nevertheless, irrespective of formal or informal routines, the necessity of being 'accountable' for one's actions is always an important consideration to be kept in mind. In community or hospital pharmacy these procedures include, for instance an obligation to:

- check that regulatory requirements are met
- that a prescriber's intentions are unequivocal
- that there are no potential drug-drug interactions or other incompatibilities
- that patients receive clear and unambiguous advice and instructions with their medication.

All of these considerations can be categorised as being *objective* or factual matters, largely uncoloured by feelings or opinions. There is either compliance with an established requirement or there is not. A pharmacist may consider that a particular drug is not classified in the most appropriate schedule or that one therapeutic agent or presentation might be preferred to another. But more often than not, he or she has little or no discretion in these matters and such opinions must defer to statutory requirements or to a prescriber's choice.

Changing times

Over the last few decades, healthcare workers, have become increasingly aware of aspects of daily life that have a moral dimension, and

consequently are far less susceptible to routines. Many of these are issues that impinge on health and illness. Matters of life and death have become much more prominent because of increasing possibilities of therapeutic intervention, legal challenges and media coverage. The more morally aware and better-informed climate of the present time means that pharmacists can no longer assume that moral considerations are outside their area of professional responsibility. Indeed, the transition of pharmacy practice to embrace pharmaceutical care may have increased the likelihood of encountering ethical conflict (Latif 2000). Pharmacy has been characterised as a marginal or incomplete profession because it includes both professional (requiring judgement and expertise) and non-professional (repetitive, service routines) duties (Latif 2000). The need to provide professional advice and counsel patients whilst managing the routines may be a source of conflict (Strand 1998): ‘Pharmacists could not dispense drugs and take care of patients at the same time’.

For those involved in community pharmacy or in clinical pharmacy in a hospital setting, it is most probable that beginning of life or end of life issues may cause increasing moral concerns in the future. Hanlon *et al.* (2000) noted in a survey of the views of community pharmacists on physician-assisted suicide that while pharmacists wanted to be regarded as ‘key members of healthcare teams...a proportion of respondents in the study [would] have no desire to take responsibility for their actions and prefer to remain in ignorance of the true purpose of a prescription for physician-assisted suicide’. Some of these considerations are discussed in Chapter 6.

RPSGB guidance

To a large extent, it is possible to characterise the values of a society or profession by focusing on attitudes relating to moral contexts, and to tease out the moral boundaries. All pharmacists in the UK and in many other countries are members of a professional body that publishes and requires members to comply with a code of practice. The publication *Medicines, Ethics & Practice: A Guide for Pharmacists and Pharmacy Technicians* (MEP) of the Royal Pharmaceutical Society of Great Britain (RPSGB) includes information on general legal requirements, and codes of ethics for both pharmacists and registered pharmacy technicians. Generally, there is a view that:

- the law informs you about what you *must* do or *must not* do
- ethics helps you to decide what you *ought* to do when the law is silent (Washington School of Pharmacy 2005).

For outline advice on ethics, UK pharmacists can turn to the RPSGB practice guidelines for a brief definition of ethics, reference to ethical dilemmas and matters of conscience and other considerations such as confidentiality (MEP July 2006, pp. 89, 90):

Ethics has been described as the systematic study of moral choices; it concerns the values that lie behind them and the language used to describe them. Ethical decision making is the process whereby one recognises that a problem needs to be overcome or a difficult choice made, identifies the possible courses of actions, chooses one, takes it and then accepts responsibility.

(When)...faced with **ethical dilemmas** pharmacists are expected to use their professional judgment in deciding on the most appropriate course of action (and) must be able to justify their decisions to their peers, and to any person or organisation which may be affected by their actions, including individual patients, the public, the National Health Service, their employers, and other health care professionals.

Before accepting employment pharmacists must disclose any factors which may affect their ability to provide services. Where pharmacists' **religious beliefs or personal convictions** prevent them from providing a service they must not condemn or criticise the patient and they or a member of staff must advise the patient of alternative sources for the service requested.

A fundamental review of the Society's Code of Ethics for both pharmacists and pharmacy technicians is underway (RPSGB 2006). A revised code is likely to reflect seven proposed key principles:

- make the care of patients your first concern
- exercise your professional judgement in the interests of patients and the public
- show respect for people
- encourage patients to participate in decisions about their care
- develop your professional knowledge and competence
- be honest and trustworthy
- take responsibility for your working practices.

What is meant by a principle? Principles are considered to be fundamental truths or laws that we employ as a basis for deliberation or reasoning, or in deciding what action to take. Sometimes the term 'principle ethics' or 'principlism' is used when a set of so-called *prima facie* ('on the face of things' or 'at first sight') obligations form the basis of a particular approach.

The Code of Ethics is likely to be sent for approval in May 2007 and the latest version is reproduced in the Appendix. Readers are advised to check on the RPSGB website www.rpsgb.org for later updates.

What is morality and should we use the term moral or ethical?

The term morality refers to right moral conduct or a moral system, and by 'moral', we generally mean those aspects reflecting the rightness or wrongness of an action or relating to the goodness or badness of human character or behaviour. The words 'moral' and 'ethical' are often used as synonyms. 'Ethics' comes from the Ancient Greek word *ethikos*, relating to nature or disposition, and 'moral' is derived from the Latin *moralis*, meaning custom. In modern usage, 'moral' commonly refers to qualities or descriptions such as right or wrong, good or bad, or is concerned with conformance with behavioural standards – in other words, practical application. Generally speaking, 'ethics' is used in dealing with moral questions from a theoretical point of view, or put more formally, it is the science of morals in human conduct. Hollis (1989) provided an excellent metaphor that encapsulates the importance and function of morality:

....every society needs moral glue, a shared conception of the good, since otherwise it will disintegrate. It is useful from an individual point of view, because life goes better if one has learned to accept the values of the society one lives in. ...Values function only if they are thought useful because they are valuable, not thought valuable because they are useful. Also there are many sets of values which could do the job, and each society needs to sanctify a particular one. But both points are met by teaching that there is a truth about how one should live.

Ethical norms

Ethical norms are rules of behaviour to be complied with or used to evaluate or direct human conduct. In other words, they are firm guidelines on how we should live. The word norm, like the adjectival form normal, implies senses of both conforming to a standard and such that it ought to be – which are quite separate matters. Normative ethics concerns basic questions such as: what is right and wrong, good or bad. To put this another way, which actions should I perform and which should I avoid? There are important links with what things are considered to

be intrinsically valuable. It is often the case that departure from recognised ethical norms renders a person liable to some form of criticism or censure: for instance, if we disapprove on moral grounds we may say that an action is blameworthy; whereas approval of an action within a moral context is spoken of as being praiseworthy.

Moral intuitions

Although some might argue otherwise, moral considerations are to a significant extent *subjective*, relating to upbringing, cultural background, reflecting personal experiences and feelings or religious teaching and faith. But if so, they are no less important for being even partially subjective. Often, though unable to explain exactly why, we may feel intuitively that something is just plain right or wrong: an action ought to be allowed or conversely should not be undertaken. Sometimes we have the sensation that *conscience* would not allow us to behave in a certain way. We may not have given any special consideration as to why, but we know that there is something seemingly within us that provokes a sensation of unease or indeed more emphatically that something is just plain right or alternatively it is wrong.

So strong and commonplace are such feelings that it was believed that all human beings had within them an immediate, and intuitive grasp of the fundamental principles of morality (sometimes referred to as *synderesis*), which unlike conscience is both infallible and general (Blackburn 1994).

In recent times, philosophers who supported the view that moral rules or principles can be discovered by intuition were known as intuitionists. W. D. Ross, a Scots philosopher, was an intuitionist and wrote an influential book *The Right and the Good* that examined the nature and implications of right, good and morally good (Ross, 1930). There are few, if any, active intuitionists today: ‘No one doing practical ethics thinks, talks, or acts as if she can adequately resolve a practical ethical controversy simply by appealing to her intuitions, about practical ethical issues. If nothing else, she must argue from those intuitions before she can reach conclusions about practical ethical issues’ (LaFollette, 2005, p. 6).

Nevertheless, for many people intuitions are at least starting points in ethical deliberation. We might say for example ‘that we believe intuitively that all killing is wrong’. But even a perhaps longstanding and obvious conviction such as this should be subjected to the same intellectual challenge as any other moral premise (a premise is a proposition

from which another can be inferred). For instance, it is appropriate to ask: Is the sense of being wrong fundamental or is it supported by or consistent with other established ethical principles? Of course there is a world of difference between having a view about the morality of a decision or an activity we are unlikely to experience at first hand, and being in an operational situation, able to influence matters, or as it were being put on the spot. We can all be theoretical ethicists and offer opinions on what we hear on the radio, watch on television or read in newspapers, and debate with passion at the pub or around the dinner table. But there is nothing quite like actual involvement to focus the mind and cause us to reflect on our actions. This may sometimes lead us to adopt rather different attitudes and behaviour than we might otherwise suppose.

Pharmacy ethics

Although the term *pharmacy ethics* is often directly linked with *pharmacy law*, it has received relatively little attention in the past as a distinct discipline. And while medical ethics has a long history and is often the subject of coverage in the news media, and nursing ethics has become increasingly prominent over the last few decades, pharmacy ethics does not have a well-established independent basis or a substantial literature (Wingfield *et al.* 2003). A reason for this may be that pharmacists have been far less likely in the past than other healthcare workers to be directly confronted with situations in which they have to make a primary decision with a significant ethical component. Nevertheless, as will become clearer within this book, all pharmacists irrespective of the branch of the profession in which they practise will almost certainly encounter circumstances at some time within their careers in which an understanding of some of the elements of moral philosophy and ethics would be advantageous.

While they are not regularly primary decision-makers on ethical matters, all pharmacists are members of organisations or are participants in activities where decisions with a moral consideration are made. They can choose whether to acquiesce and simply go along with the decisions of others – it really isn't my responsibility or my business – or be prepared to make a considered contribution. In many cases, the stance may be entirely unproblematic. However, occasionally, if they are involved in the implementation of a decision, a pharmacist may take the view that at very least by implication they cannot dissociate themselves entirely. The trend towards team working, particularly in a hospital environment, may increase the likelihood of this.

Community or hospital pharmacists may be uncomfortable with some aspects of reproductive therapy and industrial pharmacists feel concerned at the promotional practices of their company. Later, in Chapter 6, we shall discuss terms such as complicity, being an accessory or enabler, referral, rights and obligations in this respect. At the very least, it is important that all decisions, whether of a technical or ethical nature, should be rational, impartial, consistent and accountable. Only on this basis could a pharmacist be considered to have acted in a sound professional manner.

Facts and values

It is worth noting a fundamental difference between facts and values, which to some extent parallels the difference between objective matters and subjective matters. Facts and values are often perceived as being polar opposites (Elgin, 1997). The one indisputable (facts) and the other (values) much more open to question. For instance, facts or objective claims are susceptible to empirical analysis or experimentation. They can be investigated and confirmed. If a factual claim is made that acetylsalicylic acid has a molecular weight of 180.2, then there are established and approved means of verification which most competent scientists would accept.

By comparison, to claim that it is wrong to lie or steal or to intentionally terminate the life of another human being expresses a subjective value claim. To be clear, what is meant here by 'subjective' is that it represents a personal point of view. Whether few or many share that point of view does not influence its subjectivity. Indeed, the claim may not be universally agreed. Even members of the same family can have different views, say on the sanctity of human life, and people across a wide social, cultural or religious spectrum will almost certainly recognise a diversity of values in their daily lives. So for these reasons alone, it is difficult to entirely rebut charges of *relativism* (relative to a particular standpoint) or *pluralism* (the existence of different and possibly incommensurable views) in values. For fuller discussion on values generally, and the objectivity or subjectivity of values, readers are referred to Pepper (1949), Mackie (1977), Blackburn (1994), Collier (2000), and Pattison and Pill (2004).

It is important to understand that numbers alone do not determine whether a value is considered to be a moral value. Even if the majority of the population under an extreme regime believed that it was right to persecute or to humiliate members of an ethnic minority, this would not

of itself make it morally right. Quite the contrary; but why? Because we believe that values are intimately tied to moral conduct. A society that practised humiliation, persecution, slavery or other vile acts would be an immoral rather than a moral one. That all of these practices have previously occurred and been condoned, but would now be rightly condemned, reflects not that morality is relative but the moral poverty of those particular cultures. Do football hooligans individually or collectively express values? Yes, in the sense that what underlies their behaviour has value in their lives. But to value aggression, casual violence, disorder and social deviance can only be achieved by denying moral values. We shall see later that moral values can be closely associated with what are known as moral virtues.

Indeed we must take care in talking of values to be clear whether we are referring to what might be termed social values, the collective value system of a community, or personal values. Do social values exist other than as a rough guide to what communities by and large value? Perhaps Margaret Thatcher intended to argue against assuming homogeneous community values in her statement that 'There is no such thing as society: there are individual men and women, and there are families'.

A fundamental problem in 'values talk' generally is not only whether values should be considered as subjective or objective but also that the concept of values itself is not fixed. As with many terms or concepts in philosophy, there is no single and universally agreed statement of the meaning of value or values. It is expressed by a multiplicity of definitions and understandings (Pattison and Pill, 2004). For some interesting and lively debate on the meaning and role of pharmacy values, see Cribb and Barber (2000), Barber (2000a–c), Holloway (2000) and Hepler (2000).

In exploring some of the basic elements of moral philosophy, we need a rather pragmatic and tangible interpretation of what values are. Perhaps the simplest approach is to take *normal values* as being 'close to the sociological notion of norms, rules, habits, expectations and assumptions', and *aspirational values* as reflecting 'notions of ideas, goals and visions that are sought rather than assumed' (Pattison and Pill 2004, pp. 7–9). Our personal values might reflect, among others, notions of honesty, integrity, tolerance, dignity, consideration and respect for persons and the environment, and friendship. In our professional lives we perhaps place particular emphasis on aspects of autonomy, dedication, conscientiousness and loyalty. Of course, what is of most interest to us here are 'moral values' and how to take moral values into account in decision making in pharmacy practice. Blackburn

(1994) indicated that ‘To acknowledge some feature of things as a value is to take it into account in decision-making, or in other words, to be inclined to advance it as a consideration in influencing choice and guiding oneself and others’.

Whether value subjectivists or value objectivists, we may allow that there will almost certainly be at least some subjectivity and valid disagreement on moral matters. That aside, considering an action to be right or wrong is of an altogether more profound significance than expressing a liking say for strawberries or the music of Mozart or disliking the works of a particular artist. The important thing to note is that while susceptible to analysis and debate, moral value claims are not empirically demonstrable. Most people would agree that it is unthinkable to contemplate deliberately killing someone to demonstrate that it is morally wrong to do so, neither would or could the killing itself demonstrate the *wrongness* of that action.

Yet it seems that the sense of the wrongness of an action is already programmed within our personal consciousness and reflects, yes, our values, our judgement of what is valuable or important in life. The word *wrong* itself in the moral sense conveys feelings of deep unease that are difficult to capture in a concise definition, and we may fall back on examples of what we mean in order to convey this impression. Analysis of the perceived wrong doings of contemporary or previous societies, or perceptions of what constitutes a good life can provide valuable insights into human morality and what is to be understood by wrong and good (see, for example, Glover 1999).

Moral relativism

What is considered to be wrong in the moral sense undoubtedly can and does sometimes change with time, laying all contemporary opinions open to a charge of *moral relativism*. In other words, what we believe to be right or wrong now may be judged differently in the future. Such thoughts of relativism have a long history, and Aristotle (384–322 BC), taught that whereas natural laws are immutable, that is unchangeable, not subject to variation, and have the same validity everywhere (as fire burns both here and in Persia), notions of justice (or men’s ideas of right and wrong) are variable (see Barnes 1976, p. 190). Aristotle’s example neatly emphasises the difference between a fact (in this case aspects of combustion) and a value (justice). The ancient Greek historian Herodotus (447–449 BC) highlighted cultural preferences for religious rites and customary observances:

For if one should propose to all men a choice, bidding them to select the best customs that there are, each race of men, after examining them all, would select those of their own people; thus think that their own customs are by far the best’.

In particular, Herodotus noted that it is customary to eat their deceased parents in some cultures and in others to ‘consume with fire’, or as we would now say cremate, but that the reverse would be unthinkable. We may counter the accusation of relativism by arguing that what is understood as moral progress is more a question of moral enlightenment following the perceptive analysis of some of the major European philosophers of the past and present, such as Kant, Rousseau, Hobbes, Locke, Hume and others. In the past, we just got it wrong, but now we know better. Though this does not altogether refute the charge; even in science, the notion of progress is not entirely value free. Fortunately, many of the changes, mostly supported by legislation, seem unequivocally obvious to a modern society. Like hindsight generally, moral hindsight, has the advantage of observing the consequences of change. We have to imagine ourselves in earlier centuries to begin to understand the unthinking toleration of slavery, the subjugation and lack of the franchise of women in a largely paternalistic society, and the appalling treatment of children in factories, as servants and in other harsh or arduous employment.

However, before we become too self-congratulatory, we must not forget that homosexuality was a criminal offence just a few decades ago in the UK and that racial segregation was exercised and legally enforced in the southern USA and in South Africa. Some recent legislative changes relating to moral principles such as banning the smacking of children (physical assault and infringement of autonomy) and prohibiting smoking in public places (a contentious competing rights/liberties issue) have not been universally welcomed. The law does not always reflect majority public opinion, as evidenced by various surveys carried out since the permanent abolition of the death penalty for murder in the UK in 1969.

Undoubtedly there are people who are in effect *amoral* or take a markedly atypical view of common morality. For some reason or other, although they may have grown up in circumstances with peers who generally share similar moral attitudes, the amoralist has no compunction about flouting or disregarding commonly accepted moral norms or reservations. The vast majority of people do, however, appear to have an intrinsic *moral portfolio*, which although varying from person to

person tends to include some fairly common elements like respect for human life, truth telling, justice and keeping promises. The moral philosopher R. M. Hare (1981) observed that: ‘...human beings...have adopted or inherited...the intuitive level of moral thinking with its *prima facie* principles, backed up by powerful feelings and attached to rather general characteristics of actions and situations’.

This seems to provide a good summation of the key points for consideration. There are certainly cultural overtones from our upbringing and experiences that relate to personal tastes and preferences, and perhaps generalisable principles to uncover. We may be able to rationalise some aspects of individual inclinations, but we shall need to probe much deeper to discover the nature and origin of moral disposition, and to be able to successfully navigate moral issues.

Varieties of ethical theories and concepts

A significant problem both with and within ethics is that there is no universally recognised and agreed ethical theory or ethical system. That this state of affairs is decidedly not due to oversight or neglect is indicative of the difficulty. Numerous philosophers and theologians have endeavoured to identify and clarify ethical principles over the centuries. In the twentieth century, there have been many attempts to get to grips with some of the fundamental problems and to formulate a widely acceptable ethical theory. That no one has yet succeeded perhaps indicates that no single system is capable of satisfying everyone and may indeed indicate something of the nature of ethics or for that matter of philosophy – there is no ultimate solution! That in itself is a measure of the problem faced by authors in writing a worthwhile textbook on pharmacy ethics and indeed every human being in confronting ethical issues.

Philosophical ‘isms’ abound, and there appears to be no limit to the number of competing ethical theories or variants that have been actively pursued over the years, and indeed centuries. Many have come and gone or have been recycled in a new form. But there are three major theories or rather theoretical concepts that individually have received fairly wide contemporary support and are often cited in ethical discussion. Two other approaches, ethics of care and clinical pragmatism, are introduced in Chapter 2.

These key three concepts are:

- deontological ethics
- consequentialist ethics
- virtue ethics.

Each theory adopts a different focus, baseline or emphasis as being pivotal in addressing moral questions, and hence can lead to alternative conclusions in considering what should be done in particular circumstances. The first two, deontological ethics and consequentialist ethics, are based on identified principles in the same way that nominated principles are likely to form the basis of a revised RPSGB Code of Ethics. The use of principles in this way is sometimes referred to as principlism. And principlism generally has the advantage of offering a clear-cut and well-defined basis for that particular approach.

Deontological ethics

Deontological ethics is essentially a duty-based theory with its roots indicated by a Greek word denoting that something is binding. Within this system, duty-based principles reflecting rights or what is right, are considered to be fundamental and mandatory, and take precedence over any consideration of outcome. As with all ethical theories, but especially in deontological ones, considerable emphasis is given to the importance of respect for the special status of human beings, a respect that should not be ignored and cannot be overridden. This respect is clearly apparent in the United Nations' Declaration of Human Rights of 1948, where the term dignity is also given prominence: 'Whereas recognition of the inherent dignity and of equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world...'.

It seems that the special nature of human beings is encapsulated in the property of dignity and, by implication, that possession of dignity entitles all human beings to certain inalienable rights or entitlements. We shall need to look carefully at just what these rights and entitlements (and indeed implied responsibilities) are and how they are derived. Another way of expressing the concept of dignity is to say that all human beings have intrinsic value, not of course monetary value or in terms of capabilities with a market value but because they possess certain inherent characteristics that distinguishes members of the species *Homo sapiens* from all other living things.

A point to note and to which we return later is that *all* human beings are included. Being mentally or physically compromised, being an infant or senile or indeed even deceased does not curtail the intrinsic dignity or value of that extant or former human being, and their entitlement to respect. We may even feel that the dignity of these individuals is a ground for deserving enhanced respect. Central to the notion of the

intrinsic value of human beings on this account is that of having a value independent of external reference or consideration. In other words, *value* in this sense just goes with being human, it cannot be further qualified or quantified. It does not depend on adjudication or the assessment of others.

This independent dignity or value stems partly from possession by human beings of a personal autonomy, that is:

- a capacity for judgement, and reflection
- an ability to decide and follow actions that are truly of one's own choosing.

Note however, that diminished or absent autonomy, as in the cases listed above (mentally or physically compromised, infants, etc.), does not invalidate intrinsic dignity or respect. We do not undertake the equivalent of animal testing of new drugs on such individuals. The Australian philosopher Peter Singer (2000, pp. 51-53), provocatively in order to reinforce his objections to animal experimentation (see also Chapter 6 of this book), has suggested that scientists should be asked 'whether they would be prepared to use a brain-damaged human being at a mental level similar to that of the animals they are planning to use'.

Singer's question, which some might find offensive or disturbing, is nevertheless entirely valid. This is not because we suppose that Singer seriously proposes that any human being should be subjected to 'animal testing' in the common understanding of the term. But rather he causes us, or rather should cause us, to think very carefully about the nature of our reasons for the moral acceptability of the one and the unacceptability of the other, and importantly, the relationship, if any, between the two. A response to Singer, at least in part, is to emphasise that *only* human beings have the capacity for judgement and an ability to undertake moral reflection. And all human beings are part of a species continuum that spans the autonomous, the mentally impaired and the deceased (Badcott 2003, pp. 127-128). Humans can contemplate the morality of their own actions and those of others, the ways in which we treat animals and our fellow human beings. Whatever animals do that appears to be altruistic is considered to be purely instinctive rather than reflective. Nevertheless, the UK embargo on the use of the great apes in medical research suggests that we do have speciesist qualms or reservations about using our nearest animal cousins for these purposes. UK research on great apes including chimpanzees and gorillas was banned in 1998, though it has been suggested that the ban might need to be reconsidered in relevant circumstances.

Immanuel Kant (1724–1804) was a formidable German philosopher, one of the great intellects of his time, whose influence extends to the present day. One of Kant's most important works in philosophy is the *Critique of Pure Reason* (1781), by which he means reason not influenced by experience. Later works focused on practical reason and the sphere of moral philosophy. Kant is notable for his attempt to identify a single overriding moral principle. Such a principle should have a rational basis that would be clear and binding. This would ensure that moral actions lead rather than respond to 'the passions' (or what we would call emotions). Interestingly, this notion is at variance with the Scottish philosopher David Hume (1711–1776), much admired by Kant, who considered that: 'Reason is and ought only to be the slave of the passions, and can never pretend to any other office than to serve and obey' (Hume 1739–1740). A modern philosophical interpretation based on evolutionary theory (naturalistic psychology) would suggest that it is advantageous to take account of both emotions and cognitive processes as providing a more reliable account of human moral motivation (Teehan 2003). Indeed human emotion is taken into account in both virtue ethics, discussed later in this chapter, and in ethics of care, which is covered in Chapter 2.

Returning to Kant, he concluded that morality is grounded 'not in the nature of man, nor in the circumstances of the world, in which he is placed, but solely *a priori*, in the concepts of pure reason'. The Latin term *a priori* means in effect that something is known or can be derived without having experience of it. Therefore, we can know it in advance. This is at variance with empirical evidence, which we are most familiar with in pharmacy: the sort of information obtained by observation, experimentation or reference to a reputable source. In Kant's view, we ought to be able to derive moral principles by the application of high-quality thought. There are three major components of Kant's approach to deontology:

1. Recognition of the objective worth of human beings that roughly equates with intrinsic value and particularly to autonomous status, and an ability to reflect and act
2. The role and force of categorical imperative
3. The 'universalizability' principle.

Kant, who was a firm advocate of respect for law, thought that 'a law has to carry with it absolute necessity if it is to be morally valid'. He considered that moral judgements should be a response to law-like *categorical imperatives* (unconditional moral obligations), and distin-

guished two varieties of such required reactions. These *hypothetical imperatives* could be divided into

- *technical imperatives* that relate to means for achieving a particular end, e.g. 'if you intend to arrive on time, then you should set off from home at 11:30 am'
- *assertoric imperatives* that relate to more generally shared human aspirations such as being in good health, e.g. 'if you wish to remain healthy, then you should eat fruit and vegetables or take regular exercise'.

Clearly, these types of logical imperative can be negated simply by abandoning the stated hypothetical objectives of wishing to arrive on time or being concerned with one's state of health. By contrast, categorical imperatives are of a quite different nature: they are unconditional and have mandatory force. Their validity is not derived from stated hypothetical conditions such as *if ...so and so.*, but from 'pure reason'; therefore, the imperative cannot be avoided or invalidated.

For Kant there was one supreme categorical imperative grounding all morality. The 'universalizability principle' requires us to act 'only on that maxim through which you can at the same time will that it should become a universal law' (sometimes referred to as the 'golden rule' – or more colloquially, as 'do as you would be done by').

Familiar examples of categorical imperatives are, as previously mentioned, telling the truth and keeping promises. Being told that you ought to do something because you promised you would cannot be countered simply by an assertion that you don't want to do it, without a risk of being reminded that you really ought to keep your promises. Similarly, lying for personal advantage or to avoid unpleasant consequences is at variance with the categorical imperative of telling the truth. The social importance of moral imperatives such as these is not difficult to appreciate. Acknowledging or expressing a categorical imperative commits a person to the requisite behaviour or action.

Outside of totalitarian regimes, social relationships can only function tolerably well where the majority of members of a society can be relied upon to deal equitably, tell the truth, keep promises and refrain from killing each other. So we might say that categorical imperatives are among the necessary conditions of a stable society or for that matter families or small social groups. Individuals who 'free ride' or flout such imperatives, as some certainly do, might gain an advantage but could not object if others did the same. Defaulting on promises or telling lies could not be established as a universal law without obviating the

possibility of individual gain. If everyone or the majority flouted the law then no-one gains and the rule of law breaks down.

The notion of majority consensus is important, though it is also important to understand that moral imperatives do not depend on consensus or popular support. Disregarding a moral imperative even by a majority does not invalidate that imperative, though there may be disagreement about the nature of an imperative and its implementation. The imperative against killing fellow human beings may convince some that capital punishment is unacceptable, but they nevertheless accept the necessity of supporting a 'just war' in which inevitably some will be killed. We rightly expect friends, family, politicians, our neighbours and colleagues and indeed anyone who influences our daily affairs to behave on the basis of categorical imperatives. They may tell us if they consider that we are in default, and for that matter, we may be reminded by that still small inner voice of conscience!

As indicated, deontological ethics is primarily concerned with duty irrespective of outcome. The moral rightness of an action largely depends on following imperatives and not in considering consequences. Thus 'do not kill innocent human beings' takes precedence over consideration of whether the deliberate or probable death of an individual might result in saving the life of one or more others. On this basis, deliberate termination of a pregnancy even though a mother's life is threatened by a pregnancy-related illness is morally unacceptable. Bombing an armaments factory located close to a residential area should not be undertaken even though the weapons being manufactured are destined for use against civilian targets and would probably produce far more casualties. Refusing to tell a lie to protect the life of a fugitive could not be condoned.

These examples are deliberately stark and somewhat extreme but emphasise the basic problem of decisions that rely exclusively on deontological ethics. The fact that in practice markedly different paths have been followed in very similar circumstances should surprise no one. An exclusively deontologically based decision made without full consideration of possible consequences would rightly be condemned as, at very least, ill judged.

Consequentialist and utilitarian ethics

The polar opposites of deontological ethics, but also based on identified principles, are varieties of consequentialist ethics. As the name suggests, the main consideration of consequentialist ethics is instrumental,

favouring action that will achieve the best possible consequence or result. The concept makes clear that it is not the nature of the action but its outcome that is most relevant in ethical behaviour. But this raises important issues of just what constitutes the best consequence: how is this to be assessed and, importantly, the best consequence for whom? We have markedly different possibilities ranging from the rather hedonistic to the more health related or perhaps even aesthetic, and various proposals have been made over the years as to what constitutes the most desirable consequence for human beings: among nominations are happiness, pleasure, absence of pain, well-being and flourishing.

But should we consider that pain and happiness are the two extremes of a spectrum? Particular concepts or varieties of pleasure and fulfilment for one person may be anathema to another. Some individuals may be relatively pain tolerant or able to accommodate more painful conditions. Indeed a substantial or complete absence of pain response, as with the very rare condition of congenital analgesia, is distinctly undesirable. Furthermore, there are important considerations concerning the extent to which some 'desirable' consequences for an individual may verge on self-centredness or self-interest, and there is always a risk of charges of egoism.

One particular version of consequentialism is utilitarianism, which owes its foundation to Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873). There are two main interpretations of utilitarian theory:

- act utilitarianism is generally associated with Bentham, who argued that the value of an act derives from the extent to which it increases general utility or happiness
- rule utilitarianism focuses on accord with rules of conduct that if followed will lead to the greatest happiness.

Within these theories, numbers become a relevant consideration. Thus the life of an individual might be held to be less valuable, if as a consequence more lives could be spared. For a valuable discussion of the arguments for and against utilitarianism, see Smart and Williams (1987).

Virtue ethics

An approach to ethical theory that has found favour in recent years in healthcare is virtue ethics. The concept is sometimes referred to as being aretetic, which simply means that it relates to goodness, excellence or

virtue, *aretê* being the ancient Greek word for virtue. Not surprisingly, therefore, the principle focus of this theory is on the moral uprightness or the goodness of the individual, or as we might say their character. The nature of any action undertaken is to some extent secondary, but only because it is to be expected that a virtuous person will have a disposition to behave morally. The virtues themselves are familiar character traits, such as being trustworthy, loyal, generous or helpful, and their association with an understanding of morality can be traced back to Aristotle (see Barnes 1976, p. 99): 'We are praised and blamed for our virtues and vices...our virtues are expressions of our choice, or at any rate imply choice'. In considering the character traits that help to make a good person good (in the moral sense), Aristotle's older contemporary and former teacher Plato (427–347 BC) identified four cardinal virtues: temperance (or moderation), justice, courage and wisdom. Aristotle himself concentrated on moderation, sometimes referred to as the Golden Mean.

By and large, indeed some people might say invariably, human beings have a choice as whether to act virtuously or unworthily. In doing so, they may bring approval or discredit on themselves. Indeed, members of the pharmaceutical profession are expected to conduct not only their professional practice in a proper manner but also to behave in their private lives in a way that does not bring discredit on the profession. 'Disreputable behaviour' could be the basis of a complaint of professional misconduct. MacIntyre (1999) has some interesting discussion on individuals moving from one role to another within their professional and the domestic lives, and exchanging sets of 'standards' required for decision making. Virtuous behaviour means, in effect, not choosing an action simply because it might gain brownie points, or not choosing it because you might be discovered and punished. Rather it means accepting that telling the truth or not behaving in a disreputable manner is reason in itself. And that applies in all our dealings, not just, so to speak, when on professional duty or wearing a white coat. It is only by 'living' virtues that virtuous behaviour becomes second nature.

In his book known as *The Nichomachean Ethics* (see Barnes 1976), Aristotle provides a comprehensive listing of both virtues and vices and indicates the fields in which they are operative. These virtues and vices are sometimes termed the 'v-list'. Vices are seen as extremes, with either excess or a deficiency, and virtues are ideally balanced between these extremes (hence Aristotle's 'doctrine of the mean'). For instance, within the sphere of pleasure and pain we find, respectively, the excess of licentiousness, insensibility as a deficiency, and temperance

as the virtuous mean. In the sphere of self-expression, boastfulness is an excess, understatement a deficiency and truthfulness the mean. Some spheres or actions like adultery, theft and murder are considered to be 'evil in themselves; it is not the excess or deficiency of them that is evil'.

To understand the role of the virtues in Aristotelian ethics properly, it is also necessary to appreciate the notion of *teleology* or ends and purposes. Everything in nature including human beings has its purpose or *telos*, and virtues enable their possessor to function well and to achieve the *telos* of *eudemonia*. The Greek word *eudemonia* is generally interpreted as being roughly equivalent to human flourishing. Within this, we might include, for example, being prosperous, successful, being self-fulfilled, being happy, being in good health or even a combination or all of these things. The term well-being is quite often used in this respect, particularly in a healthcare context. Pharmacists contribute to the maintenance or restoration of a patient's *telos* or well-being through the medicines and therapeutic advice provided.

But the *telos* for human beings also includes the exercise of reason. Aristotle emphasised that humans are distinguished from other animals by having the capacity to reason. According to Aristotle, our purpose or *telos* in this world is to develop and nurture reason to the best of our abilities, and live our lives accordingly. You may have noted the importance that Immanuel Kant also placed on human reason. Thus we may flourish and be happy in a non-instrumental way; that is not as a consequence of our particular actions but in having used our minds well.

Doubtless we ourselves should like to cultivate these elements, virtue and reason in all of our decision making. It would be nice to think that we are virtuous people and that all of our actions are compassionate and soundly based. So, can we take it that that is about all there is to virtue ethics? Well, even the experts consider that there isn't a satisfactory short answer to the question of 'What is virtue ethics?' (Hursthouse 1999). There are no simple 'v-rules' to employ that will tell you exactly what to do and how to behave in a moral context, and just as importantly, how not to behave. The right action is just what a virtuous agent would undertake in the given circumstances.

Another important Aristotelian concept is *phronêsis*, usually translated as practical wisdom, which is wisdom that comes with experience whether in pharmacy or any other discipline. Pharmacy graduates are required to undergo a period of practical experience, the preregistration year, before being admitted to membership of the Society. Moral

wisdom and virtuous behaviour are a little like that, but without the official period of supervision, although we can all identify ethical behavioural role models in our own lives. Hursthouse (1999) emphasised this important Aristotelian insight:

...that moral knowledge, unlike mathematical knowledge, cannot be acquired merely by attending lectures, and is not characteristically to be found in people too young to have much experience of life. We do not think of moral or practical wisdom – of knowledge of what one should do – as easily come by, as something that an adolescent is likely to have, even if the adolescent is a genius at mathematics or science or the stock market and has been to lectures on normative ethics.

Although it is sometimes said that virtue is its own reward, virtue ethics does not altogether rule out feelings. The Scottish eighteenth century philosopher David Hume also emphasised the emotional response that often accompanies moral situations and defined virtue to be: ‘Whatever mental action or quality gives to a spectator the pleasing sentiment of approbation; and vice the contrary’. Feelings or emotions are not central to virtue ethics (they are not the primary motivation), though there may be a certain satisfaction in ‘doing the right thing’, particularly where this comes at significant personal cost or perhaps has required an individual to rise above his or her less virtuous ‘normal’ character. In Chapter 2, we will discuss ‘ethics of care’ in which emotion and feelings have a more central role.

As with other contemporary ethical theories there are competing accounts of virtue ethics. The differences are most apparent in considering the extent to which the particular version offers complementary advantages to duty or rule-based approaches. Radical virtue ethics firmly sites character-based judgements as having precedence over rule-based systems. The more moderate approaches can accommodate both character- and rule-based facets to advantage.

Additionally, virtue ethics has its valid criticisms, among these being that it is:

- not a codifiable system: impossible to devise a valid or practicable set of rules for action; therefore cannot identify ‘the right’ action
- vulnerable to cultural relativity (are virtues and vices culturally immune or sensitive?)
- impossible to know for sure which character traits constitute virtues
- open to conflicting implications from the virtues themselves: does honesty always take precedence over loyalty? (Hursthouse 2003).

Summary of the three key theories

So just where does this leave an initial summary of some of the key aspects of these three ethical theories? All of the conceptual approaches identify important aspects of moral relevance:

- duties and obligations
- outcomes and maximising benefit
- moral character or disposition.

The alternative approaches, though not entirely incompatible, do not readily lend themselves to being merged or ‘homogenised’ without risk of becoming unwieldy or watered down. In contemplating an ethical situation, there is much to be said for giving due consideration to aspects of both duty (deontological) and outcome (consequentialist/utilitarian), and importantly, setting such consideration within a context of ‘interests’. We need to know who has a legitimate interest and who will be affected by a proposed action. What grounds (or what is the basis of) that or those interest(s)? How do interests relate? Are they complementary or in conflict? Can any or some interest(s) be said to outweigh or trump other interests? ‘Rights’ are often said to outrank or trump other considerations.

At the same time, as far as the individual practitioner is concerned, becoming more reflective and familiar with ethical analysis may be the preferred pathway toward the Aristotelian ideal of virtue. It is not so much a matter of doing moral gymnastics or exercises as perhaps cultivating an awareness of moral considerations. The philosopher John Mackie (1977, p. 186) saw each virtue as ‘a disposition for making (right) choices, and one that is trained or developed by experience rather than inborn’.

It remains to re-emphasise that there is no single or preferred approach in ethical analysis and that individuals must develop their own systems with which they feel most comfortable. Almost inevitably, circumstances will vary from one ethical issue to another. At very least, we must always remember that, although we have much in common, all human beings are uniquely individual. Also, in a culturally diverse situation, awareness of and sensitivity to the religious and cultural backgrounds of patients and colleagues may be extremely important. Yes, there will always be similarities, but there will also be significant differences.

In philosophy, the process of *analogy* has sometimes been put to good use in drawing out underlying aspects that can relate an issue to

previous experience, and an analogical process known as *casuistry* was once much favoured in the Catholic Church and used to explore special circumstances within a context of general rules. A term favoured by philosophers is *ceteris paribus*, meaning ‘all things being equal’. To an extent it is the universal get out clause, for in reality things are seldom if ever equal! A comment such as: ‘parents’ rights and responsibilities for their underage children, *ceteris paribus*, take precedence over consideration of a child’s autonomy’ should always flag up the possibility of a moral conflict and the need for caution.

Finally, a practitioner may be faced with a moral dilemma in which a choice must be made between two or more seemingly mutually incompatible and possibly equally desirable or undesirable alternatives. Somehow a balance has to be struck or a hard decision taken (see Chapter 3). A better understanding of ethical theory will not provide a magic solution to such dilemmas, but it may help in achieving a more rational, caring and accountable solution.

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2

Key moral concepts in healthcare

The ‘Georgetown mantra’

In their classic textbook on biomedical ethics, Beauchamp and Childress (2001) grouped together four principles that could be used by clinicians in evaluating ethical aspects of professional–patient relationships. These principles have been widely employed in a variety of healthcare settings, and because of the authors’ academic base in the Kennedy Institute of Ethics at Georgetown University USA, the four principles have become known collectively as the ‘Georgetown mantra’:

- beneficence
- non-maleficence
- respect for autonomy
- justice.

Central to the book’s overall thesis is that ethical judgements can be justified by reference to certain principles. The rubric of beneficence, non-maleficence, respect for autonomy and justice, is used to form a bridge between so-called common morality (the norms that all morally serious people share) and the higher-level theories of morality that philosophers explore. Importantly, Beauchamp and Childress stressed that reliable, balanced judgements can be made even where there are competing claims from two or more of the principles.

Critics are not convinced that the authors succeeded in overcoming this fundamental problem of how to resolve the matter when principles conflict. In some respects, one principle good, two or more principles potentially problematic. Which of the principles takes precedence or are they considered to be of equal importance? It is not too difficult to imagine circumstances where the claims of beneficence and non-maleficence, or respect for autonomy and justice appear to be pulling in opposite directions. This conflict may be particularly intractable when attempting to accommodate the views and beliefs of two or more people. The principles themselves have the merit of being easy to remember and, at very least, serve as mental ‘post-its’, or to mix the metaphor, forget-me-nots of key factors in making healthcare decisions.

Beneficence and non-maleficence

Beneficence relates to acting in ways that benefit a patient, essentially doing good or being actively kind. Neither the RPSGB's guide *Medicines, Ethics and Practice* (MEP; July 2006) nor the consultation document (RPSGB November 2006) expressly refers to a patient's *good* or *benefit*. But these characteristics are implicit in the terms (patients') *interests* or *care*, and in requirements *to provide the best possible healthcare for the community*. *Non-maleficence* is not the direct opposite of beneficence but concerns avoiding harming a patient. The phrase 'above all do no harm' is often used – do good if you possibly can, but above all do no harm. Both principles have a very long history in medicine and are clearly stated in the *Hippocratic oath* written in ancient Greece about 430 BC (Lloyd 1978):

- I will use my power to help the sick to the best of my ability and judgement
- I will abstain from harming any man by it.

At first sight, the implications of the principles of beneficence and non-maleficence are apparently clear and straightforward, but in practice may be rather less so. Perhaps what needs to be added is a requirement to take account of *intention* or *purpose*, and *context*. Prescribing medication with the intention of relieving a symptom, but which induces an unanticipated adverse response, is hardly beneficent from a patient's point of view. Indeed, the result is distinctly maleficent, that is harmful. But such circumstances, though not uncommon, do not undermine the two principles – because the intention was to be both beneficent and non-maleficent. The doctor did not intend to harm the patient. We may say that the harmful effect was *contingent*, that is dependent on an uncertain event or circumstance. But what if the harmful consequence was not (entirely) unexpected?

Such circumstances are not uncommon, even beyond the activities of the now notorious Dr Harold Shipman. Administration of powerful sedatives or analgesics in palliative care to terminally ill patients (beneficence) may have the effect of shortening life. The intention is one of palliation in severe pain (beneficence), but the prospect may be that the patient will die. Because the consequence of death was at the very least a strong possibility, can we say that harm was deliberate maleficence – not to put too strong a point on it, *euthanasia* (the bringing about a gentle easy death in the case of incurable and painful disease)? The answer to the question is contentious. Deliberate killing, even for

painful and incurable illnesses runs counter to moral norms and is a serious legal offence. Doctors tend to rely on Catholic moral casuistry – *the doctrine of double effect* (Flew 1979):

Where some course of action is likely to have two quite different effects, one licit or mandatory and the other illicit, it may be permissible to take that course intending the one but not the other (see also Chapter 3).

The word ‘licit’ is simply a term meaning lawful or legitimate and seldom used outside of the legal profession. Though the doctrine of double effect itself may not wholly convince a sceptic, Boyle (2004) appears to identify a crucial factor:

The distinction between intended harms and merely foreseen harms in the doctrine of double effect can be justified by appeal to a limitation on the human capacity to pursue good.

There are real limitations in healthcare; some of them are economic and relate to costs and budgetary limitations, and others reflect current technological or therapeutic boundaries or safety considerations. Ethical problems may be associated with any of these constraints. The beneficial and intended effect of alleviating pain sometimes comes at a high cost. Palliative care teams who pursue the good of their patients are well aware of the therapeutic limitations of their actions. According to circumstances, beneficence, and non-maleficence might best be thought of as being relative rather than absolute terms. In this respect, they are sometimes curtailed by limitations on the power to pursue good and consequently are often in the forefront in arriving at a balanced ethical decision.

Respect for autonomy

Autonomy is literally a capacity for self-government in the personal rather than political sense. It concerns the right to make one’s own decisions and to pursue one’s own actions, commensurate with an ability to be open to reason and to consider consequences. Autonomy is often coupled with moral agency because of the Kantian idea that only those who can reason, form self-interested judgements and reflect on their actions have that ability.

That no one is entirely free in any of these respects is a feature of both the natural and cultural worlds. That our rights and our abilities to decide are invariably curtailed both by law and by circumstances means that autonomous decisions are almost always limited. Children

below a certain age, the senile and those otherwise mentally impaired are considered to be incapable of fully autonomous decisions – *others* have a right and responsibility to decide for them *in their best interests*.

The trend in healthcare over the last few decades has been to encourage and facilitate patients' participation in decisions relating to their health and welfare – in other words, to exercise their autonomy. Various initiatives such as that of *The Expert Patient*,¹ an opportunity for patients to participate more fully in decisions concerning the treatment and progress of chronic illnesses, and concordance,² as an informed collaborative alliance between patient and practitioner are underway. Any limitations in response to these initiatives may result not only from acknowledged differential expertise but also from the seemingly inevitable deference to authority that tends to limit genuine patient autonomy (Badcott 2005). John Stuart Mill's insistence that, 'Each is the proper guardian of his own health, whether bodily, or mental and spiritual', may fall well wide of the mark with respect to patients' aspirations and expectations (Gray 1998, pp. 14–17).

Informed patient consent

Informed patient consent and its converse, refusal of treatment, are legitimate moral considerations that have become much more prominent in recent years. They underlie general therapeutic procedures and interventions but have a special relevance to participation in clinical trials. The latter is discussed more fully in Chapter 6. The requirements of formal consent and refusal hinge on respect for personal autonomy. What is generally understood by the term consent is to express agreement or willingness to a proposition. So what does informed consent entail? O'Neill (2003) suggested that the positive intention of informed consent is to 'provide assurance that patients are neither deceived nor coerced'. She emphasised that, '[c]onsent is a propositional attitude, so intransitive; complete, wholly specific consent is an illusion'.

The first part of O'Neill's assertion is quite clear. The absence of deception or coercion means what it says. Patients should not be persuaded to participate in a clinical trial either by being intentionally or

¹ The idea of developing a major initiative on 'Expert Patients' was set out in the Government's 1999 White Paper, *Saving Lives: Our Healthier Nation*. Copies of the publication *The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century* (2001) can be downloaded from the UK Department of Health website: <http://www.dh.gov.uk/Home/fs/en>

² The concept of concordance envisages a sharing of responsibility and power in the professional–patient interaction (Weiss and Britten 2003).

inadvertently misled or by the concealment of information that might have an adverse effect on their decision to take part. Secondly, they should not be subjected to unreasonable pressure. O'Neill's remaining point about 'intransitive propositional attitudes' is a rather ponderous philosophical phrase, rather reminiscent of US Secretary of Defense Donald Rumsfeld's comments on 'known knowns, known unknowns, and unknown unknowns'! But it is an important one. It relates in philosophical terms to knowing or rather not knowing what someone else believes. For instance when a patient says 'I believe that x ', or 'I understand that y ', can we be really sure that what they say coincides with what they believe? We can set aside for the time being truthfulness and telling lies; we will return to these later in the chapter. In absolute terms, O'Neill is quite right to insist that it is impossible to establish or to ascertain that both parties, the consentor and the one by whom nominal consent is received, have an entirely common understanding of just what has been agreed. This of course applies in all written or verbal communications, and may be exacerbated by marked differences in vocabulary, education or language difficulties. The onus is on the health professional to ensure that, at far as possible, a patient is aware of exactly what participating in a study would mean to them (the patient).

By way of illustration, one American medical ethics primer (Erlanger 2000), included a very demanding checklist for the prudent physician:

The **prudent person rule** requires that the patient knows and understands:

1. The diagnosis
2. The nature and purpose of the proposed treatment
3. The known risks and consequences of the proposed treatment (excluding those too remote and improbable or too well known to bear on the treatment decision)
4. Included should be the doctors' and the hospital's success and failure rates with the proposed treatment and the 'judgment errors made in the course of care if such care affects the care of the patient'
5. The benefits expected of the proposed treatment and the likelihood of their being realized
6. All alternative treatments, with all the information for them mentioned in 3 and 4 above

7. The prognosis if no treatment is give

8. All costs and burdens of the treatment and of the alternatives mentioned in 5 above.

In practice, it is difficult to imagine that anything as formidable as this schedule would or could be followed, though in the increasingly litigious healthcare environment of the USA, such measures are perhaps essential. The dangers of information overload are clear, but perhaps one aspect that is missing is any reference to the nature and implications of participation in comparative clinical trials (Chapter 6). Nevertheless, the manual does make a vital point concerning the communication or transaction between practitioner and patient: 'For better or for worse, healthcare practitioners find themselves in a situation where they need to become moral negotiators with moral strangers'. That statement in itself points to the necessity of a more open and equitable relationship.

Nevertheless, Corrigan (2003) was rather sceptical that informed consent procedures, intended to overcome the power differential between patient and paternalistic authority, would protect individuals' rights and welfare. Her empirical studies suggest that:

There needs to be a realisation that the type of illness a patient is suffering from, her anxiety about the likely trajectory of her illness, her expectations about treatment and, in general her implicit trust in the doctor and medical science mean that 'informed choices' based on adequate understanding of the information and on careful consideration of the potential benefits and risks, are difficult to achieve in practice. Furthermore, not only is the concept of informed consent problematic within its own terms of reference, but the ideas of autonomy, freedom and choice belie the extent to which they are both limited and regulated.

On this basis, truly informed consent may be much more aspirational than achievable.

To summarise, it is generally considered that valid legal consent by patients is dependent on three essential components of the transaction:

- competence: patients' capability of understanding the full implications
- freedom: freely given without coercion; patients should be free to withdraw their consent at any time without being penalised in any way
- information: relevant and adequate to permit sound consent.³

³ Comment attributed to Sir Ian Kennedy in *Legal Issues for Nurses*, Chris Cox. See Royal College of Nursing website www.rcn.org.uk

Justice

In the context of healthcare, justice refers to distributive (see resource allocation in Chapter 6) rather than corrective or retributive justice. By and large, justice concerns the equitable distribution of benefits and burdens unless exceptional conditions apply (Flew 1979). It covers fairness or even-handedness in dealing with patients and freedom from discrimination, and it is generally reflected in the phrase, allocate each to their own. Justice in healthcare tends to be largely focused on access to or denial of treatment in one form or another and may be something of a movable feast. For instance, one might ask where is the justice when some patients obtain access to expensive new drugs, the cost of which significantly erodes the available budget and increases waiting times for others? Does it make a difference if those expensive new drugs are potential lifesavers? Should we penalise chronic smokers with serious chest ailments or the clinically obese? Balancing and adjudicating priorities within limited resources must necessarily compromise some elements of justice and fairness.

The philosopher John Rawls (1972) suggested that a sense of justice was vulnerable to bias, being influenced by one's personal standpoint. His theoretical concept was of justice as fairness with an imaginary *veil of ignorance*, such that parties should contract into basic social structures or provisions without knowing in advance the position or role they would occupy. Of course, we cannot adopt a veil of ignorance in practice, but Rawls's concept both highlights the dangers of how personal bias colours our sense of what is fair and just and emphasises the desirability of some form of independent assessment. There is no simple answer to the question of who gets dialysis or who receives a transplant when demand exceeds supply. In reality, there is no veil of ignorance; pure chance and the perceived postcode lottery may be significant factors. Calculations based on potential *quality-adjusted life-years* (QALYs) is one solution, but can hardly be seen as *just* if your personal QALY score means that you are ruled out or passed over for treatment. And of course QALYs tend to favour the young and disadvantage the old.

The four Georgetown principles: potential for improvement?

The Georgetown approach and principlism generally are particularly vulnerable to criticism on grounds of:

- inevitable conflict between principles

- resultant need to balance or prioritise (that is give added weight to one or more principles over another).

Beauchamp and Childress (2001) attempted to accommodate these vulnerabilities by asserting that in our daily lives, we deal with competing demands by making balanced judgements all the time. A structured way of carrying this out is by using a method known as reflective equilibrium. John Rawls (1972) first used the term ‘reflective equilibrium’ in his important work *A Theory of Justice*, though the method itself is attributed to Nelson Goodman (1983) working with processes of inductive logic. (See also Follesdal (2005) for a discussion of the role of reflective equilibrium in ethical justification.)

In practice, the method of reflective equilibrium operates just as the name indicates. Whatever the problem, we can gradually adapt our beliefs as to what could and should be done to achieve a reliable, coherent and defensible solution. This means firstly, identifying the facts, the relevant moral principles and the conflicting aspects; secondly, asking challenging questions and testing the answers against the defined problem. The process can be repeated over and over again; moving forwards and backwards with each refinement until a balanced resolution is obtained.

Reflective equilibrium sounds almost too good to be true, and quite possibly it is. Can it really eliminate moral conflicts? Many critics do not believe that it can operate without leaving loose ends, unresolved conflicting elements or a residue of moral regret that an obligation toward one or more principles has been circumvented. There have been attempts to overcome these problems by introducing additional considerations, such as either a coherence approach or a mutuality principle. There is not space here to go into detail, but coherence takes into account the relationship between the negative and the positive facets of each of the four principles (e.g. do not harm – promote good) and interprets these within the sphere of current professional rules and practices (DeMarco 1997, 2004). The mutuality principle builds on the notion of value coherence and is seen by its author as an obligation to encourage enhancement of values when conflicts arise. For instance in the well-known ethical dilemmas involving children of Jehovah’s Witnesses and the need for blood transfusion, professional staff should be encouraged to investigate non-blood-based alternatives as a means of accommodating the differing moral values of those involved.

Although the four Georgetown principles are among the central moral concepts in healthcare today, they should not be allowed to

eclipse other no less important issues. In the remainder of the chapter there is discussion of human rights, and trust and truthfulness. We also include a brief introduction to two further approaches to ethics in healthcare, which are preferred by some practitioners: ethics of care and clinical pragmatism.

Human rights

Human rights are also considered in Chapters 1 and 6. In Chapter 1 it was suggested that ‘rights’ in the sense of broad entitlements can be derived from a concept of human dignity. The United Nations Declaration of Human Rights indicates that it is by virtue of the property of dignity that human beings possess certain inalienable rights. These rights underpin the limitations on how people should be treated and what they are entitled to do. We say that these rights are inalienable because to deny or obstruct such rights is considered to be an infringement of something both fundamental and intrinsic to every human being. Of course a declaration from the United Nations or any other public body does not of itself protect many human beings in some countries from infringement of their rights every day of the year.

The concept of ‘rights’ is itself by no means unproblematic. Grounding or basing ‘rights’ in a concept of human dignity just pushes the difficulty of arguing for the validity of ‘rights’ a stage further back. It becomes necessary then to justify both the concept of human dignity and how that concept itself supports an understanding of human rights. Eventually in arguing for any moral belief we come to a point that is, in effect, for that individual ultimate or fundamental. As Glover (1977) indicated, such a belief is axiomatic – other beliefs can be derived from ultimate beliefs, but they themselves cannot be proved. That is, ultimate moral beliefs are foundational and incapable of further justification. These beliefs may be attributed to religion or dogma, even though humanists and others may share the same common values though deny their origins. Indeed Anscombe (1958) suggested that longstanding moral beliefs may persist even where adherence to religion has declined:

To have a law conception of ethics is to hold that what is needed for conformity with the virtues failure in which is the mark of being bad *qua*⁴ man (and not merely, say, *qua* craftsman or logician) – that what is

⁴The term *qua* is a useful piece of philosophical shorthand that simply means in the capacity of or by virtue of being. Here Anscombe is simply emphasising the difference between being a bad man (i.e. morally bad person) and being a bad (i.e. poor) craftsman.

needed for this, is required by divine law. Naturally it is not possible to have such a conception unless you believe in God as a law-giver; like Jews, Stoics, and Christians. But if such a conception is dominant for many centuries, and then is given up, it is a natural result that the concept of 'obligation', of being bound or required as by a law, should remain though they had lost their root; and if the word 'ought' has become invested in certain contexts with the sense of 'obligation' it too will remain to be spoken with a special emphasis and a special feeling in these contexts.

In law, most 'rights' are not absolute or entirely inalienable, and they can sometimes be set aside or overridden. There is also an important distinction between inalienable and being absolute (Bayles 1976):

They [human rights] are [said to be] inalienable because they belong to people by virtue of their being human. So to lose a human right one must cease to be human. But since human rights are claims, they can be outweighed by other justifiable claims. That is, sometimes there are sufficient moral reasons for not respecting, or completely respecting, human rights. As in all conflicts of moral principles, human rights and other moral reasons must be weighed against one another by an as yet poorly understood and ill-defined process.

Hence, it might be better to think in terms of human rights as conditional 'entitlements', but, as 'rights' is the term used in the United Nations Declaration of Human Rights, the European Convention on Human Rights and the UK Human Rights Act (1998), it is much too late to advocate a change. With respect to the UK Act, as John (2005) emphasised, it is only Article 3 relating to prohibition of torture that is considered to be inviolable. All other rights defined within the Act including the right to life (Article 2), respect for privacy (Article 8), freedom of thought, conscience and religion (Article 9), and freedom of expression (Article 10) '...may be excluded or restricted to the extent necessary to uphold a democratic society'.

Right to life is protected by law but can be legally overridden by conviction for a crime for which execution is the prescribed penalty, or because of the use of force in self-defence, to evade lawful detention or to quell a riot or insurrection.

We can therefore look at human rights in three ways (Sen, 2004):

- as an unconditional consequence of some intrinsic property such as simply being human
- through limited membership, for instance citizenship of a country
- in consequence of legislation.

So it is important to know and understand what *grounds* the rights claimed in a particular instance. Now in the first of these ways, there is no necessity to opt in – everyone is automatically included. For instance, recognition of certain unconditional rights is made clear in the Declaration of Human Rights. The fundamental right already exists in nature, as Thomas Hobbes the influential sixteenth–seventeenth English philosopher would have it. The United Nations did not create it. What the United Nations declaration did was to clarify and formalise recognition of that fundamental right. The second way is contingent or circumstantial, and sometimes discretionary or restricted, such as being a British or a Roman citizen or a member of the RPSGB. Being a citizen of a country or a member of a trade union or professional body confers certain freedoms or rights as an entitlement. Legislation, such as the Human Rights Act 1998, is important because it may help to clarify certain understandings of rights that may have been assumed but not before defined. For a discussion of the general idea of legal rights and their relationship with moral rights, see Raz (1984).

Some philosophers and legal theorists are sceptical about human rights as a property that people have without legal underpinning. For those who think otherwise, the inclination is to attempt to ground rights in a natural law tradition, such as Hobbes or Hugo Grotius (1583–1645) who wrote (Urmson and Reé 1995):

Natural law is a dictate of right reason, which points out that an act, according as it is or is not in conformity with rational nature, has in it a quality of moral baseness or moral necessity; and that, in consequence, such an act is either forbidden or enjoined by the author of nature, God.

Importantly, natural law is not envisaged as emanating from God but is rather intrinsic to itself and on a par, say, with mathematical knowledge. More recent natural law theorists tend to argue for the importance of human values or in somewhat Kantian mode that human reason is able to recognise moral values. The distinguished philosopher of law H. L. A. Hart (1955) in considering the question, ‘are there any natural rights?’, argued that there was one natural right, that of an equal right to freedom. Hart provided an elegant if rather cerebral explanation of the connection between restrictions and freedoms:

If we justify interference on such grounds as we give when we claim a moral right, we are in fact indirectly invoking as our justification the principle that all men have an equal right to be free. For we are in fact saying in the case of promises and consents or authorizations that this claim to interfere with another’s freedom is justified because he has, in exercise of

his equal right to be free, freely chosen to create this claim, and in the case of mutual restrictions we are saying in fact that his claim to interfere with another's freedom is justified because it is fair; and it is fair because only so will there be an equal distributions of restrictions and so freedom among this group of men. So in the case of special rights as well as general rights recognition of them implies the recognition of all men to be free.

The significance of Hart's analysis is to suggest that a right to freedom, whether positive or negative, necessarily brings with it the potential that someone else will claim that your exercise of a right infringes their own rights. In a sense, restrictions and openness to exceptions are necessary conditions of there being equal freedoms.

Trust and truthfulness

Throughout most of the modern world, the practice of medicine and healthcare is based on a paternalistic model. This is, in part, a legal paternalism. By law, doctors and other health professionals undergo formal training and examination (which offers protection against incompetence, charlatans or 'quackery'). Health professionals control availability of potent medicines, exemptions from work, access to social security support and compensation (Badcott 2005). The relationship is one of differential power, dependency and curtailed autonomy. Patients by and large acquiesce in this state of affairs, either because they assume that it is the way of the world or as a matter of 'Hobson's choice': they can't change it, so might as well just go along with it.

Greater emphasis on encouraging patients to take more direct responsibility for their ailments, particularly by recognising the importance of patient expertise in longer-term illnesses or through concordance or shared decision making, may in time achieve a more balanced relationship. But irrespective of the particular practitioner–patient model, trust and truthfulness are important and fundamental considerations that apply to all professional practitioners, whether health related or not, and to their clients. Any such client occupies a position of *vulnerability* (the practitioner incurs a corresponding *obligation* in consequence of the professional relationship). The patients have needs, which they themselves cannot meet, and are reliant on the skills and expertise of a practitioner. Hence there is an implicit deference to the authority of the practitioner. Implicit also is an expectation that the practitioner can be relied on, can be trusted and will be truthful. Trust and truth are words that seem to coexist. Being discovered in a lie demonstrates that the liar cannot be wholly trusted.

We will pass over some of the more philosophically rigorous aspects of what constitutes truth, which are not particularly relevant for our purposes, and concentrate on the moral considerations. Is it ever morally justifiable to lie or to conceal the truth? We might be of the opinion that truth telling and respect for human life (thou shalt not kill) are or can be moral absolutes. Rather like sterility and pregnancy, there are no qualifications or get out clauses. Or are there? MacIntyre (1994) suggested that children learn rules of truth-telling while young: firstly, when caught out in a lie they soon discover that it is wrong to lie (for instance, they may be punished). Later, in some cultures, they learn that some types of lie are permitted – particularly in circumstances where a lie may protect or defend the vulnerable. (See also, Chapter 3 (gender differences in reasoning) in which Kohlberg's studies on moral reasoning in children is discussed.)

We sometimes talk of 'telling a white lie', where the lie is generally but not always fairly modest and told out of consideration for the recipient. It is the more substantial 'white lie' that is most commonly cited in the context of healthcare ethics. For instance, is it always essential to tell 'the truth' to a patient who may not know that their illness is likely to be fatal? The practitioner may have concluded that withholding that information, concealing the truth, is in the patient's best interests. The patient might easily become depressed or seek to end her own life if the truth is revealed. Perhaps a patient who suspects that she is not being told the truth, but is reluctant to ask their GP, may question a nurse or their pharmacist. 'What exactly are these pills for anyway? Doctor says they are to help me.' How do you respond? Is your duty to be open and honest or do you tell your own white lie or refer the patient to their GP? It is not too many years ago that prescription medicines were labelled anonymously, as 'The tablets', 'The capsules', 'The mixture', 'The ointment', etc., rather than *nomen proprium* (the proper name of the drug). This was an essential part of the general mystique of paternalistic medicine and the value of placebos.

In these arguably more enlightened times, where at least the concept of patient autonomy is clearly recognised and indeed emphasised, is it ever morally permissible to lie or conceal the truth? The primary consideration is perhaps to consider whose interests are served by telling the lie. The answer is probably only in very exceptional circumstances where the ends might justify the means, and in the knowledge that rather like a child caught out in a lie, such action could be seen as a betrayal of trust if it ever became known. Mackie (1977) advised: 'And if doctors habitually tell seriously ill patients what are meant to be

reassuring lies, not only will their lies fail to reassure but even a true statement that the patient is not ill as he fears will also be unconvincing'. Bok (1999) made somewhat similar cautionary comments:

...certain kinds of disadvantage and harm are almost always overlooked (by liars). Liars usually weigh only the immediate harm to others from the lie against the benefits they want to achieve. The flaw in such an outlook is that it ignores or underestimates two additional kinds of harm – the harm that lying does to the liars themselves and the harm done to the general level of trust and social cooperation. Both are cumulative; they are hard to reverse. How is the liar affected by his own lies? The very fact that he knows he has lied, first of all, affects him. He may regard the lie as an inroad on his integrity; he certainly looks at those he has lied to with a new caution. And if they find out that he has lied, he knows that his credibility and the respect or his word have been damaged...

Of course a requirement for trust and truth is not the sole prerogative of health practitioners. Healthcare operates on the basis that patients, by and large, are truthful and trustworthy. They give honest answers to direct questions and comply with medication schedules – well, some do, some of the time, but confidence in patient compliance is not very high. How often do you question a patient receiving a repeat prescription? Are they making impromptu adjustments to their dosage or schedule, perhaps to mitigate an untoward reaction, without informing their pharmacist or GP? Only the patient knows about their measure of compliance.⁵ Non-compliance is unlikely to be readily disclosed; it is difficult to assess independently or to monitor, but it is suspected to be widespread. Pharmacists are experts in the field of medication, and they are also 'gatekeepers' for medicines. Is a more active role in assuring patient compliance not only an essential part of pharmaceutical care but also a moral duty? Do patients have a corresponding right to expect that their pharmacist will ensure not only that they have been given appropriate professional advice on the nature and employment of their medicines, but will ensure as far as is possible active and conscientious compliance?

Postscript: trust, keeping promises and consequences

It seems clear that at very least, conditions based on trust and truth telling are, *ceteris paribus* (our old friend meaning all things being equal

⁵The familiar word compliance has been deliberately used here meaning 'following directions'. More generally, the terms 'concordance or concordant' are preferred to emphasise the partnership between patient and health professional.

again), very important pillars of ethical relationships. Yet, as indicated, telling a white lie might sometimes be justified to maintain or bring about a beneficial circumstance that telling the plain, unvarnished truth could undermine. We could interpret this as a duty to tell the truth being set aside for an advantageous consequentialist reason. Ross (1930) made a very similar point with respect to keeping promises; for trust, truth telling and keeping promises operate in the same sort of territory. Importantly, Ross emphasised that his is not a utilitarian justification:

It may be said that besides the duty of fulfilling promises I have and recognize a duty of relieving distress, and that when I think it right to do the latter at the cost of not doing the former, it is not because I think I shall produce more good thereby but because I think it a duty which is in the circumstances more of a duty. ...normally promise-keeping, for example, should come before benevolence, but that when, and only when the good produced by the benevolent act is very great and the promise comparatively trivial, the act of benevolence becomes our duty.

Ross's example of the defence of reneging on a promise is that he would feel entirely justified in breaking an engagement with a friend in order to prevent or assist with a serious accident. John Stuart Mill's argument supportive of illegal action to save a life (see Chapter 3, gender difference in reasoning) takes a somewhat similar line (see Gray, 1998): 'In such cases, as we do not call anything justice which is not a virtue, we usually say, not that justice must give way to some other moral principle, but that what is just in ordinary cases is, by reason of that other principle, not just in that particular case.' In other words, context may influence our decision on which competing moral principle takes precedence in particular circumstances. We shall touch on conflicting principles at several points in the book, but especially in Chapter 3 under the heading 'moral dilemmas'.

Is care a virtue?

The word care is something of a linguistic chameleon. We tend to overlook it or take it for granted unless drawn to our attention. Care as such, is not listed in Aristotle's table of virtues and vices. If it were, we might perhaps expect care as an altruistic characteristic, to be positioned as the mean between the excess of paternalism and the deficiency of self-centredness. van Hooft (2003) defined the virtue of caring as 'the comportment of the self towards others, which has the inherent goal of enhancing the existence of those others, whether they are others in inti-

mate relationships to me, or others for whom I have professional responsibility...’ And Halwani (2003) suggested that we should think of care not as a simple natural virtue but as an important one harnessed by reason and contributing to a flourishing life. Indeed, care is undoubtedly a moral concept central to the very nature of professions such as medicine, pharmacy, nursing, dentistry, veterinary practice and others that in one way or another provide healthcare.

How does the moral aspect of care arise? Firstly, the healthcare practitioner by virtue of her professional status owes a duty of respect and obligation to serve the interests of the patient. She does so in the context of the vulnerability that underpins the special relationship between a patient and a healthcare provider. The relationship is to an extent voluntary, in that the patient is not required to present a prescription or seek advice at a particular pharmacy. But in doing so, patient and practitioner enter into an informal or quasi-contract (see Goodin 1985).

Among the various dictionary definitions of care, we can select two that cover the important aspects most directly related to healthcare:

- care as an instrumental therapeutic activity: that is, intended to achieve a particular effect, whether prevention, alleviation or elimination
- care as socio-emotional behaviour.

In simple terms, it is suggested that what we are talking of is both *caring for* and *caring about* a patient. Care, as an instrumental activity, is the sense of providing for therapeutic needs. It is what we do when we dispense a prescription or provide professional pharmaceutical advice to a patient. By and large, dispensing itself is a rather dispassionate and impersonal technical process, carried out with appropriate expertise and with the application of experience. But pharmaceutical care is not limited to specialised expertise in dispensing prescriptions, updating pharmaceutical knowledge or maintaining professional competence. More and more, all of the healthcare professions have become aware of the importance of patient care in the sense of relationship with, that is caring about, individual patients. This is the ethical side of patient care in which the patient is treated as an individual human being, to be respected, cared for and consulted. It is in this context that the concordance aspects of pharmaceutical care are vitally important. Many older pharmacists will recall that relationship with a patient in their earlier practice was probably limited to formal confirmation of the patient’s identity, determining whether or not they had been prescribed the medicine on a previous occasion or providing customers with rather

impersonal advice relating to counter prescribing. The stereotypical image of the rather staid, dignified and somewhat formidable individual in a white coat was something that customers and patients had come to expect. That image, as far as it is more than a caricature, should be firmly consigned to the past.

Ethics of care

Some of these elements of the ‘caring for’ side of healthcare have been developed to provide a distinctive *ethics of care*. Where virtue ethics (see Chapter 1) is associated with cultivating a virtuous character or developing a virtuous attitude, *ethics of care* places much more emphasis both on and employing, natural altruistic emotions. The notion of human beings possessing what constitutes an ‘irresistible compassion’ is associated with, among others, Thomas Jefferson and Adam Smith. In 1759, Smith wrote:

Howsoever man may be supposed, there are evidently some principles in his nature, which interest him in the fortune of others ...Of this kind is pity or compassion, the emotion which we feel for the misery of others, when we either see it, or are made to conceive it in a very lively manner. That we often derive sorrow from the sorrow of others is a matter of fact too obvious to require instances to prove it.

This innate capacity for sympathy and compassion may well have an evolutionary basis as an important requirement for societal living, and there is a considerable literature concerning the nature of altruism. Philosophers and evolutionary biologists have utilised games theory and well-known models such as ‘prisoner’s dilemma’ and ‘zero sum’ to try to demonstrate why evolution has generally favoured cooperation and social living over frank self-interest. Altruistic behaviour is a vital aspect of this. For some introductory reading in this area, see Ridley (1997) and Wright (2000).

An intriguing question that may have occurred to some readers is why we appear to be much more responsive to proximate moral matters than those more distant. In other words we tend to care for and about those in need on our doorstep, whether we know them personally or not, and much less so for others. This is another question that has exercised moral philosophers a great deal. The ‘Good Samaritan’ in us means that most people would help the victim of an accident we encountered, but we might be less inclined to respond to a letter seeking urgent financial help, perhaps to relieve famine or a major disaster

much further afield. Peter Singer used the example of our likely responses when on the one hand we encounter a small child in danger in a pond and, on the other, the needs of children starving overseas. Singer argued that to claim that the child's immediate danger obliges us to respond whereas the plight of distant starving children doesn't is morally inconsistent. For discussion of these issues see Reader (2003). And, shifting the emphasis from the individual to the corporate, should international pharmaceutical companies voluntarily or even be required to supply medicines at low or no cost to the distant needy?

It has been suggested by Greene (2003) that:

...our ancestors did not evolve in an environment in which total strangers on opposite sides of the world could save each other's lives by making relatively modest material sacrifices. [They]...did evolve in an environment in which individuals standing face-to-face could save each others lives, sometimes only through considerable personal sacrifice. Given all of this, it makes sense that we would have evolved altruistic instincts that direct us to help others in dire need, but mostly when the ones in need are presented to us in an 'up-close-and-personal' way.

On this basis, face-to-face encounters involving someone in need can stimulate an instinctive, compassionate response. Furthermore, recent research suggests that the obvious tension between deontological and utilitarian approaches in moral dilemmas reflects not just philosophical differences but also functional differences in the structure of the brain (Greene et al. 2004).

There is a strong resonance between the empathetic character of compassion and what has become known as 'ethics of care', which has its roots in feminist ethics. Miller (2005) addressed some of the moral links between, need, care and obligation. The suggestion of 'ethics of care' is that too much attention to rights and justice, and an assumption that individuals (patients) are fully autonomous and able to exercise rational judgement in their affairs, neglects the crucial contribution of caring relationships. Lloyd (2005) summarised the situation succinctly:

The interpersonal and emotional dimensions of human life have been overlooked through our preoccupation with individual rights. ...Feminist ethics argue that the model of the rational autonomous individual means that the dependent dimensions of the self are repressed rather than being seen as inherent within the human condition. It follows that we lack an adequate understanding of the human need for care, despite its centrality to our existence.

These factors have been recognised in four of the RPSGB's seven principles (RPSGB November 2006) of ethical practice to ground the revised Code of Ethics; these are much more directed toward caring for and identifying patients as individuals:

- make the care of patients your first concern
- exercise your professional judgement in the interests of patients and the public
- show respect for people
- encourage patients to participate in decisions about their care.

What does an ethics of care mean for pharmacy practice? It does not mean allowing one's emotions free rein to the detriment of considered personal judgement. Following the lead of nursing ethics, it perhaps should mean (substituting 'nurses' by 'pharmacists'), 'that, having noticed the health-related needs of patients or clients, pharmacists are motivated by seeing these needs to respond to them. Caring consists in the motivational link between sensitive perception and the caring response' (van Hooft 1999). That motivational link between perception and caring response is an important factor in resolving ethical issues. Most pharmacists do not participate in a bedside context, but van Hooft emphasised that an ethics of care can provide the motivation to initiate action to bring about desirable institutional or organisational change, and changes in health policy. And having identified shortcomings in their professional competences, pharmacists may be better motivated to respond to them and undertake the necessary remedial action.

Clinical pragmatism

One method of dealing with ethical decisions or moral dilemmas that has received significant support in recent years within medicine and healthcare is generally known as *clinical pragmatism*. The dictionary definitions of pragmatic and pragmatism refer respectively to 'Dealing with matters with regard to their practical requirements or consequences', and 'a philosophy that evaluates assertions solely by their practical consequences and bearing on human interests' (*Concise Oxford Dictionary*, 8th edition 1990).

The corpus or movement associated with pragmatism as a philosophical system derives from the work of three American philosophers from the late nineteenth and early-mid twentieth centuries: Dewey, James and Pierce, whose work is described in *The Oxford Companion to Philosophy* (1995) as:

...characteristic idea ...that efficacy in practical application – the issue of which works out most ‘effectively’ – somehow provides a standard for the determination of truth in the case of statements, rightness in the case of actions, and value in the case of appraisals.

It is important not to see pragmatism as a variant of consequentialism or utilitarianism (discussed in Chapter 1). Outcome is important, but only to the extent that it relates to values and purposes. Much of the detail of formal pragmatism need not concern us here. However, the broad concepts, particularly that of John Dewey (1859–1952), lend themselves to accommodating or negotiating the variety of opinions, cultural and religious differences likely to be significant factors in dealing with moral problems in a team setting or indeed with some patients (Dewey 1929). We shall see that the basis of Chapters 5 and 7 of this book – the ‘four stage professional decision-making process’ – has some of the elements of clinical pragmatism.

However, the essential difference with clinical pragmatism is that once the interested parties have identified and agreed what the clinical and directly related facts are about, attention shifts to the factors that reflect any ethical disparities. This should take account of the various perspectives of the patient and/or family, and members of the health team. The intention is to arrive at a consensus to enable formulation of a mutually acceptable action plan. Fins (1998) indicated that:

Clinical pragmatism is especially well-suited to dealing with the challenges posed by difference because it treats moral rules and principles not as absolutes that trump decision making but as hypothetical guides that identify a range of reasonable moral choices when patients, families, and clinicians find themselves in morally complex circumstances. The view of principles as hypothetical guides is especially critical when patients of diverse cultural and religious backgrounds bring cultural norms or guiding principles to the clinic that differ from those of the dominant culture.

The process therefore takes place within a context intended ‘to resolve ethical dilemmas in clinical (or health care) practice by approaching conflicts systematically and with a special focus on the interpersonal dimensions of moral problem solving’.

Furthermore, an important aspect is not just to achieve mutual consensus but also to set out the basis of why the agreed solution is consistent with the ethical issues in order to be able to provide a rationale and justification to others. This latter is of course closely related to what we would understand as the requirement for accountability that we are familiar with in responsible pharmacy practice.

At first sight, the system appears to be too good to be true. We have already acknowledged that within a diverse society, and particularly in a multicultural society, there will be fundamental and sometimes directly opposed opinions on what is and what isn't morally acceptable. Surely in arriving at consensus some deeply held beliefs must be overridden to bring this about? But the approach taken can avoid the rather stark ethical confrontations that would be all too easy to encounter by making an effort to understand and take into account the patient's and/or family's non-medical socio-cultural background and individual life goals. Dewey (1929) noted that: 'The problem with restoring integration and cooperation between man's beliefs about the world in which he lives and his beliefs about the values and purposes that should direct his conduct is the deepest problem of moral life'. At the end of the day, it is the patient and sometimes his or her family who deserve most consideration in respecting *values*, and the influence of our personal conduct. Although this may sometimes be problematic for healthcare workers, it need not mean that their own *values* are sacrificed. As Felleman (2005) said:

Pragmatism does not deny the knowledge and experience of clinical experts but does recognize both the limits of knowledge and the differences in lived experiences which can lead to differing understandings.

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3

Moral reasoning

This chapter is a very brief introduction to moral reasoning. It includes a modest coverage of logical reasoning structures and considers some psychological background that relates to current ideas on moral reasoning. The logical structures are quite simple versions of what is known as propositional calculus. This is a system in which letters or symbols are used to facilitate analysis of reasoning. Some basic symbolic arrangements can be learned and used to test the validity of moral assertions. Those who think that they can consider moral argumentation without a need for such systems, or are fazed by what appears to be an unusual form of algebra, might prefer to jump over those particular sections. Rest assured that an understanding is not that difficult to achieve and that students of philosophy soon get to grips in much the same way that pharmacy students are not overawed by complex chemical formulas.

Why include coverage of propositional calculus if we don't really need it? Mainly this is because it is a useful technique by which to examine a little more formally the components of an argument. Should we believe the case argued by a politician on resources in healthcare or on assisted dying, or question the arguments used by a colleague in support of an ethical stance? First of all, of course, we should consider whether the individual making the statement is a credible source; in other words can the information be relied on. But above all, we need to know if the main thrust of the argument follows from statements or claims used in its support. Secondly, many years ago, one of the authors was introduced to a small paperback book called *Straight and crooked thinking* (Thouless 1953). Although the book written by a Cambridge lecturer in psychology contained only a small amount of propositional calculus, in the space of less than 200 pages, it carefully guided the reader through the seductive paths of various forms of false or dishonest arguments. Not having 200 pages to spare in this book, an even smaller dose of calculus will have to suffice. And beware emotive words or expressions! As Thouless pointed out (Thouless 1953, pp. 9–10):

Once we are on the look-out for this difference between factual and emotional meanings, we shall notice that words which carry more or less strong suggestions of emotional attitudes are very common and are ordinarily used in the discussion of such controversial questions as those of politics, morals and religion. This is one reason why men can go on discussing such questions without getting much nearer to a rational solution of them.

Use of words such as scandal, callous, insensitive, heartless, agonising, secrecy, despair, desperate and privilege may well be appropriate according to circumstances, but they also tend to encourage our emotional support for the views expressed. So-called ‘tabloid headlines’ make effective use of such terms and are often intended to provoke a sympathetic ‘ooh-aah’ response from the reader. And even titles from ‘the qualities’ are not immune: ‘Agonising wait for organ scandal relatives’ (*The Guardian* February 2001), ‘Cancer treatment privilege of the rich?’ (*The Sunday Times* October 2005).

Common tactics, which some people use rather frequently and often without appreciating that they are invalid methods of reasoning, are referred to as

ad hominem arguments or
tu quoque arguments.

Again, don’t worry about the Latin tags. Such expressions are often used in the legal profession and in philosophy. They are useful because they act as shorthand for various notions or concepts – and are very well known to everyone working in those areas. Here, an *ad hominem* argument (literally an argument against the man) is an attack on the particular person and intended to discredit what he or she says or any claims that he or she makes. For instance:

Pharmacist A states that he believes that a duty of care toward the patient should always take precedence over individual conscience.

Pharmacist B comments that he remembers that pharmacist A was a bit of a firebrand at college and frequently getting involved in controversy or scrapes.

Therefore pharmacist A’s assertions are dubious.

The *tu quoque* argument (literally ‘you too’) is also intended to reduce or deflect the force of an argument that a person is making.

Person A indicates that he believes that using animals to test medicines is morally wrong.

Person B responds that he knows that person A isn't a vegetarian and wears leather shoes.

The assumption is that A is inconsistent in his beliefs so his views on animal testing are unreliable.

In reality, the logical validity of a particular claim is independent of the *ad hominem* or *tu quoque* assertions and stands or falls on its own merits. What someone has said or done in a different context or capacity may well be completely irrelevant.

Background

Undoubtedly a major influence on Western philosophical thought, and moral reasoning in particular, has been Ancient Greek philosophy. And the Socratic method of dialogue in which pupils are encouraged to think for themselves by participating in discussion and responding to helpful, probing questions put to them by their teacher (Socrates c. 470–399 BC) is an important learning technique that is applicable to dealing with ethical issues. Rhetoric is the art of using language in persuasive argument and was a major component of the study of philosophy in medieval universities. However, rather like philosophy generally, moral philosophy remained for centuries a rather staid academic discipline, with a reputation for intellectual rigour but not greatly appreciated or valued in everyday life. It was perhaps because of this aura of refinement, reliance on formal logic and deductive processes that moral philosophy might well have remained insulated from the real and distinctly untidy world of moral problems – a somewhat rare example of almost total lack of relationship between theory and practice.

During the second half of the twentieth century, an increasing preoccupation with bioethical matters arising at least in part from impressive technological progress in medicine but also from a greater focus on human rights and autonomy, changed all that. A paper by the British-born philosopher Stephen Toulmin (1973) drew attention to the dramatic shift in the perception of the value of ethical analysis. The title of the paper 'How medicine saved the life of ethics' indicated how moral philosophers and others began to apply their theoretical knowledge to tackling real ethical problems.

It is not surprising therefore, that practical or applied ethics has gradually emerged as an established subfield of philosophy in which philosophers can contribute to the careful, thoughtful and theoretically informed discussion of practical ethical issues (LaFollette 2005a). Moral

reasoning is defined in the *Stanford Encyclopedia of Philosophy* (LaFollette 2005b) as ‘Individual or collective practical reasoning about what we ought to do’. It is very easy to overlook the familiar word ‘ought’ in passing; seemingly a simple enough word relating to advisability, prudence, duty or rightness. But the significance of ‘ought’ and its connection with ‘is’ has occupied, and to a large extent baffled, very many philosophers on and off for the past 250 years. Even earlier still, Socrates posed one of the fundamental moral questions: how should I (or ought I to) live? Saying that I ought to have my hair cut has an altogether different connotation to saying that I ought to be good or I ought to help my sick neighbour.

The Scottish philosopher David Hume really set the cat among the pigeons in his consideration of the connection between moral good and evil (actions of the mind) and the external objects – the actions of other people, animals, etc. – to which these moral terms may be applied. Hume was aware that scientists of the Enlightenment dealt in matters of fact and reason and made statements such as the nature of X ‘is’ Y based on empirical evidence, but they were also inclined to make value statements concerning what ought to be. He argued that morality is not an object of reason (Selby-Bigge 1978, pp. 468–469):

Take any action allow’d to be vicious: Wilful murder, for instance. Examine it in all lights, and see if you can find that matter of fact, or real existence, which you call vice. In which-ever way you take it, you find only certain passions, motives, volitions and thoughts. There is no other matter of fact in the case. The vice entirely escapes you, as long as you consider the object. You can never find it, till you turn your reflexion into your own breast, and find a sentiment of disapprobation, which arises in you, toward action....So that when you pronounce any action or character to be vicious, you mean nothing, but that from the constitution of your nature you have a feeling or a sentiment of blame from the contemplation of it.’

Intrigued by these considerations, Hume reached the general and famous conclusion known as Hume’s law, that it is impossible to derive an ‘ought’ from a factual ‘is.’

For as this ought, or ought not, expresses some new relation or affirmation, ‘tis necessary that it should be observ’d and explain’d; and at the same time that a reason should be given, for what seems altogether inconceivable, how this new relation can be a deduction from others which are entirely different from it.

Claims that rely on deriving a value statement from a factual statement are said to commit the *naturalistic fallacy*. What Hume was talking about were factual statements such as ‘A murdered B’, and value statements such as ‘what A did was morally wrong’. Statements such as ‘A was found guilty of murdering B’, ‘murder is forbidden by law’ and ‘A was sentenced to life imprisonment’ are factual. But in terms of pure formal logic, ‘value’ statements containing the words ‘should’ or ‘ought’ cannot be logically derived from factual ‘is’ statements.

Some of the philosophical considerations and arguments are quite complicated and need not concern us, but we can still ask questions about the common sense status of the ‘moral ought’. Think back to Chapter 1 in the discussion of the differences between facts and values. Among the values listed were honesty, integrity, tolerance, dignity, consideration and respect for persons and the environment, friendship and loyalty. So if someone says to you, you ought to be honest or you ought to be trustworthy, how does the ‘ought’ arise? Well, it may have been provoked by something you said or did, perhaps an indication that you might not return the overpayment of change you received. We all know what ‘ought’ means here. But we also know when we think about it, that the ‘ought to be honest and trustworthy’ is a direct consequence of and arises from our system of morality and values. When we think of individual values and what they mean in real life, no doubt we often have in mind exemplars of behaviour that typify those values or their denial.

So, an act or an intention to act in a way that has value content may attract an ‘ought’ simply by virtue of the fact that our moral systems exemplify values. And our moral systems provide us with circumstantial expectations of ‘ought’ and ‘ought not’. Mackie (1977, p. 79) used the term institution, meaning ‘an established way of thinking, a moral tradition, demands that I show some concern for the well-being of others, or at least of some others, and this demand may have been written into ordinary language among rules about what can or cannot or must count as a reason.’ Additionally, what goes and what does not go may change over time as a moral institution changes, as evidenced by the profound impact of a growing awareness of basic human rights on slavery, employment, women’s suffrage and homosexual freedom from persecution.

So, returning to the direct matter of moral reasoning, we shall need to recognise that it is a form of practical reasoning about ‘what we ought to do’ and should take account of those moral values that are important in our lives. The latter will not as much shape as reflect the

principles to be used in justification of a particular moral stance. The moral system that we individually espouse, the values and the virtues, not only enable us to respond to Socrates' question, 'How should I live?' but also help us to tackle the moral question 'What should I do?', which require us to respond. We will assume here that moral reasoning, or rather practical moral reasoning, is simply a variety of general reasoning concerned with the provision of healthcare with a moral dimension. It is instrumental reasoning; that is, it has a job to do. When faced with questions of what to do (what to buy, where to go, whether to go, what to eat or who to invite, etc.), most of us are not paralysed by analysis. Although we may take some time to make up our minds, quite often a clear decision emerges and we act on it without further ado or a backward glance. Or we may be the type of person who dithers, seemingly cannot readily reach a decision even for trivial matters.

Yet sometimes we may be faced with apparently irreconcilable options in dealing with an ethical issue. The alternatives apparently carry equal weight. What should you do? How should you decide? 'Buridan's ass' is a philosophical fable that concerns a rational animal, an ass that starves simply because it is unable to decide between which of two hay bales to eat. Philosophically, the implication is that we delay our choice until reason determines which option is to be preferred, though the ass never reaches that decision state. Whichever category into which we ourselves fall, whether decisive or more cautious, we probably follow an almost universal system of:

1. weighing the facts
2. setting these facts against possible outcomes
3. deciding on the preferred course of action.

Decision making involving an ethical dimension follows much the same sequence but is often complicated by needing to address and take account of conflicting ethical issues. We should not underestimate the importance of these aspects nor the values of those involved within the affected web of relationships. David Thomasma (2003) noted that:

...all ethical dilemmas involve a clash of cherished values embodied in long-held principles. For any person in a dilemma it is difficult to prioritise these cherished values, for example, telling the truth and saving lives, because they both seem to be highly prized and sometimes irreconcilable. Finding the right balance among these and other values is the heart of the moral life.

On this assessment we shouldn't be at all surprised when we encounter clashing values, within ourselves, between others and ourselves or amongst others. We shall address these issues more directly later in the chapter under the heading of moral dilemmas. What we can say here is that where healthcare decisions with a moral dimension are concerned, the influence of bioethics has, at the very least, brought about a sensitivity that the style of reasoning is unlikely to be simply algorithmic. So what is wrong with algorithms? Well, algorithms are familiar enough procedures (often used in computing) that indicate a sequence or set of instructions for, shall we say, getting from A to Z. In other words, starting from an initial state the sequence describes the operations required to reach a specific end state. Simple examples would be the instructions for making something like a cake or batch of tablets or an ointment. In some instances, the sequence may also be based on yes or no responses to specific questions and following the indicated pathway.

Certainly, algorithms do have their uses in some problematic ethical situations. Pellegrino (2000) suggested an algorithm for considering a proposal to withdraw life-sustaining treatment, and Iserson *et al.* (1995) gave a rapid approach to ethical problem-solving in emergency medicine. The point to emphasise, however, is that very many morally problematic situations do not readily lend themselves to following prescriptive sequences. They require far more subtlety, more reflection and more negotiation than that would allow. If that were not the case, we could replace moral deliberation by a computer program, and many moral philosophers and bioethicists would become redundant. Some might think that would be no bad thing! The fact that they are not, or at least not yet, suggests that algorithms do not provide the answer.

Rational inquiry

Rational inquiry concerns the way, or perhaps ways, in which we can establish beliefs and judgements in an objective manner. In logic or philosophical reasoning, a premise is a proposition set down, assumed or proved from which another can be inferred. Thus a process of reasoning is considered, on the one hand, to be *deductive*, that is logically sound, where a conclusion is entailed by or follows from its supporting premise or premises. On the other hand, we say that a process of reasoning in which a conclusion is supported by, but not entailed (i.e. it is simply inferred) by, its premises is *inductive*. So where do moral judgements lie?

It would be reassuring to think that even if not susceptible to an entirely rule-based approach, ethical problems could be approached on a fairly rational, logical and consistent basis. Philosophy is nothing if not rigorous and practical philosophy should be no less so. The reason for doing, having done, not doing or not having carried out some action in pharmacy practice or indeed in any walk of life should be amenable to a general statement such as: 'I decided on this course of action for this/these reason(s)'. That is, there is a consistent and adequate combination of supporting premise(s) and conclusion. The requirements for accountable decision-making generally and for the structure of moral reasoning are essentially the same, though, of course, in moral reasoning there must be a reference to one or more ethical principles:

- a combination of premises, in this case the facts of the matter, plus
- a reference to general ethical principles and
- a conclusion (consistent with the factual and moral claims).

The relationship between the premises (matters of fact and cited moral principles) and the conclusion is a deductive one. A simple illustration would be as follows.

Human embryos are an integral part of human life (premise 1 = fact)
 Deliberately taking human life is morally wrong (premise 2 = general moral principle)
 Therefore, killing human embryos is morally wrong (conclusion).

If we take this example a stage further, it could be argued that a fertility treatment that produces surplus embryos is morally wrong.

Human embryos are an integral part of human life (premise 1 = fact)
 Fertility treatment produces surplus embryos (premise 2 = fact)
 Deliberately taking human life is morally wrong (premise 3 = general moral principle)
 Killing embryos is morally wrong (conclusion 1)
 Therefore, fertility treatment that produces surplus embryos is morally wrong because it results in deliberate killing surplus embryos (conclusion 2).

Now it should be immediately clear where and how some problems in moral reasoning arise. Interpretations can be applied to the general moral principle itself that deliberately taking human life is morally wrong. Even if the majority agree that deliberately taking human life is morally wrong, many might argue that there can be extenuating circumstances or exceptions such as 'killing in self-defence' that would render the action morally justifiable, or perhaps more correctly, not

morally blameworthy. Clearly a claim of self-defence is not applicable here. But, exactly what constitutes or comes within the remit of human life can be and often is open to much debate: should we include, for example, spermatozoa? egg cells?, zygotes?, embryos?, fetuses? Of course there may be, according to circumstances, competing moral principles. An ‘advance refusal’ reflecting autonomous choice – ‘I do not wish to be resuscitated if I fall into a coma’, or ‘I do not want to receive antibiotic therapy if I develop pneumonia’ – could counter the principle of benevolence. And by and large, rights are said to trump other considerations.

What we do need to clarify and establish in any circumstances where moral claims are being made or moral reasoning is being used is:

- what are the essential facts?
- what if any, moral principles are being cited or employed?
- is the use of those principles valid and being properly interpreted?

The status of emotions in reason

As healthcare workers with a predominantly scientific background, pharmacists have a strong inclination to treat the process of reasoning as being necessarily objective, and operated on firmly inductive lines. But is it appropriate to suggest that our moral reasoning and decisions should be similarly rational and wholly dispassionate? What of our own feelings about a situation or those of others? Do these not play a part in our reasoning? The classical image of scientists is perhaps that of being cool, calm and collected with meticulously reasoned theories based on hard evidence. Artists, of course, are passionate and liable to the emotional mood swings that enhance their creativity. But remaining calm and focused does not mean that emotion does not play a part. We have already touched on this in Chapter 2 (p. 41). The Scottish philosopher David Hume (1711–1776) recognised that the passions, or as we would say nowadays emotions and feelings, have a strong influence on moral deliberations (Selby-Bigge 1978 pp. 413–415):

Nothing is more usual in philosophy, and even in common life, than to talk of the combat of passion and reason, to give the preference to reason, and to assert that men are only so far virtuous as they conform themselves to its dictates. Every rational creature, ‘tis said, is oblig’d to regulate his actions by reason; and if any other motive or principle challenge the direction of his conduct, he ought to oppose it, ‘till it be entirely subdu’d, or at least brought to a conformity with that superior principle.

Hume went on to argue, in effect, that our actions are greatly influenced by emotions and that reason is very much the junior partner. Recent work in cognitive neuroscience suggests that Hume's assessment has a measure of scientific support and that our moral transactions may have a much more biological basis than otherwise supposed. The brains of healthy volunteers were monitored using functional magnetic resonance imaging when subjects were presented with a battery of moral dilemmas (Greene *et al.* 2004). One of these was the well-known trolley scenario in which participants are faced with only two options (Foot 1978). Individual participants must decide whether to allow a runaway trolley (a kind of bogey used in railway maintenance) to continue along the track where it will certainly kill five people or to switch the points to a branch line where just as certainly one person will be killed. This scenario is often used to encourage discussion on a number of moral issues including duty-based versus utilitarian considerations, and violation of rights.

In broad terms, the research tended to show increased activity in areas of the brain responsible for socio-emotional processing when duty-based judgements were being made, and that greater activity in cognitive areas was associated with utilitarian judgements. These findings resonate with the rather common sense notion that duty-based judgements, doing the right thing, matters of conscience, etc., are supported by corresponding emotions, whereas a focus on outcomes, and particularly utilitarian considerations, is in line with more hard-nosed, rational and dispassionate inclinations.

Greene and co-workers tentatively suggested that socio-emotional responses may be adaptations inherited from primate ancestors and relate to cultural taboos, as opposed to the more recently acquired abstract thinking and high-level cognitive control.

So, it may be that we need to work with our emotions rather than try to suppress or entirely exclude them from our moral reasoning – indeed that may be impossible. This was the conclusion reached by Gaudine and Thorne (2001) in considering ethical decision making in organisations (see also the need to balance objective considerations with intuitions, values and emotions indicated by Seedhouse (2005) and discussed in Chapter 5 (p. 110)). Gaudine and Thorne (2001) argued that emotion is not essentially opposed to a rational ethical decision process. It should not be ignored or necessarily avoided. Emotional arousal can trigger identification of a moral dilemma and encourage a tendency towards making prescriptive moral judgements, whereas low emotional response may inhibit recognition of a dilemma. Future studies by the

authors may investigate the influence of gender differences and the possibility that men may be less sensitive than women to recognising ethical dilemmas. On a general note, recognising the importance and role of emotions in decision making would appear to be consistent with the rather softer image of ‘virtue ethics’ (Chapter 1) and ‘ethics of care’ (Chapter 2).

Moral reasoning and the pharmacist

So, how might pharmacists approach the question of how to go about moral reasoning? A good starting point is perhaps to try to identify the main features of the competing moral issues – if there is no apparent conflict there *may* be no ethical problem. At very least, whenever practice impinges on beginning of life and end of life issues, it is advisable to run through the elements of the Georgetown mantra (beneficence, non-maleficence, autonomy and justice) to ensure nothing has been overlooked. Have you considered the possible effect of your intended action on the interests of all concerned, including yourself? However, you may have already identified that there are marked and possibly diametrically opposed ethical opinions on a proposed course of action – to supply or not supply, to continue treatment or not. The decision may not be yours or yours alone, but that should not of itself inhibit forming an opinion. The term moral dilemma is often used in situations somewhat akin to that faced by Buridan’s ass.

Gender differences in reasoning

Lawrence Kohlberg (1927–1987) was an American psychologist who brought together important aspects of social psychology, morality and education. His research focused on how children and adolescents develop a personal moral code. In particular, Kohlberg was interested in the reasoning processes they used, and he wanted to determine whether in fact there are universal stages in moral development. Moreover, he believed that examination of the ways in which children of different ages deal with moral problems would be an indicator of how moral beliefs are acquired. He used a series of hypothetical dilemmas that required a moral choice to be made (similar to the trolley scenario already discussed) and recorded the responses of boys from the age of seven through to early adolescence, and early adolescence through to the age group 22–28 years.

One of Kohlberg's best-known hypothetical dilemmas has a fictional pharmaceutical setting (Kohlberg 1968):

A woman was dying from a special kind of cancer. There was only one drug that doctors thought might save her. It was a form of radium that a pharmacist in the same town had recently discovered, but was charging ten times what it cost him to make. The sick woman's husband Heinz explored every possible avenue to borrow the money. He was unsuccessful and only raised about half of the sum required, telling the pharmacist that his wife was dying, and asking if he could pay the outstanding amount at a later stage. The pharmacist refused, indicating that he intended to make as much money as possible from his discovery. In desperation Heinz considers breaking into the pharmacy to steal the drug.

Clearly, the storyline is a rather outlandish fabrication in most respects. But it is exaggerated simply to provoke a response from participants. Among the questions asked were:

- Should Heinz steal the drug? Why or why not?
- Is it wrong for him to steal the drug? Why or why not?
- Does Heinz have an obligation or duty to carry out the theft? Why or why not?
- Would circumstances change if it were not Heinz's wife but a pet animal or a complete stranger who was dying? Why or why not?
- Is there an obligation to obey the law? Why or why not?

Analysis of responses to probing questions such as these with a variety of different vignettes enabled Kohlberg to develop a model that showed moral reasoning progressed through three distinct levels of moral thinking with six identifiable stages. He considered these to reflect culturally universal stages of moral judgement.

Kohlberg found that moral judgements by most younger children was associated with level I behaviour, whereas most 13 year olds operated at level II with an eye to maintaining a good impression with their peers and elders. At stage 3, this meant being well behaved and generally 'nice', and at stage 4, it meant becoming generally dutiful and showing respect for authority. Kohlberg was of the opinion that the majority of adults did not reach a level of moral maturity that could be characterised as level III. It has been suggested that most of the familiar moral theories would fit at either stage 5 or stage 6 (Baier 1973), so it is both surprising and not a little worrying that by implication we should expect that these would not be familiar concepts or considerations for many adults.

Table 3.1 Kohlberg's stages of moral reasoning

<i>Level</i>	<i>Features</i>
I Preconventional: based on self-interest	<ol style="list-style-type: none"> 1. Obedience and punishment (obeys rules to avoid punishment) 2. Individualism, instrumentalism and exchange (conforms to obtain rewards)
II Conventional: based on conformity to social norms and expectations	<ol style="list-style-type: none"> 3. 'Good-boy' morality (conforms in order to receive approval, maintain relationships and avoid being disliked) 4. Conformance with law and order (to avoid censure or sense of guilt)
III Postconventional: centred on justice and based on universal ethical principles	<ol style="list-style-type: none"> 5. Social contract (conforms to democratic law and concepts of individual rights) 6. Development of individual principles and conscience (conforms to avoid self-criticism)

It is interesting to note that the law in England and the Wales indicates that on the whole children under 10 years of age are unable to weigh up what is right and what is wrong and to deliberately break the law. Consequently, they are exempt from what would otherwise be considered as criminal acts. The Latin term *doli incapax*, meaning incapable of crime, was previously used but has now been abolished. In Scotland, children under the age of 8 years are considered to lack the mental capacity to commit a crime, though most offenders under the age of 16 are dealt with through the children's hearing system. The United Nations Committee on the Rights of the Child has recommended that the age of criminal responsibility should be raised in all the UK countries.

Although Kohlberg scripted the above pharmacy-related vignette, the general theme of the 'morality' of stealing to save a life was one explored by John Stuart Mill about 200 years earlier, and is worth quoting in full (Gray, 1998, p. 201):

It appears from what has been said, that justice is a name for certain moral requirements, which, regarded collectively, stand higher in the scale of social utility, and are therefore of more paramount obligation, than any others; though particular cases may occur in which some other social duty is so important, as to overrule any one of the usual general maxims of justice. Thus to save a life, it may not only be allowable, but a duty, to steal, or take by force, the necessary food or medicine, or to kidnap, and

compel to officiate the only qualified medical practitioner. In such cases, as we do not call anything justice which is not a virtue, we usually say, not that justice must give way to some other moral principle, but that what is just in ordinary cases is, by reason of that other principle, not just in the particular case. By this useful accommodation of language, the character of indefeasibility (cannot be annulled) attributed to justice is kept up, and we are saved from the necessity of maintaining that there can be laudable injustice.

There is a significant twist in the interpretation of Kohlberg's important studies. Carol Gilligan, who was a research student of Kohlberg, re-examined his analysis of the results obtained with the pharmacy vignette. Kohlberg had continued his work to illustrate stages in what he concluded were distinct differences in moral development between boys and girls. The extended studies with girls suggested that they did not reach the higher stages of moral development or have such a well-developed sense of justice or ability to achieve rational, moral decisions as boys. Girls' moral development was inclined to stop at level 3, which related to a concern with the approval of others. Gilligan argued that it is not that girls fail to achieve the higher levels of moral development but that they adopt a different approach to moral reasoning.

The pharmacy vignette had been presented for comment to two children, Jake and Amy. Jake declared that Heinz should steal the medicine because his wife's life was the most important consideration. Here Heinz rather follows the line taken by John Stuart Mill (i.e. justice must give way to some other principle, that of saving life). Amy, however, believed that theft was not the answer because Heinz might be caught and sent to prison, not resolving the problem but making things far worse. She suggested that Heinz should talk to the pharmacist, who despite his initial reluctance might agree to supply the medicine without charge. Subsequent research by Gilligan reinforced her own view that girls and women, while respecting the law, are far more aware of the importance of relationships in a conflict situation (Gilligan 1982). They are comfortable with feelings of empathy and have an ability to listen to others. Women are less concerned with achieving control and exhibit a readiness to circumvent moral rules that might in some circumstances impede resolution.

Like Kohlberg, Gilligan identified three stages of moral development, progressing from selfish or self-interestedness, to social or conventional morality, and ultimately to post-conventional or principled morality. As a generalisation, men tend to relate to concepts of rules and justice, and women are more inclined toward caring and personal

relationships. From this analysis, an ethics of care may indeed provide a more natural basis for women than for men (see Chapter 2). However, if Thomas Jefferson and Adam Smith are correct in their assumption that human beings (presumably both women and men) possess an irresistible compassion, then it seems wholly appropriate to recognise these emotional elements within the broader relationships that are an integral part of the processes of healthcare. Furthermore, if an ethics of justice is considered to be rational and objective with due consideration of fairness, impartiality and equality, and susceptible to rule-based decision-making by autonomous agents, then it may be also be viewed as rather overly hard-nosed. Rule-based systems are just that. They are inclined to be inflexible. Rule-based flexibility is self-contradictory. Under these circumstances, the fact that a patient is also a human being, susceptible to concerns, fears, phobias or misunderstandings about their illness, and responsive (either beneficially or adversely) to those contributing to their treatment, may be only a subsidiary consideration.

Where resources are limited, busy and hard-pressed staff may all too easily focus on more clearly defined objective measures and neglect any residue of irresistible compassion. Empirical studies carried out as part of a multinational study on 'Dignity and Older Europeans' identified that many older people in the UK felt that consideration of their dignity was often neglected (Calnan *et al.* 2006). It is also clear that some aspects of healthcare are much more relevant as far as an ethics of care is concerned. If nursing qualifies as the most relevantly 'caring' profession (the image of Florence Nightingale ministering to the sick comes readily to mind), then pharmacists, for whom patient contact and interaction is often much more limited, would arguably tend toward the other, 'deontological' extreme. Just follow the rules, you can't go wrong. But a strong case can be made that, once a moral issue or ethical dilemma is identified, consideration of the emotional state of the patient and the emotional interaction between patient and all other health professionals with whom they interact becomes vital. A young woman, perhaps an underage teenager seeking advice on contraceptive methods or access to the 'morning after' pill requires a community pharmacist to employ far more than forensic or pharmacological knowledge (Wingfield 2005).

Moral dilemmas

Because of the nature of healthcare and medicine, it is not surprising that there have been many well-publicised circumstances characterised

as being ‘moral dilemmas’. Moral dilemmas are associated with incompatible alternatives. Generally there are two possible choices carrying equal obligation. You must choose between them, you can’t do both. For example:

pharmacist *P* is obliged to...*A*, and can do *A*
 pharmacist *P* is obliged to...*B*, and can do *B*
 pharmacist *P* cannot do both *A* and *B*.

Here, *A* might be an obligation to respect a patient’s autonomy, and *B* could be the obligation to respect some information given to the pharmacist in confidence by the patient’s wife. The pharmacist is only too aware of his responsibility to both patient and spouse, but he cannot act on the information he has been given without compromising one or the other. It seems that whatever the pharmacist does will be morally reprehensible because he will either do something wrong (betray the wife’s confidence) or fail to do something he should (perhaps counsel the patient that his failure to follow the strict dosage regime could be fatal).

For those of you who haven’t been put off the idea of using symbolic logic, the structure of a dilemma can take various forms, but a common variant is what is designated a *constructive dilemma*:

if *p* then *r*
 if *q* then *r*
 but either *p* or *q*, so *r*.

The terms *p* and *q* are the conditional premises and have become known as *the horns*. Whichever option you choose, *p* or *q*, has the undesirable consequence *r*. In the above example, the undesirable consequence *r* is the breach of a fundamental moral principle. The word dilemma derives from the Greek word meaning an assumption, or in this case two assumptions. The well-known phrase ‘being on the horns of a dilemma’ captures the notion of being tossed by a bull whichever horn you grasp. Hence the means of dealing with a dilemma is to deny one of the disjunctive premises, that is *take the dilemma by the horns*.

Most of the dilemmas that hit the headlines tend to be associated with the weighty matters of life or death, or more recently, access to healthcare resources. This is hardly surprising. Should a critically ill, brain-damaged infant be maintained in a persistent vegetative state indefinitely? Should terminally ill patients be given access to expensive and/or experimental drugs as a matter of right? Should those suffering with AIDS (acquired immunodeficiency syndrome) or cancer gain access to experimental drugs before licensing? Should someone who is termi-

nally ill and suffering intractable pain be given assistance to die? You can list for yourself what are the key issues and major moral implications. Some of them are discussed in Chapter 6.

All of these questions relate to real-life moral dilemmas where the answer to the question of what to do means, in effect, following one duty or obligation and denying another. Mention has already been made of the 'trolley scenario', and 'Heinz and the life-saving drug'. These fictions or vignettes have the advantage of being readily manipulated by philosophers or ethicists to explore the various boundaries and facets of the dilemma, and the ways in which people reason and respond. Latif (2000) indicated that discussion of ethical case studies could be used to increase the moral reasoning skills of pharmacy students. The sorts of questions posed by Kohlberg help to probe and draw out the nature of a particular dilemma. The 'trolley scenario' has even been used as a comparator to emphasise the difference between killing and letting die. Naylor (1988) refers to a 'transplant case' vignette originally proposed by Judith Jarvis Thomson in 1985 for just that purpose. Suppose, perish the thought, that by killing one healthy person with a rare blood group you could provide five other people of that same blood group with the spare body parts that would save their lives. In both cases, 'trolley' and 'transplant', there is a choice between saving five lives and killing one person. The supposition is that most people asked to comment on the two situations would tend to agree that it would be morally permissible to divert the trolley to save the lives of five persons, thereby causing one death, but unthinkable to cold-bloodedly kill a healthy person for their body parts. Why?

Before dismissing the question as being wholly fantastic, just consider that many countries would now scramble fighter aircraft to 'escort' an airliner with terrorists on board. In an emergency, the lives of larger numbers of people on the ground would take precedence over the passengers. The essentially utilitarian judgement is of a similar nature to that of bombing an aircraft or armaments factory close to a civilian residential area in wartime to save the lives of the larger number of people potentially in jeopardy from those armaments or aircraft under construction. Naylor's analysis (1988) suggests that the moral difference between the two cases turns on avoidability/unavoidability, numbers, rights and consent. In the case of the 'trolley', an instant decision is needed – there is no time to discuss or prevaricate. The utilitarian decision to maximise the number of lives saved (the only morally relevant factor) is defensible because there is no opportunity to seek the consent of the single unavoidable victim. But for 'transplant', the potential to

save lives is trumped by the avoidability of violating the rights of the potential donor. Neither for that matter is time of the essence. And in more familiar circumstances, no one is seized on the streets for forcible blood 'donation' or relatives compelled to 'donate' a kidney or other body tissue even though such acts could save lives. We continue to rely on well-tried procedures of obtaining autonomous consent for these life-saving measures.

Some fictional moral dilemmas are distinctly compelling. Glover (1999) used the term coercive moral dilemmas to describe psychological techniques deliberately intended to induce mental anguish. In the film *Sophie's Choice*, which has a Second World War setting, a mother must sacrifice one of her children to save the other. How to choose – how could one possibly choose? Only fiction, but it does not require too much imagination to feel for oneself the anguish in Sophie's dilemma. Choices somewhat similar to this, though not coercive, are made when a mother's life is threatened and can only be saved by sacrificing an unborn child. If no action is taken, possibly both will die. Or, as Wingfield (2005) has said, should a pharmacist risk compromising the autonomy and trust of a young and possibly emotionally unstable patient and breach confidentiality by informing a parent when emergency contraception is sought?

Of course not all dilemmas have a moral component and what we are speaking of in general terms is simply that situation where a choice must be made between two equally *undesirable* alternatives. Note that the alternatives must be both undesirable and arguably equivalent with respect to undesirability. Neither alternative desirable outcomes nor undesirable outcomes that are markedly different in seriousness can be considered to constitute moral dilemmas. A choice between two beneficial actions is a matter of making a choice based on knowledge of the candidate therapies, and the patient's characteristics and preferences: in other words making an informed decision. Similarly, making a choice between treatments with clearly unequal undesirable consequences is fairly straightforward. But remember the Latin phrase *ceteris paribus*? All things being equal, or in this instance unequal, may be complicated by circumstances.

Some philosophers have argued against there being genuine symmetrical moral dilemmas. For instance, the relevant moral principles can be weighted hierarchically and the highest weighted principle takes precedence over any other: no dilemma. But can we be sure that, say, any one principle should always take precedence over another irrespective of circumstances? What is sometimes referred to as a utilitarian

calculus can be carried out to determine the net beneficial approach. One problem that has been identified with both weighted principle and consequentialist approaches is that there may be a residue of ‘moral distress’:¹ – the residual concern or element of guilt that in having taken one course of action another has been overruled, neglected or set aside. Studies carried out in Sweden indicated ‘ethical dilemmas and moral distress are present among pharmacy personnel in their everyday work’ (Kälvemark 2004). To alleviate such distress requires attention to work organisation and management in which (Kälvemark Sporrang, 2005) ‘Ethics must be seen as a process and ethical decisions as the result of a dialogue... When ethics is regarded as a process it becomes obvious that ethical judgements are seldom a case of an individual person knowing for sure what is right or wrong ...moral decision-making involves a complex interaction between people with different experiences and knowledge, situated in a certain setting. Therefore the focus must be upon the context.’

It is worth restating the view of Thomasma (2003) that:

....all ethical dilemmas involve a clash of cherished values embodied in long-held principles. For any person in a dilemma it is difficult to prioritise these cherished values, for example, telling the truth and saving lives, because they both seem to be highly prized and sometimes irreconcilable. Finding the right balance among these and other values is the heart of the moral life.

Recognition of the possibility of a clash of values within the complex context of attempts to resolve a moral dilemma will not of itself solve the problem but may help to bring about an acceptable accommodation.

Fallacies

Fallacies are logical mistakes in reasoning and have been of interest to philosophers since at least the time of Aristotle (384–322 BC). An individual fallacy is either deliberate or inadvertent and contains a factual mistake in one or more premises or draws an erroneous conclusion from correct premises. Some of the more common types of logical fallacy have been given recognised names, some of them in Latin like the *ad hominem* argument described at the beginning of the chapter. Here are a few other examples.

¹ Moral distress has been defined as ‘when one knows the right thing to do, but institutional or other constraints make it difficult to pursue the desired course of action’ (Raines 2000).

Argument ad baculum: an argument appealing to fear because supposedly dire consequences will follow.

Argument ad populum: an argument that appeals to prejudices, rather than facts and reasons.

Non sequitur: generally, a fairly obvious case of a conclusion that self-evidently does not follow from its premises.

Post hoc, ergo propter hoc: it followed after, therefore it was caused by. Generally, applied to arguments in which there is no plausible connection between an event or circumstance and what followed. The phrase is not normally applied in therapeutic medicine in circumstances such as ‘she got better after taking the tablets’ because her getting better way well have resulted from taking the tablets.

Red herring: an irrelevant tactical argument intended to divert attention from the main considerations.

Slippery slope: applied where the consequence of accepting someone’s argument is to invalidate one’s own position. Alternatively, and more commonly, slippery slope is cited when it is argued that a change in the law or in a procedure will not stop there but lead to other perceived adverse consequences.

Straw man: either putting up a false argument then attacking it as something of a diversionary tactic, or to argue against a position that no one holds or could be expected to hold.

There are very many more fallacious argument structures. Gary Curtis, an American philosopher whose doctoral thesis examined logical form and fallacies, maintains a comprehensive ‘fallacy files’ website (see Curtis 2006).

It used to be the case that fallacies were viewed strictly as logically invalid arguments (the logico-centric approach). More recent scholarship has indicated that far more attention should be given to the context in which fallacious argumentation occurs and the often-complex processes of communication and interaction (Eemeren and Grootendorst 2004). Despite Thouless’s (1953) comments, discussed at the beginning of this chapter, we should not altogether set aside the contribution of emotion in all human relationships including argumentation. Gilbert (1994) was all for cautioning against absolute reliance on reason:

What we have to abandon is the idea that there is a good child and a bad child of human psyche. While emotions can run hot, and that can lead to unfortunate consequences and even devastating results, the same is true of reason. Vast injustices and horrible events have been perpetrated in the name of ‘cold reason’.

For our purposes here, a better awareness of the nature of some of the common errors in reasoning whether supportive or against a particular standpoint is valuable. But undoubtedly, there is also a place for respecting the importance of the 'emotional' considerations recognised in ethics of care (Chapter 2). In consequence, it may be possible to get closer to a 'rational solution' to controversial questions by not altogether excluding irrational aspects.

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4

Professionalism and accountability

The nature of professionalism

Throughout its existence, pharmacy has been constantly concerned with establishing itself as an independent health profession (particularly independent of doctors) and to be seen by others – colleagues, patients and the public – as professional (Denzin and Mettlin, 1968, Appelbe 1985, Holloway 1991, Anderson 2001, Appelbe and Wingfield, 2005 pp. 284–287). It is, therefore, worth reflecting briefly on the nature of the word ‘professional’, which has been used both to distinguish professional activities from those of the ‘amateur’ and, separately, to distinguish from those of a ‘tradesman’. The first distinction implies undertaking work for some recompense as opposed to sheer love of the work; such as the difference between professional and amateur actors. The second distinction arises from predominantly British eighteenth century traditions of the proper activities of a ‘gentleman’ as a person of high moral character and trustworthiness possessed of sufficient wealth and leisure to avoid the need to make a living. From this second concept derives the notion that making money (‘being in trade’) is somehow distasteful and sullies the nature of a true professional (Friedman and Phillips 2003).

Clearly concepts of professionalism have shifted somewhat in our current century, although the taint of commercialism may still be detected in the acceptance (or not) of the pharmacist as a health professional in the ‘chemist shop’. Moreover, the term has extended far beyond the original gentlemanly occupations of the church, the law and medicine to include the activities of electricians, plumbers and hair-dressers to name but a few. When people say ‘he or she is a true professional’ or ‘she behaved unprofessionally’ these phrases have some meaning and could as easily be applied to a decorator as a surgeon. So how can we define professionalism?

During 2005, the Royal College of Physicians (RCP) set up a working party on medical professionalism to ‘look at issues such as the role of the professional in society, how professional people are educated

and trained, and how they practise' (Royal College of Physicians 2005). The following account draws on submissions made during the working party consultation as well as a wide bibliography on the subject of professionalism. As its starting point, and ours, the RCP used the current *Oxford English Dictionary* definition of a profession.

An occupation whose core element is work based upon the mastery of a complex body of knowledge and skills. It is a vocation in which knowledge of some department of science or learning or the practice of an art founded upon it is used in the service of others. Its members profess a competence to practise, integrity and morality and altruism, and the promotion of public good within their domain. These commitments form the basis of a social contract between a profession and society, which in return grants the right to autonomy in practice and the privilege of self-regulation. Professions and their members are accountable to those serviced and to society.

This definition is not dissimilar to that propounded by Dale and Appelbe in 1976 (pp. 103–104).

Nowadays just about every aspect of this definition could be challenged as being inconsistent with modern concepts of professionalism or as being applicable to a great many activities that are not conventionally regarded as professions. Indeed, Harry Cayton – then Director for Patient and Public Involvement (in the UK National Health Service (NHS)) at the Department of Health – described it as a 'wonderfully pompous, self regarding definition' in his submission to the RCP Working Party (technical supplement to the RCP report).

Pharmacy and professionalism

So how would pharmacy measure itself against this definition? Certainly, pharmacists must acquire a great deal of knowledge and skill to practise, but there is no unique mystery to the gaining of such attributes: anyone who has aptitude and works hard can do it. Scarcely any health professional would anyway claim to have complete 'mastery' of any topic in our fast moving world of technical and medical advances. Is pharmacy a vocation – a calling, a desire to be of service, to help others? This is probably still a strong motivation for all health professionals but could equally be so for many other trades. A true vocation does not look for payment. Such selflessness no longer characterises any profession or trade (although it is true of the amateur).

The definition says that professionals ‘profess a competence to practise’. This has always been true of pharmacists and is the rationale for their establishment as an independent profession, the creation of a register and associated disciplinary sanctions. In recent years, this profession to competence now has to be proved, through evidence of relevant continuing professional development and probable revalidation to practise in the future. Less easy to prove, however, is the possession of the virtues of ‘integrity, morality and altruism’, or indeed to determine to what extent these should be displayed. So far as altruism (regard for others, unselfishness) is concerned, Dame Janet Smith in her evidence to the RCP asserted, ‘No professional should be expected to provide a service without proper remuneration and support systems to live a normal, happy family and social life’. In the past, health professionals may have been prepared to sacrifice their home life for the occasional emergency call-out. This is no longer a reasonable expectation in an NHS that promotes constant accessibility when patients want it – which is more or less all the time. Moreover, pharmacists are increasingly expected to collaborate and contribute to efforts to address health inequalities and to promote ‘public good’ through advising on healthy lifestyles whilst struggling to maintain their own.

Is there a social contract between pharmacists and their users? If such a contract is manifest by trust between the parties, then this is still intact but somewhat jarred by successive health scandals at the turn of the twenty-first century (Bristol Royal Infirmary Inquiry 2001, Royal Liverpool Children’s Hospital Inquiry 2001, Shipman Inquiry 2005). Increasingly, as we shall see below, some virtues expected of health professionals are no longer a matter of trust but must be documented and proven thorough a series of processes and before a range of regulatory bodies.

Professional autonomy for pharmacists arguably began to be undermined with the advent in 1948 of the NHS, within which the role for pharmacists was solely that of supplier of medicines. Moreover, as recently as 1970, the *Statement upon Matters of Professional Conduct of the Pharmaceutical Society* charged pharmacists thus (Dale and Appelbe 1976):

The therapeutic efficacy of prescriptions should not be discussed with patients or others in such a manner as to impair confidence in the prescriber’ and ‘A pharmacist... will dispense the prescription exactly in accordance with the prescriber’s wishes...’.

Little scope for professional autonomy there! As the decades advanced, the activities of the pharmacist shifted from skilled compounding of pharmaceutical remedies to what was perceived as the mere handing out to patients of manufacturer's packs of proprietary medicines, with little time for or expectation of advice. This trend was resisted firstly in hospital practice in the 1970s and 1980s as pharmacists took on and received recognition for their clinical skills in maximising the value and optimal use of medicines. Further support for the pharmacist's professional responsibilities came in 1982 in the High Court judgment in the 'Migril' case (Dale and Appelbe (1983, p. 220); further examples are given in Appelbe and Wingfield 2005 (pp. 292–295). This judgment stated that pharmacists were independent practitioners and should not be deterred from querying prescriptions with the prescriber where an error may have occurred.

Later development of clinical roles for pharmacists in primary care and a new 'NHS contract' in 2005 for community pharmacists look set to redress this trend further. In some ways, this late arrival to professional autonomy may be regarded as valuable since pharmacists have never had the opportunity to develop the omniscience and paternalism against which medical practitioners have had to struggle in the last few decades. A new concept of professional autonomy in partnership with the patient is now perceived as the proper role of health professionals (Wingfield 2006). There is some argument as to who should set the standards and values of a given profession but mutual ownership of them seems to be the way forward.

Most pharmacists would agree that there is some difference between being engaged in 'just a job' as opposed to being a member of a profession: part of that difference lies in the adoption of certain values and part lies in the increased accountability our society expects of those upon whose advice they choose to rely.

The ethical basis for professionalism

Why should professionals care for their clients? The glib answer is that it is their duty. So is there an ethical basis (as opposed to a legal one) for a 'duty of care'?

We have seen in Chapter 1 that the moral basis for ethics is usually approached in three ways: duty-based concepts of what should be the right motivations behind our actions, consequential considerations of maximising happiness for the greatest number of individuals and

thirdly the exercising of virtues possessed by those regarded as virtuous, morally praiseworthy, individuals.

Duty-based morality

Most would agree that 'a doctor, by virtue of her professional title, has a particular role to play in relation to patients, that is, she owes them a duty of care, usually expressed as the duty to act in their best interests' (Foster 2001, p. 33) and that this is also true for pharmacists and for all health professionals. Such an expectation has been manifest in the pharmacy Code of Ethics published by the RPSGB since its inception in 1944 (Appelbe and Wingfield 2005, p. 289) and was no doubt accepted well before then. For doctors, the exhortation to 'first do no harm' has been a colloquial summation of the Hippocratic oath for many centuries and is further expressed in the prime duties of beneficence and non-maleficence promoted by Beauchamp and Childress (2001). Such moral duties are no less powerful within pharmacy. We expect to be better off when we take advice from our professionals; we certainly do not expect to be worse off or harmed by them. Sometimes, however, these expectations may overlook the fact that health professionals are also human and subject to human frailties and error. Just as it is 'natural' to hold a father more culpable for killing his son than we would hold the same murder by a stranger, so many hold pharmacists and doctors more to blame for failures than they would those in other less risky walks of life – even though the error is the same.

Another approach to the moral basis for a duty of care lies in the distribution of power. From the Middle Ages to the recent past in Britain, education was largely available only to a small elite, exclusively male and perpetuated by rank, wealth and privilege. The masses were mostly wholly uneducated, in thrall to religious dogma and superstition and their lives were, to use the well-known cliché, 'nasty, brutish and short' (Hobbes 1651). In those circumstances, those in possession of education laid claim to having a duty to care for those less fortunate than themselves. The formation of professional associations, mostly in the nineteenth century, with codified expressions of how the duty of care of their members would be demonstrated were an attempt to rectify the imbalance of power between the professional and client. Although such power imbalances are overwhelmingly less evident in modern times, they still exist and professionals are still trusted not to exploit such imbalance or, more desirably, to redress them.

Yet another facet of duty-based morality can be recognised as a reflection of human rights. Patients who consult a pharmacist or who use their services do so in the expectation that they have a right to good quality, current information, or to an intervention that is safe and up to date or to a service that will be of benefit to them. Human rights to respect for autonomy, private life and beliefs mean that professionals must reflect these concepts when discharging their duty of care.

From all of the above, it is implicit that operation of duty-based concepts of professionalism is grounded in concern for the individual, not in the wider context of populations and society as a whole.

Goal-based morality

If we turn now to utilitarian arguments for professionalism, then these can be equally compelling. We shall see below that the external consequences of not practising professionally are many and various and the sanctions can be very severe. However, we are concerned here with internal motivations: the desire to use one's knowledge and skills to better the lives of as many people as possible. The pharmacist is concerned with the optimal use of medicines as a means to manage disease and suffering in the populace. The outcome of this concern may have differing consequences for the patient or user at an individual level as opposed to consequences within a community or particular patient group.

The most common example of the operation of utilitarian arguments in pharmacy practice is the distribution of resource to deploy medicines (see also Chapter 6). Involvement in prescribing policies, management of drug budgets, even helping customers choose medicines for self-care involves considerations of optimal use of limited funding, value for money, cost-effectiveness and efficiency within populations with competing needs. Professionalism is needed from the pharmacist to limit the sacrifice of priorities and preferences of individuals in the process.

Ethical imperatives to maximise happiness for the greatest number of people are also at work in policies for public health and health-promotion activities. In the UK, the goals of the NHS are now as much about helping the well to stay that way as to help the sick according to their needs (a duty-based concept accepted by government and delivered through the NHS). Campaigns to tackle smoking, obesity and heart disease, or to promote sexual health, are utilitarian endeavours in which

pharmacists are expected to participate. The community pharmacy contract introduced in 2005 (The NHS (Pharmaceutical Services) Regulations 2005 SI No.641) makes this clear by requiring pharmacists to take part in local and nationally determined health-promotion campaigns. Most were (and still are) already carrying out such activities at least in part to meet an internalised professional commitment to help people to get or stay healthy.

Research is an aspect of healthcare practice where utilitarian arguments can swamp deontological consideration of the treatment of individuals (see also Chapter 6). Well-known examples arose during the Second World War when Nazi doctors used utilitarian arguments to justify their experiments. Foster (2001, p. 16) commented 'there is nothing in utilitarianism as such to prevent acts which our intuition (or conscience or moral values) would regard as abhorrent'. The role of doctors who carried out or even directed the Nazi experiments was ultimately held to be contrary to the very essence of professionalism. Health professionals simply cannot instigate, condone or refrain from remedying activities where professional (ethical) duties to individual patients are ignored. Such considerations must, therefore, inform the involvement of pharmacists in research or treatment, even when such activities may have been approved earlier or instigated by others. On a lighter scale, vaccination is an example where some harm/burden to individuals may be necessary to benefit the majority.

Virtue-based morality

It is in the possession of professional virtues that many may recognise professionalism. These may be listed as an obligation to care; to display honour, integrity, humanity, confidentiality, humility, compassion, empathy, trust, understanding and probity; to use good judgement; and to exhibit good behaviour. Joining a profession implies a commitment to all these values, at least within the professional setting. It is expected that these values will be 'internalised' – in other words adopted as one's own personal values – as part of the process of becoming a professional. This can be a tall order and is inconsistently applied. Most members of the public would not necessarily lose faith in their pharmacist if he committed adultery, but they, and the professional regulators, are less forbearing when it comes to making use of Internet porn or where the subject of the adulterous relationship is also a client or patient.

Accountability

Personal accountability

If ethics is about ‘doing the right thing’ then where lies accountability for doing the right thing, or seeing that the right thing is done (and the wrong thing is not)? As we have seen above, this accountability is internal and personal for most health professionals. We want to do a good job, to feel we have done our best and to be able to sleep at night without anxiety. This is the essence of personal accountability – our conscience or duty to ourselves, if you will – for the quality of the service we provide as pharmacists. It arises, to a greater or lesser extent, from allegiance to the moral basis for being professional.

However, a major limitation on the degree to which we can accept such liability is the extent to which it remains personal. A further definition of a professional, now dropped from current descriptions, is that of being an independent practitioner. This constraint was grounded in an assumption that only a truly independent private practitioner could bring real independence of thought to his or her practice. Being an employee was thought possibly to compromise this independence, though such fears have rarely been borne out. Few professions still reflect this concept. Barristers-at-law still assert a need to practise individually to be truly detached and independent. Solicitors, of course, practise in collections of partners and their professionalism has been challenged because of this. Few now would accept that professionals must compromise their professionalism and judgment simply because they are employed, not least because by far the majority of health professionals are, in fact, employees. Nevertheless, personal accountability can be influenced or even prejudiced by the employer–employee relationship. We return to this topic later and in Chapter 6.

A further limitation on personal accountability will be increasingly hard to address. In an operating theatre, on the wards, in a clinic or in the management of a long-term condition in the community, a whole range of health and social care professionals and support staff may be responsible for the provision of some aspect of care. To what extent then should each hold themselves personally accountable for their contribution? In the past, the doctor or consultant was tacitly regarded as the final holder of professional accountability. This explains some justifiable resistance amongst medical practitioners to the encroachment of other professionals on what had previously been seen as their ‘territory’. The modern approach is teamwork: each professional making their own

unique contributions to the whole, or, more likely, a given contribution being made by a range of different health professionals. An example may be found in the development of supplementary prescribing in which nurses, pharmacists, radiographers, physiotherapists and podiatrists have acquired responsibilities for prescribing under certain circumstances. Establishing who exactly should be held accountable for causing harm may well become problematic.

If professionalism reflects an attempt to address a power imbalance, to what extent is the patient now expected to undertake some responsibility for the outcome? In health strategy papers (Department of Health 1999, 2000), the concept of the 'Expert Patient' was launched, drawing upon the idea that patients who knew a great deal about their condition, how it felt and how they coped with it should work in partnership with their doctor or perhaps pharmacist to improve management of that condition. In this situation, who carries accountability for failure in any given part of that relationship? What of the patient who does not reach 'concordance' on the management of their condition? What of the patient who deliberately flouts advice and this action leads to harm? Even more controversially, what of the patient on regular medication for many years who fails to notice that some change in their medication should have been challenged? Is it always the sole accountability of the pharmacist?

We should also consider how the development of registered pharmacy technicians might affect the professional accountability of the pharmacist. To what extent can a pharmacist who delegates certain activities to a trained supporting member of staff then abrogate accountability for those activities? It is worth reflecting here on the terminology used in the field of accountability.

The terms 'responsibility' and 'accountability' are often used interchangeably and not infrequently mixed with the term 'liability'. We suggest that this can be confusing and unhelpful and suggest definitions for these terms (Box 4.1).

These are by no means adopted across the plethora of regulations, codes, official directions and guidance that seek to set out the accountabilities of health professionals. Moreover, the term 'accountability' is not widely used in countries other than the UK, preference being given to 'responsibility' or 'answerability' (technical supplement to the RCP report).

Accountability takes many forms and can be owed to a wide range of individuals and bodies. Tilley and Watson (2004, p. 174) in their textbook on accountability in nursing and midwifery identify no fewer

Box 4.1 Suggested definition of terms used in professional accountability**Responsibility**

Your job is to do a specific task but not necessarily more

Accountability

Your job is to achieve a specific outcome, ensure others do their specific tasks and can be called to account for failure

Liability

Can be called to account in law and possibly pay if failure leads to harm

than six entities to whom a nurse researcher may be held accountable: the sponsor, the research ethics committee, the research participants, research ‘gatekeepers’ such as the employers of staff who are to be interviewed, the profession of nursing and to the wider public. This list would be equally applicable to pharmacists undertaking research. The approval and scrutiny of clinical trials and most medical research is now the remit of formally constituted research ethics committees and rigorous submission procedures. Nevertheless, because of their special expertise and knowledge, pharmacists involved in research may still expect to be accountable for the proper balance between the best interests of individual participants and overall benefit to a wider population.

Accountabilities are also heightened if the recipients of care are vulnerable, such as would pertain with children, persons with learning disabilities or the ‘frail elderly’. For example, efforts to secure informed consent to treatment or disclosure of information will be more exacting and time consuming than for competent adults; accountability will be correspondingly higher. Accountabilities will reflect the level of skill and expertise exercised by the pharmacist: a consultant pharmacist with special expertise in oncology, for example, will be held more accountable than junior pharmacists with no such specialist skills. Accountability may also reflect seniority: a superintendent pharmacist can be accountable for professional activities in more than 1000 pharmacies, or a specialist pharmacist in public health could be accountable for ensuring service quality in a large number of surgeries or pharmacies.

Involvement of pharmacists in prescribing policies and health promotion opens up new, and as yet, unclear prospects of accountability. Could a pharmacist be held to account for advice provided to a surgery, for example, if a patient was thereby denied his or her preferred

medicine? Could a pharmacist be personally accountable for failure to provide appropriate health-promotion advice or for provision of incorrect or inappropriate advice? The answer is almost certainly yes, but no such cases have arisen formally. Such considerations remain for the conscience of the pharmacist concerned at present. Distinctions also arise between anticipation of health advice being offered to a patient in a 'traditional' healthcare setting such as a hospital bed or doctor's surgery compared with possible resistance to the same advice offered to a customer in a busy pharmacy or in their own home. The degree of client autonomy may be radically different – is it reasonable to apply the same accountability to the pharmacist in both settings? It may be reasonable to expect a full medication review to be undertaken for each patient attending a special clinic for diabetes but not necessarily for every patient handing in prescriptions at a pharmacy.

Professional accountability and codes of ethics

The creation of a professional register is a way of publicly stating that members of the profession claim particular knowledge and expertise that had to be proven to enter the register. Indeed, the derivation of the word 'profession' stems from the Latin *professo*, a verb meaning to take an oath or make a public declaration. It follows that members of a profession accept and expect to be held accountable by the profession for certain qualities and to be removed from the register if found wanting. Other perspectives on the role of a profession may be less charitable: 'all professions are conspiracies against the laity' (Shaw 1906) or more functional 'a body organised for the performance of duties' (Andrew Phillips, technical supplement to the RCP report), but most professions will have a statement of the values expected of members of a profession as well as concrete duties.

An account of the disciplinary mechanisms in the pharmacy profession may be found elsewhere (Appelbe and Wingfield 2005); we focus here on the role of Codes of Ethics, particularly those in pharmacy and the health professions. The pharmacy profession in Great Britain adopted a register in 1933 and the Statutory (disciplinary) Committee first deliberated on a matter of misconduct and fitness to stay on the register in 1936. Nevertheless, the profession did not undertake a formal declaration of its ethical standards until the publication of the first *Statement on Matters of Professional Conduct* in 1944. This title was changed to the Code of Ethics in 1984 and this title is still used, although the content has been revised every ten years or so. Codes (of

ethics or otherwise) generally express an agreed set of rules and standards of conduct expected of a group of individuals. They are as likely to apply to members of a golf club or a trade association as to a profession. So what is the nature of an ethical code?

In 2002, the Professional Associations Research Network (Friedman 2002) examined 52 codes of conduct produced by UK professional associations and published an overview of their content. The research identified a number of common themes underpinning the philosophy of such codes, their structure, language and enforcement. International efforts to at least achieve some convergence amongst codes of ethics for health professions commenced with the Tavistock Group (Smith *et al.* 1999, Berwick *et al.* 2001), although the outcomes were mostly concerned with economic and resource constraints in health systems. In earlier years, these aspects had been considered by Appelbe (1992), and later Redman (1995) suggested that all healthcare providers should be brought together in a consistent moral framework but to date, each profession continues to develop its own code. Convergence of healthcare regulation under the Council for Healthcare Regulatory Excellence may eventually address this issue.

Codes of ethics in other countries

In recent years, several national and international pharmaceutical bodies have promulgated Codes of Ethics and we digress slightly to consider certain factors common to each. The form of these codes varies according to the geographical and legal system of each country. They may be national, as with Great Britain and New Zealand, or federal, applying to a number of states such as in Australia and Canada, or produced by international bodies such as the Federation Internationale Pharmaceutique (FIP) and the Groupement Pharmaceutique de l'Union Europeane (GPEU). A further variation may be found in France, where the Code of Ethics for pharmacy is part of a general code for all health professionals, namely the Code de Deontologie des Pharmaciens, which is part of the French Code de Sante Publique.

The contents of national or federal codes tend to reflect the same principles and reflect the obligations of the FIP Statement (see below). The basic principles are comparatively short although each have added obligations or guidelines: Australia has nine 'principles', New Zealand has 10 while Canada has 10 'values'. Apart from Great Britain (which has just completed the revision of its code; see the Appendix), these three countries have produced codes within the last two years that

reflect modern thought on ethics and codes. They maintain the basic philosophy that the prime role of the pharmacist is the health and safety of patients, to comply with the legislation and other pharmaceutical guidelines and to uphold the status of the profession. Additionally, they refer to other ethical duties such as maintenance of high standards of competence, respecting confidentiality, being truthful and recognising patient autonomy by promoting their dignity, integrity and right to make their own judgements.

The two international codes are different from each other. The FIP document (approved New Orleans 2004) is short and succinct and sets out on one A4 page a series of obligations 'based on moral principles and values to enable national associations of pharmacists, through their individual codes of ethics, to guide pharmacists in their relationships with patients, other health professionals and society generally...'. The GPEU code of 1996, which was itself based on the FIP Code of 1993, is limited to community practice and is rather longer and heavy on detail.

Finally we look at the French Code de Deontologie des Pharmaciens. It forms Chapter V of the general Code de Sante Publique for all health professionals and is divided into three sections. The first section sets out what the Code is and its purpose; the second section is the Code of Ethics itself, which applies to all pharmacists; and the third section deals with various issues in community, hospital and veterinary practice. The Code comprises short obligations that reflect the well-established areas of concern in ethics such as welfare and duty to patients, upholding the status of the profession, independence of pharmacists, confidentiality and relationships with patients.

Benefits and drawbacks of Codes of Ethics

There are also some general comments worth making on the good and bad points about Codes of Ethics. One should ask whether a Code of Ethics is in any event necessary. The study by Professional Associations Research Network makes reference to at least one profession that has none (Society of Automotive Engineers in the United States (Friedman 2002 p. 2)). However, for health professions such as pharmacy this is really not an option. Public and government expectations¹ are that standards of conduct and behaviour should be published and the

¹This expectation is now statutory in article 45 of the Pharmacists and Pharmacy Technicians Order received Royal Assent in February 2007.

profession's disciplinary processes depend to some extent (but not entirely) upon the standards set out in the Code of Ethics. On the positive side, a Code of Ethics is usually the result of reasoning, analysis and debate amongst both eminent members of the profession concerned and lately between 'ordinary' members of the profession and the public. A Code of Ethics can be a useful guide for action, particularly for students or newly qualified pharmacists. The Code of Ethics is public (the RPSGB began to make all their official documents available on their website in the early 2000s) so other health workers and patients will know what to expect from pharmacists. In an ideal world, a Code of Ethics should be 'short and sweet' but that leads to a paradoxical situation in which a statement of ethical principles perhaps is of little value without copious guidance on how to apply these principles in practice.

This aspect leads to the main drawbacks of a Code of Ethics. Such a code frequently need interpretation and is rarely applicable in all situations. If it is too principled or too 'aspirational' then it may fail to say anything of practical use and may allow defending lawyers in a disciplinary case to argue from a strict construction of the words themselves rather than the intention behind them. It needs constant updating to keep in line with advancing practice, and it may become wordy and unwieldy in order to be comprehensive (and often is, therefore, unread). Philosophically, the more detailed a Code of Ethics, the more it may take away choice and judgement for the professional, inhibiting the application of decision-making skills and weakening professional autonomy and accountability. A code tends to 'accentuate the positive', spelling out expected professional behaviour, but rarely describing behaviour that is *not* professional, probably because the possibilities are endless. This does cause difficulties, however, in the framing of complaints of misconduct. In referring to judgement, most codes recognise only that of the professional not the views of the patient, although that is changing to reflect the concept of 'concordance' between pharmacist and patient. Finally, a Code of Ethics is rarely of help in resolving conflicts, especially where these involve balancing one ethical goal against another or between the law and ethical goals. We examine this aspect further in Chapter 5 on decision making.

In the early 2000s, two new accountabilities were incorporated into the Code of Ethics for pharmacists (and for most other health professionals). The first of these is concerned with disclosure of information about others involved in healthcare whose conduct may jeopardise patient safety – the so-called 'whistleblower' requirement. The second is a similar obligation to report oneself to the authorities if 'you have good

reason to believe that you ...may not be fit to practise for reasons of health, conduct or competence' (RPSGB Code of Ethics July 2005, Part 2 Paragraph A.1 (m)). These requirements erode any notions of self-regulating professions also being self-protectionist and reinforce the expectation that professionals will exhibit exemplary conduct both within and outside their sphere of practice.

A final consideration in this discussion on professional accountability arises from issues of personal conscience and the delivery of healthcare. The Code of Ethics allows pharmacists to decline to provide a service if so doing conflicts with their personal religious beliefs or personal convictions. This may mean that a pharmacist thereby declines to provide what is otherwise thought to be in the patient's best interests. Exercising this discretion creates other accountabilities: to make such reservations known to employers, to ensure that they are conveyed to patients, either directly or through other staff, and to ensure that alternative sources of the service are identified for the patient. Although such 'conscience clauses' are a common feature of Codes of Ethics for health professionals, it can be argued that they are untenable for geographically scarce, rare or very specialised services – and are in any event an inappropriate reservation to find in a health professional who otherwise does not make moral judgements but provides care based on need. We develop this point a little further in Chapters 5 and 6.

Although our focus on accountability is primarily concerned with its ethical basis, it would be incomplete without a brief overview of other aspects of accountability, namely accountability in law, accountability within the health service through 'clinical governance', accountabilities arising from employment and from practice in a commercial environment.

Legal accountability and liability

The law holds certain individuals accountable for their actions or omissions through the law of tort, most commonly invoked in an action or suit for professional or clinical negligence. There are many excellent accounts of these matters in other textbooks (see the General bibliography); we merely outline the principles here. The law of tort falls within a division of law – civil law – that is quite distinct from criminal statutes passed through Parliament. The civil law has developed from common law principles of fair play (equity) and duties owed by individuals one to another into a body of law that adjudicates in disputes

between citizens (hence ‘civil’ law). For our purposes, the concept of professional negligence involves the establishment of three legal principles:

- firstly that the professional owed a duty of care to the client
- secondly that there was a breach of that duty of care (either by an act or a failure to act)
- thirdly that the breach of care caused harm to the client.

If these three matters can be established, then the client may pursue a claim for compensation in respect of the harm suffered. From the perspective of pharmacists, they will always owe a duty of care to the client – patient, customer or user – when they offer services, advice or information in their capacity as a pharmacist. So the first test will almost always be met.

To determine whether a breach of this duty has occurred means that a standard of care must be established. Then a judgement must be made as to whether or not the pharmacist met the standard or, put another way, whether or not the pharmacist (and possibly other staff) has acted properly. For many years the expected standard would be expressed as the ‘Bolam test’ derived from an important case in 1957 (*Bolam v Friern Hospital Management Committee* 1957). This case established a principle that ‘a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art’. Replace medical with pharmacy terms, ignore the sexism and the dated language and, with a minor extension from the *Bolitho* case (the body of medical opinion must also rest on a logical basis: *Bolitho v City and Hackney Health Authority* 1997), this is still the test applied in relation to most cases of professional negligence involving health professionals. This does not mean that the ‘experts would have done the same thing, but they would regard the defendant’s actions as within the range of acceptable practice’ (Montgomery 2003, pp. 169–170). However, since 1957, the professions and politicians have produced ever more explicit and transparent expressions of what the acceptable standard of practice should be. These may be found firstly in Codes of Ethics or Practice and associated guidance and then within NHS instruments such as National Service Frameworks or guidelines produced by the National Institute for Health and Clinical Effectiveness (NICE). Moreover, a significant source of appropriate standards may now be found within specialisms, many of which have set up consultant positions, ‘special interest groups’ or designated ‘health professionals with special interests’ (these standards also underpin clinical governance accountabilities, see below).

The final test for professional negligence is to prove ‘causation’. That is, that the failure in performance led directly to harm for the client. Often this can be the hardest aspect of a negligence case to prove. Patients may be suffering from several diseases or conditions, or taking several different medications, that will also cause them harm. Again, the evidence from ‘expert witnesses’ may be crucial in establishing the likelihood of causing harm and the extent to which the failure of the health professional may have caused it. Ultimately, if causation is proved, the remedy is compensation to the ‘victim’ via a tariff of injuries and penalties set from time to time by the courts.

The law of tort is not concerned with proving intent to injure or malice (in criminal law termed ‘a guilty mind’ or *mens rea*) or with finding moral fault or guilt. It is concerned with establishing whose fault caused injury and, therefore, who is to pay compensation. The criminal law does continually set statutory baselines for some aspects of the duty of care; for example, health and safety at work legislation sets out duties of all those involved in the safety of the workplace. In some instances, notably Section 64 of the Medicines Act (Protection of purchasers of medicinal products – ‘not of the nature and quality intended’), this criminal liability is absolute, but within the law of tort the duty of care will rise with the degree of risk involved in the professional activity. This parallels the personal aspects of accountability for special skills or expertise described above.

Accountability arising from the provision of healthcare

Health professionals have always been externally accountable for their activities both through professional regulatory processes and through the law of tort. Within the NHS, additional accountability could be exerted through employment conditions and limitations on promotion and progress, but essentially the quality of healthcare was more or less assumed to be good because professionals delivered it. A series of ‘healthcare scandals’ during the 1990s (Bristol, Alder Hey, Shipman) demonstrated that reliance could not continue to be placed solely on existing systems of accountability. This period also coincided with a change of parliamentary power from a long spell of conservative leadership to ‘new labour’. One of the new government’s priorities was to modernise public services – a process that led to the introduction of a new concept in healthcare called ‘clinical governance’.

Again we shall provide only a summary of the introduction of clinical governance to healthcare here and confine ourselves to its effect on

accountability. The concept of clinical governance was first described in 1997 and expanded in a government paper, *A First Class Service*, in 1997 (Department of Health 1997). Powers to give statutory force to the concept were taken in the Health Act of 1999, which introduced a ‘duty of quality’ on all NHS bodies and institutions. Subsequent legislation extended these powers to cover the private healthcare sector too. The concept is defined officially as:

Clinical governance is the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence can flourish.

Or more colloquially as, ‘health professionals must now demonstrate how they know and can show that the quality of care they provide is good’.

These developments have two main consequences for professional accountability: firstly, they make more transparent the standards that are expected within a health professional’s duty of care (in civil law too); secondly, they extend the range of bodies and agencies to which health professionals are now accountable. In the first area, much of the professional judgement (some might say guesswork) involved in selecting treatments has been formalised in the production of national (England) NHS guidelines produced by NICE, and similar arrangements for Scotland, Wales and Northern Ireland. The NICE guidelines have the effect of establishing therapeutic norms – not compulsory but health professionals may expect to have to justify significant departures from the recommendations without good reason.

Similarly standards for NHS services in certain therapeutic areas or for certain categories of patient – cancer, children and young people, the elderly – have been explicitly published as in England as National Service Frameworks (similar arrangements in other home countries). Again these establish the norms of quality expected of NHS bodies and those who work within them. Other examples include guidelines issued by clinical specialties that set the norm for the quality of duty of care expected of a professional claiming expertise in that particular specialty. Once these norms become established within the NHS, then it becomes hard for the private healthcare sector to justify delivering healthcare to a lesser standard; thus the norm becomes universal (and the expected standard for the duty of care expected in civil law).

Once standards become more transparent, then it becomes possible to hold healthcare bodies accountable for their delivery. A series of government-sponsored, albeit independent, agencies have been established to monitor, audit and inspect health service quality. In England, these were successively the Commission for Health Improvement, then the Commission for Healthcare Audit and Inspection (renamed the Healthcare Commission). A comparable system of quality assurance has developed in private healthcare and social care such that the respective agencies are likely to merge and implement consistent standards across all these sectors by the end of the first decade of the twenty-first century. In effect, these processes are concerned to establish accountability on behalf of the service user or patient. Therefore, instead of accountability only becoming a serious issue after a patient has been harmed or makes a complaint, clinical governance is intended to head off failures of quality before they happen.

For the individual pharmacist, clinical governance raises new accountabilities. If an NHS employee, the pharmacist becomes accountable to the employer for delivering his or her contribution to overall service quality. If contracted to provide a service, such as the discharge of the community pharmacy contract, the pharmacist must demonstrate to the contracting NHS organisation how clinical governance is built in to the dispensing of prescriptions and the provision of other professional services. Moreover, pharmacists also become accountable to local public authorities and to patient groups.

Accountability arising from employment

We mentioned in our opening considerations of professionalism that independent practice (being self-employed) until relatively recently was regarded as the hallmark of a true professional. This notion still persists in the legal profession whereby barristers fiercely argue that their independent practices (albeit collected within chambers) allow them to represent all comers, no matter how unsavoury, and to remain free from unprofessional (or non-professional) influences on their judgement as to how to conduct that representation. In healthcare, however, the vast majority of health professionals are employees. So what effect might this have on their professional accountabilities?

Employment involves a contract between employer and employee. Put bluntly, the employer pays an employee to undertake work on his behalf. Such an arrangement imports duties between employer and employee, and a substantial body of employment law now codifies what

those duties are, such as entitlement to sick pay or holidays or obligations to keep commercial secrets. Duties also imply accountabilities and an employee is not free to act totally independently of the contractual expectations of his employer. This has implications for professional accountability and how it may be apportioned between employer of the professional and the professional employee. A good model for how these accountabilities are usually distributed lies in the concept of employer's vicarious liability.

In a case of clinical negligence, it is usual for the action or suit to be brought against the corporate entity – hospital trust, primary care organisation or a pharmacy company – that provides the service in question. This is for two reasons. Firstly, the corporate body is likely to have rather more funds available for compensation than the average individual. Secondly, it is a well-established legal principle that an employer is vicariously liable for the actions of his employees. This may be compared to the principle of third-party car insurance, where an insurance company is liable for injuries caused by the driver who has taken out cover with that insurance company. Becoming an employee means that your employer legally accepts liability for any action for compensation arising from your activities. Protection for the patient at least is guaranteed.

However this concept does not mean that an employed professional can never be held accountable personally for his or her actions. A patient may choose to sue several parties, not just the employer. The employer may counter-sue the employee, particularly if the employee did not follow employment guidelines, policies or rules for carrying out the work. The employer may have been unaware of the activities of the employee and may not consider them as part of the employment contract for the employee. It is for this reason that many employees choose to take out their own independent indemnity insurance, particularly if they are also undertaking self-employed activity as part of their overall work portfolio.

Being an employee necessarily means that a pharmacist will be influenced and shaped by the culture of the employing organisation and may be accountable for meeting corporate goals as well as those applicable to patient care. All employers have to establish a culture that responds to consumer demands, and while this demand may be less acute in the public sector, much of the modernisation of the NHS over the period from the late 1990s to the present has been aimed at empowering patients to be treated more like consumers. The establishment of a corporate culture and the manifestation of organisational and business

ethics are explored in Chapter 6. We also consider the special position of accountability in community pharmacy below.

Accountability arising from the commercial environment

For many decades, the UK Code of Ethics for pharmacists strove to preserve the ‘gentlemanly’ aspects of professionalism in the face of commercial pressures. Codes variously forbade advertising, price-cutting and other incentives to sell or buy, ‘touting’ for business and promotion of one pharmacy business over another – the so-called ‘invidious distinction’. However progressive challenges in the 1990s from the Office of Fair Trading and the requirements of competition legislation have seen such ‘ethical’ constraints virtually disappear. In community pharmacy, professionalism must be maintained within a fiercely competitive commercial environment, and this changes some traditional accountabilities and introduces new ones. In the pharmaceutical industry, however, the operation of a stringent Code of Advertising Practice persists, albeit with underpinning law that allows enforcement action if needed.

Customers are not necessarily the same as patients. While the NHS strives to promote choice and accessibility for NHS patients, this is far from being a universal expectation let alone a reality, and it will arguably never be so when a patient is in urgent need of medical care. All ‘clients’ of a community pharmacy exhibit a continuum between the traditional dependency of a patient (particularly patients with long-term conditions necessitating specialised support perhaps) and the full-blown autonomy of an empowered customer who knows precisely what over-the-counter painkiller she requires and does not seek or welcome any professional input into the transaction at all. The pharmacist has accountabilities and a duty of care to all clients but a similar continuum of scale must apply. Customers can and do ‘vote with their feet’ and a business must respond to the demands of consumers or perish. In this way, the otherwise absolute ethical principle to avoid harm to clients may be considerably attenuated if the client claims to know what she is doing and has an intention to shop elsewhere if necessary.

Employees and owners share a goal of economic prosperity. Policies and practice within the business will be geared towards sales and maximising profit. Large companies will be looking to demonstrate financial acumen and management to make them worthy of investment within the City. All employees, professional or otherwise, will be expected to play

their part in this endeavour. Public image, public reputation, media and consumer group opinions all become crucial factors in maintaining confidence not just in the high quality of professional services but in the capacity of the enterprise to prosper and grow. In this situation a pharmacist may well experience 'ethical anxiety' in the attempts to balance accountability for delivering good patient care (and possibly refusing to make sales or provide services) with accountability as an employee to work towards the goals of the enterprise.

To a fairly limited extent, the law attempts to preserve the professional ethic of a company providing pharmacy services. The superintendent pharmacist (The Medicines Act, Section 71) is charged with ensuring that supplies of medicines on any pharmacy premises are made in accordance with law and that the business is always under the personal control of a pharmacist. The Code of Ethics then supplements this very basic control with a variety of requirements for the superintendent pharmacist to ensure the proper professional conduct of the business. However, at the time of writing, these aspects of the legislation were being reviewed (Health Act 2006 Part 3, Chapter 2, which was passed in Parliament on 19 July 2006) and the role of the superintendent pharmacist was being questioned. Balancing the accountabilities of professionalism and commercialism remains an everyday conflict for many pharmacists at all levels within community pharmacy practice.

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5

The professional decision-making process

Why have a process for decision-making?

Before embarking on an exploration of professional decision-making, we should first ask whether it is different from any other decision-making. In principle, probably not; we all have to make decisions all the time, every day: some trivial, some of great moment. But mostly we do not consciously follow a process to deal with them. However, there are several features of decisions made by healthcare professionals, including pharmacists, that single them out for special consideration. Firstly, the stakes are higher. As we have seen in Chapter 4, pharmacists can be held to account several times over, and publicly, for the actions they take. Similarly, the consequences that may arise from a decision by a pharmacist will frequently affect the care of someone else and, in some instances, very adversely.

Moreover, decisions by pharmacists (and other healthcare professionals) are only part of an approach to solving problems. Indeed it is arguable whether one can really solve complex professional problems; one may resolve some aspects but be unable to deal with others. Some questions may not be in contention: for example the strength or dose of a medicine provided you can find an authoritative reference source; the wishes of the patient provided they are in front of you and able to respond.

A solution may require the processing of significant amounts of information, which will take time but may ultimately yield a clear answer. It is more likely, however, that some decision-making must proceed in the face of uncertainty, particularly as to whether the chosen action is the ‘best or right’ course to take. For example, would you always deny a patient access to pain-killing controlled drugs because her prescription is not legally valid? Would you always tell the police about suspected abuse of a sexually active young teenager? Conflicts can arise between the law or policy guidelines and best patient care, or between differing ethical goals such as telling the truth or respecting the patient’s

wishes. A decision-making process can help you to analyse the bits of a problem that can be solved with some certainty and provide a framework to identify those remaining aspects that call for your judgement as a professional.

We would make other claims for the value of a decision-making process. Such a process can provide:

- a mechanism to allow you to practise dealing with problems before they arise
- a method of structured thinking that improves your ability to respond rationally when urgent problems arise and you are under pressure
- a means of identifying the values involved in your decision-making
- a means of identifying areas of certainty and uncertainty
- a basis for risk management in prospect
- a basis for your defence in retrospect
- an aid to reflective practice and improvement of practice
- a technique that allows inclusion of all aspects of a problem – clinical, legal and ethical.

So what features should we expect to find in a good decision-making process?

A good decision

Systematic structure

The vast majority of us take decisions at great speed and with little reflection. Just as adults develop facility in taking decisions that we would not expect of a child, so experienced pharmacists frequently do not recognise that the process they use to take difficult decisions in practice has evolved from experience, the use of precedent, judgement and that old favourite ‘common sense’. However, it is possible to ‘slow down’ the process and break it up into stages and steps that, in reality, may have been addressed in a matter of minutes or less. An analysis of what you did and why you did it is of help the next time you are presented with a similar decision to make. It helps to make clear to inexperienced pharmacists the issues you identified in the problem, how you tackled the uncertainties in each and how they influenced the final decision. As well as providing an opportunity for reflection, a systematic structure allows you to anticipate problems.

In any practice situation, a pharmacist should at least give some consideration to the key accountability question: *What happens if some-*

thing goes wrong? In retrospect, a systematic structure for decision-making may provide some defence and insight into why you made the decision that you did. An analysis undertaken of what might go wrong before an event – a *risk assessment* – is even better. In most instances, particularly with complex systems involving many individuals, such as dispensing prescriptions or taking blood pressure or a drug history, some aspects of the process can be known with reasonable certainty. For these, it may be appropriate to delegate tasks to trained staff working within standard operating procedures, leaving the more uncertain areas to the pharmacist. Once the routine aspects of the situation have been addressed, the pharmacist can apply judgement and experience within a systematic framework of questions and options to achieve a resolution of the remaining problem.

Rational reasoning

A good professional decision should be underpinned by reason and rationality. To consider an absurd example, let us say that in your work as a pharmacist you decline to deal with patients whose surnames suggest they are of Scottish origin – McClean, McTavish, Mackenzie, for example. Your reason is that you don't like the Scots! Clearly, this is not an acceptable reason for your decisions. Extend the scene to a refusal to deal with substance misusers, or homeless people, or alcoholics and at first sight we may assume that these are not decisions that could resist challenge, at least not in a healthcare context. But what if a specific individual is so violent or abusive that he causes offence or danger to other patients? Exclusion from the service might then be seen as reasonable. Or consider the supply of the emergency hormonal contraceptive. In this case, limitations of conscience and belief in the inviolable right to life may constitute an adequate reason for some pharmacists not to take part. These are examples of ethical dilemmas: do you owe a greater duty of care to an addict or to other customers? Do you owe a greater obligation to your own conscience and protection of a possible fetus or to the teenage girl who may never have intended to risk pregnancy?

We can see from the brief examples above that it is important to reflect upon the reasons behind the decisions you take. Not only that but to consider whether the reasons are rational (i.e. reasonable in the circumstances). This leads on to recognition that uncertainty can also arise because we cannot always establish all the required facts. We cannot always know what the views of the patient might be, nor of relatives and carers, but we will probably have to try and find out. We cannot

always predict whether side-effects will manifest themselves, nor whether the patient will cope with them nor whether the likelihood of a cure is all that certain. We may have to make interim decisions and take more when specific aspects become better known. When asked to predict our decisions, we use phrases such as ‘well it all depends, it depends on the circumstances’. If challenged to justify our decisions, most of us will hopefully recall the particular circumstances that decided us to take one option in preference to another.

Value-based reasoning

One way of establishing that reasons are rational would be to base them on evidence. Pharmacists are very familiar with this approach. However, basing decisions solely on evidence can lead to ‘Spock reason’ a term coined by Seedhouse (2005; from the Vulcan character in the television series *Star Trek*) to denote decision-making based on suppression of emotional response and reliance on logic alone. Evidence must be considered alongside values, particular those of the patient. Seedhouse gave as an example the situation where a family has emigrated and achieved considerable success and prosperity in a foreign land, but nevertheless returns home because a teenage son has never been happy with the move. The father’s valued relationship with his son overrode the logical judgement that staying overseas was materially the better option.

Patients may be provided with and understand that treatment A is better than B or even no treatment, based on empirical evidence, but nevertheless may choose to take another option based on what they value in their life. The decision may not seem rational to you as the pharmacist but is very much so for the patient, who will bring his or her own values into play. Pharmacists, too, have values but some limits are placed on the extent to which they may be invoked as a reason to deny or not be involved in patient treatment or care. Values on the sanctity of life, usually deriving from strong religious beliefs or personal convictions, are increasingly at issue at the beginning and end of life. The norm in healthcare is to recognise these values through ‘conscience clauses’ but such an approach may eventually prove unsustainable if withdrawal from involvement becomes widespread.

Recorded decisions

Which brings us to the final feature of a good system – did you make a record? Unfortunately, pharmacists have traditionally been poor at

recording their activities and decisions but this is changing. One cynical interpretation of the impact of clinical governance and its focus on monitoring and audit is expressed as ‘if it isn’t recorded, it didn’t happen’. It may be unwise to rely on one’s memory to recall the circumstances that justified a decision when the challenge arises days, weeks or even in the case of civil litigation, years after the event itself. It is not suggested that every decision you take as a pharmacist must be recorded, but certainly you should reflect on whether your resolution of a particular problem might subsequently be challenged. In other words, will it ‘come back and bite you?’ If you used judgement in reaching your decision, are you prepared to defend the considerations you took into account in arriving at that judgement? Or in lesser cases perhaps, have you left a record for those staff, pharmacists or not, who may have to deal with the next stage of the problem and you may not be there?

The RPSGB re-issued guidance on ‘recording interventions’ in April 2006. This guidance includes amongst the reasons for keeping a record: ‘to have an accurate record available for scrutiny where decisions could be challenged’ and amongst the occasions when this might be necessary mentions ‘Interventions that could potentially be queried or refuted’. As information technology progresses, it is likely that many patient record systems used by pharmacists will have provision for making records of such decisions – perhaps under ‘critical incidents’, although this term is more usually used for patient safety incidents. However, not every user of pharmacy services is a patient who is prescribed medicines; it may be necessary to create records for those who buy non-prescription medicines or who simply seek advice. We suggest that this is an area of practice that should be researched to make practical suggestions as to where such records should be made, what information should be kept and how the records should be systematised for ease of retrieval.

Identifying issues and resources

It is rarely possible to make a good decision without information. The information needed for a professional decision is likely to be clinical, legal or ethical – or all three. Generally speaking, pharmacists have little difficulty identifying clinical issues or in knowing where to look to find the information needed to clarify them. While we acknowledge that most problems that pharmacists have to address will include clinical issues, we will confine our examples and analyses to legal and ethical issues. Identification of legal issues may also seem to be a fairly easy

task for most pharmacists; they are well schooled in the detail of statutory law such as the Medicines Act and the Misuse of Drugs Act. However, they may be less familiar with other types of law that must also be considered and we explain this more fully at the beginning of Chapter 7.

How do we identify an ethical issue? Pharmacists may find this more problematic. There may be several reasons for this. Many of our ethical sensibilities derive from our upbringing, our culture, our parents, friends and mentors, and we may already have fairly well-established views on what is right and wrong even before embarking on a pharmacy course. We do not always recognise that what we hold dear, our values, may not be the same for everyone. In our training as pharmacists, we will have been told about the profession's Code of Ethics and that may have added to our awareness of the particular areas where ethical behaviour may be called into question. The limitations of such codes have been explored in Chapter 4.

Another set of rules does not help us in identifying where ethical questions arise or how to deal with ethical dilemmas. Mullan (2000, p. 241) suggested that 'Every encounter between pharmacist and patient has implicit ethical implications; pharmacists are under a duty to ask questions. The Code does not assist pharmacists to prioritise conflicting ethical obligations; rather it gives general guidance without balancing the pharmacist's duties and responsibilities.' Seedhouse (1998, p. 89) went further in asserting, 'health professionals not only need codes of practice (and a certain amount of legal knowledge) but also (and much more importantly) a wide acquaintance with ethical theory and modes of moral reasoning'.

Most approaches to decision-making assume that health professionals already have this acquaintance. This is particularly so of the 'four bioethical principles' propounded by Beauchamp and Childress (2001; see also Chapter 2). So it is usual to suggest that the principles for ethical decision-making are to respect the autonomy of the individual, avoid harm, where possible achieve benefit and consider fairly the interests of all those affected. This can unfortunately be too superficial and limiting unless a proper study is undertaken of how these four principles were determined. It may not be apparent that concepts of confidentiality or consent or telling the truth are implicit in the analysis of what is encompassed by each of the four principles. In the UK since 1998, another approach is to use the subject headings within the medical core curriculum (Consensus Group 1998) (such as consent and refusal of treatment, medical research, confidentiality, resource alloca-

tion) and provide vignettes or scenarios illustrating a real or hypothetical situation and a series of questions to answer (Parker and Dickenson 2001, Baxter *et al.* 2002, Tingle and Cribb 2002). Braunack-Meyer (2001), after surveying the views of 15 Australian general practitioners (GPs), classified ethical issues as:

- issues of conflict or choice: ‘situations in which...persons ought both to do or not do something’
- issues that may compromise long-term relationships
- issues involving threats to the practitioner’s integrity or reputation.

Another perspective on the personal, internalised nature of ethical issues is described in relation to business ethics. Trevino and Nelson (1999, p. 89) referred to the ‘disclosure rule’: would you feel comfortable telling your parents, children, spouse or clergy about your actions (the ‘Mum test’) or seeing your decisions highlighted in *The New York Times* or a television documentary (the ‘TV test’).

Ethical issues frequently arise because of the inadequacy or inappropriateness of law. The classic example is usually given of the legally invalid prescription presented for a patient in urgent need of morphine for pain (some latitude is now allowed (see RPSGB Practice and Quality Improvement Directorate 2006)). Do you stick to the letter of the law and refuse to supply or do you break the law and supply because your highest obligation is to do good for the patient? This is an example of an ethical problem. An ethical dilemma is rather more rare in current pharmacy practice but arises when ‘two or more choices are morally justifiable, but only one is capable of being acted upon’ (Weinstein 1996, p. 83). Weinstein exemplified such a dilemma arising when a prescription calls for medication that is likely to cause serious side-effects in the patient. Enquiries to the prescriber have aroused his anger and put future good working relationships in jeopardy. You have an obligation to act to protect the well-being of the patient but also to maintain good relations with professional colleagues – which should take precedence? One might go further and suggest a further conflict between the patient’s right to be fully informed and her need to trust in the doctor’s judgement.

Our most practical suggestion is to characterise ethical issues as matters where your actions may affect the rights of others, may cause others harm or limit benefit, particularly to their health, or may affront their values or culture.

Finally we should consider making maximum use of resources that may help your decision-making. You will be very familiar with clinical

reference texts and resource but much more is available. We have discussed above the limitations of the Code of Ethics, but it is supplemented with a great deal of advice on standards of practice, performance and responsibilities to inform the appropriate 'duty of care' expected of you in a given situation. Employing organisations, in the NHS or in the private sector, will also have volumes of protocols, policies and manuals on their expectations and those of service users. National guidance, such as National Service Frameworks, NICE guidelines, may provide assistance on what to do. Norms of treatment established within specialist practitioner groups, perhaps for palliative or cancer care, might also inform your decisions. But most valuable of all might be the wisdom and experience of your colleagues. Not just pharmacists but nurses, carers, relatives, counter staff all may have information to support your aim: to make appropriate decisions on the basis of good reasons.

Decision-making systems

The 'four-stage approach'

Below we set out in detail a methodology that we have found useful and which has been widely adopted in undergraduate, preregistration and practice education and training for pharmacists (also in Appelbe *et al.*, 2002). While we believe it meets most of the criteria set above, it is itself an adaptation from other approaches and is only one of many 'systems' proposed to assist the resolution of professional problems. We outline some of the alternatives later but concentrate here on what we will call our 'four-stage approach'. It is essentially pragmatic and utilitarian.

'Our' four steps are:

1. Gather relevant facts
2. Prioritise and ascribe values
3. Generate options
4. Choose an option.

To isolate legal and ethical issues from any clinical considerations, we use the following true scenario to illustrate application of our four-step process.

Two pharmacists were reprimanded by the Statutory Committee in 1991 following convictions for the supply to a 17-year-old youth of sodium cyanide in one case and strychnine hydrochloride, potassium permanganate and glycerol in another (Anon. 1991a,b).

Why were such supplies considered wrong? What thought processes should have been gone through in reaching a decision as to whether to supply? Pharmacists are permitted to supply all these substances from a pharmacy, so why were convictions as well as a reprimand given? Would it have been right to supply in other circumstances? If so, on what knowledge would you have based your decision?

What is needed before any decision can be taken is as many facts as possible. We shall call this:

Stage 1 Gather relevant facts

1 What criminal law applies here?

First, you will want to know what the criminal law says. Ask yourself, 'will I be breaking the law if I supply?' In the case of potassium permanganate, you may supply, but there are packaging and labelling regulations to consider. You may supply glycerol; indeed, you can buy glycerol (or glycerine) from the food shelves of a supermarket. Neither of these substances is controlled as a medicine or a poison. Sodium cyanide and strychnine are both Part I, Schedule 1 poisons with special conditions attaching to their supply. Most of the criminal law that applies to pharmacy practice will be in the Medicines Act, the Misuse of Drugs Act or the Poisons Act, although there is a whole range of other criminal legislation that may apply, e.g. the Environmental Protection Act, the Health and Safety at Work, etc. Act, the Customs and Excise Management Act.

2 What NHS law applies here?

In this example, you do not have to consider NHS law because the supply is a 'private' one and not within the terms of the NHS contract. There are other aspects of administrative law, such as employment protection, that will apply to pharmacy practice, but in the examples in Chapter 7 we mostly consider NHS law, specifically the Terms of Service requirements and clinical governance.

3 What civil law applies here?

In this example, the young man managed to cause an explosion by using glycerol and potassium permanganate together. Would the supplying pharmacist have been partly to blame for any damage that may have

resulted? To some extent, yes, because pharmacists are expected, by virtue of their expertise and training, to exercise a greater duty of care than other retailers over the supplies they make. In the case of strychnine and cyanide, sales are restricted to pharmacies precisely because pharmacists are expected to know the dangers inherent in their use and only to supply responsibly after due enquiries have been made. The areas of civil law that are most likely to be an issue in pharmacy practice are negligence, confidentiality and defamation.

4 What guidance does the Code of Ethics give here?

As a pharmacist, you have to meet standards that are in excess of the minimum that the law requires. At the time of this case, the Code of Ethics said 'A pharmacist must take steps to ensure that all chemicals supplied will be used for a proper purpose and in appropriate circumstances'. The Code went on to give guidance that all oxidising agents, such as potassium permanganate, may be used for the preparation of explosives. (Such requirements are now implicit in the legal requirement to exercise 'due diligence' when supplying any chemicals.) What enquiries should you make? What facts will you need to show that you made reasonable enquiries to satisfy these requirements?

5 What professional knowledge do I have that applies here?

Notwithstanding all the legal and ethical constraints or guidance that you are aware of, you will also be applying your technical and clinical knowledge to the situation. You probably learned in chemistry classes that certain chemicals make explosive combinations. You should also know about any material you sell or supply; this is made explicit in poisons law for example, where you should only sell to a person to whom a poison 'may properly be sold'. You would know that cyanide and strychnine are immensely potent poisons. Do you think it would be safe to supply these to a 17-year-old? Many of the problems you encounter in pharmacy practice will require the use of your knowledge of therapeutics, pharmaceuticals, good pharmacy practice, etc., as well as knowledge of law and ethics.

6 Where can I look or whom can I ask for help?

Finally, but just as important as any of the above, is whether there is any precedent you can follow, any policy that covers this situation, any

other 'rule book' or senior pharmacist that perhaps you should consult. Many pharmacists are employees who will have corporate protocols and procedures to follow and, most valuable at the start of a career, a range of experienced pharmacists who can be asked for advice. Delaying action to take advice is always an option to consider.

When you have the answers to these questions or you decide that they do not apply, then you will have assembled the raw material from which to make your decision. Increasingly, pharmacists may expect to be challenged on their assembly of facts: what questions were asked, what was the condition of the patient, what possibilities were excluded, etc. Good practice usually demands that records should be made at the time to demonstrate a conscientious and informed approach and justify the ultimate decision taken.

Stage 2 Prioritise and ascribe values

When you have all the information that you can get, you will find that some facts are going to be more important than others. In this example, the fact that the purchaser in the above example is male is interesting but not important; his age, however, may influence your eventual decision. Even if the purchaser were a middle-aged respectable-looking individual, you might still consider the nature of the substances or combination of substances to be of overriding importance. You are prioritising the facts.

Moreover, you will want to weigh up the consequences for yourself, perhaps for your employer, for the young man, for his parents and neighbours and for the reputation of pharmacy of making these supplies or not. The relative importance you attach to these issues will also depend on your own personal opinions and attitudes. In other words, you are ascribing values to the facts you have assembled.

There will be a whole range of individuals and affected parties whose interests you should consider.

1. First, you will want to promote the health and welfare, or at least cause no harm, for the patient or, in this case, the purchaser.
2. The interests of other players in the example must also be considered. What would be the consequences to the patient's carer, parents or relatives? In this case, neighbours, or even perfect strangers, might have suffered serious harm from the sale of potential explosives or poisons to this young man. Or you may have information about an HIV-positive individual that might raise in your mind questions about the interests of the patient as compared with those of other people who were sexual contacts.

3. You have a duty as a pharmacist to uphold the reputation of the pharmacy profession (a key responsibility of a pharmacist in the Code of Ethics). This means that you should do nothing to undermine confidence in you as an individual pharmacist and as a representative of the profession to which you belong.
4. You also have a duty to cooperate with healthcare professionals and others for the benefit of patients and the public (another key responsibility in the Code of Ethics). Some later examples show how you may have to weigh your obligation, or that of your staff, to preserve the patient's faith in the doctor against the potential risk of harm to the patient.
5. If you are employed, your employer carries liability for what you do in the course of your employment: 'vicarious liability'. This liability is not limitless; if you fail to follow your employer's instructions or the terms of your employment contract then you may be held accountable for your actions. In most situations, you will also have a duty to maintain other people's confidence in your employers in the same way as you represent your profession.
6. Finally, you will have your own set of moral and cultural values that create obligations to yourself. Again, some later examples may show how attitudes and moral convictions may be the overriding consideration for some individuals, although the Code of Ethics (personal responsibilities for pharmacists providing professional services) makes it clear that such matters must not be allowed to compromise your first priority – the welfare of the patient.

So, how can we summarise this stage? Decide what priority and value you attach to the interests of the following:

- the patient or customer
- those near to the patient: parents, carers, dependants
- those in contact with the patient: neighbours, contacts, the public at large
- your own profession and other professionals with whom you work
- your employer and work colleagues
- yourself.

Good pharmacy practice requires that you balance the disparate interests of all the parties concerned and are prepared to record where necessary and justify the reasoning that led to your eventual decision. This means that you will move onto the next stage automatically.

Stage 3 Generate options

In other words, ask yourself: 'What could I do in this situation?'

In this example there will be at least four options:

1. Supply none of the items
2. Supply all of the items
3. Supply some of the items
4. Delay to seek advice.

You might suggest other variations such as selling some or all of the items, subject to certain conditions, such as a written request specifying reason for purchase or giving the authority of someone you know to be responsible. By careful analysis, you will be able to establish the likely consequences of each course of action and then choose which will have the best chance of a good outcome or, in some cases, the least likelihood of causing harm.

You are now ready to move to the final stage.

Stage 4 Choose an option

In other words ask yourself: 'What should I do in this situation?'

Remember that, when making your choice, you may have to be able to justify why you made that one. This is not as daunting as it may seem as you will be able to draw on many sources of help to reach your decision, such as your reference books and manuals, your colleagues, your employer or your professional and trade body. Gradually you will add to this your own experience, your knowledge of real life, perhaps your knowledge of the purchaser (or in other cases patients and their families) or the local environment in which you are practising pharmacy. The whole process develops your professional judgement, which distinguishes the professional from the technician and indicates an ability to respond to unfamiliar and unexpected situations that fall outside the rule-book.

When you first looked at the example used, you almost certainly made a rapid decision that you would not have made these supplies of sodium cyanide, strychnine, potassium permanganate and glycerol. We would suggest that this is the correct option. But in reaching it, you unconsciously and very quickly ran through your technical and legal knowledge, assessed the purchaser, considered the consequences of supplying or not and what options you had and then chose not to supply. It probably took you less than a minute to decide, although it might take a little longer to decide how you would explain your decision to the would-be purchaser!

See Table 5.1 for a summary of the four-stage decision-making process.

Table 5.1 Summary of the four-stage decision-making process

<i>Stage</i>	<i>Components</i>
1. Gather relevant facts: what applies here?	Criminal, NHS and civil law The Code of Ethics Council statements Professional and other knowledge
2. Prioritise and ascribe values: what are the interests of various parties?	The patient The public Carers Relatives and neighbours Other healthcare professionals The pharmacy profession Your employer Yourself
3. Generate options	What could you do? What are the possible consequences of each option? How likely are the consequences?
4. Choose an option	What should you do? Can you justify the chosen option?

Development of decision-making in pharmacy

The four-stage approach described above is used in the worked examples of decision-making set out in Chapter 7. While this method was first published to British pharmacists in 1997 (Wingfield *et al.* 1997), its origins go back somewhat further.

Developments in pharmacy appeared in the 1990s in America with Weinstein (1996) publishing a systematic approach to decision-making. He proposed a four-step approach only marginally different from that used by us above

1. Gather the facts
2. Identify the values that play a role
3. Generate options open to you
4. Select an option and justify it.

Earlier still, the literature referred to related approaches, all involving the breaking down of a problem by asking a series of questions. O'Neill (2005; unpublished) in the APPLET teaching resource project suggested a similar approach, itself drawing on methodologies explored by Portilo (1999). It is again expressed as a series of steps:

1. Gather all relevant information
2. Identify and clarify the ethical problem(s)
3. Analyse the problem by considering the various ethical theories and approaches
4. Explore the range of options or possible solutions
5. Make a decision
6. Implement and then reflect on the decision.

A briefing from the NHS Confederation (2005) (addressed to health service managers) described a slightly different six-stage process developed in conjunction with the British Medical Association.

1. Recognise that the situation raises an ethical issue or dilemma
2. Break the dilemma into its component parts
3. Seek additional information, including the patient's viewpoint
4. Identify relevant legal or professional guidance
5. Critical analysis of the dilemma
6. Be able to justify the decision with sound arguments.

Parker (2003) suggested another variation, described as a modified version of the Pellegrino method, in material to support the UK network of clinical ethics committees. This suggested 11 stages.

1. What are the relevant clinical and other facts (e.g. family dynamics, GP support availability)?
2. What would constitute an appropriate decision-making process?
 - who is to be held responsible?
 - when does the decision have to be made?
 - who should be involved?
 - what are the procedural rules e.g. confidentiality?
3. List the available options
4. What are the morally significant features of each option, e.g.
 - what does the patient want to happen?
 - is the patient competent?
 - if the patient is not competent, what is in his or her 'best interests'?
 - what are the foreseeable consequences of each option?
5. What does the law/guidance say about each of these options?
6. For each realistic option, identify the moral arguments in favour and against
7. Choose an option based on your judgement of the relative merits of these arguments using the following tools:
 - how does this case compare with other cases?
 - are there any key terms the meaning of which needs to be agreed, e.g. 'best interest', 'person'?
 - are the arguments 'valid'?

- consider the foreseeable consequences (local and more broad)
 - do the options ‘respect persons’?
 - what would be the implications of this decision applied as a general rule?
8. Identify the strongest counter-argument to the option you have chosen
 9. Can you rebut this argument? What are your reasons?
 10. Make a decision
 11. Review this decision in the light of what actually happens, and learn from it.

The same website makes reference to the framework of Jonsen *et al.* (1992). This suggests seeking answers to these questions in the following order.

1. Indications for medical intervention: establish a diagnosis, what are the options for treatment, what are the prognoses for each of the option?
2. Preferences of patient: is the patient competent? If so what does he/she want? If not competent, then what is in the patient’s best interest?
3. Quality of life: will the proposed treatment improve the patient’s quality of life?
4. Contextual features: do religious, cultural, legal factors have an impact on the decision?

Trevino and Nelson (1995, pp. 85–90) describe a different stepwise approach, this time in the context of business ethics.

1. Gather the facts
2. Define the ethical issues
3. Identify the affected parties
4. Identify the consequences
5. Identify the obligations
6. Consider your character and integrity
7. Think creatively about potential actions
8. Check your gut.

Seedhouse, a New Zealand professor of health and social ethics, prefers a conceptual rather than stepwise approach. In 1988, he published on the use of an ‘ethical grid’ (Seedhouse 1988) as a basis for decision-making and later (Seedhouse 1998) added concepts of the Rings of Uncertainty and the Autonomy Test as tools to aid all healthcare professionals in their ethical decision-making. Still later (Seedhouse 2005) he made powerful arguments to balance decisions based on evidence and logic with greater trust in our intuitions, values and emotions. We will not try to paraphrase the ethical analysis propounded by Professor Seedhouse; interested readers should explore the original texts. The

extent of patient involvement in decision-making is also subject to analysis and debate. Wirtz *et al.* (2005) made favourable reference to the concept of 'concordance' as developed within pharmaceutical care as an example of patient-centred medicine.

It can be seen that there are many ways to address the making of 'good' professional decisions but the ability to do so is surely one of the qualities that underpins the professionalism that we discussed in Chapter 4. A process for decision-making is clearly valuable but so is the ability to recognise and apply the likely manifestations of ethical issues as they present in practice. We explore these in Chapter 6.

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6

Ethics in practice

This chapter is intended to give a thumbnail sketch of a range of topics that are usually considered under the term ‘medical’ or ‘healthcare’ ethics. In addition, we consider a few areas that are not usually so classified but which are relevant to pharmacy, such as business and organisational ethics and the use of animals in drug research. In most cases, although not all, it is helpful to consider established principles of healthcare law alongside ethical considerations. However, for a full account of the law, readers are advised to consult the bibliography cited.

Human rights and healthcare

The explicit inclusion of human rights in healthcare law and ethics topics is of recent origin. Many of the tenets of human rights have been present in English common law for centuries and concepts of confidentiality or doing good and not doing harm appear in the Hippocratic oath of the Ancient Greeks. Since the Second World War, the UK was a leading force in establishing and ratifying the European Convention on Human Rights and subsequently maintained for many years that there was no further need to introduce legislation to give effect to its principles. Nevertheless, the UK was found wanting on many occasions by the European Court of Human Rights and this led eventually to the incorporation of the European Convention on Human Rights into English law: the Human Rights Act 1998. Both before and after that date, implementation of a wide range of antidiscriminatory directives from the European Union have further raised awareness that human rights extend to all individuals, irrespective of gender, race, disability, religion, age or sexual preferences.

Thus awareness of human rights is being integrated into concepts of consent and the treatment of vulnerable patients; into improved access to healthcare resources for disadvantaged patients and into enhanced respect for patients’ privacy, dignity and lifestyles. This awareness is fostered by specific legislation to address shortcomings, through case law on particular challenges and by the adoption of Codes

of Practice and related training throughout the NHS and private health-care sectors. No health professional should be practising in modern times without an awareness of human rights.

Ethical basis

Most people hold the view that human life is special and that certain expectations and privileges attach to being human. Many would be hard-pressed to say exactly where this conviction comes from but the most common source would be from religious or cultural beliefs. We almost all agree that it is wrong to kill someone: Christians may cite the Bible; Muslims might cite the Koran; humanists may cite their own values and reasoning as to what is humanitarian; others might just say it is common sense. However, they all agree that human existence should normally be preserved and not extinguished deliberately. The ‘right to life’ or, more accurately, the ‘right not to be killed’ seems a fundamental feature of how we should live – an ethic of human existence, a ‘human right’. But we can all think of examples when people are allowed to kill each other: in time of war, for example, or to protect a victim from murder. So human rights often come with limitations. Moreover what other human rights should civilised countries be ensuring for their citizens? Dignity, respect for the autonomy of the individual, non-discrimination and respect for the equality of individuals are all at the core of religious and secular values. We consider below those Articles of the Human Rights Act that should be borne in mind by pharmacists.¹

The Human Rights Act 1998

Article 2 Protection of right to life

‘Everyone’s right to life shall be protected by law.’ This opening statement is then qualified by exceptions in the case of ‘riot or insurrection’, ‘defence of a person from unlawful violence’ and ‘in order to effect the lawful arrest or to prevent the escape of a person lawfully detained’. There was originally an exemption for capital punishment but this is no longer lawful in the UK. So that is what Article 2 actually says; what does it not say? It does not say that you have a right for your life to be

¹Schedule 1 of the Act lists Articles 2 to 18 with two amending protocols covering matters such as prohibition of slavery, prohibition of restrictions on political activity of aliens, protection of property, right to education and abolition of the death penalty.

indefinitely preserved – in other words, you do not have a right to unlimited medical treatment irrespective of the cost to the public purse. It does not say that you have a right to die. We consider this last point further in relation to legal and ethical issues surrounding the end of life and resource allocation (p. 149).

Article 3 Prohibition of torture: an absolute right

‘No one shall be subjected to torture or to inhuman or degrading treatment or punishment.’ You might be forgiven for thinking that such considerations should never bother the pharmacist or be an issue in healthcare. But there may be occasions when you are dealing with a patient who is alleging recent or past ill-treatment. You may be dealing with patients in care or in prison who appear to be subjected to physical abuse or medicated without their consent or knowledge. Some would argue that aggressive treatment or lack of proper medical care and hospice resource in terminal care verges on the inhuman.

Article 5 Right to liberty and security

‘Everyone has the right to liberty and security of person.’ This statement is also qualified, as in Article 2, with exceptions prescribed by law such as arrest and detention ordered by the courts or on suspicion of committing an offence and ‘the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drugs addicts or vagrants’.

You will be able to see that UK law concerning ‘notifiable diseases’ and provisions for the detention and treatment of those with mental disorders fall within this exception. Article 5 goes on to require that anyone detained should be told why, promptly and in his own language, brought promptly before a judge and given a fair trial.

Article 6 Right to a fair trial

Article 6 elaborates further on the features of a fair trial, all of which are proper considerations to be made when considering the care of the mentally ill.

Article 8 Right to respect for private and family life

‘Everyone has the right to respect for his private and family life, his home and his correspondence.’ The customary exceptions include

national security, prevention of crime and protection of health, morals and the rights of others. This is the nearest the UK gets to a right to privacy. In healthcare, this right has been cited to prevent disclosure of medical records in court and is at the heart of legislation on data protection and confidentiality. 'Respect' would also mean an absence of prejudice against a patient's lifestyle perhaps or sexual preferences; a right that is made explicit in Article 14 below.

Article 9 Freedom of thought, conscience and religion

'Everyone has the right to freedom of thought, conscience or religion; this right includes freedom to change his religion or belief and freedom, either alone or in community with others and in public or private, to manifest his religion or belief, in worship, teaching, practice and observance.' The usual exceptions also apply to this right. The incorporation of this right into the social culture of the UK is apparent everywhere with the growth of mosques and gurdwaras, the development of television channels and schools for specific faiths, the observance of a wide range of 'feast' days or special occasions in religious calendars, to name a few. Implications for pharmacists could arise in the management of Ramadan fasting on medication regimens or religious restrictions on working hours that compromise opening hours or service times for pharmacy services.

Article 12 Right to marry and found a family

'Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.' No further exceptions are provided for this right but 'national laws' have extended the possibility of founding a family amongst same sex couples or single individuals. What they have not done is create a law that guarantees a right to medical assistance in founding a family although NHS policy now does permit a limited amount of help at the tax payer's expense.

Article 14 Prohibition of discrimination

'The enjoyment of the rights and freedoms set forth in this Convention (European Convention on Human Rights) shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a

national minority, property, birth or other status.’ No exceptions. You will readily recognise the roots of the last few decades of statutory legislation outlawing progressively all forms of discrimination, firstly in employment and later in access to services, including, of course, health-care.

Pharmacists, like all healthcare workers, must maintain absolute neutrality and lack of prejudice in their dealings with patients and other users of their services. We should be providing care on the basis of need – but – there may then be a conflict between Article 9 and Article 14 when we consider, for example, the provision of contraception. A pharmacist may argue that freedom to observe her religious conscience prevents her from supplying emergency hormonal contraception. What then if a patient claims that this refusal is actually on the basis of disapproval of her lifestyle or sexual behaviour? So far, the right to a ‘conscience clause’ is well established in codes of ethics or practice for health professionals. As antidiscrimination measures move to a positive promotion of ‘diversity’ and ‘inclusivity’ in UK society, this may come under challenge.

The European Convention on Human Rights was a reaction against the inhuman and barbaric treatment of human beings during the Second World War. The Human Rights Act provides protection for the individual from the overweening power of the State and redress in the UK courts, rather than at Strasbourg. While at first sight such considerations may seem somewhat divorced from healthcare, the NHS is an agent of the State and pharmacists, when employed by or providing services for the NHS, are also carrying out State or public functions. Patients are, by definition, vulnerable to some degree and those who treat them should respect and promote their humanity. Patients may seek redress against NHS employees or contractors if their human rights are not respected. Even without this sanction, the ‘golden thread’ of human rights should be ever present in the culture of healthcare and manifest in professional codes of ethics and in daily practice.

Capacity and consent

The legal and ethical principles of consent are relatively new to pharmacists. Unlike most other health professionals, pharmacists have not traditionally ‘got close’ to patients; their work has rarely involved touching patients, still less injecting patients or subjecting them to surgery. However, as pharmacists move into clinical roles – for example, the taking of finger prick samples for analysis or the examination of

patients before prescribing – such physical interventions will necessitate the securing of consent to treatment. Moreover, consent is now increasingly important in an electronic age, where pharmacists, alongside all other health professionals, retain and have access to a wide range of sensitive personal information about patients. A clear understanding of the nature of consent is essential to the confidential management of such information and the securing of consent to disclosure.

Ethical basis

The securing of consent for any health intervention, whether or not it involves physical contact, is essentially the embodiment of respect for the subject's autonomy. Individuals who are competent adults are said to have 'capacity' to accept or refuse an intervention, be it the disclosure of medical information to another, the acceptance of medication, submission to surgery or participation in a clinical trial. A duty to respect an individual's informed choice, even if it seems ill advised or positively harmful, is now implicit in all aspects of healthcare. More pragmatically, the success of any intervention is much assisted when the patient fully understands and has confidence in what is being offered and is happy to cooperate and be involved. This cooperation has moved conceptually from 'compliance with' or 'adherence to' instructions from the doctor to 'concordance' – a term used in relation to optimal use of medication in collaboration with the patient.

Such a term properly reflects informed consent, a process of negotiation and agreement to the treatment being offered rather than an exhortation to 'follow the doctor's orders'. In modern healthcare practice, the taking of decisions on behalf of the patient is acceptable only in a very limited number of circumstances – unconsciousness, infancy and early childhood, some forms of mental or learning impairment – and only then when a number of other considerations apply. Indeed, the process of seeking consent is now described as 'joint decision-making' in guidance from the Department of Health (see Further reading).

Lidz and colleagues (2003) suggested three components of ethically valid consent:

1. The consent must be voluntary
2. The consent must be given by a competent individual
3. The consent must be taken in the light of sufficient information and understanding of that information to enable a decision to be made.

Tests for securing valid consent, and circumstances when consent might be unattainable are now well established in law and a brief account appears below.

Legal considerations

Consent to treatment

It is a principle that has long been recognised in the common law² that every person has the right to protect his bodily integrity from invasion by others. This means that even innocuous touching is potentially a ‘battery’ against that person, although the *de minimis non curat lex* principle (the law does not concern itself with trifles) applies to casual contact. Exceptions only arise where the individual has given consent or is specifically permitted in law, such as the making of an arrest where force is needed. In healthcare practice, the purpose of consent is ‘to provide those concerned in the treatment with a defence to a criminal charge of assault or battery or civil claim for damages for trespass to the person. It does not provide a defence to a claim that they negligently advised a particular treatment or negligently carried it out’ (Re R (a minor) 1991). Distinctions are also made between implied consent, such as proffering the forearm to give a blood sample, and expressed consent, such as signing a consent form before undergoing surgery. In either case, the consent must be voluntary, that is, not coerced. You should always make clear, therefore, that refusal is always an option; consent should not be given merely to ‘avoid upsetting the doctor’ or not to appear ‘an awkward customer’. Conversely, if a patient is fully informed but really does not wish to make her own decision, it can be left to you, the pharmacist, although as a prudent practitioner you might wish to make a record.

Capacity (also called ‘competence’) is the subject of many aspects of law. For simplicity, a competent person – one who has full capacity – is anyone over 18 years of age (this is the position in English law). This is the age on which ‘majority’, as opposed to being a ‘minor’ in the eyes of the law, is achieved. The presumption is, therefore, that everyone over the age of 18 has capacity – is competent – to give consent to or refuse treatment (Re T (adult: refusal of treatment) 1992). (See also p. 127 the discussion of children aged 16 or over and consent to medical treatment.) For those who are adult but lack capacity or for those who

²In England and Wales, common law is the reasoned decisions of judges while statutory law is written law passed by an Act of Parliament (Ankier 2005, p. 110).

are legally still minors, the law has prescribed a number of safeguards to protect their interests while allowing them to be treated where necessary. No one is allowed to consent on behalf of adult patients. If an adult patient lacks capacity, for example if she is unconscious, the doctor or possibly the pharmacist must decide whether an intervention is necessary in her 'best interests'. In reaching this decision, the clinician may take into account information from friends and relatives but they may not give consent on behalf of an incompetent adult patient.

Lack of capacity may arise through mental illness, which is partially addressed in the Mental Health Act 1983 (and its amendments). This principally covers those with a legally defined 'mental disorder'³ and provides when their rights to autonomy and refusal of treatment may be overruled. Until 2005, the law did not address decision-making on behalf of patients who did not fall within the terms of the Mental Health Act but who nevertheless lacked capacity, such as those with learning disabilities, those suffering acute but temporary mental distress or those who anticipated loss of mental capacity through a terminal condition. The Mental Capacity Act 2005 aimed to address these gaps. Where the patient is a 'minor' (under 18, under 16 in Scotland) then other adults are permitted to give consent to or refuse treatment on their behalf in accordance with a variety of statute and case law. This law is explored a little more fully below in relation to the healthcare of 'vulnerable patients'.

Finally, valid consent depends upon information. It can be argued that in healthcare it is virtually impossible to achieve completely informed consent; even the clinician will not necessarily know all the possible effects of an intervention in a particular patient or how to measure whether the patient actually achieves the desirable level of understanding and ability to make a decision. Nevertheless, successive rulings in case law have established that you should be able to demonstrate that you have provided sufficient information (not just of the proposed intervention but also of alternatives) and you have tried to establish that the patient is able to 'comprehend...and retain...the treatment information, believe [it] and weigh it in the balance to make a choice' (Re C (adult: refusal of treatment) 1994). Moreover, whereas the standard for failure of duty of care in relation to delivery of treatment is normally that of Bolam and Bolitho – accepted as proper and logical by a responsible body of similarly skilled professionals (p. 86) – the standard for disclosure of information, particularly of risks, may arguably be what the

³To be redefined in 2007 proposed amendments.

patient would accept as reasonable and logical (Pearce v United Bristol Healthcare NHS Trust 1998).

Before leaving the subject of consent, we should briefly mention what form it should take. A signature on a consent form is not necessarily proof that valid consent has been obtained; conversely, the absence of a consent form does not automatically mean that consent has not properly been secured. In the event of argument, the test will be whether the giver of the consent had capacity, was acting voluntarily and had sufficient understanding of enough information to enable them to make a decision.

Consent to disclosure of information

Consent to disclosure of information is considered more fully below under confidentiality but the principles of consent remain the same: an adult patient must have capacity to give consent to disclosure, has the right to refuse to give consent and must be fully informed as to what information will be disclosed, why and to whom.

Confidentiality

Ethical basis

Confidentiality is a further manifestation of the ethical imperative to respect the autonomy of the patient, or indeed the autonomy of anyone who has provided information to you with an express or implied requirement that it be kept secret. Respecting confidentiality is a deontological duty and an aspect of virtue ethics (Chapter 1) whereby the ethical health professional should demonstrate good faith and maintain the trust of the patient that confidences will be kept. On a practical (or consequentialist) basis, the effectiveness of healthcare would be undermined and the general public could be at risk if patients could not trust their health professionals to keep their confidences and illness went untreated.

The concept is generally well understood: we ‘confide’ in others; we have ‘confidence’ in their discretion; we expect them to recognise what, within the information we impart, is ‘confidential’ and we would not wish to see widely shared or published in the newspapers. Respecting confidentiality in healthcare practice is a very old concept. The Hippocratic oath (Mason and McCall Smith 1999) uses the words ‘All that may come to my knowledge...which ought not to be spread

abroad, I will keep secret and never reveal.' In less flowery language, the Declaration of Geneva of 1994 (Mason and McCall Smith 1999) required a doctor to 'respect the secrets that are confided in me, even after the patient has died'.

Modern healthcare practice increasingly challenges such absolute principles. Examples include the need to share information with a widening range of social and healthcare professionals who care for the patient, and with administrators and managers who need to audit activity and manage patient records, the need to disclose in the interests of public health or prevention of crime; and, not least, through the advent of electronic records that can be transmitted at the click of a mouse and are vulnerable to 'hacking' and other forms of Internet corruption. Most significantly, the advent of the Data Protection Act of 1988 has encouraged two ideas: that patients have the greatest interest in the maintenance of their medical confidences and, therefore, they (not doctors) reserve the right to consent to (or refuse) disclosure and to control the nature and extent of disclosure; secondly that patients also have a right to know what information is being kept about them, why it is being kept and to whom it might be passed on, and why. In other words, legislation has elevated the autonomy of patients to the same status as any other 'data subject' in relation to information kept about them.

For pharmacy, reference to confidentiality appeared in the first Pharmaceutical Society of Great Britain ('Royal' was conferred in 1998) Statement Upon Matters of Professional Conduct of 1941, but only in relation to maintaining the patient's confidence in the doctor. Not until 1984 did a rather more modern interpretation appear, making reference to a general respect for the confidentiality of patient information and requiring patient's or guardian's consent to disclosure '*except where it is in the best interests of the patient to do so*' (author's italics). In recent years, the concept of 'best interests' or more precisely the concept that a health professional is the best judge of a patient's best interests has come under challenge. Consent to disclosure, just as we have seen in the section on capacity and consent above, is becoming a matter of joint decision-making rather than an assumption that 'patients won't mind'.

By 1992, the Pharmaceutical Society of Great Britain renamed their Statement as a Code of Ethics and, perhaps reflecting the development of data protection law and the Gillick case (p. 127), elaborated on the principle of confidentiality in much greater detail including circumstances when confidential information either could or should be disclosed without consent. This approach has continued in successive codes (see the Appendix for current Code of Ethics).

So the ethical basis for the current position is that information about a patient is an integral part of the autonomy of that patient; just as touching or treating a patient should normally only be undertaken with their consent, so the collection and transmission of confidential information about them should normally also only proceed with their consent.

As discussed in Chapters 1 and 2 and in the first section of this chapter, a new strand of ‘rights based’ ethics has developed from United Nations and European conventions on human rights. In relation to confidentiality, these go further than the common law in Britain and refer to a right to ‘respect for private and family life’ (Box 6.1).

Box 6.1 Article 8 of the Human Rights Act

Everyone has the right to respect for family and private life.

There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well being of the country, for the prevention and detection of crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Although we said above that the concept of confidentiality is relatively simple and well understood, it should be noted that the application of a whole series of conflicting and confounding interests affecting confidentiality means that taking decisions in particular clinical situations can be very problematic. Within the NHS, there is a significant quantity of ‘quasi-law’ (Montgomery 2003, p. 15) in the area of confidentiality. By this we mean guidance and codes that assume semi-statutory status in relation to the legal ‘duty of quality’ (Health Act 1999, Section 18), better known as clinical governance. You will find particularly good sources of guidance in the practical application of confidentiality to healthcare from the Department of Health (2001, 2003).

Legal considerations

According to Foster and Peacock (2000, p. 2), ‘the obligation to keep confidences is historically a bizarre cocktail of tort, equity, contract, property and downright judicial imagination’. Nevertheless, the concept

is well embedded in case law because, as they go on to elaborate (p. 3), 'there is an important public interest in maintaining clinical confidentiality'. (Most cases concerning issues of confidentiality entail a balancing of the interests of the individual against the interests of others. The famous case of *W v Egdell* (1989) involved the patient W who was in Broadmoor hospital having killed five people. His initial application to be transferred to a regional secure unit was blocked by an independent consultant psychiatrist (Dr Egdell), so W then applied to the Mental Health Tribunal for a conditional discharge, knowing that the Tribunal would not see Dr Egdell's unfavourable report. When Dr Egdell became aware of this, he sent his report to the hospital medical director and the Home Office. W subsequently sued Dr Egdell for breach of confidence. W lost because the court held that the public interest in protecting the public from W was greater than the public interest in maintaining clinical confidentiality for W. Now, of course, W might have brought a case citing his rights to respect for privacy under the Human Rights Act. However, the constraints set out in the relevant clause of the Act (Box 6.1) would suggest that the outcome would be the same as in the 1989 case.

More difficult judgements arise when balancing the interests of a patient against those of family members, close relatives or sexual partners. The advent of HIV infection has created dilemmas of disclosure to sexual partners or to patients generally if a health professional becomes HIV positive, or to fellow prisoners if one of their number is HIV positive. Within the context of the family it is not easy to allow a wife to insist on confidentiality in the face of violence from her husband but that is her right. Conversely, the public interest in preventing child abuse may well outweigh the personal interests and fear of an adolescent that such information must remain confidential. Conflicts can also arise for health professionals carrying out public functions, such as staff employed in occupational health schemes or army doctors.

As well as case law, a substantial body of statute law affects the confidentiality of clinical information. Criminal justice law and data protection law allow and sometimes require disclosure of information to assist in the prevention and detection of crime. The courts can require disclosure of patient records to assist in consideration of legal actions. Laws requiring disclosure to the authorities apply, for example, to the control of 'notifiable diseases' (Public Health (Control of Diseases) Act 1984), notification of abortions (Abortion Act 1967), births and deaths (Births and Deaths Registration Act 1953) and certain road accidents (Road Traffic Act 1988).

The Data Protection Act 1998 covers all data that may identify a 'living subject', which, in the case of clinical data, may simply be the naming of a very rare disease and a partial post code. It follows that disclosure of truly anonymous data or data relating to someone who has deceased is not contrary to the Act although the latter remains contrary to professional codes of ethics. The Act not only sets stringent conditions before any personal data for a subject can be recorded, organised or used but it also gives almost total rights to the subject to see what facts are being held about them and to require them to be deleted or altered if incorrect. In the case of clinical records, limited discretion is still permitted to the individual health professional to withhold some information if it may harm the patient's mental or physical health or unnecessarily identify other individuals. However, the presumption is that all such records should be 'open' to access by the patient to whom they relate. The concept of 'openness' is also at the heart of the Freedom of Information Act 2000, which requires bodies carrying out public functions – such as NHS hospitals, primary care organisations and those contracted to the NHS – to make publicly available information about their activities. However, this Act specifically does not apply to the disclosure of information that can identify patients whose interests remain protected by the Data Protection Act.

Space does not permit a proper exploration of the body of case law and interpretation of statute law that applies to clinical confidentiality; interested readers are referred to the sources in Further reading.

Vulnerable patient groups

Vulnerable patient groups would include children, the elderly, those with impaired learning abilities and the mentally disordered.

Ethical basis

In general, the concept of paternalism is out of fashion in Western medical practice. The idea that a health professional can take decisions on behalf of adult, competent patients without their involvement is no longer tenable. However, many patients and other users of pharmacy services may be neither competent adults nor fully autonomous in their capacity to make decisions about their care. In these circumstances, the substitution of the judgement of the pharmacist as to what is the 'best interests' of the patient can be permissible – within limits. Pharmacists should recognise that with the possible exception of unconsciousness,

the capacity of many patients to take decisions will fluctuate. An individual with learning disabilities, for example, may not be able to decide safely on what medical options they should select, but they are probably quite capable of deciding what meals they would like to eat or what clothes to wear. An elderly person with developing dementia may be lucid and decisive in some areas of their choices and not in others. A child of 14 has far more capacity to take decisions than a 3 year old. A patient with a mental disorder who may be under compulsory treatment still has the right to take decisions about aspects of treatment that do not relate to the mental disorder, such as contraception.

An adult whose capacity is impaired is sometimes termed ‘vulnerable’ in healthcare parlance. Vulnerable adults require special consideration when ensuring their involvement in and valid consent to their care and treatment. In addition, special attention may be needed to respect and enhance what autonomy they still possess – in other words to ensure that they are respected and treated with dignity. Pharmacists should also be wary of treating vulnerable adults as though they were children. Simple measures should be employed, for example checking with the patient whether she is happy for you to address her by her first name or local terms such as ‘love’, ‘mate’ or ‘duck’; not making assumptions that apparent incomprehension means lack of mental ability, she may be deaf or the terminology you are using may be unfamiliar; conforming to the patient’s concepts of decency when being treated in a ward or being taken to the lavatory. When you are dealing with patients who are in the care of others – be it at home with care from social services, in residential care or in prison – take particular care to ensure that consent really is voluntary and that treatment is not being instituted simply for administrative or operational convenience.

Legal considerations

Unconsciousness

Where the patient is unconscious, a body of common law and case law (*Re F v West Berkshire Health Authority* 1990) has been established to assist in taking decisions about their medical treatment. This is often described as the doctrine of ‘necessity and best interests’. This recognises a situation where there is a need to act urgently to save life or prevent deterioration in a patient’s mental or physical well-being. The health professional must, therefore, decide that intervention is necessary and then take whatever action he or she judges to be in the patient’s best

interests. This concept has extended to the involvement of relatives, carers and friends in seeking to ascertain what would have been the patient's wishes on a whole variety of matters, such as past and present wishes and feelings or religious or cultural views, had they been capable of expressing them. We return to this topic under the Mental Capacity Act (p. 128).

Children

The age of majority in England and Wales was reduced (from age 21) to age 18 in 1969 and further reduced to age 16 in relation to consent to (not refusal of) a young person's own medical, dental or surgical treatment (but not research, cosmetic surgery or organ donation; Family Law Reform Act 1969, Section 8(1)). A similar provision exists in Scottish law (Age of Legal Capacity (Scotland) Act 1991, Section 1(1)(b)). Since the advent of emergency hormonal contraception as an over the counter medicine, pharmacists are now familiar with the further implications of the landmark judgment given in the Gillick case (*Gillick v West Norfolk and Wisbech Health Authority* 1985). This case turned upon whether a young person under 16 could be offered contraceptive advice and treatment without the consent of a parent. In essence, the judgment of Lord Fraser in this case recognised that the young person might give their own consent, and refuse to allow disclosure to the parent, if 'the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed'. The judgment also suggested five 'tests' as to how this understanding might be assessed, usually known as 'Gillick competence' (Box 6.2).

Although the Gillick case established that being under 16 might still allow a young person to give consent to their own contraceptive treatment, no lower age limit was set. However, later legislation stated that a child under 13 years does not have the capacity to consent to sexual intercourse (Sexual Offences Act 2003). This has led to some concern about the ability of a pharmacist to respect the wish for confidentiality of a child who is sexually active but under 13. The key consideration here is the possibility of abuse. If the girl is under 13 and the male partner is over 16 and/or a relative, then the possibility of abuse of power must be investigated. If the male partner is under 16, such a situation would still constitute rape. Detailed guidance on what to do in situations such as these is available from the RPSGB (see Further reading).

Box 6.2 Tests for Gillick competence (applies in England and Wales only)

(Note: the original case related to doctors; the principles have since been extended to other health professionals and to matters other than contraceptive advice.)

A pharmacist would be justified in proceeding with contraceptive advice without the parent's consent or even knowledge provided that the pharmacist was satisfied of the following.

1. The girl would, though under 16, understand the pharmacist's advice
2. The pharmacist could not persuade her to inform her parents or allow the pharmacist to inform the parents that she was seeking contraceptive advice
3. The girl was very likely to have sexual intercourse with or without contraceptive treatment
4. Unless the girl received contraceptive advice or treatment, the girl's physical or mental health or both were likely to suffer
5. The girl's best interests required the pharmacist to give her contraceptive advice, treatment or both without parental consent

Vulnerable Adults

The management of adults who lack some or all capacity to take decisions has been the subject of legislation for many decades. The Mental Health Act 1983³ provides lawful procedures for the detention and compulsory treatment of patients with defined mental disorders. However, even for these patients, and sometimes for those who are admitted 'voluntarily' for treatment only, no one – relatives, carers or friends – can act as a proxy and give consent to treatment on their behalf. Treatment may proceed on the basis of necessity and best interests as though they lacked consciousness. The application of mental health legislation is extremely complex and interested readers are referred to the Further reading list for details.

The position of persons who lack some or all capacity but who do not fall under the remit of the Mental Health Act 1983 was not addressed in the law until the Mental Capacity Act of 2005 (in Scotland, rather earlier with the Adults with Incapacity Act (Scotland) 2000). The 2005 Act aimed to 'empower and protect vulnerable people who are

³Significant amendments to the 1983 Act were in progress at the time of writing. In Scotland, the relevant legislation is the Mental Health (Scotland) Act 1994, as amended.

not able to make their own decisions'. It spelt out key principles and prescribes tests (Box 6.3) for the assessment of a person's capacity to make a decision and for criteria to assess 'best interests'. You should also be aware of a Safeguarding Vulnerable Groups Bill that was progressing through Parliament at the time of writing this chapter (August 2006).

Box 6.3 Concepts in the Mental Capacity Act 2005 (not verbatim)

Principles

- A presumption of capacity in every adult
- A right for support for individuals to make their own decisions
- Individuals retain the right to make what might be seen as eccentric or unwise decisions
- Anything done for or on behalf of people without capacity must be in their best interests (not yours or that of the organisation)
- Interventions for people without capacity must be the least restrictive possible

Determination of best interests

- Must not be made merely on the basis of age, appearance or behaviour
- Must permit and encourage patient to decide as much as she can
- Must assess whether patient will have capacity in the future and if possible delay till then
- Must consider patient's past and present wishes and feelings, especially if written down
- Must take into account, if practicable and appropriate, views of persons with an interest in the patient's welfare
- In relation to life-sustaining treatment, must not be motivated by a desire to bring about the patient's death.

Of particular importance for those adults who anticipate future incapacity, perhaps from impending death or encroaching dementia as the result of their medical condition or advancing age, the Mental Capacity Act formalises statutory rules for the making of advance decisions to refuse treatment (the 'Living Will') and makes it a criminal offence to ill-treat or neglect a person who lacks capacity. At the time of writing, consultation was in progress on a Code of Practice for 'acting and making decisions on behalf of those who lack the mental capacity to do so for themselves'. Legal arrangements for the creation of Lasting Powers of Attorney (to allow the designation of someone else to take

decisions about the care of a person who anticipates losing capacity) and Advance Directives were also in progress. The Act will start to come into force in 2007.

Issues at the beginning and end of life

In recent years, drug intervention has become increasingly important and something of a commonplace with respect to 'beginning of life' and 'end of life' issues in healthcare. The interventions most relevant to pharmacists are:

- routine contraception
- emergency contraception
- termination of pregnancy: non-surgical or therapeutic abortion (mifepristone or RU-486).

Potentially future and related issues include:

- assisted dying
- fertility treatment (not discussed here; see Schenker (1997) and McLean (2005))
- genetic screening.

Apart from moral considerations, what the life and death issues such as those listed above have in common is that they do not fall readily into what may be thought of as the normal business of therapeutics (the branch of medicine concerned with the treatment of disease, or in other words the healing arts). It could, of course, be argued that this would be to take too narrow a view of what constitutes therapeutics. There is no reason why our conception of what constitutes therapeutics should not change with time and even within a lifetime. Who could have predicted just a few decades ago that treatment of erectile dysfunction would become a commonplace therapeutic matter? And at very least, concerns with infertility or unwanted pregnancy, erectile dysfunction or a wish to end one's life may have an adverse effect on personal health and well-being (which indeed they may). Furthermore, taking a rather oblique evolutionary tack, infertility can be seen as simply a deviation from the species *norm*. But while being wholly natural biological phenomena, for individual human beings infertility, unwanted pregnancy or erectile dysfunction can represent a significant feeling of personal impairment or distress that would benefit from corrective action.

The influence of multiculturalism

Individual pharmacists often express a variety of views or reservations on the moral implications of beginning of life and end of life interventions. Religious beliefs, socio-cultural background and perhaps the age group of the individual will have a strong bearing on a person's general attitude to many aspects of life and death, and indeed with regard to causes and treatment of disease. The whole basis of medicine and therapeutics is subject to strong cultural influences, which may become more apparent and significant in multicultural societies. Consequently, the 'cultural competence' of pharmacists may be seen as increasingly important with respect to '...the ability to provide care to patients with diverse values, beliefs, and behaviors, including tailoring delivery to meet patients' social, cultural, and linguistic needs' (Diggs and Berger 2004).

We might expect, therefore, that the moral challenges of dealing with beginning and end of life interventions will be exacerbated by the context of working in multicultural teams and in caring for patients from a variety of cultural backgrounds. In the case of *Smeaton v Secretary of State for Health* (2002), which concerns the legality of the prescription, supply and use of the morning-after pill, Mr Justice Mumby stated:

As Professor Hart pointed out (see *The Morality of the Criminal Law* (1964) pp. 39–41), both Sir James Stephen and Sir Patrick Devlin assumed a society marked by a high degree of homogeneity in moral outlook and where the content of this homogeneous social morality could easily be known. He suggested that neither of them had envisaged the possibility that society is, and on one view had already by the 1960s become, morally a plural structure.

Be that as it may, it can hardly be disputed that the last few years have marked the disappearance in an increasingly secular and pluralistic society of what until comparatively recently was in large measure a commonly accepted package of moral, ethical and religious values. This means that on many of the medical, religious and ethical issues which the courts increasingly have to grapple with there is simply no longer any generally accepted common view. One of the paradoxes of our lives is that we live in a society which is at one and the same time becoming both increasingly secular but also increasingly diverse in religious affiliation....So the starting point of the law is an essentially agnostic view of religious beliefs and a tolerant indulgence to religious and cultural diversity.

Such views are shared by Turner (2001), who spelt out the implications of multiculturalism for medical ethics:

‘Commonsense’ moral philosophies of medical ethics must recognise the multiplicity of modes of practical moral reasoning. The existing models of moral reasoning in bioethics simply do not face the challenges that exist in highly pluralistic social settings. Bioethics as a discipline will take an important step when it stops presuming the existence of a stable, settled, order and begins to acknowledge the multiplicity of moral worlds.’

For Turner, the way forward is to apply some of the methodology and practices of anthropology and the social sciences that can more readily accommodate cultural diversity. For the practising pharmacist, the important consideration is to be both aware of and sensitive to religious and cultural aspects in their work.

Beginning of life

The most relevant procedures for pharmacists are routine contraception, emergency contraception, termination of pregnancy – non-surgical or therapeutic abortion (mifepristone or RU-486) – and to a far lesser extent fertility treatment.

Ethical issues

With routine or emergency contraception, and therapeutic abortion, the direct and primary consideration is that of the woman herself – she has interests in her own well-being, and specifically in not becoming pregnant. As an autonomous individual and subject to medical advice, she is entitled to proceed with contraception and to expect not to be harmed by contraceptive treatment (duty of care). But it is also necessary to take into account the rights of others, for instance the right not to be harmed. Healthcare workers claim rights to freedom of conscience and rights are also claimed, in contraception and abortion, on behalf of the embryo and the fetus (extending from roughly 9 weeks post-fertilisation to birth), or even from the point of fertilisation or implantation.

There has been much debate over whether contraception (routine or emergency) constitutes killing (the most extreme and absolute form of harm) either at the pre-implantation stage or of the embryo itself. Supporters of contraception point out that contraceptive agents inhibit conception, and that the vast majority of spermatozoa die spontaneously without involvement in fertilisation. What seems to be a major

ethical stance is a general intention to do good and not harm, and to respect rights, although those of the mother generally carry most weight. This is tempered by attempts on the part of political, legal and health authorities to establish appropriate limits and guidelines (see below). Ethical concerns for ‘pro-life’ supporters and health professionals alike are two-fold: biological questions, such as at what stage is an embryo or fetus sensitive to pain; and, secondly, criteria that indicate when life begins. Concepts and contested claims concern the validity and moral implications of:

- potentiality: a viable ovum or spermatozoon has potential to develop into a human being
- continuity: a claim that life begins at fertilisation
- personhood: an embryo can be considered as an embodied person.

These issues form part of the discussion concerning moral status generally and are important because the associated legislation determines just how germinal cells, embryos and fetuses are to be treated (what their rights are). All of the procedures noted above require the assistance or involvement of others, variously doctors, nurses and pharmacists. Their rights and concerns also deserve consideration but have to be balanced by a duty of care to the patient in the broader sense.

Legal considerations

Under the 1967 Abortion Act, abortion can be undertaken at up to 24 weeks provided two doctors agree that there is a greater risk to the woman’s mental or physical health from continuing the pregnancy than from terminating it. This is in line with general agreement on being earlier than the developmental stage at which a fetus is considered capable of sustained independent survival (23 to 28 weeks). The precise wording associated with the 24 week limit is: ‘to be considered being capable of being born alive, a foetus must be capable of sustained independent survival’ (Abortion Act 1990 amendment to the Abortion Act 1967). Emergency terminations may lawfully be carried out at any point in cases where a woman’s life is seriously threatened or a child is likely to be born with severe mental or physical impairment.

End of life

Health professionals are also involved with those who wish to pursue a ‘right to die’, even if they are only the suppliers of the medication that

may be used in this way. Wingfield and O'Neil (2006) suggested the following.

Ethicists attempt to analyse the circumstances of dying according to normative moral theories of intentions, consequences and virtues demonstrated. The principle of 'double effect' provides that an act with both a good and bad effect may be ethically permissible if only the good effect is intended and the good result outweighs the bad result. We can then argue as to whether death is preferable to intractable pain, what constitutes an intolerable life, which disabilities are insupportable and which are not. Such questions are, of course, individual and intensely personal. Arguments about the difference, if any, between acts and omissions also exercise moral philosophers. Is 'letting die' morally different from killing? Most of us instinctively feel it is but are more hard-pressed to explain why or to set the borders between unacceptable killing and allowing a merciful death. Debates about a 'slippery slope' also abound: if we allow this step, then another will surely follow until we are allowing the unthinkable – legalised murder of our weakest citizens.

The word euthanasia or more usually the phrase 'active euthanasia' is derived from the Greek words *eu* meaning goodly or well, and *thanatos* meaning death. It is associated with bringing about a gentle and easy death particularly in the case of incurable and painful diseases. In practice, active euthanasia means any form of termination of life by a doctor.

Ethical issues

There is a considerable philosophical literature that grapples with some of the ethical 'pros and cons' of end of life issues. A useful starting point is to consider the approach adopted by Dworkin *et al.* (1998). In philosophical terms, the authors argued that the claimed asymmetry between accepting a right to refuse treatment and denial of a legally and morally permissible assisted dying is untenable.

Our starting point is the claim, which we are assuming is shared by those who oppose medically assisted dying, that a competent patient has a right to refuse any proposed medical treatment, or to withdraw from existing medical treatment even if she knows that this will result in death. The general strategy is to argue that, if one accepts this, then one ought to accept that a patient may request physician-assisted suicide and that under certain conditions it is permissible, and ought not to be criminal, for health care providers to give such assistance.

Several major classical philosophers have expressed views about suicide that may have a bearing on end of life considerations. Socrates declared that a man should not take his own life but wait until summoned by the gods. Nevertheless, having been himself condemned by the judges for being found guilty of corrupting the youth, he committed suicide by drinking a brew of hemlock, as a form of capital punishment. Aristotle in the *Nichomachean Ethics* takes a rather hard line (see Barnes 1976, 1116a6–24):

But to kill oneself to escape from poverty or love or anything else that is distressing is not courageous but rather the act of a coward, because it shows weakness of character to run away from hardships, and the suicide endures death not because it is a fine thing to do but in order to escape from suffering.

In Aristotle's table of virtues and vices, the sphere of action is 'fear and confidence', an excess is rashness, the mean is courage, and a deficiency cowardice (Barnes 1976, 1107b18–20). Thomas Aquinas (1224–1274) argued against suicide on the basis of being contrary to nature, injuring the community and being a sin against God, for 'it belongs to God alone to pronounce sentence of death and life'. In *The Second Treatise on Civil Government*, John Locke (1690) declared that: 'though man in that state (of liberty) have an uncontrollable [sic] liberty to dispose of his person or possessions, yet he has not liberty to destroy himself...they are his [God's] property, whose workmanship they are, made to last during his, not another's pleasure.'

David Hume (1711–1776), a profound religious sceptic, was among the few to defend suicide in appropriate circumstances in his *Essay on Suicide*: 'That Suicide may often be consistent with interest and with our duty to ourselves, no one can question, who allows that age, sickness or misfortune, may render life a burthen [sic], and make it worse even than annihilation' (Fieser 1995).

Immanuel Kant (1785) provided several insights into aspects relating to ending a life. His basic premise was:

He who contemplates suicide should ask himself whether his action can be consistent with the idea of humanity as an end in itself. If he destroys himself in order to escape from painful circumstances, he uses a person merely as a mean to maintain a tolerable condition up to the end of life. But a man is not a thing, that is to say, something which can be used merely as means, but in all his actions be considered as an end in himself.

Kant introduced two important concepts that have become major issues in modern healthcare ethics generally: dignity and autonomy.

In the kingdom of ends everything has either value or dignity. Whatever has a value can be replaced by something else which is equivalent; whatever, on the other hand, is above all value, and therefore admits of no equivalent, has a dignity. ...Autonomy is the basis of human and every other rational nature.

Kant's writings on human beings treated solely as ends, with respect for dignity and autonomy, can be used to argue that ending a life either by suicide or assisted dying, and even the use of pain control that might accelerate death, is morally unacceptable. However, it has been argued that Kant's theories do not support *a priori* objection to euthanasia where moral agency is permanently lost, such as in persistent vegetative state or the latter stages of Alzheimer disease (Gunderson 2004).

Legal considerations

Euthanasia is not identical to 'assisted dying', which means helping a patient to end their life at his or her wish, though the ethical dilemmas are somewhat comparable and UK law (see below) treats them essentially in the same way. For a summary of the key legal considerations and the ethical issues related to the ending of life see Wingfield and O'Neil (2006), and for a general review of relevant legislation in some European countries and the unlikelihood of overarching European legislation see Pridgeon (2006). The Steering Committee on Bioethics on behalf of the Council of Europe coordinated a survey on matters of law and practice relating to euthanasia (reported in January 2003). The UK respondent indicated that:

Euthanasia is regarded as murder in all jurisdictions of the UK. In *England & Wales*, murder is a common law offence. In *Scotland*, murder is also a common law offence. In the medical setting, *R v Cox* (1992) confirmed that if a medical practitioner carried out an action with the intention of ending life, whether or not for compassionate reasons or at the patient's request, this would constitute murder.

One European country where euthanasia is currently undertaken is the Netherlands. Here, euthanasia or physician-assisted suicide can only be carried out at the express, explicit and carefully considered wish of a patient. The key factors are the voluntary nature of the patient's wish and that the suffering is unrelievable (neither terminal illness nor phys-

ical suffering is essential). The practice of euthanasia is not permitted by statute, but Dutch law accepts a standard defence provided that strict guidelines have been followed. In a nationwide survey in the Netherlands, most pharmacists questioned were supportive of both euthanasia and physician-assisted suicide (Lau *et al.*, 2000).

A House of Lords' debate on 12 May 2006 (Assisted Dying for the Terminally Ill Bill), over whether 'assisted dying' should become a legally permitted procedure, provoked strong and passionate discussion both for and against, inside and outside of Parliament. Although passing an amendment in favour of a six months' delay effectively rejected the 2006 bill, the Government has indicated that it would not block a further hearing. A change in favour of assisted dying would necessitate pharmacist involvement in assisted dying procedures.

The case of Mrs Dianne Pretty

Mrs Dianne Pretty who suffered from motor neurone disease wanted to end her life but was unable to do so unaided. She sought an undertaking from the Director of Public Prosecutions that her husband would not be prosecuted under Section 2(1) of the Suicide Act 1961, which states: 'A person who aids, abets, counsels or procures the suicide of another, or an attempt by another to commit suicide, shall be liable on conviction on indictment to imprisonment for a term not exceeding fourteen years.'

The Director of Public Prosecutions refused to give such an undertaking. Mrs Pretty challenged his decision first in the Divisional Court and then in the House of Lords on the basis that prohibition of suicide under English law represented an infringement of various rights enshrined within the European Convention. The appeal to the House of Lords was rejected (*Mrs Dianne Pretty (Appellant) v Director of Public Prosecutions (Respondent) and Secretary of State for the Home Department (Interested Party)* 2001), as also was the subsequent and final appeal to the European Court of Human Rights.

Both judgments provide valuable commentaries to legislation relating to suicide and human rights. And both express considerable sympathy for Mrs Pretty's personal plight, though unsurprisingly comments are strictly applied to interpreting the law. The European Court's judgment concerning the applicant's claim (under Article 8) that she was prevented by law from exercising her choice to avoid what she considered would be an undignified and distressing end to her life captures the nature and tone of the UK Suicide Act 1961.

The Court found, in agreement with the House of Lords, that States were entitled to regulate through the operation of the general criminal law activities which were detrimental to the life and safety of other individuals. The law in issue in this case, section 2 of the Suicide Act, was designed to safeguard life by protecting the weak and vulnerable and especially those who were not in a condition to take informed decisions against acts intended to end life or assist in ending life. ...It did not appear to be arbitrary for the law to reflect the importance of the right to life, by prohibiting assisted suicide while providing for a system of enforcement and adjudication which allowed due regard to be given in each particular case to the public interest in bringing a prosecution, as well as to the fair and proper requirement of retribution and deterrence.

In the second part of the final sentence of the extract there appears to be a veiled inference that at least some cases of assisted suicide are carried out for entirely compassionate or altruistic motives and have been dealt with sympathetically by UK courts. However, to recognise this formally and *a priori* might prejudice the protective nature of the Act. The European Court of Human Rights ruled against Dianne Pretty's application on 29 April 2002. She herself died on 12 May 2002 after slipping into a coma following severe breathing difficulties. The distinguished judge Dame Elizabeth Butler-Sloss commented on the case of Dianne Pretty in a lecture given at the University of Newcastle upon Tyne (2006).

...the individual has the right to make decisions for himself about his own death, and the right to instruct others to refrain from treating him, but he does not have the right to ask for anyone else's assistance. In this way the law makes a somewhat technical but absolutely fundamental distinction between a failure to treat (which is termed an 'omission'), and a positive act designed to bring about a person's death. The former is permitted, but the latter is not.

Mrs Pretty had the misfortune not to be kept alive by artificial means.

...Mrs Pretty's case highlighted the need for us as a society, to ask ourselves what is best to be done about these cases. How are we to be the kind of humane society we want to be, whilst at the same time respecting such fundamental principles as the protection of life, and the protection of the vulnerable? In my view it is extremely difficult to strike a balance in these cases. On the one hand the law's compromise (based on the act-omission distinction) could be said to lack a degree of reality. Some might say that it seems rather false to distinguish between the termination of artificial ventilation and the giving of an injection. Indeed, it may seem that the consequences of allowing the former but not the latter may be inhumane.

While at the time of writing, advance directives were not legally recognised in the UK (likely to change in 2007; see pp. 129–130), advance refusals made by a person over the age of 18 in ‘England and Wales are legally binding if they are valid and applicable in the circumstances (unless overruled by the Mental Health Act concerning treatment for a mental disorder)’ (Mental Capacity Act of 2005).⁴

Conscience clauses

A right of healthcare workers to follow their consciences has assumed considerable importance over the last few years in the USA and to a somewhat lesser extent in the UK. A fundamental question to ask in this respect is to what extent should a person’s ‘right to x’ be met by another person’s corresponding ‘obligation to supply x’? Irrespective of what might be claimed by some as ‘natural rights’, all the procedures listed as beginning or end of life issues (apart from assisted dying) are generally, though not entirely, accepted by society as represented by Parliament and endorsed by the law. But should a woman’s right under the law to, say, contraception mean that this right can only be exercised by imposing obligations on others? Clearly, the law as it stands cannot compel this action but relies on there being at least some, perhaps a majority, who are prepared to act thus.

What are sometimes termed ‘good Samaritan laws’, which might require the assistance of passers-by at the scene of an accident, would not be appropriate here. Indeed the term ‘good Samaritan law’ would appear to be something of an oxymoron: that is an inherent contradiction in suggesting compulsion for what might be seen as a common duty. At the same time, there are legal opt-out clauses (some encapsulated in professional codes of ethics) for conscientious objectors. The general approach is to permit opting out but at the same time require that any objector makes provision for a patient to obtain the service elsewhere, and the objector must not indulge in criticism or counselling against the proposed action. Though objectors might profoundly disagree, this latter can be seen as acting in the best interests of patients and reflecting a professional obligation to respect patients’ rights to participate in decisions about their care.

⁴Draft Council of Europe resolutions concerning the provision of assistance to patients at the end of life were rejected in 2003 and again in 2005, but with the intention of returning to the matter at a later date. Documents EDOC 9898 and EDOC 10455 provide very useful background (<http://assembly.coe.int/>).

However, what may remain a problem for some who hold strong conscientious objections is that, though a pharmacist may opt out of actual supply (no direct involvement), in advising a patient of an alternative source of supply (duty to refer) he becomes complicit in or an accessory to the process of supply. Mellema (2006) argued that the very act of referral 'facilitates or enables a harm'. It enables a harm to occur and is arguably not distanced, diminished or diluted by the relatively minor and indirect contribution. The stark example of refusing to give a knife to someone who is intent on murder, but indicating where one may be obtained, illustrates the point. This is not intended to suggest that contraception or abortion should be equated with murder, although perhaps for some people this is indeed considered to be the case. The likelihood that a patient, even if humiliated by denial of supply or redirection, will eventually inevitably and independently obtain a supply elsewhere is unlikely to persuade a strong objector that his complicity would be morally acceptable.

In declining a request to supply emergency contraception, any prevarication by a pharmacist would be understandably traumatic for the patient. This, in turn, raises questions about membership of professional bodies and to what extent that membership should be conditional on signing up to a code of practice in its entirety. Indeed such a code might be amended from time to time, perhaps requiring individual endorsement of a revised code as a condition of continuing membership. A related question arises with respect to employment and whether employers should be able to refuse to employ or continue to employ a pharmacist who wishes to exercise a conscience clause.

In December 1996, American pharmacist Karen Brauer was sacked by her employers for refusing to dispense a contraceptive mini-pill Micronor (Zwillich 2005). Brauer's objection on conscientious grounds was that Micronor acts by preventing implantation of an already fertilised egg. During interview, Brauer admitted that she had lied to the patient in claiming that the product was not in stock. We can only surmise that Brauer considered that telling a lie was the lesser of two evils (similarly justifiable, though far less extreme than lying to save someone from a Nazi search party), but severely damaged her conscience case by offering to transfer the prescription to another pharmacy.

Unlike the situation in the UK, the status of conscience or refusal clauses in the USA is complicated because pharmacies and the practice of pharmacy are controlled by individual states, and not on a federal

basis. Some states are planning to legislate allowing refusal to dispense contraceptive products on moral grounds, whereas others intend to oblige all pharmacies to dispense any legally compliant prescription. However, a Michigan State proposal, the Conscientious Objector Policy Act (House Bill 5006), would allow conscientious objectors to opt out in advance from participation in a particular procedure, and they would not be required to accommodate patients or colleagues. Even more far reaching, the US House of Representatives has approved the 2005 appropriations bill for the Departments of Labor, Health and Human Services, and Education that includes a clause that would protect individual healthcare workers from any penalty if they refused to participate in abortions or to refer patients, even in cases of rape or emergency need. The bill requires Senate approval and presidential signature before passing into law.

Ethical basis for conscientious objection

Ethical considerations of conscience turn mainly on rights, and duties or obligations: in particular whether a right automatically attracts a corresponding duty or obligation from others and whether that right trumps someone else's right to follow their conscience and refuse to meet an obligation or duty. Secondly, there is the matter of whether conscientious refusal is compatible with any degree of accommodation with a patient. A pharmacist who on conscientious grounds refuses to supply contraceptive treatment may consider that any action or comment on their part to indicate to the patient other options would necessarily render themselves complicit, as an accessory or enabler, to the very procedure to which they object.

Legal considerations in conscientious objection

The principle focus of legal considerations concerning abortion and emergency contraception can be traced back to the Offences Against the Person Act 1837 and its 1861 revision; this made it an offence to administer drugs or to employ instruments to procure miscarriage. The Abortion Act 1967 did not decriminalise abortion but allowed immunity from prosecution under the 1861 Act provided that certain conditions were met. The option of conscientious objection is covered in Section 4, Conscientious objection to participation in treatment (medical termination of treatment):

(1) Subject to subsection (2) of this section (general provisions and restrictions) no person shall be under any duty, whether by contract or by any statutory or other legal requirement, to participate in any treatment authorised by this Act to which he has conscientious objection: provided that in any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming it.

The Act recognises that conscientious objection would not be upheld where there was risk to life or of grave and permanent mental or physical injury to a pregnant woman. The law provides no statutory definition of conscientious objection and offers no interpretation of what is meant to participate. A key question, therefore, is just what is meant by 'to participate' in treatment authorised by the Act? This is clarified to some extent in case law by *R v Salford AHA ex parte Jannaway* (1989). Mrs Jannaway was a health centre secretary who refused to type a letter concerning a referral for abortion. Jannaway's assertion was that typing a letter was in effect participation in treatment under the Act; consequently, she was entitled to refuse to participate on the basis of conscientious objection. The case was dismissed on the grounds that in 'its ordinary and natural meaning... (participation) referred to actually taking part in treatment administered in a hospital or other approved place...for the purposes of terminating a pregnancy' (see Foster 2005).

For pharmacists the most likely involvement with the process of abortion would be in dispensing pretreatments or abortion-inducing agents such as mifepristone (Mifegyne), misoprostol or gemeprost. The Jannaway judgment would not appear to hold here, as a pharmacist who objected on grounds of religious belief or personal conviction might argue that participation of a pharmacist was an essential step within the ordinary or natural meaning of participation. Hence he would not be under any duty, whether by contract or by any statutory or other legal requirement, to participate in any treatment authorised by this Act to which he has conscientious objection. Irrespective of this, a pharmacist does have recourse to conscientious objection in a provision set down within the RPSGB Code of Ethics and Standards (A.1. Pharmacists providing professional services).

(k) Before accepting employment pharmacists must disclose any factors which may affect their ability to provide services. Where pharmacists' religious beliefs or personal convictions prevent them from providing a service they must not condemn or criticise the patient and they or a member of staff must advise the patient of alternative sources for the service requested.

These provisions could be employed by a pharmacist with respect to conscientious objection to dispensing or supply of materials to procure abortion under the Abortion Act 1967, contraceptive agents, emergency hormonal contraception or indeed medicinal substances to be used in assisted dying should this ever become legally sanctioned. Interestingly, the question of conscientious objection by a pharmacist to supplying emergency contraception over the counter without prescription was raised in the House of Commons in 2005 (Hansard 2005). The questions concerned the necessity for an objecting pharmacist to refer a patient to another pharmacist, and also whether the Secretary of State would make provision for a pharmacist with conscientious objection to be able to rely on the rights created by Section 4 of the Abortion Act 1967. In a written answer, Caroline Flint (then Parliamentary Under Secretary for Public Health) stated:

Emergency hormonal contraception (EHC) is not a method of abortion. In 2002, there was a High Court Ruling that the supply and use of EHC is lawful and that prevention of implantation, which is brought about by emergency contraception products, does not amount to procuring a miscarriage under the 1861 Offences Against the Person Act. The conscience clause set out in section 4 of the Abortion Act is therefore not relevant to the supply of EHC.

The 2002 High Court ruling referred to by the minister, following judicial review by Mr Justice Munby, included a comprehensive analysis of what does and what does not constitute a miscarriage – Parliament did not define the term in the Offences Against the Person Act 1861. A transcript of the ruling (*Smeaton v Secretary of State for Health*, 2002), which provides valuable background reading, can be downloaded (<http://www.oup.com/uk/orc>). The judge's assessment was found by some to be deeply unsatisfactory (Keown 2005).

The parliamentary answer concluded with a statement of the RPSGB conscience clause (above) with the (supposed) implication that the clause dealt adequately with both questions from the pharmacist's perspective. Pharmacy technicians are not specifically mentioned in the relevant legislation.

Ethical issues in genetics and pharmacogenetics

It is no exaggeration to say that progress in the field of molecular genetics has moved at a phenomenal rate since Crick and Watson's elucidation of the double-helical structure of DNA in 1953. Advances in

techniques of analysis, replication, automation and computing power have resulted in identification of many genes strongly associated with monogenetic diseases. While the causation of disease processes may be far less deterministic than scientists would wish, and other personal characteristics and environment factors are major influences for pre-disposition or resistance, the possibilities of targeting genes or their expression products are becoming realities (Ashcroft 2003).

Genetic screening and genetic knowledge

Genetic screening is sometimes employed where there is a family history of hereditary disease; it is dependent upon locating a suitable marker close to a specific and relevant gene. Medical application of genetic testing is mainly two-fold:

- to identify the presence of genes that may predispose to certain monogenetic diseases in (a) children and adults or (b) (prenatal) embryo, fetus or the newborn
- potentially to identify genes that have a major influence on drug metabolism.

Monogenetic diseases include the recessive disorders cystic fibrosis, sickle cell and Tay–Sachs disease. Huntington's chorea or Huntington's disease is a late-onset genetic disorder with almost complete penetrance and, therefore, highly predictive. Testing for Down syndrome (an extra chromosome 21) is widely employed in prenatal diagnosis. The monogenetic diseases are relatively rare, but there is anticipation that much more common disorders such as heart disease and some forms of cancer with both polygenetic and environmental causation may be susceptible to genetic screening in the future.

Ethical issues around genetic knowledge

Knowing that you carry a gene that predisposes to a potentially serious disease is not a simple matter. For this reason alone, the importance of ensuring fully informed consent before proceeding with a test and the availability of expert counselling is vital (see Nikku (1997) for a discussion of informative paternalism).

With genetic screening, moral concerns often focus on the wider implications of knowing that an individual carries a gene with a high probability of developing disease (the *BRCA2* breast cancer gene confers a lifetime risk of 80–85%). Not only those who opt for testing but

also relatives for whom ignorance was bliss may be confronted with concerns about their own genetic risk profile – does an individual have the right to impose this burden on others by default? Life assurance companies may at some time wish to take a client's genetic data into account either by refusing to insure those considered being at high risk or by loading the premium. A UK moratorium on the use of information from predictive genetic tests by insurance companies has been extended until November 2011 (excluding Huntington's disease in policies of over £500 000).

Moral concerns broadly relate to either (a) considerations of privacy, consent and confidentiality or (b) ones of embryo selection. Endorsement of the voluntary and non-discriminatory status of genetic screening, and requirement for informed consent, are crucial and pivotal. The Nuffield Council on Bioethics produced a comprehensive report on *Genetic Screening: Ethical Issues* in 1993 (supplement in 2006; see also Carter 2001).

Legal considerations around genetic knowledge

There are four relevant policy documents or declarations:

- United Nations Declaration of Human Rights (1948)
- Universal Declaration on the Human Genome and Human Rights of Unesco (1997)
- Asturias Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of the Council of Europe (1997)
- Charter of Fundamental Rights of the European Union (December 2000).

The Human Tissue Act 2004, covering England, Wales and Northern Ireland, provides the legal framework for storage and use of tissue obtained from living human beings, and also removal, storage and usage of tissue and organs from deceased persons. Similar legislation is operative in Scotland (The Human Tissue (Scotland) Act 2006). Relevant material within the Act includes material that consists of or includes human cells. It excludes cell lines, hair or nail from living people, and live gametes or embryos, which are regulated under the Human Fertilisation and Embryology Act 1990. The Act also brought into being the Human Tissue Authority, which is the statutory regulatory body. The Authority issues Codes of Practice, the first of which (1 July 2006) set out detailed requirements for obtaining consent, which is seen as the relevant fundamental principle. In brief:

For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question. Adults are competent to consent if they can:

Understand the nature and purpose of the proposed procedure

Understand and retain information relevant to the decision

Weigh the necessary information to arrive at a choice (Code of Practice).

Reproductive opportunities

Broader and more familiar ethical concerns relate to embryo screening and sex selection; with occasional talk of ‘designer babies’ or, in the extreme, eugenics (see Baldwin 2005, Harris 2005). Embryo screening by tissue typing to produce so-called ‘saviour siblings’ is now permitted following a Human Fertilisation and Embryology decision in July 2004. This enables parents to proceed to full pregnancy when and if an embryo free from a serious genetic disorder is successfully tissue matched with a sick sibling.

Ethical issues around reproductive genetics

Ethical issues that arise concerning reproductive opportunities include consideration of the interests and dignity of the ‘saviour sibling’, which may be compromised, and, in particular, concerns over means and ends and the instrumental use of a (potential) human being (see Spriggs 2005, Chico 2006). See also Sheldon and Wilkinson (2003), who considered the implications of means and ends, risk of embarking on a slippery slope and potential for physical or emotional harm, but conclude that ‘...the selection of saviour siblings should be permitted, especially given that prohibiting it would result in the preventable deaths of a number of existing children’.

A phrase that has become perhaps all too familiar is ‘playing God’, with the implication that too much human intervention in the process of bringing a child into the world is morally unacceptable and we shouldn’t go there. This could be put another way by suggesting that nature should be allowed to take its course, either a child will carry a gene with a high risk factor for disease or it will not – we should not interfere with the genetic lottery of life. For many who observe or treat children or adults who suffer from inherited diseases, sometimes extremely painful or distressing, the possibility of prevention by selec-

tion appears to be a clear choice. Others are like the profoundly deaf couple Paula Garfield and Tomato Lichy, who were delighted when their daughter Molly was born, also with profound deafness (*Guardian* 21 March, 2006). There is a risk, which this story illustrates, that by attempting to eliminate serious disease or impairment through selection, some existing sufferers may feel diminished and that their own lives are not properly valued by others.

Legal considerations around reproductive genetics

The Human Fertilisation and Embryology Authority, set up in 1991 under the Human Fertilisation and Embryology Act 1990, enforces the necessary legislation controlling reproductive genetics. Of interest in this area are the *Concordat and Moratorium on Genetics and Insurance* Department of Health (2005), discussions of the regulatory issues in Brownsword (2004) and Sheldon (2005) and the possibility of tort law claims (Chico 2006).

Pharmacogenetics

Medical applications of genetic knowledge, including genetic screening and microarray screening systems, will enhance identification and characterisation of genetic elements and support opportunities to employ pharmacogenetics concepts.

Perhaps for pharmacists, the advent of the new pharmacogenetic era will be of most direct interest (for a brief overview see Kalow (1997)). Pharmacogenetics relates genetic constitution to variable drug response and may eventually provide the basis for optimising individual treatment with some drugs. More predictable efficacy with fewer side-effects would represent a significant improvement in patient care, consistent with the principles of beneficence and non-maleficence.

Ethical issues around pharmacogenetics

The Nuffield Council on Bioethics undertook a study on the ethical issues of pharmacogenetics and reported in 2003. The key findings relate to concerns with confidentiality and of access to personal information – consideration of justice and fairness would have a bearing on whether one should be penalised for knowledge of one's genetic heritage. In essence, many of the ethical considerations are closely similar to those relating to genetic screening.

The Nuffield Council study also recognised the risk of neglecting the needs of minor subgroups of patients with atypical pharmacotherapeutic profiles that might not be commercially viable for research and development expenditure (see also Hoedemaekers *et al.* 2001). While there is an obvious benefit in knowing that a particular drug would be ineffective or injurious in some patients, it could mean fewer available options for treatment. Again, justice and fairness are considerations when assessing whether business and society in general should support the extremes and not only the majority within a normal distribution curve. Deontological theories, and claims of justice and fairness, assert that all human beings deserve equal consideration and such assertions could be expected to feature in national and international policies, whereas utilitarian arguments might be favoured by commercial organisations. The recommendation from the study was that development for such groups might attract special funding or tax incentives similar to that for 'orphan diseases' (p. 168). Other issues relate to the speculative nature of the pharmacogenetics concept (Hedgecoe and Martin 2003, Badcott 2006).

Legal considerations around pharmacogenetics

There are currently no specific legal considerations that apply to pharmacogenetics, but most of the legislation that applies to genetic screening, particularly regarding confidentiality (March *et al.*, 2001), and freedom from discrimination would be relevant here. As a cautionary note for the future, Rothstein and Epps (2001) made the following comment.

Physicians and pharmacists might be subject to liability if they lack sufficient knowledge of genetics to adequately interpret diagnostic tests, prescribe appropriate pharmacogenomic-based drug therapy in proper dosages, consider pharmacogenomic-based drug interactions, or properly dispense pharmacogenomic-based prescriptions. ...As information regarding the genotype of an individual becomes increasingly important to safe prescription and dosage, pharmacists might be charged with greater knowledge of their customers' genetic information than they now require. The increased amount of genetic information in pharmacies raises privacy and confidentiality concerns, especially where pharmacists belong to large pharmacy chains or corporations with widely accessible, centralized records. For physicians and pharmacists, the issue of continuing professional education and record maintenance will become more important, not only for improving competence but also for preventing liability.

The above sections have been largely concerned with how you, the pharmacist, might encounter ethical issues in relation to individual patient care. Below we consider some other areas where ethical issues arise in a wider context: within a cash-strapped state-funded health system, within an organisation that delivers healthcare or employs pharmacists, in the development and marketing of pharmaceuticals and in the use of biotechnology to develop novel medical care. As the role of the pharmacist develops and expands, these are areas where an understanding of some of the ethical arguments surrounding these topics will inform your practice and your ability to work in concert with the whole healthcare team.

Resource allocation

Ethical basis

The tabloid press call it ‘rationing’; health ministers call it ‘priority setting’ or ‘demand management’; we will call it ‘resource allocation’. Whatever name is used, one of the thorniest of the ethical dilemmas that beset healthcare is how to deliver it within a finite budget or financial resource. The topic abounds with almost unanswerable questions. Should we give priority to older people over children – or the other way round? How do we balance the expenditure of, say, funding treatment for a single patient with a rare congenital heart disease against the cost of a lost opportunity (‘opportunity cost’) to treat perhaps 100 patients with crippling rheumatoid arthritis? How do we measure the need or the best outcome when different patients experience illness and pain differently? Should we spend more money on prevention of illness rather than treatment? Should chronic disease take precedence over acute care?

Responses to these questions involve recourse to deontological concepts of duty: duty to care for the patient epitomised by the ‘Hippocratic’ model of complete clinical freedom to allow the clinician to focus on the needs of individual patients to the exclusion of wider cost constraints. Add to this a rising concern with ‘rights’ to treatment fostered by the passing of the Human Rights Act, the very public financial difficulties of the NHS and a political impetus towards increased patient choice and a ‘voice’ in the provision of healthcare. Conversely, the discipline of health economics leans heavily on a utilitarian approach. It attempts to quantify and measure using devices such as QALYs to chart a path through the morass of conflicting interests and constraints that characterise any health service and determine what

options 'offer the greatest happiness for the greatest number'. Alongside these largely irreconcilable approaches, we should demonstrate the virtues of compassion, empathy and understanding to deal with exceptional cases or to recognise particular patient viewpoints that do not fit the conventional priorities in healthcare planning and resource.

We have no answers either, save to endorse the view expressed by Newdick (2005 p. 15): 'If the process of resource allocation is inevitable, it should treat patients equally, fairly and within a consistent framework of principles. By themselves, ethical principles do not indicate which patients should receive priority.'

As well as examining the various contexts – economic, political, clinical and legal – in which NHS resource allocation has to operate, Newdick forcefully argued for the development of a nationally applied framework for taking decisions on NHS resource allocation. He lamented the unwillingness of successive British governments to acknowledge this need and instead to rely on a 'bottom up' approach wherein, 'other than through guidance from NICE and NSF [National Service Frameworks] guidelines, local resource allocators (such as NHS and Primary Care Trusts) are given no assistance on how to allocate resources' (p. 93). One consequence of this incomplete approach is the rise of judicial challenge to such local decisions (see below) and unwelcome pressure from the media and politicians on local health bodies to fund specific individuals or even sufferers from 'fashionable' or 'sexy' diseases.

How do problems of resource allocation affect you as a pharmacist? For many years, community pharmacists have been obliged to assist both customers and patients to choose which medicines they can 'buy' with limited resources. This includes basic advice on the value for money of different over the counter medicines to assisting 'non-exempt' patients to decide how many items on their prescription form they can afford. Choices here are usually confined to the best interests and preferences of that particular patient, with limited need to consider wider concerns. Pharmacists acquired the 'right' to prescribe medicines within a supplementary prescriber arrangement in 2003 and to prescribe independently in 2006. Pharmacists in these roles now have to weigh objective, evidence-based decisions on the accepted optimum drug regimen against individual clinical judgement about what is right for that patient and against macro funding constraints such as practice prescribing budgets and Primary Care Organisation (PCO) allocation of funds. Significant numbers of pharmacists are directly employed in PCOs to manage prescribing budgets. Most pharmacists routinely give advice on the value

of medication: some are part of hospital clinical teams; others develop protocols or write formularies and management plans. In these endeavours, pharmacists are prioritising resources and thereby assume accountability for deciding which drugs shall be funded and to what extent.

Having agreed that ethical principles of themselves are of little help, how best can pharmacists respond professionally when called upon to allocate scarce health resources? Some pointers can be found in examining the legal challenges to current methods.

Legal considerations

We looked briefly in Chapter 4 at how a patient might bring an action in clinical negligence for harm caused by treatment (or lack of it). Decisions to deny access to specific drugs or interventions on cost grounds might conceivably be the basis of such an action. However the 'target' is more likely to be a health service body than an individual practitioner and, in any event, the legal remedy of judicial review is likely to be more appropriate and productive. Nevertheless, Newdick (2005, p. 164) argued that clinicians – who must now include pharmacists who prescribe – should, as well as having the best interests of the patient uppermost in mind, also ensure that the patient is aware of and involved in the process. He suggested that a truly transparent and honest approach should allow the doctor to be able to say to the patient:

1. I will always act in your best interests
2. Sometimes for reasons of NHS policy, treatment may be only available in limited circumstances. I will inform you of that policy
3. If you have exceptional need for treatment which is not generally available I will inform you about it
4. In such a case I will, if you wish, advise the health authority of your special need and request that you be treated as an exceptional case.

It follows that pharmacists should also challenge themselves to be able to adopt this approach in their dealings with patients. Certainly, the case is becoming stronger for healthcare professionals to be open and honest with patients when their treatment is affected by resource allocation decisions, both from an ethical standpoint and to minimise any possible action in clinical negligence.

A second remedy that is more prevalent is to bring a judicial review against the health body or against the Government itself. Judicial review is an instrument of justice whereby the decisions of public bodies can be challenged. Grounds for challenge can be that the body acted

illegally (meaning the body had no power to make the decisions – it was acting outside of its powers – *ultra vires*), or its decision was irrational or that there was some procedural impropriety in how it was reached (Montgomery 2003 p. 68). Section 3 of the NHS Act 1977 (England and Wales; in Scotland the NHS (Scotland) Act 1978) places an open-ended duty upon the Secretary of State to provide health facilities and services ‘to such extent as he considers necessary to meet all reasonable requirements.’ However judicial reviews⁵ have established that Secretaries of State and health bodies are entitled to take into account resource constraints when making their decisions on allocation of funding.

This principle was perhaps most famously demonstrated in the ‘Child B’ case (*R v Cambridge & Huntingdon HA* 1996) where funding was refused for ‘unproven’ treatment of a 10-year-old girl with leukaemia. Problems with funding new treatment have arisen with beta-interferon for multiple sclerosis (*R v Derbyshire HA ex p Fisher* 1997) and in the case of herceptin for certain forms of breast cancer. Public challenges and the threat of action under the Human Rights Act appear to have been sufficient to elicit political interference with the judgement of health bodies funding such treatment.⁶ The practical consequences of these cases means that the law expects all public bodies – and their staff – to make decisions in accordance with processes that are clear, transparent, coherent and consistent, to give reasons for their decisions and to disclose the rationale behind their resource allocation policies.

Finally, and much closer to everyday pharmacy practice, there are some statutory limitations on the availability of medicines within the NHS: the ‘black’ list of medicines that are not prescribable at all on the NHS and the Advisory Committee on Borderline Substances list of treatments that will only be funded for patients that meet specific criteria to qualify for treatment under the NHS (NHS (General Medical Services Contracts) (Prescription Drugs) Regulations 2004 (SI 2004 No. 629)). Even here judicial review has been used to challenge non-statutory restrictions for Viagra and erectile dysfunction.⁷

⁵For a full account of judicial review and other law relating to health resources see Mason and McCall Smith (1999) Ch. 11, Montgomery (2003) Ch. 3, Newdick (2005) Ch. 5

⁶News reports include the BBC News reports ‘Hewitt has left the NHS toothless’ (10 November 2005) and ‘Woman wins Herceptin court fight’ (12 April 2006) (<http://news.bbc.co.uk/1/hi/health/4422662.stm> and [/4902150.stm](http://news.bbc.co.uk/1/hi/health/4902150.stm); both accessed July 2006). Also see *R (on the application of Rogers) v Swindon NHS Primary care trust and the Secretary of State for Health (Interested Party)* 2006.

⁷Through a challenge from the manufacturer (Pfizer) against an administrative instruction only in *Health Service Circular (R (Pfizer Ltd) v Secretary of State for Health* 2002).

Organisational and business ethics

Ethical basis

It may seem odd to suggest that an organisation can have ethics; an ethical value system can really only belong to a person. However, if we change the description to 'organisational ethical culture' or even just 'organisational culture', you may readily see how the apparent ethics of an organisation reflects the ethics of the individuals who work in it. This reflection is uneven: the managing director of a multiple pharmacy chain, the Head of a Pharmacy School, the Chief Executive of an NHS Trust or a pharmaceutical company each has far more influence than more junior employees over the ethical culture of the enterprise. He or she 'sets the tone' as it were; middle managers reinforce the culture and the most junior staff are expected to operate within it. All of us are immediately sensitive to the ethical values of the organisation in which we work. It is manifest in managerial styles, the systems for promotion, incentives and bonus schemes, the way in which junior staff are treated and the corporate 'face' presented to the public. We can sum it up as being 'the way we do things round here'.

As a pharmacist, you are the embodiment of your organisation's ethics; how you behave towards other employees and to clients indicates the nature of the organisation itself. If you own a small independent pharmacy then you set the ethical culture for that business. If you are within a larger organisation, you will set, reinforce or respond to (or possibly frustrate) the values manifested within it. Such values may be explicit by way of 'mission statements', policies, guidelines and company statements on a range of matters and formalised through reward systems, recruitment criteria, training programmes and decision processes. Equally powerful are informal systems whereby individuals displaying certain characteristics seem to 'get on', some are 'heroes' within the organisation and some are not, certain procedures become ritualised and specific language is used to 'rubbish' or elevate specific groups of staff or activities.

What has this to do with pharmacy? Firstly, almost all pharmacists work within organisations (however small) and all of us have to engage with them on a regular basis. An understanding of how organisations work can be fundamental to success in this context. Secondly, most organisations generate conflicting goals: in a business, the pursuit of profit is essential for survival; in a hospital, meeting targets is similarly crucial for future status; in universities, publishing the 'right' research

attracts government funding; a drug company has to generate new products to compete on a global stage. All of these goals can conflict with the best patient care and pharmacists must balance these conflicts in their daily practice. The ability and scope that you have to balance these conflicts will usually depend upon your position within the organisation.

Trevino and Nelson (1999) suggest that business ethics can best be considered on four levels:

1. Ethics and the individual
2. Ethics and the manager
3. Ethics and the organisation
4. Ethics and the world.

We would suggest these levels are applicable across most organisations, whether strictly 'in business' or not.

As an individual employee, you, like most others, want to feel good about what you do; you want to feel valued, that the work you do is worthwhile, that you can be trusted to deliver for the organisation. Additionally, as a pharmacist, you want to be sure that there is no inappropriate constraint on your ability to act with professional integrity, to help patients and to promote health more generally. The best employers of pharmacists will foster and support such freedom; where it is compromised, pharmacists may leave if they can or subvert the organisation's systems if they cannot. When the systems endanger patient safety, then you have an ethical obligation to seek their change and/or to 'whistle blow' (Chapter 4) if such pressure fails. Indeed, the perception that NHS managers were using a bullying rather than negotiating style in relation to nurses led to action by a 'whistle blower support group' organisation called Freedom to Care. This body published a *Charter of Public Accountability* in 2001 (now updated) calling for those who run large organisations to demonstrate transparency, justification and freedom to exercise professional autonomy in their organisational structures and practice.

The larger the organisation, the more likely there are to be managers and, if very large, a whole range of 'middle managers'. All of these individuals can reinforce or undermine the ethical culture of the organisation. Moreover, most will be responsible for other staff – often dozens, hundreds or even thousands – so their ethical values are likely to influence many more people than an individual pharmacist. Whether or not these middle managers are pharmacists, in a healthcare or pharmacy enterprise they should be promoting patient care, public

health and employee integrity. If you are a pharmacist in a management position, or indeed with any authority within an organisation, then this ethical obligation will extend to those working 'under' you, alongside you and above you, irrespective of whether they are also pharmacists or not.

The power to 'set' the culture lies at the most senior level (as discussed above). It is a well-known organisational truth that change cannot happen unless and until it has the support of the most senior individuals in the enterprise. This is equally true of expected ethical behaviour in employees. To take a non-pharmacy example, it is useless to expect middle and junior employees to file honest claims for expenses if it is obvious that the managing director does not. Similarly, expectations that complaints from patients or customers should be listened to and acted upon will be more likely to be fulfilled if the chief executive listens and responds to the views of employees. As we have explained above, the most senior individuals, pharmacist or not, in an organisation that delivers healthcare or employs pharmacists professionally have an ethical obligation to promote professional integrity and patient care.

The balancing of conflicting interests at organisational level has led to the concept of 'stakeholders': individuals or groups of people whose interests are of importance to the organisation and must be served. Where the enterprise is a small pharmacy, these stakeholders may be local and parochial; an NHS Trust or Primary Care Organisation will have to take into account the interests of whole regions of the country and work within national policy for the NHS. Still larger organisations will operate on an international scale and have to deal with national and cultural values very different from those of their home base. We look at the ethics of the pharmaceutical industry on a global basis below. Increasingly, organisations are expected to demonstrate 'corporate social responsibility'. This means that they have social, as well as financial responsibilities. In many organisations this is manifest in philanthropic activity such as the endowment of institutions, the sponsoring of events and so forth.

From this very brief outline, we would suggest that pharmacists must expect to take responsibility for their own contribution within an organisation and be prepared to challenge instructions to behave unethically or in a way that compromises patient care. We would also suggest that you should be aware of your responsibility for the larger outcomes of your actions and consider whether you can or should intervene if they appear to be unethical.

Legal considerations

There is, of course, a vast body of law and other regulation that affects the operation of organisations. Obvious examples arise in employment law, health and safety law, environmental protection law and trading standards law. All of these seek to establish in legislation ethical base lines to protect individuals from the potential excesses of organisations in pursuit of profit, production and efficiency. Some aspects of this law that are particularly relevant to pharmacy are covered in textbooks on pharmacy law and ethics (Mullan 2000, Merrills and Fisher 2001, Appelbe and Wingfield 2005); more general information is available in a wide range of business and corporate law books.

Research ethics and clinical trials in therapeutic research

All medicines employed in pharmacy are subjected to two linked phases of activity: discovery and validation. Some botanical species like the opium poppy were discovered by chance to have medicinal value some 2000 or more years ago and validated by simple trial and error. The vast majority of the more potent and selective drugs used in the UK today have been subjected to systematic processes of discovery, evaluation, testing and approval. Since the introduction of voluntary assessment by the Committee on Safety of Drugs in the UK in 1964, formal regulatory approval of all medicines has become rigorous and mandatory. For a brief discussion of the European Medicines Agency for the Evaluation of Medicinal Products (EMA) see Harman (2002).

Formal validation involves testing both in animals and in humans. In the first instance, there is a requirement for testing in animals for evidence of potential activity, mode of action, metabolic route and toxicity. Once empirical safety and activity are confirmed, subsequent testing in human beings is undertaken to determine basic pharmacokinetics, pharmacodynamics, and to evaluate effectiveness and freedom from adverse effects. All human beings and non-human animals have interests, for instance in not being harmed, and this is at the heart of ethical considerations (the use of animals in research is discussed on p. 161).

Clinical trials in human beings have two main functions:

- to demonstrate efficacy
- to identify possible adverse (side) effects.

Early forerunners of today's clinical evaluation procedures are James Lind's demonstration of the ability of citrus fruit juice to prevent scurvy,

a disease common among sailors on long voyages (*A Treatise on Scurvy*, 1754) and William Withering's studies with foxglove preparations to treat dropsy, oedema caused by congestive heart failure (*An Account of the Foxglove and some of its Medical Uses*, 1785). By modern standards, these studies would be considered to be rather crude and it is unlikely that much thought was given to matters of patient autonomy. But the real precursor of the modern comparative clinical trial procedure is probably the Medical Research Council's evaluation of streptomycin in the treatment of tuberculosis, reported in the *British Medical Journal* in 1948. The so-called gold standard of contemporary clinical trials is the double-blind placebo-controlled study, where neither patient nor practitioner knows who receives an experimental treatment or who receives a control (an established comparator or placebo).

Clinical trials are undertaken on a phased basis, with increasing numbers:

- phase I: small-scale study in healthy volunteers (about 20–80) to assess pharmacokinetics, safe or tolerable dosage and route of administration
- phase II: patients (100–300) suffering from relevant disease to provide evidence of effective dosage, and safety
- phase III: patients (1000–3000) to establish formal safety, effectiveness and comparability
- phase IV: postmarketing studies in patients to identify low-level adverse effects (unlimited > 3000).

Although very many clinical trials and experimental studies are largely unproblematic, they are not always routine matters and risk free. In March 2006, eight young, healthy male volunteers participated in a phase I study involving an experimental T cell agonist TGN1412 in London. All six of those who received the active drug rather than placebo rapidly developed severe widespread functional failure in what appears to have been a cytokine storm. This is an exaggerated response that occurs when the normal reaction of T cell stimulation of cytokines becomes uncontrolled. The incident provoked many questions about the nature of this particular study (ethical and technical), and the controls, prestudy assessment and recruitment policy. For a brief background to some of the issues see Moberly (2006), and Goodyear (2006).

Ethical issues

Various aspects of randomised clinical trials have an ethical dimension. In participating in clinical trials, both healthy volunteers and patients

are entitled not to be harmed and for respect to be shown for their autonomy. A duty of care to prevent harm is generally taken care of by (a) ensuring the adequacy of pretrial safety data and (b) by appropriate supervision and monitoring during and if necessary following the trial. The most important issues concern personal autonomy and consent. This means being sure that the patient:

- is fully aware of the main aspects of the study, including an assessment of possible personal benefits or risks
- has a clear understanding that they may receive an inactive placebo
- does not feel obliged to participate for any reason and knows that he or she may withdraw at any stage without being penalised.

In other words, the patient's or volunteer's consent must be truly informed and voluntary. In philosophical terms this means *express consent*, as opposed to *tacit*, implied or supposed consent. Intervention without express consent is an assault. Additionally, patients are entitled to expect that their personal details will remain confidential unless anonymised or express approval and reason for disclosure is given.

A pivotal aspect of non-open, comparative clinical studies is that treatment is allocated not by a practitioner exercising judgement and knowledge of an individual patient but by following a randomisation schedule. Studies are 'blinded' to eliminate the risk (as far as is possible) of bias that could call into question the reliability of a study and its conclusions. It is only because there is genuine doubt about the efficacy or adverse profile of a potential but unproven treatment that a study involving a control group and randomisation may be justified.

The term 'equipoise' is sometimes used to indicate the balance of knowledge prior to a clinical trial study. It means that there must be indisputable uncertainty concerning what is the best or optimum treatment. At the same time, physicians have an express obligation to benefit their patient's illness or disease. Randomisation with or without blinding prevents a practitioner from exercising personal judgement with respect to a patient's medication. Hence there is a tension between therapeutic obligation to an individual patient and therapeutic research that tends to be overlooked or glossed over when patients are entered into clinical trials. To put it rather crudely, a practitioner's deontological obligations and the interests of individual patients are compromised by what is in effect utilitarian research, duties toward unknown future patients.

This raises the question of duties to others generally. One could argue that randomised clinical trials together with practitioners' personal

experiences are the cornerstones of therapeutic practice. If we wish to enjoy the benefits of medicine generally, then perhaps there is something of a Kantian obligation to contribute in this way, a moral duty or condition of entitlement. By participating in randomised clinical trials, patients contribute to a common good without which the evidence base of therapeutics would be greatly diminished. That is the dilemma. There has been considerable debate over the competing claims and ethical significance of clinical *equipoise*, meaning briefly that the doctor should believe that no one treatment is better than any other. However, there is much debate reflecting the collective uncertainty of what has been called a 'community of physicians', and the therapeutic uncertainty of an individual physician in determining treatment (for a discussion of the ethical concept and the implications of equipoise, see Freedman (1987)). It does not seem possible to obtain the sort of generalisable knowledge that good comparative randomised clinical trials may provide, and on which practitioners rely, without some risk of compromising a duty of care to a patient. Under these circumstances, the importance of informed consent and voluntary participation is paramount.

But what of those eligible but who refuse to participate in trials when invited? Might they be viewed as 'free riders', standing to benefit but who don't contribute to the costs? Claims of 'free-riding' are not restricted to clinical trials. Similar assertions have been made about those parents who withhold their children from measles, mumps and rubella vaccination to avoid a perceived risk of adverse effects, but at the same time relying on the herd immunity and diminished risk of their child contracting measles from majority compliance. In a free society, parents have an opportunity to do their best for their children within reason, and it could be argued that the primary decision is not to allow their child to be vaccinated, and that the advantage of the herd immunity to their child contributed by the majority is an unintended consequence. But for the 'common good', the fundamental question is whether the state should intervene, supported if necessary by court action, to require all children to receive, for example the measles, mumps and rubella vaccination? Compulsory treatment of any sort would represent a form of legal paternalism. Wolfe and Sharp (2002) have commented:

Vaccination is unique among de facto mandatory requirements in the modern era, requiring individuals to accept the injection of a medicine or medicinal agent into their bodies, and it has provoked a spirited opposition...how should the mainstream medical authorities approach the anti-vaccination movement? A passive reaction could be construed as

endangering the health of society, whereas a heavy handed approach can threaten the values of individual liberty and freedom of expression that we cherish. This creative tension will not leave us and cannot be cured by force alone.

While all patients who participate in clinical trials are to a greater or lesser extent vulnerable depending on their particular disease or ailment, children and the mentally impaired are particularly vulnerable. We say that children and the mentally impaired lack the competence or capacity to take autonomous decisions. The Royal College of Nursing publishes a useful primer on research ethics that includes advice on personal responsibility, respect and autonomy, vulnerable people (children and adults), research with vulnerable groups, and it emphasises the need to ensure confidentiality, protect confidentiality and balance risk of harm against potential benefit.

Legal considerations

For comprehensive coverage of the legislation affecting clinical trials and therapeutic research see Ankier (2005). The World Medical Association in its Declaration of Helsinki has made influential policy statements: Ethical Principles for Medical Research Involving Human Subjects (adopted June 1964, amended 1983, 1989, 1996, 2000, 2002 and 2004).

The Medicines for Human Use (Clinical Trials Regulations) 2004 (Statutory Instrument 2004 No. 1031) covers requirements for informed consent of potential clinical trial participants and incorporates the provisions of the European Clinical Trials Directive (EC2001/20) into UK law. Paragraph 3(1) of Part 1 of Schedule 1 to the UK Regulations defines informed consent for capable adults:

A (capable) person gives informed consent to take part in a clinical trial only if his decision:

(a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and

(b) either

(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate consent, is given orally in the presence of at least one witness and recorded in writing.

The regulations define an incapable adult as an adult unable by virtue of physical or mental capacity to give informed consent. (See fuller discussion on pp. 117–121 and pp. 128–130 on capacity and consent, and the role of the Mental Capacity Act 2005.)

Provision is also made in the 2004 Clinical Trials Regulations for minors who are defined in the regulations as being under the age of 16 years. Consent must be given on behalf of a minor prior to inclusion in a trial by a parent or person with parental responsibility. For emergency treatment only, there is a descending hierarchy of possible consenters: parent, personal legal representative (not connected with the trial), professional legal representative (nominated by the relevant healthcare provider but not connected with the trial).

New European legislation, 'Regulation of Medicinal Products for Paediatric Use' that will considerably increase the amount of testing on medicines specifically intended for use in children will be incorporated into UK law by the end of 2006 and will be overseen by an expert Paediatric Committee. The legislation specifies a number of requirements and incentives, including a six month extension of patent protection, and a new category of Paediatric Investigation Plan (PIP). (Regulation (EC) No.1901/2006 of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for Paediatric Use and amending Regulation (EEC) No.1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 came into force 26 January 2007.)

Use of animals in research

Thousands of animals, including rodents, rabbits, guinea pigs, some monkeys and higher apes are used in the assessment of the mode of action and toxicity of new chemical entities with potential to become medicinal substances. Over 2.85 million procedures with animals were undertaken in Britain in 2004 – an increase of approximately 63 000 above 2003 (Statistics of Scientific Procedures on Living Animals, Great Britain 2004 – Home Office, Science Research Statistics).

Ethical issues

Significant reports on animals in research were published by a parliamentary select committee on Animals in Scientific Procedures (July 2002), and by the Nuffield Council on Bioethics (2005). The Nuffield

Council Committee declined to put forward one particular view as being ‘right’, but summarised four possible ethical positions:

- ‘anything goes’
- ‘on balance’ justification
- moral dilemma (neither animal research nor avoiding research that could benefit human beings or other animals is morally acceptable)
- abolitionist.

There are two main points of criticism of the use of animals for drug testing.

1. The use of animals for such purposes is morally wrong – in particular, it is speciesist (the lives of animals are considered to be of less value than those of human beings). In other words, because animal lives are less valued they can be treated as a means to human ends, even where this involves causing pain or distress. (For discussion on various interpretations of the term speciesism, see Fjellstrom (2002).)
2. Using animals to try to predict the behaviour of drugs in human beings is scientifically invalid. It relies on a mistaken analogy between the biological systems of animals and humans – there are similarities but often there are crucial differences. Even if some biochemical or enzyme systems are common to both humans and some other animal species, those systems operate within the holistic context of the individual species. Hence the pharmacological and toxicological behaviour of the drug may be species dependent.

The two criticisms can be made independently or in conjunction: the use of animals in research is morally indefensible and/or intellectually unsupportable, or as a fallback position if one fails.

The philosopher Peter Singer (2000, pp. 45–46) has been associated with some of the key and often-controversial elements of the moral arguments regarding the exploitation of animals. Singer has argued that: ‘The basic principle of equality does not require equal or identical *treatment*; it requires equal consideration’. He is right to draw attention to the fact that some non-human animals would score higher on a sentience scale than, for instance, babies and the mentally impaired. Yet, taking other aspects into consideration, we would not consider the latter to be candidates for drug testing because of their relatedness within the human species continuum (Badcott 2003).

Major points in the House of Lords’ Select Committee discussion emphasised that moral treatment should relate to possession of certain characteristics (sentience, higher cognitive capacity, capacity to flourish, sociability and attributing value to possession of life), and recognised

the importance of setting appropriate limits and weighing and relating morally relevant factors to those limits. The Committee reflected on (a) the acknowledged sentience of some non-human animals, (b) the supposed uniqueness of human beings and consequent entitlement to use animals for their own purposes, and (c) claims of a duty (indeed an imperative) to try to prevent pain and suffering in human and other animals. They concluded that 'it is morally acceptable for human beings to use other animals, but that it is morally wrong to cause them unnecessary or avoidable suffering' (HL Paper 1501/Ordered to be printed 16 July 2002).

There appears to be a unanimous consensus that the use of animals in research must be accompanied by continuing efforts to replace this use by development of valid non-animal alternatives, to reduce the numbers of animals used in research, and to refine the techniques if they must be used (replace, reduce and refine – the so-called 'Three Rs' proposed by Russell and Burch in 1959). For discussion of the concept and progress with the Three Rs, see Flecknell (2002), Gruber and Hartnung (2004) and de Boo *et al.* (2005).

Legal considerations

The use of animals in research in the UK is controlled within The Animals (Scientific Procedures) Act 1986. All relevant procedures, premises and personnel are subject to licensing within the Act, and the Home Office operates an inspectorate to ensure compliance. The Act covers all live (non-human) vertebrates at various stages of development, but also the common octopus from the time when capable of independent feeding. Under the Protection of Animals Act 1911 (1912 in Scotland), it is an offence to cause unnecessary suffering to any domestic or captive animal. The Royal Society publishes a useful summary, *The Use of Animals in Research: A Guide for Scientists* (2004; www.royalsoc.ac.uk). European Council directive 86/609/EEC makes provision for the use of animals for experimental and other scientific purposes and has been transposed into UK law.

The pharmaceutical manufacturing industry

Since the latter part of the nineteenth century, the provision of medicines has shifted progressively from extemporaneously prepared pharmacopoeial medicines or specialities to large-scale industrial proprietaries for either over the counter sale or for supply on prescription. The

modern pharmaceutical industry, largely dominated by Western European and North American manufacturing companies, is the principle source of the vast majority of research, development and clinical evaluation of new medicines.

Ethical issues

While responsible for introducing a great many prophylactic and therapeutic compounds that have saved or improved countless lives, the industry often attracts highly critical comment from the media and others regarding excessive profits and questionable promotional practices (misleading advertising; inducements encouraging GPs to prescribe or to increase numbers of prescriptions written; funding for conferences or attendance; pressure on researchers to manipulate results; failure to act promptly or acknowledge (even suppress) reports of adverse effects) (see Kassirer 2005). These criticisms tend, by and large, to relate to accountability. Dukes (2002), suggested that the industry's accountability is two-fold: 'commercial duty to shareholders; and duty to the community'. It would seem reasonable to suppose that it is behaviour reflecting a conflict between these duties (to shareholders and to the community) that is at the bottom of many of the criticisms. All commercial companies are literally in business to make a profit, and research-based pharmaceutical companies must be highly profitable to provide a return to investors and to fund future research and development. The high marketing spend relative to investment in research is a continuing provocation to critics.

This is not the place to debate the relative merits or otherwise of private and public enterprises or indeed the morality of profit as such. But the morality of pharmaceutical business practice is a different matter. In 2006, the multinational pharmaceutical company Merck, Sharp & Dohme was suspended from the Association of the British Pharmaceutical Industry for malpractice. The malpractice involved an offer of assistance to GPs with blood pressure monitoring and control, but only to those GP practices that regularly used the company's antihypertensive drug Cozaar (losartan). This is the second suspension since the introduction of a more rigorous Code of Practice at the beginning of 2006.

Legal considerations

Promotional activities of UK pharmaceutical companies are subject to the Medicines Act (1968), the Medicines (Advertising) Regulations

(1994, SI No.1932, as amended) and subsequent amendments, legislation that controls misleading advertisements and European Union directives on the advertising of medicinal products for human use. In addition, most major UK-based industrial pharmaceutical companies are members of the Association of the British Pharmaceutical Industry, a trade body that operates an industry Code of Practice (2006) and deals with breach of code complaints.

Failure to act by individual pharmacists who consider that unethical practices are current or have taken place within their organisation (this applies equally to community, hospital and industrial pharmacists) may constitute a breach of the RPSGB's Code of Ethics on grounds of professional misconduct (see RPSGB 2005). The Public Interest Disclosure Act (1998) may offer some protection for those who 'blow the whistle' on employers.

Global availability of medicines and developing countries

Most of the major international pharmaceutical companies are now truly multinational or global, with subsidiaries in both developed and developing countries. The ethical problems of pharmaceutical advertising and promotion are further complicated by market conditions and indigenous culture. But perhaps the most important consideration is the extent to which 'Big Pharma' has an obligation (if any) to make products available at a price locally affordable in developing countries. The question has both commercial and humanitarian implications. The commercial aspect centres on profit maximisation (a duty to shareholders). The wider the distribution, the greater are potential sales and profits. But most developing countries are unable to afford to pay Western market prices for their medicines. Some pharmaceutical companies do charge significantly lower prices in some of these markets, presumably a lower profit margin can be sustained and there is net marginal value. The economic term 'Ramsey-Pricing' is often used to relate 'the set of price differentials that yield the highest possible social welfare, subject to a specified target profit level for the producer, usually a normal, risk-adjusted return on capital' (Danzon and Towse 2003). Scherer and Watal (2002) note that: 'In an ideal world, pharmaceutical manufacturers would pursue Ramsey-Baumol-Bradford price discrimination, setting relatively high prices for their patented products to recover R&D investments in the most affluent nations while selling drugs at only a modest markup

above marginal production and distribution cost in nations with weak ability to pay.' However, there are dangers that some of these lower cost drugs may appear in Western countries as parallel imports, thus both depriving intended beneficiaries and undercutting established market prices.

Ethical and legal issues

The ethical situation concerning global availability of medicines is extremely complex and not only directly concerned with the equitable availability of medicines. It includes consideration of such factors as the purpose and implications of the patent system and who should contribute to the cost of pharmaceutical innovation: 'How much of the total cost should a US retiree, a French worker, or an Ethiopian peasant be expected to contribute?' (Jack and Lanjouw 2005). Elements of justice and fairness are difficult to unravel within the context of the often overlapping rights, responsibilities and obligations (both legal and moral) of multinational companies and national governments.

The various initiatives to try to move towards a tolerably equitable solution include the World Trade Organization's 'Trade-Related Aspects of Intellectual Property Rights' Agreement (TRIPS) introduced in 1995. The intention was to ease the tension between rigorous application of the patent system and the availability of affordable medicines in developing countries (Scherer and Watal 2002). Under the agreement, developed countries were obliged to bring practices and laws into conformity with TRIPS within one year, and the requirement for the least developed countries has been extended to 2016 for pharmaceutical products. Further clarification of TRIPS was obtained at the Doha Ministerial Conference of 2001 to support access to public health and existing medicines, and development of new medicines. TRIPS is intended to foster measures to protect public health, and governments can issue compulsory licences to allow manufacture of a patented product primarily for use in their own market without the approval of the patent holder. Licences can also be issued to allow importation of products manufactured under compulsory licences elsewhere. While multinational pharmaceutical companies can expect to benefit from wider recognition and enforcement of the patent system, developing countries have to rely on compulsory licensing under TRIPS to manufacture or obtain access to first-line drugs at affordable prices. For a comprehensive review of some of the key moral and legal issues see Resnik (2001).

Essential medicines

The International Pharmaceutical Federation (FIP) Statement of Policy Improving Access to Medicines in Developing Countries (September 2005), states that:

Medicines are now the major weapon for successful prevention and treatment of many illnesses. Access to effective medicines should, therefore, be considered to be a basic human right. However, one third of the world's population lacks access to essential medicines. In the poorest parts of Africa and Asia, this figure rises to one-half of the population.

The World Health Organization (WHO) promotes universal and equitable access to basic health services and essential medicines. It has been producing a list of 'essential drugs' since 1977. The list is updated biennially and the current list was revised in March 2007. The core list presents a list of minimum medicinal needs for a basic healthcare system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. The first WHO list of essential medicines for children should be available in autumn 2007.

Yet producing a list does not of itself ensure access despite the statement on health-related rights in the United Nations Charter:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

Ethical and legal issues

What are the ethical issues? The fundamental considerations are human rights and corresponding duties or obligations that are partly enshrined in law but mostly arising in consequence of declarations or agreements. Hogerzeil (2003) commented:

Human rights, part of international law, are rights that every human being possesses, irrespective of race, religious or political beliefs, legal status, economic status, language, colour national origin, gender, ethnicity, etc. In other words, human rights are accorded to every human being. They apply to all individuals and groups on the basis of equality and non-discrimination. Even if they are not always honoured in fact (*de facto*), everyone is entitled by international law (*de jure*) to enjoy benefits of human rights.

In 1986 the International Commission of Jurists and others convened a distinguished group of experts in international law to consider the nature and scope of States Parties (countries that have accepted a treaty or agreement), and produced *The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights* (Asher 2004). Guideline 6 concerns ‘Obligations to Respect, Protect and Fulfil’ and clarifies that failure of States to provide primary healthcare to those in need may amount to a violation of obligations. The WHO identifies, monitors and analyses court cases from developing countries where individuals or groups have claimed access to essential medicine on the basis of failure to fulfil State obligations (Hogerzeil 2006). For a discussion of some of the fundamental philosophical issues concerning access to essential medicines, see Ashcroft (2005).

Orphan diseases, orphan drugs

The term orphan disease is used to describe those ailments of a chronic or life-threatening nature that are so rare that drug development is not commercially viable using the usual criteria. In Europe, the term is applied to indications with an incidence of no more than 5 in 10 000 persons. Some, possibly many, so-called tailor-made pharmacogenetic medicines would fall into this frequency category, although it is not suggested that all orphan drugs are of a pharmacogenetic nature.

To some extent, those who suffer from orphan diseases can be considered to face a double jeopardy – the disease itself and a dearth of possible treatments. Irrespective of this, the fairness and possible exploitation of subsidising orphan drug development costs have been questioned (McCabe *et al.* 2005): ‘Special status in resource allocation will avoid difficult and unpopular decisions, but it may impose substantial and increasing costs on the health care system. The costs will be borne by other, unknown patients, with more common diseases who will be unable to access effective and cost effective treatment as a result.’

The deontological–utilitarian tension is apparent in this particular assessment. There are no simple and equitable solutions when resources are limited.

Legal considerations

The Regulation on Orphan Medicinal Products (Regulation EC No.141/2000) was adopted by the European Parliament on 16

December 1999, and published in January 2000. The background to and purpose of this regulation is stated in Article 1.

(1) some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions; these products are called ‘orphan’.

(2) patients suffering from rare conditions should be entitled to the same quality of treatment as other patients, it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry; incentives for the development of orphan medicinal products have been available in the United States of America since 1983 and in Japan since 1993.

Incentives for pharmaceutical companies include lower regulatory fees, and exclusivity and freedom from direct competition for a period of 10 years following marketing authorisation.

Commission Regulation (EC) No.507/2006 of 29 March 2006 provided for the granting of marketing authorisations ‘...on the basis of less complete data than is normally the case (for) medicinal products which aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases or medicinal products (to be used in certain emergency situations) ...or medicinal products designated as orphan medicinal products in accordance with Regulation (EC) No.141/2000.’

A review of responses to a public consultation on Article 10 of Regulation (EC) No.141/2000 (requiring a report on the experience acquired as a result of the application of this regulation, together with an account of the public health benefits which had been obtained) raised a number of issues including whether some products should be designated as *super orphan* medicinal products on account of potential patient numbers, with the possibility of differential incentives inversely proportional to prevalence; some stakeholders have shown concerns about the effect of new provisions on data protection on orphan drug status; some stakeholders were concerned that the status of orphan medicines that have become blockbusters should be reviewed.

AIDS and the regulation of medicines

One of the most significant, devastating and wide-reaching influences of the latter part of the twentieth century was the appearance of the human

immunodeficiency virus (HIV), leading to the development of AIDS, early in the 1980s (Sepkowitz 2001). The disease was initially untreatable and complicated by lack of clear causation, but once its nature had been characterised, there followed rapid research and development for a range of promising antiviral agents and launch in 1987 of the first treatment approved by the US Food and Drug Administration, zidovudine. But the success of the pharmaceutical industry in creating effective anti-AIDS drugs was notable also for becoming the arena for a pivotal political battle between AIDS activists and drug regulators.

All developed countries and very many developing countries operate systems of regulatory control to ensure that medicines are relatively safe and effective before they are made available to treat the general public (see above). The AIDS lobby in the USA – large in number, knowledgeable, politically astute and legally well represented – argued that for many of those with AIDS time was of the essence. They were literally dying and wanted rapid access to experimental drugs even though these were not properly validated and approved, and they were prepared for the possibility that treatment might do more harm than good. AIDS sufferers considered that the cautious step-by-step processes of evaluation and regulation, and in particular blinded placebo-controlled studies, were inappropriate.

So successful was lobbying in the USA, that arrangements were made to permit use of experimental drugs at various stages after phase I trial for those facing imminent death, not only for AIDS sufferers but eventually also for those with advanced breast cancer, Parkinson's disease, Alzheimer's disease and juvenile diabetes. The average delay between application and approval by the Food and Drug Administration was reduced from an average of 34.1 months in 1986 to an average delay of 12.6 months in 1999 (Sepkowitz 2001).

The conventional wisdom of drug regulation had been successfully challenged by the AIDS lobby and, by default, on behalf of others with terminal illnesses. However, apart from fostering a fundamental review of regulatory requirements and procedures, medicines for treating non-life-threatening conditions would seem to be generally well served by the classical slow and steady approach. Paradoxically, the well-known serious cardiovascular problems associated with the cyclo-oxygenase 2 inhibitor Vioxx (rofecoxib), and terrible problems experienced by volunteers in the phase I assessment of TGN1412, tend to reinforce the case for having a robust regulatory system, but nevertheless one that is continuously under review and learns from mistakes.

Ethical issues

The legal regulation of potent medicines is generally considered to come into the category of legal paternalism. We associate paternalism with old-style medicine in which 'paternalistic behaviour' was what characterised practitioner-patient relationships, with echoes of 'doctor knows best'. This was, in effect, a well-meaning and informal but culturally dominant system intended to limit freedom and responsibility. Why? Because it was considered that patients, just like children, do not have the knowledge or experience to exercise judgement in their own best interests. Legal paternalism is the special case in which, because of the perceived hazardous nature (here, poisons and potent medicines), it is considered that access should be restricted and controlled. The circumstance can be stated more formally (Hospers 1980): 'Legal paternalism is the view that the law should at least sometimes, require people to act (a) against their will or (b) for their own good, in that way protecting them from the undesirable consequences of their own actions.'

The standard counter to legal paternalism relies on the libertarian views of John Stuart Mill (Gray 1998):

The principle (governing absolutely the dealings of society in the way of compulsion and control) is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.'

The medicines prescription laws have also been philosophically classified as 'justified hard (or strong) paternalism', as opposed to weak paternalism (Rainbolt 1989). Like legal paternalism, weak and strong paternalism are centred on the basis of the defective knowledge and experience of the patient, and take into account means and ends. If the means (lack of knowledge, for example of medicines or the perceived advantage of wearing car seat belts) might frustrate those ends (desire for cure, relief of illness or surviving a car crash) then weak paternalists argue that laws to impose behaviour against the will of the individual are legitimate. The view is commonly taken that in the long term, rather like children, patients will come to appreciate that such laws are beneficial and in their interests. Strong paternalists argue that someone who adopts the line advocated by Mill that freedom to pursue one's own ends (taking medicines without appropriate supervision) is more

important than concerns for personal safety is acting irrationally and requires the protection of law.

Legal considerations

The legal situation is covered by the provisions of the Medicines Act 1968, and Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI No.3144).

In the UK, it is sometimes possible for patients to obtain access to unlicensed medicines on a 'named patient' basis (NHS Pharmacy Quality Assurance Committee 2004, Medicines and Healthcare Products Regulatory Agency 2006).

The EMEA has issued a guideline for consultation (end/deadline 1 July 2006) on 'Compassionate use of Medicinal Products, pursuant to Article 83 of Regulation (EC) No.726/2004.' The consultation clarifies that:

Compassionate use programmes facilitate the availability of promising medicinal products to patients at an early stage in the drug development process. A number of national programmes, making medicinal products available either on a named patient basis or to cohorts of patients, are currently in place in individual Member States (MS). ...This document aims to provide guidance on the criteria and the procedure focusing the possibility provided for in Article 83 (1) of Regulation (EC) No 726/2004). It should be read in conjunction with Article 5 of Directive 2001/83/EC, as well as the respective MS's legislation, as the case may be. ...When a MS envisages the need to make a medicinal product, as defined in paragraph (1) and (2) of Article 83, available for compassionate use, the Competent Authority of that MS must notify the EMEA.

In response to recommendations from the Bioscience Innovation and Growth Team (industrial trade association), the Department of Trade and Industry indicated (28 May 2004) that: 'The UK has helped to shape the EU review of pharmaceutical legislation that has now been completed. Proposals for an accelerated assessment procedure, conditional authorisations and harmonisation of compassionate use procedures have been agreed. It is expected that these proposals will be implemented by end-2005 and should have a positive impact on patients gaining early access to medicines'. It appears that the timescales have slipped somewhat.

Stem cell research

Pharmacists are unlikely to have direct involvement with stem cell medicine, at least for the foreseeable future. Nevertheless, some understanding of the ethical and legal background is advantageous. Stem cells are ‘pluripotent’, undifferentiated cells carrying the genetic potential of all the specialised cell types of the body (there are 216 potential cell types (van der Kooy and Weiss 2000)). These cells can be directed into development pathways for different cell types with different specialised functions. Such cells are present in the early embryo, in the fetus, in the blood of the umbilical cord and are also present in adult tissues. Just how the development of these stem cells is controlled is not fully understood, but there is considerable interest in the therapeutic potential to use them to repair and restore tissues and organs (for example in heart disease, blood and neurological diseases and damage). Diseases such as Parkinson’s disease, diabetes and Alzheimer’s disease are important candidates. Research that might bring these possibilities closer to fruition is at a very early stage.

Ethical issues

The major ethical questions concern the supply of research material and research funding. In July 2006 in the USA, the American president vetoed a congressional act that would have provided federal funding to enable research on stem cell lines in frozen embryos marked for destruction (Schwarz 2006). Currently, the primary sources of human stem cells are human embryonic or cadaveric fetal tissue. The Warnock Committee Report (1984), which substantially informed the 1990 Human Fertilisation and Embryology Act, recommended that research on embryos should be limited to 14 days following fertilisation – the time at which generation of the nervous system ‘primitive streak’ begins. In the future, it may be possible to derive adult stem cells from a patient’s own somatic cells (using the ‘Dolly the sheep’ technique of somatic cell nuclear transfer), which would have the important advantage of avoiding rejection problems.

In principle, stem cells could be obtained from embryos or fetuses that arise either contingently (‘spare’ embryos or fetuses’) or deliberately ‘created’ for the purposes of research by somatic cell nuclear transfer. The European (Oviedo) Convention specifically prohibits the latter in Article 18.2 (Andorno 2005). The North East England Stem Cell Institute has been granted a licence from the Human Fertilisation and

Embryology Authority (July 2006) that will allow women to receive a 50% reduction on the cost of fertility treatment in exchange for donating 'spare' embryos for research. This represents a departure from previous policy, which prohibited direct payment for eggs.

Legal considerations

Relevant UK legislation includes the provisions of the Human Fertilisation and Embryology Act 1990 (enacted to regulate *in vitro* fertilisation and for which the licensing body is the Human Fertilisation and Embryology Authority), the amending Research Purposes Regulations of 2001 (The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 SI No.188) and the Human Tissue Act 2004 (see p. 145). For a general discussion of some of the legal considerations relating to stem cell research see Brownsword (2002) and for a briefing paper that addresses ethical, legal and social issues, see Corrigan *et al.* (2005).

In a chapter such as this, it is difficult to limit the scope of topics to be covered. We hope we have covered those that are of immediate relevance to pharmacy practice at the time of writing and to a few developments that are in progress. There will be more. We hope to cover them in later editions if there is a demand!

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7

Worked examples in decision-making

Imminent changes at the time of writing (August 2006)

Material in this chapter first appeared in Appelbe, Wingfield and Taylor's *Practical Exercises in Pharmacy Law and Ethics* (1997, 2002). No further editions of that book are planned. Throughout, unless otherwise stated, the references (i.e. chapter numbers in parentheses) and analyses within this chapter refer to *Pharmacy Law and Ethics*, 8th edn (Appelbe and Wingfield 2005). Thus the law is that prevailing in England, Scotland and Wales and the ethical positions refer to the RPSGB Code of Ethics. At the time of writing, regulation of pharmacy was undergoing radical changes: caveats must, therefore, be made concerning the currency of this material.

The Health Act 2006 came into force in July 2006. This Act provides enabling powers to change the provisions in the Medicines Act 1968 concerning personal control and supervision within community pharmacies. It also created the concept of a 'responsible pharmacist' with day to day accountability for the running of a community pharmacy. The detail of these changes will be enacted through secondary regulations, still to be published. The analysis of Problem 8, therefore, is subject to changing requirements in relation to supervision and personal control. In addition, references to the role of superintendent in Problems 8 and 12 may also be changed depending upon the requirements of Health Act 2006 Regulations.

Review of the RPSGB Code of Ethics began in January 2006. Throughout all of the problems in Chapter 7, analysis has been made according to the RPSGB Code of Ethics as it was at August 2006. Although the content of the Code is unlikely to change significantly in the review period, the presentation and order is likely to be radically different. Readers are, therefore, advised throughout to consult the Appendix to this book, which will contain the latest version of the RPSGB Code of Ethics (planned to be presented to the members' Annual General Meeting in May 2007).

Using powers under Section 60 of the Health Act 1999, proposals concerning the regulation of pharmacists and pharmacy technicians were published in April 2006 within the Pharmacists and Pharmacy Technicians Order 2006. Consultation was in progress at the time of writing. These proposals are likely to revoke the Pharmacy Act 1954 and may affect Problem 10.

A review of the regulation of non-medical healthcare professions (the Foster review) was published in July 2006. This may have implications for the continuation of the joint role of RPSGB in professional regulation and representation. In turn, this may affect the role of the inspectorate of the RPSGB.

Finally, some problems (such as Problem 4) make reference to requirements set out in the Terms of Service for what is now called the 'community pharmacy contract'. A 'new contract' was introduced in 2005 (The NHS (Pharmaceutical Services) Regulations 2005 SI 2005 No.641 (as amended) but this has had limited effect upon the analyses provided in these problems.

Introduction

We use several terms in this chapter that may need some explanation. These are mainly to do with the kinds of law that apply to pharmacy practice. Although it is an oversimplification, it is helpful to classify these with reference to the sanction or penalty that may follow a breach of each kind of law.

Thus, society requires breaches of criminal law to be followed by prosecution and a penalty, such as prison or a fine. Specific offences are created under criminal law, and an enforcement authority, usually the police, is appointed. Examples in the area of pharmacy are prosecution by the police, probably the local drug squad officer, for failure to maintain the controlled drugs register, which is a breach of the Misuse of Drugs Act. Similarly, for many offences created under the Medicines Act, such as failure to supervise the sale of a pharmacy medicine, the Royal Pharmaceutical Society is the enforcement authority and can bring its own prosecutions to court (Chapter 22).

Other parliamentary legislation creates a division of criminal law called administrative law, which gives power to public bodies to regulate certain activities (Chapter 1). The NHS 'Terms of Service' are an example (Chapter 26). The sanctions for a breach of Terms of Service are administrative through the local health body's disciplinary process, which includes power to 'withhold remuneration' or ultimately to

disqualify a pharmacy contractor from holding an NHS contract. Whereas a fine under criminal law is paid to the courts and reverts to the treasury, a withholding will be retained by the health body which has power to administer NHS contracts.

In the hospital and primary care service, the Department of Health has power to discipline and fine NHS and Primary Care Trusts which fail to meet the ‘statutory duty of quality’. This is defined in the Health Act 1999 as ‘a duty to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare that it provides to individuals’ and is usually referred to as ‘clinical governance’ (Chapters 23 and 26). Clinical governance requires attention to the clinical quality of the care being given – such as ensuring that there is a good evidence base for the selection of medicines prescribed for a particular condition – and to the operational quality of the service itself – safeguarded through risk management, including risk assessment, the setting of standards, use of standard operating procedures, audit mechanisms and review. It is this second aspect of clinical governance that is relevant to the legal and ethical issues raised in the problems which follow.

Guidance on what standards should apply is regularly issued in a range of ways, such as Department of Health Directions, policy guidance, National Service Frameworks and Healthcare Commission requirements. All of these approximate to mandatory standards in that failure to implement them without good reason could result in financial penalties for the NHS body and would be a source of censure in the event of civil litigation (see below). It is also likely that staff and managers who failed to implement adequate clinical governance arrangements would find their continued employment in jeopardy.

You should also note that now clinical governance is statutorily applicable to the activities of community pharmacists, through the ‘new’ NHS contract introduced in 2005. Additionally, the principles are implicit in the key responsibilities of a pharmacist and are explicitly required in the preamble to the service specifications which are appended to the Code of Ethics.

Civil law provides remedies for breach of common law duties owed by individuals to one another. This is a separate branch of law with a system of courts distinct from those used for criminal law. Breaches of common law duties can lead to a civil action by the injured party (plaintiff) against another (respondent) for compensation. The most likely area for pharmacists to become involved in a civil action is negligence (Chapters 1 and 23). When a customer comes to a pharmacist for a

service or advice, the pharmacist has a 'duty of care' to that customer (i.e. to act responsibly, competently and professionally). If the pharmacist fails in some way and that failure results in 'damage' or injury to the customer, then the customer might be able to claim compensation from the pharmacist for negligence.

Other common law duties that could arise in practice include a duty to maintain confidentiality over patient information and to be discreet in discussions about patients to avoid 'defamation' (Department of Health 2001, 2003). Suppose that a pharmacist knew that an unmarried woman had had a positive pregnancy test and then gossiped, with inappropriate rude remarks, about this to other staff or customers in the shop. The woman might then have a claim against the pharmacist for breach of confidence and for making defamatory remarks about her that tended to lower her standing in the eyes of others.

We also talk about vicarious liability (Chapter 21), which, in this context, means the responsibility assumed by employers for the actions of their employees and their consequences. If you are not an employee, perhaps working as a locum or freelance consultant, then you should ensure that you are covered by liability insurance to cover any claims made against you (see also the Code of Ethics (Appendix to this book), Chapter 23).

Finally, we refer to the concept of 'taking all reasonable steps' (sometimes called 'due diligence') as a defence, which recognises that, although it is not always possible to be absolutely certain about every aspect of a problem, you should be 'reasonably certain'. Suppose that you receive a phone call from someone who says that she is the pharmacist at a hospital and that there is an unconscious patient in casualty who appears to have taken a drug overdose. The patient has a medication record card from your pharmacy in his wallet – will you tell the pharmacist what medication he is taking?

Before giving this information you must take 'all reasonable steps' to establish that the call is genuine. You do not know from a phone call who is at the other end. If you are given a return phone number you do not know if this is genuine without checking. So you might obtain the number of the hospital from an independent source, perhaps directory enquiries, and then phone to check that someone of the name you have been given is working there.

Such tactics are not foolproof, but they are 'reasonable' in the circumstances and show that you are discharging your duty to care enough about patient confidentiality not to disclose details to casual callers, who might just be from the local newspaper!

We have already outlined in Chapter 5 of this book the four-stage process used in this chapter. It only remains to suggest how you might work through these problems for best value.

How to work through the problems

Each of the following problems describes a situation that calls for you to apply your legal and ethical, and other, knowledge of pharmacy practice to provide a solution. The complexity and the breadth of areas covered increases with each problem. It is best to start with Problem 1 and work through them in order, as some later problems will build on points made in earlier problems.

Each problem is firstly set out with suggested issues you might consider and references to more information on law and ethics within *Pharmacy Law and Ethics*, 8th edition (Appelbe and Wingfield 2005). We think the best way to tackle them is to cover up everything except the problem to start with and see what issues you can identify. Then compare them with our list. You can then go on to write down your existing knowledge of the law and ethical rules applying to these issues before looking up the references given later on the page.

When you have done that try to carry out a full analysis of the problem using the procedure outlined in Chapter 5 of this book. Then you can turn the page to see how we have worked through the procedure to come to our own conclusions. We think you might need about half an hour to ‘crack’ each problem, perhaps a little longer for those situations that are the least familiar to you.

Each problem has a fully worked solution. In addition, at the end of some of them, there are ‘variations on the same theme’ that you might like to tackle or bring to a group discussion. Have a go at thinking up your own variations and compare your reasoning with those of your colleagues. By practising and taking your time to solve these examples, you will find it much easier to respond to similar problems when they arise in real life.

1 PROBLEM

Who decides what is an emergency?

In the past, pharmacists had no discretion whatsoever over the supply of prescription-only medicines (POM). Giving a salbutamol inhaler to an asthmatic or supplying two tablets of phenytoin to an epileptic who had come away on holiday without medication were criminal offences. Since the late 1970s, the ‘emergency supply provisions’ (under the Medicines Act) recognised that life throws up all sorts of situations where patients are in ‘immediate need’ of prescription medicines but do not have any with them. The NHS Terms of Service also recognise that an urgent supply may be made provided the provisions of the Medicines Act are met.

The law, as always, lays down only minimum conditions for an ‘emergency supply’ and the Code of Ethics provides a principled context by saying that pharmacists must use their knowledge for the well-being and safety of patients and the public. But no rulebook can cover every situation that the practising pharmacist may have to face.

Try this problem.



SCENARIOS

The weekend visit of the mother who has diabetes

Mrs Fraser comes into your pharmacy on Saturday afternoon and says that her mother, who has diabetes and is frail, is at Mrs Fraser’s home in quite a state. Her mother has come to stay for the weekend and forgot to pack her tablets. Mrs Fraser has tried ringing her own local surgery but could get no reply. What can you do to help?

What issues should I consider?

- Criteria for making an 'emergency supply'
- Restrictions on the supply of POM
- The principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Limits of vicarious liability
- Therapeutics: management of diabetes
- Good practice: use of patient medication records.

Where should I look in *Pharmacy Law and Ethics*?

'Emergency supply' (Chapter 8)

Supplies of prescription-only medicines (Chapter 8)

Negligence (Chapter 23)

Code of Ethics (Chapter 23)

Vicarious liability (Chapter 21).

Stage 1: gather relevant facts

Of course you will try to establish the name and other details of the medicine(s) being taken by Mrs Fraser's mother. Then move to decision-making.

What criminal law applies here?

Normally, POM may only be supplied against the written authority of a medical practitioner. Before even contemplating an 'emergency supply at the request of a patient', there are a number of preconditions, which can be summarised as follows.

The pharmacist must interview the person requesting the medicine and be satisfied that:

- there is an immediate need for the POM and
- it is impracticable to obtain a prescription without undue delay and
- the person requesting the medicine has had it prescribed for them by a doctor, supplementary prescriber, etc. registered in UK? before and
- the details of the dose to be taken are established.

Note that there is no mention of 'emergency' or a definition of what that term means. The test is whether you, as the supplying pharmacist, are satisfied that there is an 'immediate need' and that it is impracticable to

obtain a prescription. To assess this, you will want more information on both Mrs Fraser's mother's condition and treatment and the local arrangements for contacting a doctor. Moreover, the regulations assume the person who is requesting the medicine is the patient and can be personally interviewed so that you can establish what the medication is, its previous prescription and dose. In this case, the patient is not in the pharmacy.

What NHS law applies here?

NHS law (in the Terms of Service) permits urgent supplies of POM medicines to be made provided the provisions of the Medicines Act are met. The 'emergency supply' arrangements mean that you can sell or supply POM without the authority of a prescription, subject to all the legal requirements. Most patients who are in need of continuous medication will be NHS patients and may be unwilling or unable to pay for medicines that they would otherwise obtain at no cost under the NHS. So can you ask for payment that is refundable when a subsequent NHS prescription is presented? Yes. The law does not address the question of payment; that is entirely up to you.

You may have to cope with repeated requests in advance of NHS prescriptions by patients who seem to run out of medication on a regular basis. Each one may well demonstrate an 'immediate need', but remember that the 'emergency supply' provisions are intended for isolated and unprecedented circumstances, not for the regular circumvention of local arrangements for obtaining repeat prescriptions and, in any event, you may only give a maximum of five days' supply in most cases.

What civil law applies here?

A useful way to answer this is to consider the consequences of supplying the medication and then the consequences of not supplying. If you do supply the medication, then you will assume liability for its being correctly identified, at the right strength and dose and for the advice and guidance you may give to Mrs Fraser as to what further action she might need to take. If you decide not to supply then you might also be held liable for any adverse consequences to both mother and daughter. However, in both cases the likelihood of action against you (or even criticism of you) will depend upon what the 'reasonably competent pharmacist' would have done in these circumstances. This is an important

principle followed in negligence cases (often called the Bolam test after the name of the respondent in an important case – (see p. 86) and one which is regularly used to judge whether action or inaction by a professional person was reasonable.

What guidance does the Code of Ethics give here?

The Code of Ethics states that your key responsibility is to use your knowledge for the wellbeing and safety of Mrs. Fraser's mother. Is this an emergency? If so, standard 15 of the Code picks up the civil law approach by saying you should consider the medical consequences of not supplying the medication.

What professional knowledge do I have which applies here?

You will already have drawn on your academic knowledge of diabetes and the medicines used to manage it. You might have briefly considered whether there were any substitute medicines that were not POM that may have been suitable for the condition or whether dietary advice alone might be sufficient. You will need to know how long Mrs Fraser's mother is staying; if this is more than five days, the appropriate course might include making arrangements for a prescription to be obtained for further supplies. You will take into account the age of the patient and circumstances such as mobility and transport arrangements for the patient and add to this your knowledge of local surgery hours and availability of local doctors. These will all be factors in helping you to decide whether there is an 'immediate need' for the medication and whether it is 'impracticable' to obtain an authorising prescription.

Where can I look or who can I ask for help?

The most accessible summary of emergency supply requirements in the pharmacy is in the annual MEP guide published by the RPSGB. Virtually all pharmacies have patient medication records, or you may be able to telephone the pharmacy used by Mrs Fraser's mother. Location of the patient's details could confirm exactly what has been prescribed and when. In other circumstances, the empty bottle of medication could substantiate its identity; sometimes the enquirer will have a repeat medication card with them or the 'repeat slip' from a computer-printed prescription.

Finally you could try yourself to contact the doctor used by Mrs Fraser's mother and verify her treatment with the medical records or contact any out-of-hours GP service to see if the supply can be authorised by a prescription. In this last case, you will then have converted the situation into one of 'emergency supply at the request of a doctor' for which he or she undertakes to provide you with an authorising prescription within 72 hours.

Stage 2: prioritise and ascribe values

Patient

By this stage you will not have much difficulty in knowing that your prime objective is establishing whether it is in the interests of the patient to make the supply and deciding that it is.

Patient's relatives, carers and contacts

Mrs Fraser also wishes to avoid having to deal with the consequences of her mother not receiving the medication that she needs and, again, you are in a position to help.

Other healthcare professionals, your profession

Your duty as a pharmacist will mean that you should take reasonable steps to involve a medical practitioner in the care of Mrs Fraser's mother if at all possible. If this is not possible, then you may resort to your authority to use the 'emergency supply' provisions. Remember that you may also make 'emergency supplies' of POM medicines at the request of a doctor, and these supplies are not subject to quantity restrictions (Chapter 8).

Employer

The decision to provide an 'emergency supply' provision is very much a personal one, and one for which the individual pharmacist is accountable, so this scenario represents a good example of a situation in which you have the opportunity to exercise your own professional judgement. Your employer would, therefore, expect you to take the decision on that basis.

Yourself

This case is relatively straightforward in that diabetes is a condition that requires continuous medication control, and there is little of moral or cultural concern in deciding to make the supply. We discuss more difficult situations at the end of this exercise and in Problem 2.

Stage 3: generate options

What *could* you do?

1. Do not make the supply
2. Do not make the supply and suggest further action
3. Make the supply in accordance with the 'emergency supply' provisions
4. Contact a doctor and make an emergency supply on his instructions
5. Delay to seek advice
6. Refer to accident and emergency department or walk-in centre.

You should then consider the likely outcome of each option.

If you followed option 1, Mrs Fraser's mother would be likely to become hyperglycaemic and possibly seriously ill. At the weekend, when accident and emergency services are likely to be at full stretch, it would be hard to defend this option as being the action of a responsible pharmacist. Option 2 might be defensible if you can locate a doctor who could readily supply a prescription, but that prescription would have to be dispensed somewhere (unless the doctor can make his own supply) so you would have to consider the local arrangements for weekend dispensing. The patient might have had other medication that could be used as a stopgap to control her condition, but we know that this is not so in this case. Option 4 is only possible if you can contact a doctor, but it can be useful for borderline cases of emergency supply on your own authority. Option 5 is unlikely to be helpful unless the advice you seek is immediately to hand. Option 6 is a relatively new option which may be possible.

Stage 4: choose an option

What *should* you do?

We think you should choose option 3. Do you agree?

We have identified 3 as the best option and the one that is defensible in the interests of the patient. We should ask, 'defensible to whom?'

The patient is unlikely to object, and neither is her daughter, Mrs Fraser, but there is a snag – you have not interviewed the person for

whom the medicine is intended and have, therefore, not fully complied with the law. The regulations refer only to the interview of the ‘person requesting’, but indicate later that this phrase is intended to mean the patient by saying that the medicine should have been prescribed previously for ‘the person requesting the medicine’. One way of overcoming this aspect of the problem might be to ring Mrs Fraser’s mother, i.e. conduct the interview over the telephone. You would need to be sure the person you were talking to was Mrs Fraser’s mother. Alternatively, you could offer to deliver the medicine personally and conduct the interview with Mrs Fraser’s mother at home.

Who else might challenge you: the RPSGB’s inspector, your own staff, other pharmacists, the GP who looks after Mrs Fraser’s mother? When making the supply, you have to make a written record of the details including a note on the ‘nature of the emergency’. This is where you write your defence. Write down the circumstances that led to your decision – the time of day, the nature of the patient’s condition, the questions you asked, the facts you established. All of these will justify your professional judgement that giving a limited quantity of the patient’s oral antidiabetic tablets was the right thing to do.

Discussion points

We have seen how the ‘test’ for making an ‘emergency supply’ depends upon whether the pharmacist is satisfied that there is an immediate need for the medication and that it is impracticable in the circumstances to obtain a prescription. Although ‘emergency supply’ is frequently an issue for community pharmacists, exactly the same law and ethical requirements applies to requests made in the hospital setting. Consider whether you think the following circumstances meet the emergency supply criteria and apply the above analysis to your decisions as to what you would do:

- the same request is made on a bank holiday
- the same request is made on a Saturday morning and your pharmacy is open until 6.00 p.m.
- the same request is made in your late-night pharmacy at 8.00 p.m. on Tuesday and there is a visitors’ clinic at the local surgery every Wednesday afternoon
- the same request is made over the telephone
- the same request is made but the patient is visiting from Bangladesh
- you are an on-call hospital pharmacist dealing with the same request at 10 p.m. on Saturday evening

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- the request is for epilepsy medication for a three-year-old who is at home with the baby sitter
- the request is made when the local surgery is open but is for a salbutamol inhaler and the patient is in front of you showing the early signs of an asthma attack.

2 PROBLEM

Rational decisions: palliative care versus drug abuse

We shall explore the ‘emergency supply’ situation a little further before going on to other matters. Let us consider the following two situations:



SCENARIOS

The clumsy toddler and the spilt medicines

You have been managing a pharmacy for several years when, while providing a contracted out-of-hours service on a Sunday, Mrs Baker comes in looking very agitated. You know that Mrs Baker’s mother is being nursed at home after a diagnosis of terminal stomach cancer. Mrs Baker says that her toddler has knocked over and spilt all of the diamorphine solution prescribed for her mother and she has been unable to contact any doctor for assistance. What do you do?

You have been managing a pharmacy for several years when, while providing a contracted out-of-hours service on a Sunday, Ms Slade comes in looking very agitated. Ms Slade is a drug abuser to whom you have been supplying methadone mixture for nearly six months under the NHS arrangements for supplies by instalments to drug abusers. Ms Slade says her toddler has knocked over and spilt all of the methadone mixture you gave her yesterday and she has been unable to contact any doctor for assistance. What do you do?

What issues should I consider?

- Criteria for making an ‘emergency supply’
- Restrictions on supply of controlled drugs
- The principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Therapeutics: management of palliative care and drug abuse
- Local knowledge of support services and out-of-hours arrangements.

Where should I look in *Pharmacy Law and Ethics*?

'Emergency supply' (Chapter 8)

Supplies of controlled drugs (Chapter 17)

Negligence (Chapter 23)

Code of Ethics (Chapter 23).

Would you take the same action in both cases? If not, on what basis do you distinguish between the two sets of circumstances and how do you justify your position? Let's try some analysis.

Stage 1: gather relevant facts**What criminal law applies here?**

It will be the same in both cases. The Misuse of Drugs Act makes no distinction between medical use and abuse of controlled drugs. Schedule 2 and 3 controlled drugs cannot be supplied under the 'emergency supply of prescription-only medicines' exemptions; indeed, controlled drugs cannot be supplied to patients at all unless you have a valid written authorisation in your possession at the time of supply. You are also legally required to record in the controlled drug register every supply of a Schedule 2 controlled drug that you make.

What NHS law applies here?

If your Sunday opening hours are contracted with your local health body, then you are required to offer a pharmacy service during those hours. This may mean that you would have difficulty leaving the pharmacy premises to deal with this problem and would probably have other patients and customers to deal with. However, as with Problem 1, NHS law only permits urgent supplies to be made in accordance with the Medicines Act provisions.

What civil law applies here? What guidance does the Code of Ethics give here?

The Appendix gives the Code of Ethics. As described in Problem 1, the same requirement to behave as would any 'reasonably competent'

pharmacist applies to both these situations. One consequence of not supplying in Ms Slade's case might be that she could commit a crime or cause trouble if she is without her methadone.

What professional knowledge do I have which applies here?

You will have detailed knowledge of the action and uses of diamorphine from your undergraduate studies, together with an understanding of cancer and its effects. You will know that it is as valuable sometimes for its euphoric action as for the relief of pain in terminal conditions. Are there any substitutes for diamorphine that you can legally supply? Perhaps a prescription-only analgesic that has been prescribed before? Further questions might elicit what other medicines are available to Mrs Baker's mother and how well they may manage the degree of pain involved.

You should also understand something of addiction and the importance of maintenance treatment. You may also know that Ms Slade's prescription is sent to you by the local drug abuse clinic and she has a supply authorised for tomorrow, Monday.

Where can I look or who can I ask for help?

This is where you will have to be very enterprising. Mrs Baker's mother will suffer if she does not have her diamorphine. Where can you contact a medical practitioner? Perhaps there is a deputising doctors' cooperative available; a deputising doctor who understands your problem may well be willing to come to your pharmacy and write a prescription. This illustrates the importance of developing and maintaining good relationships with other healthcare professionals. You are much more likely to resolve these kinds of problem if you know the doctor you are speaking to and have perhaps helped out with advice or information in the past.

Alternatively, could the local hospital find a doctor who would be prepared to authorise the supply? Are there any other pharmacists in the area who could suggest other doctors? If these are possibilities, can Mrs Baker get to these doctors and will there be a pharmacy open when she does? Could you possibly stay open until a prescription arrives or could you come back specially to dispense the prescription? Could you offer to deliver the medicine after the doctor agrees to call in and give you a prescription? Have you thought about the exemption that allows you to supply a controlled drug to a doctor on the personal promise of a written requisition within 24 hours?

Are you going to make the same effort for Ms Slade? If not, why not? Might there be further evidence you would require from Ms Slade?

Stage 2: prioritise and ascribe values

Patient

Mrs Baker's mother is being cared for at home and, as she has been prescribed diamorphine, is probably close to death. Lack of diamorphine for her may result in significant pain and distress and may even hasten death. Ms Slade is reasonably fit but will certainly suffer some discomfort and distress if she does not have her regular methadone. She might be tempted to use inappropriate substances to satisfy her cravings, which could potentially cause her death.

Patients' relatives, carers, grandchildren, contacts

Mrs Baker is already looking after her mother and a toddler. She will be distressed if her mother suffers; could this compromise the care of the toddler? Is it possible that the toddler may have ingested any of the medicine in either case? Ms Slade also has a toddler in her charge and indicates that she will have to 'go out and score' if she does not have her methadone. She may, therefore, represent a risk to her child (RPSGB 2006), colleagues, neighbours or the general public if she is without her methadone.

Other healthcare professionals, your profession

As in Problem 1, your duty is to involve a doctor if at all possible, and this is strengthened by the serious sanctions that may be used against you if you supply a controlled drug without authorisation. Set against this is an overriding obligation to do what you can to help the patients.

Yourself

Your attitude to these two cases is likely to be different. You may well want to do anything you can to help Mrs Baker; you may be less willing for Ms Slade. Such differences may arise for many reasons. You may have had experience of nursing someone with cancer and empathise with Mrs Baker. You may have experienced or heard of colleagues' experiences with addicts, who not infrequently lie to obtain extra

supplies of their medication. You may not feel too sympathetic to either situation when you have given up your precious Sunday to come into work.

As a pharmacist, your decision to help must not be based on emotion or personal prejudice; you must be able to justify your action on rational grounds.

Stage 3: generate options

What *could* you do?

1. Do not supply
2. Do not supply but suggest further action
3. Do supply enough for immediate need
4. Delay and seek further advice.

Let us consider the consequences of each option and introduce another concept: probability. We have seen that all sorts of things might happen as a result of the choice you make but, then again, they might not. What is the likelihood in each case?

We think that option 1 is not defensible in either case. There is a high probability of adverse effects for both patients if you do nothing. We would not recommend option 3 because of the criminal sanctions you would incur, although it might conceivably be an option in an extreme emergency. Option 4, which might at first sight seem unhelpful, could be very useful if the delay can be short. If you said, 'Can you call back in half an hour while I try to sort things out', this will allow you time to collect your thoughts, finish what you were in the middle of, delegate some tasks to others, make phone calls in the absence of the enquirer, who may be anxious or oppressive, and allow time for discussion with colleagues or check records.

Stage 4: choose an option

What *should* you do? We think option 4 followed by option 2 is defensible. Do you agree?

Note that Problem 1 looked at a situation where a supply under the 'emergency supply' provisions was defensible, whereas Problem 2 looks at a situation where they cannot be used. It is the pharmacist who judges the 'immediate need' and the 'practicability' of obtaining a prescription. The pharmacist will also inevitably use his or her own judgement as to whether or not the patient's need is urgent. We also

recommend that you keep the patient or customer informed about what is happening, explain to them the reasons for the decisions you take and make a record of your actions even if you decide not to supply.

Discussion points

Consider the following requests which might arise when working on a Sunday, how you might respond and analyse your reasons:

- a request for sleeping tablets which have just run out
- a request for tablets to manage depression which have just run out
- a request for the ‘after sex’ pill (we go into this in more detail in Problem 15).

3 PROBLEM

A real emergency

The previous two problems dealt with urgent situations that may or may not have been emergencies. When you look at the regulations for ‘emergency supply’ you will see that these words do not appear in the relevant regulations, apart from in the records you must make. Also, a careful study of the regulations suggests that the circumstances envisaged do not equate to the dictionary definition of an ‘emergency’, i.e. a state of danger, a life-threatening condition. Moreover, the fact that the regulations permit the supply of oral contraceptives and of original packs of ointments and creams reinforces the view that the legislators were not contemplating situations that were immediately life threatening (Harrison 1988). However, in our third problem we consider a real emergency.



SCENARIOS

The teenager and the coleslaw salad

You are the pharmacist in charge of a busy in-store pharmacy within a large edge-of town supermarket. You cover three 12-hour shifts on alternate days mid week and it is nearing 2.00 p.m. when you take your lunch break. You hear a commotion outside the dispensary and find a small group of customers looking anxiously at a teenage girl who is sitting on the floor. She is very distressed, having difficulty in breathing and her face, especially her lips, are swollen. She manages to tell you that she has a peanut allergy and thinks there must have been some in the coleslaw salad she had just eaten in the supermarket café. Her friend hands you an EpiPen that she’s found in the casualty’s handbag and asks you to administer it. What will you do?

What issues should I consider?

- Criteria for making an 'emergency supply'
- Administration of parenteral POM
- The principles of negligence and a duty of care
- Key responsibilities of a pharmacist in the Code of Ethics
- The nature of anaphylactic shock and its treatment
- Local knowledge of support services, in-store and elsewhere
- Professional indemnity insurance or other cover.

Where should I look in *Pharmacy Law and Ethics*?

Criteria for making an 'emergency supply' (Chapter 8)

Administration of parenteral prescription only medicines (Chapter 8)

The principles of negligence (Chapter 23)

Key responsibilities of a pharmacist in the Code of Ethics (Chapter 23)

Stage 1: gather relevant facts**What criminal law applies here?**

We set out the conditions for making an 'emergency supply' at this stage in Problem one. We don't think you will have any difficulty in deciding that this is an emergency although you would ordinarily have to establish whether the casualty had received the medication before. In the Medicines Act, no-one is allowed to administer POMs unless to themselves or by or acting in accordance with the instructions of a 'practitioner'. There are a number of exemptions, however, for some parenteral injections for the purpose of saving a human life in an emergency. The list includes adrenaline (epinephrine) injection.

What NHS law applies here?

None.

What civil law applies here?

The legal position on the obligation to render first aid is perhaps surprising. UK civil law has no 'good Samaritan' expectations that citizens will go to the help of others when they are in danger. Thus, strictly speaking, you have no more obligation than, say, the café waitress or the

till operators to help this teenager in distress. If you were, for example, a trained first-aider and had a badge or a notice saying that you were, then the expectation might be different. By advertising your special skill, you may be considered to have a 'duty of care' to render first-aid to those who seek such help.

The position of pharmacists or other health professionals who are in contact with the public is less clear since there is a widespread expectation from the public that all healthcare professionals will be able to help and, what's more, will do so. Here the danger is of attempting to help beyond your competence. No claim in negligence could result from a failure to help; if you claimed to be competent to help and then performed less than competently or if, by claiming competence, your intervention prevents/hinders others who could have helped, a claim in negligence could conceivably arise.

Set against this is well-established case law (*R v Bateman* 1925) that first-aiders are not expected to be miracle workers. Similarly, in the classic situation where a passenger has a heart attack on an aeroplane and a fellow traveller who happens to be a heart surgeon offers to treat him, the surgeon is not expected to deliver the same standard of care as he would if he were working back home in his operating theatre.

What guidance does the Code of Ethics give here?

Rightly or wrongly, the public does look to pharmacists to render first-aid in many situations (see the Appendix). The need to demonstrate an awareness of emergency first-aid features amongst the performance indicators expected in order to register as a pharmacist. The key responsibility of a pharmacist to use their knowledge for the well-being and safety of patients and the public must imply a responsibility to be prepared to give first-aid, if at all practicable. This expectation is reinforced by Standard 15 of the Code of Ethics.

Where can I look or who can I ask for help?

Leaving aside for the moment that in reality you would have no time for consultation, what might you do to anticipate such problems in the future? What do you know about the treatment of anaphylactic shock? What does this condition look like? What presentations of parenteral adrenaline (epinephrine) are available and how are they administered? How do patients use Epipen? Can it be administered through clothing?

Are there any trained first-aiders amongst the supermarket staff? Are there any procedures already in place for dealing with such an emergency? You will know how to telephone the emergency services but do you know how long it may take them to reach the supermarket? Are there any surgeries within immediate reach?

In the introduction, we talked about the concept of clinical governance and risk management. Did you know that there is a dummy version of Epipen available that you could practice with? Giving some thought to what might happen and making preparations to deal with problems before they happen is a major part of good clinical practice; it will also help you to sleep more easily at night!

Stage 2: prioritise and ascribe values

Patient

You will have no difficulty in deciding that your overriding priority is to do whatever you can to save the life of the teenager who has collapsed in your pharmacy.

Patient's friend, onlookers, your staff

The utility of others in this setting is to do something useful! Get someone to ring for an ambulance, find the first-aider, run to the surgery, read out the instructions on the Epipen.

Other healthcare professionals, your profession, your employer

Your ability to cope with crises such as this will reflect on the standing of pharmacists in general and of your employer with the outside world. While not an immediate priority right now you will want to bear this in mind in the future. You will also not want to be worrying about whether you are insured for your contemplated actions or whether your employer will cover you; check this out before you start your employment.

Yourself

Leaving aside the legalities and professional imperatives governing the action you will take, nothing will be as difficult to live with as the knowledge that you might have been able to save someone's life and didn't try. This will bear heavily on your choice of action.

Stage 3: generate options

What *could* you do?

1. Do nothing.

As a conscious decision we think you will have little difficulty in recognising this is an option which would be difficult to defend. Worse, you may be perceived as callously doing nothing, simply because you don't know what to do.

2. Call for medical assistance.

This is certainly the least you can do, isn't it? Call for the emergency services and call for internal support as well. Don't overlook a check on whether the friend or even the bystanders have any knowledge about using Epipen.

3. Administer the Epipen yourself.

The merit of this option will depend very much on the outcome. You could save a life or watch it being lost despite your efforts. Even very prompt administration of adrenaline is not always successful; inept administration, especially by the wrong route, might just make things worse. Do you have another option?

4. Help the friend to administer the Epipen.

Is this any better than option 3? Both will depend on how much knowledge is possessed by the person doing the administration. When individuals are aware that they have a severe allergy and are prescribed medicines like Epipen, they should be given clear instructions on how to use them. Perhaps the casualty has shared this knowledge with her friend?

Stage 4: choose an option

What *should* you do? We think that unless you could be very sure that the friend knew what to do, we would choose option 3. Do you agree? There is little tradition in this country of being sued for failed emergency first-aid although it is possible. We think it is much more likely that there would be criticism and even adverse publicity if you did not try to help, however inexpertly.

Discussion

We hope very much that you are never challenged by a scenario such as this, although it is drawn from real life. Clearly the counsel of perfection is to find out how to deal with such eventualities before they happen. We give a few more examples of preparing for risks in later problems. You might also like to consider the legal and ethical aspects of the following variation:

- the patient is a child on the verge of an asthma attack and his mother is so panic-stricken that she hands you his inhaler to administer.

4 PROBLEM

Recycling medicines for the Third World

As a pharmacist, you are responsible for safeguarding the quality of the medicines you supply and for using your knowledge to ensure that no one is put at risk from defective medicines. Establishing the origin and history (i.e. the provenance) of medicines is part of your duty as a pharmacist. Try to deal with this problem.



SCENARIOS

The priest in Ethiopia

You receive a phone call from Mr Jarvis, whom you know to be a local priest who has just returned from working in Ethiopia. He wants to return there every few months to help in the medical outposts in the rural areas and is very anxious to take with him any medicines you can spare. He wants to collect any medicines you have that have been returned by patients. Can you help?

What issues should I consider?

- Restrictions on supply of POM
- Rules on wholesale dealing
- Rules on environmental protection and waste disposal
- The principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Law and ethics facts sheets on this subject, which include WHO guidelines
- Knowledge of pharmaceuticals, especially stability and potency
- Good professional practice
- Use of outside resources (e.g. employer, professional organisations).

Where can I look in *Pharmacy Law and Ethics*?

Supplies of prescription-only medicines (Chapter 8)

Wholesale dealing (Chapter 10)

Environmental protection (Chapter 21)

Negligence (Chapter 2)

Code of Ethics (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

When medicines are issued to patients they are then the property of those patients. If, however, they are voluntarily returned to you for disposal they become your property and change their status. The position of medicines under the combined effect of hazardous waste legislation and the 'new' pharmacy contract, both introduced in 2005, has become complex. Guidance is available from the RPSGB (2005). Under environment protection legislation, medicines are no longer classed as 'special waste' but certain medicines, such as cytotoxics, will be classed as 'hazardous waste'. They have to be disposed of without risk to people or the environment and controlled drugs have to be 'denatured' so that they cannot be recovered and reused. In the meantime you must store the returned medicines safely.

Making a supply of a POM for onward supply to someone else is a wholesale supply. Certain conditions must be met and records must be kept. A series of fact sheets are available from the RPSGB. The fact sheet (RPSGB 2004a) on export of medicines includes guidance on drug donations to developing countries; a copy of the WHO guidelines is also available from the Society.

What NHS law applies here?

The 2005 community pharmacy contract includes an 'essential service' requirement that community pharmacies should accept back prescribed medicines returned by patients (Chapter 26 and relevant Appendix). Your local NHS health body should provide facilities at no charge so that a licensed waste disposal contractor takes away medicines that have been returned by patients.

What civil law applies here?

We have already discussed in the Introduction to this chapter the fact that pharmacists have a 'duty to care' about all who seek to use their services; this would apply as much to potential patients in Ethiopia as to those in the UK. You should consider what steps you could take to ensure that the medicines you supply are what they say they are and that they are in good condition and fit for use. This could be a tall order when applied to returned medicines. How do you know what has happened to them while in the patient's possession?

What guidance does the Code of Ethics give here?

Your key responsibility is to use your knowledge for the well-being and safety of patients and the public (see the Appendix). Standard 2 in the Code, which relates to stock, says that medicines returned to a pharmacy from a patient's home, a nursing or residential home must not be supplied to any other patient. This standard also spells out your duty of care to exercise control over 'any medicine, food supplement or health-care related product' by saying that you must not supply if you have reason to doubt its quality or safety. You should also note a clause in Standard 4, which allows the reissue of patient's own medicines in the hospital context, under certain conditions.

So you might think that this means that you cannot help Mr Jarvis; not so. The law and ethics fact sheet mentioned above sets out a series of conditions, derived from WHO guidelines, under which you might be able to help after all.

Finally Standard 4 on pharmacy premises and facilities, and Standard 16 on collection and disposal of pharmaceutical waste make it clear that, in accepting back such medicines, you would be expected to have in place instructions on how to manage their temporary storage safely to minimise risk to patients, the public and staff.

What professional knowledge do I have that applies here?

This is an area where your pharmaceutical training should help. There will be some instances, perhaps when sealed original packs are returned, when the contents will be known with reasonable certainty. If the expiry date is some way distant, then they are more likely to be in good condition. If they have been stored in the medicines cabinet of a well-run nursing home, they are unlikely to have been subject to adverse storage

conditions or to have been tampered with and so on. Only you, as the pharmacist, can assess these factors and then you will assume responsibility for deciding whether the medicines are fit for reuse. A good test might be whether you would be prepared to take them yourself!

There are other considerations. What kind of medicines do they want in Ethiopia? Almost certainly not antidepressants, hormone replacement therapy, anorexics or hypolipidaemic agents. They are much more likely to need anti-infectives, vaccines and analgesics. What kind of medicines do your patients return?

Where can I look or who can I ask for help?

If you are an employee, your employer might have a policy on such matters or might already be involved in existing schemes to help provide medicines to Third World countries. Some Rotary clubs and similar organisations have local arrangements for collecting and sorting supplies for wider international schemes.

Stage 2: prioritise and ascribe values

Patients, relatives, carers, contacts

Significant quantities of drug donations made in response to local disasters in the Third World have been reported to be useless or, worse, have tied up resources in sorting and disposing of them which could have been better used (see Discussion). People in the Third World have an equal right to those in the developed world to receive medicines that are fit to use and appropriate for their needs. Those trying to help them do not want to waste their time sorting out the identity of medicines and trying to guess whether they are of value. So your duty as a pharmacist is to provide only that which it is in the patient's interest to receive. The WHO guidance makes it clear that the recipients of any donations should provide a list of what is required.

Other healthcare professionals, your profession

In this case, Mr Jarvis does not indicate that he is working with any organised scheme that may include doctors and pharmacists in the assessment and sorting process. You should check whether this is the case; there may well be other schemes which focus on the needs of Ethiopia, to which Mr Jarvis can add his efforts.

Your employer

Because your employer would carry vicarious liability (Chapter 21) for what you do in this case, you must consult your employer if you have one. Activity in this area can be misconstrued by the media – think of headlines such as ‘major company dumps inferior drugs on Third World’ – and, as ever, you must be able to defend any decisions you have taken on which medicines to supply.

Yourself

Do you think it is right to supply medicines in the way Mr Jarvis suggests? You might feel it is more appropriate to provide money, either directly or through a national charity, to allow the purchase of ‘new’ medicines for Ethiopia’s needs. Or you might feel that you should help in whatever way you can as such medicines will otherwise simply be destroyed. You might even have preferences for which countries should be helped, but this should not be allowed to obscure your objective professional judgement on what you should do. Finally, we have given you an example in which you know something about the enquirer, Mr Jarvis. As a pharmacist, you also have a duty not to be gullible – can you think of other situations when you might be wise to consider exactly what the recipient might do with any returned medicines you supplied?

Stage 3: generate options

What could you do? Let us suggest the following:

1. Say you cannot help Mr Jarvis
2. Agree to supply returned medicines to Mr Jarvis if he would like to come and collect them
3. Make supply direct to the mission hospital on Mr Jarvis’s instructions
4. Delay and seek advice
5. Ask Mr Jarvis for a written proposal as to what he wants to do
6. Ask Mr Jarvis to come to your pharmacy and discuss his proposal with you
7. Donate non-medicinal items instead, such as plasters, bandages and dressings.

A detailed analysis of the consequences of these options is probably unnecessary. Option 1 is ‘safe’, but more would be expected of the reasonably competent pharmacist. Option 2 is definitely ‘unsafe’ for the

reasons already discussed. Option 3 would be lawful but would still be 'unsafe' without a great deal more enquiry. Option 4 will give you an opportunity to make a considered decision. Do not allow yourself to be rushed unnecessarily by pressure such as suggestions that other local pharmacies have supplied Mr Jarvis without any reluctance. If you seek advice from your employer you may find that they already participate in national schemes and would not wish to donate locally.

Options 5, 6 and 7 are all reasonable, depending on what further information you can elicit.

Stage 4: choose an option

What should you do? We think option 4 is the best choice, followed perhaps in due course by 5, 6, 7 or even 1 if appropriate. Do you agree?

Discussion

The guidelines from the WHO emphasise that drug donations to needy areas must not be made without close communication between donors and recipients about real needs. This guidance is reiterated in the RPSGB Fact sheet four (2004a) from the Fitness to Practise and Legal Affairs Directorate. You might like to look up the case of a pharmacist who was 'struck off' after, among other things, misappropriating drugs donated by a pharmaceutical manufacturer on the understanding that it would be sent for relief of a disaster in Poland (Anon., 1996a).

5 PROBLEM

Protecting the reputation of the profession

We have seen in Problem 3 that the pharmacist is rightly regarded as the custodian of the nation's drugs and the expert when it comes to establishing the provenance of medicines. Sometimes you will discover situations where your loyalties are exposed to scrutiny. Consider this case.



SCENARIOS

The residential home and the 'rogue' tablets

You are a community pharmacist and have just signed a contract to provide a pharmaceutical service to several residential homes. On your first visit to one of them, The Willows, you find in the medicines cupboard a large plastic pot with the remnants of a Brufen label on it. The pot now contains about a hundred unmarked pink tablets. A label from another pharmacy has been added saying 'painkillers'. What would you do?

What issues should I consider?

- Nature and quality of the medicine
- Medicines Act labelling regulations
- Possibility of fraud, 'passing off'
- NHS Terms of Service – 'as so ordered'
- The principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Standard 2 on stock
- Therapeutics: use of non-steroidal anti-inflammatory drugs
- Local knowledge of other healthcare professionals
- Use of outside resources, e.g. employer, professional organisation.

Where should I look in *Pharmacy Law and Ethics*?

Nature and quality of medicines (Chapter 14)

Labelling regulations (Chapter 15)

NHS Terms of Service (Chapter 26)

Negligence (Chapter 23)

Code of Ethics (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

There are a number of possibilities. The staff at the residential home may have changed the tablets or the container themselves. The supplying pharmacist may simply have provided an additional label for them to use. This is not an offence, although it will probably breach the conditions for the home to be registered with the local authority and indicates poor practice on the part of the supplying pharmacist. Remember that Brufen tablets are a POM and may not be supplied within the NHS 'bulk prescribing' arrangements, nor would they be classed as 'homely remedies' that the home staff might acquire for themselves.

Remember, too, that in residential homes, clients are cared for as they would be in their own home. It is possible that a resident has chosen to take his or her own prescription to a specific pharmacy or has made a special request that the medicines should be dispensed by a specific pharmacy. Residents may go home for the weekend or go on holiday and obtain emergency prescriptions etc. Thus, there may be several different pharmacies supplying medication for patients in residential homes.

It is also possible that the pharmacy supplying most of the medication for the residents has provided a pot containing something other than Brufen, although it is to be hoped that it is ibuprofen in some form. Perhaps there was a shortage of Brufen and an equivalent was supplied instead. In this case, the supply has breached the Medicines Act labelling requirements, which is a criminal offence.

Worse, perhaps there was a deliberate attempt to 'pass off' the pink tablets as Brufen when they clearly are not. This, too, would be a breach of the Medicines Act and would also constitute fraud, both criminal offences. You would certainly consider whether this was because

the product was illegally obtained, either through a perversion of the parallel import arrangements or by failing to go through the UK licensing arrangements at all (Chapter 3).

What NHS law applies here?

Most medication for residential homes is supplied against NHS FP10 or GP10 (in Scotland) prescriptions, although some homes may be for residents who are private patients. If the authorising NHS prescription specified Brufen and this was not supplied, the supplying pharmacy would be in breach of its NHS Terms of Service, which require the contractor to supply what the doctor ordered (Chapter 26).

In theory, at least, a doctor who is looking after residents on a private basis can acquire any medicines against a signed order and leave them at the home with instructions to the carers on when and to whom they should be administered. It is not unknown for NHS prescribers to supply a 'stock' of medicines and then write retrospective NHS prescriptions to cover supplies already made from stock. Such arrangements are a breach of the doctor's Terms of Service and, if known to the supplying pharmacist, could also place him or her at risk.

What civil law applies here?

Fraudulent supplies would be an obvious breach of the pharmacist's duty of care towards all patients who are the recipients of his or her services. If those patients suffered injury or adverse effects, perhaps in this case a diminution of analgesia or unexpected side-effects through taking a medicine that was not what it seemed, the supplying pharmacist would be liable for these consequences. The home staff, too, would expect medicines to be what they said they were and could use this situation to terminate their arrangements with the supplying pharmacy.

What guidance does the Code of Ethics give here?

Part of the key responsibilities of a pharmacist says you should not engage in any activity that may bring the profession into disrepute (Code of Ethics; see the Appendix). It would be important not to jump to conclusions here – there might be a legitimate explanation but there probably is not. How should you deal with the knowledge that a fellow pharmacist might not be behaving as he or she should?

This key responsibility and the associated standard on stock (2) will apply here; pharmacists must ensure that there is certainty in establishing identity, origin and chain of supply for any medicine. The standard also says that medicines should stay within their original foil or blister packaging up to the time of dispensing. Why are there no markings on these pink tablets? Could they have been removed from their packaging to disguise their origin?

You might like to turn to Chapter 24 at this point, particularly the cases under Parallel Imports, which outline some unfortunate cases of pharmacists who markedly failed in their duty to protect the public from the risks associated with medicines of uncertain origin and quality.

Let us go even further and consider whether these medicines might be counterfeit. Again, Standard 2 of the Code of Ethics gives further guidance – should you need it – saying that such material must be isolated from other medicines and that a pharmacist must report to the RPSGB or other appropriate body any discovery of suspected counterfeit medicines.

Finally there is a specific standard, 17, on advisory services to nursing and residential homes. It is not clear in this situation whether The Willows is contracted to receive an advisory service and you might want to find this out.

What professional knowledge do I have which applies here?

You will know what conditions Brufen is used for and what the effect might be if patients who needed Brufen did not receive it. You might ascertain the seriousness of the situation by asking care staff and patients how helpful the ‘Brufen’ was in controlling pain. In order to be registered, the home will have to meet certain conditions, which will cover arrangements for the supply of medicines. For residential homes, this is likely to be a combination of the local social services authority, the Commission for Social Care Inspection and eventually the Healthcare Commission (Chapter 26). You could find out who carries out this task in your area.

Where can I look or who can I ask for help?

You will certainly make discreet enquiries of the care staff about this pot of ‘Brufen’ to ascertain whether any of your suspicions might be correct. You might be able to obtain further facts by asking about ‘stock’

supplies; perhaps this pot was the subject of a signed order from a doctor who looks after some patients in the home. Are there additional bottles marked 'Brufen' for individual patients and do these also contain unmarked pink tablets?

You may feel that this is going beyond your remit as a community pharmacist. Who else can you turn to? When talking to the care staff, they may have identified the local community services pharmacist, who often gives advice on the handling of medication in both nursing and residential homes. You might seek advice from this pharmacist; he or she might also know who carries out inspections in the Willows.

You will have reasonable misgivings about the legitimacy of this 'Brufen' and can seek advice from the RPSGB's local inspector. He or she could make many more enquiries than you and establish whether your concerns are justified. You might prefer to seek advice from your employers or the National Pharmacy Association (NPA) and let them help you decide what the next steps should be.

Stage 2: prioritise and assign values

Patients, relatives, carers, contacts

You cannot tell for certain whether patients are at risk in this situation, but they certainly might be. You have a duty to take whatever action is necessary in the interests of the patient. At this stage, this may mean no more than suggesting this 'Brufen' is left on one side for you to make enquiries, while making arrangements for a replacement supply. You might want to consider at what stage carers, relatives and others might expect to be aware of the situation; probably not until the facts have been more fully established.

Other healthcare professionals

In keeping with this approach, the patient's doctor might expect to know about this situation as soon as possible. Regrettably, there have been cases of collusion between doctors and pharmacists to make fraudulent supplies of medicines, which suggests caution in informing the doctor just yet (Anon., 1995a,b, 1996b). But if the pot of 'Brufen' is the doctor's stock and the care staff have been authorised to use it in prescribed circumstances, you might want to discuss alternative arrangements with the doctor or ask to see a clearly written account of what those 'prescribed circumstances' are.

Your profession

You are charged with behaving with ‘dignity and probity’ and you have discovered circumstances that may indicate that a pharmacist colleague has not been behaving professionally. Are you going to overlook this or report it? You also have a key responsibility to work in partnership with other health professions to provide the best possible healthcare for patients. Amongst the personal responsibilities of a pharmacist providing professional services is a requirement to report to the Society any concerns that a pharmacist’s behaviour may be putting the public at risk (whistle blowing – see Chapter 4 of this book and also Problem 10). There is a clear likelihood that patients may suffer adverse consequences if medicines are not what they purport to be; cooperation is never intended to put patients at risk.

Yourself

Similar arguments may be applied to your own personal approach to such a situation. Do you think it’s right to report a fellow pharmacist? Under what circumstances? Is there any other course of action that might be less contentious?

Stage 3: generate options

What could you do?

1. Do nothing
2. Remove the pot of ‘Brufen’ and do nothing
3. Remove or quarantine the pot of ‘Brufen’ and tell the care staff not to use it until you have made some enquiries.

Let us just stop here and consider consequences. If you select option 1, the patients may continue to be given tablets of unknown provenance. Moreover, if you select options 1 or 2, the pharmacist who made the original supply may continue to make similar supplies to patients in other homes or from the pharmacy, with possible risks to them all, particularly if they are elderly or confused.

Stage 4: choose an option

What should you do? We think you’ll have to take option 3. Do you agree?

Alas, you have not quite finished yet. What enquiries are you going to make? In a case like this, all you have is a number of facts and a few theories as to how these facts came about. Much more investigation is needed to draw any conclusions, and here help is at hand. We will go further and say we think you should pass this information to the RPSGB's inspector. Telephone the RPSGB, outline your concerns and ask an inspector to call. Then it becomes their problem, not yours!

PROBLEM

Responsibility for the supply of unlicensed medicines

You can rely on the existence of a marketing authorisation to guarantee the quality, safety and efficacy of most of the medicines that you supply. The holder of the marketing authorisation will also be liable for any adverse effects resulting from the use of his product. If you make up a medicine yourself in the pharmacy, say for a particular patient, you become liable for those aspects. What if a doctor prescribes a medicine for use in a way that is outside the marketing authorisation? Try this problem.



SCENARIOS

The child and the Phenergan Elixir

You are asked to check an NHS prescription calling for Phenergan Elixir for an 18-month-old child. Your dispenser tells you that, as the 'book' says that Phenergan should not be used in children aged under two, the surgery has been contacted and they have said it is OK to dispense. What would you do?

What issues should I consider?

- More facts: which 'book', who was spoken to and by whom?
- Medicines licensing requirements
- Exemptions for licensing for pharmacists
- NHS Terms of Service – 'as so ordered'
- NHS 'blacklist'
- Principles of negligence, liability for adverse effects, joint liability
- Key responsibilities of a pharmacist in the Code of Ethics
- Personal responsibilities of a pharmacist providing professional services
- Therapeutics: action and uses of promethazine
- Use of outside resource: drug information services
- Good practice: maintenance of records.

Where should I look in *Pharmacy Law and Ethics*?

Licensing of medicines (Chapter 3)
 Exemptions from licensing for pharmacists (Chapter 3)
 NHS Terms of Service (Chapter 26)
 Principles of negligence (Chapter 23)
 Code of Ethics (Chapter 23)
 Joint liability (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

The legal category of a medicine is determined by its marketing authorisation and by legislation under the Medicines Act. Where a medicine is used in circumstances outside the marketing authorisation, supply may be unlawful unless there is an authorisation by a doctor to use it in this way. Provided that the medicine does not appear on the POM list, there are circumstances when you may supply unlicensed medicines on your own authority; see ‘counter prescribing’ exemptions for pharmacists, Chapter 3. In this case you have a valid prescription authorising supply.

What NHS law applies here?

The NHS Terms of Service in the 2005 community pharmacy contract require you to dispense ‘drugs or medicines’ as ordered by the doctor and that such supplies shall comply with appropriate standards such as the *Drug Tariff*, *European Pharmacopeia*, *British Pharmaceutical Codex* and so forth (see Chapter 16). The *Drug Tariff* permits you to supply any medicine (i.e. not on the ‘black list’; see Chapter 26), although the local health body can ask the prescriber to justify the prescription at a later stage. In practice, this rarely happens, and is particularly unlikely in this case as Phenegan is a licensed medicine and raises no issue for the Prescription Pricing Authority.

The Terms of Service also say that you must supply medicines with ‘reasonable promptness’ but a new provision in 2005 also allows you to refuse supply if to do so would be contrary to your ‘clinical judgement’ (Article 9(1)(c) of Part 1, Schedule 1 of the NHS (Pharmaceutical Services) Regulations 2005).

What civil law applies here?

All healthcare professionals have a 'duty to care' for the interests of the patients they serve. Thus, in prescribing a medicine for circumstances outside the marketing authorisation, the doctor has automatically assumed liability for any adverse effects that may result; conversely, the marketing authorisation holder (who is usually the manufacturer) would be entitled to disclaim all such liability.

What about you? As a pharmacist you also have a 'duty to care' about the patient. You may share liability with the doctor for any adverse effects resulting from a medicine that you supplied that you knew was going to be used outside the terms of its marketing authorisation. Precisely how much liability will depend upon how far you went ('reasonable steps') to establish that the doctor knew exactly what he was doing and what the consequences might be, and then took appropriate action to protect the patient's interests as well.

You might like to look now at two cases where joint liability, shared between doctor and pharmacist, resulted in substantial compensation (damages) being paid to the complainant (see negligence cases in Chapter 20).

What guidance does the Code of Ethics give here?

The Code of Ethics (see the Appendix) makes no specific reference to unlicensed medicines. However, extrapolating from your key responsibility to use your knowledge for the well-being and safety of patients and the public, you know that licensed medicines are of proven safety, quality and efficacy. So you could not use your exemption as a pharmacist to counter-prescribe unlicensed non-prescription medicines for whatever you fancied to recommend!

In addition, implicit in the key responsibilities is your duty to take whatever action is necessary in the interests of the patient, which will include a consideration of the consequences of supplying, or not supplying, the Phenergan Elixir. Moreover, the key responsibilities imply that you have a duty not to impair confidence in your own and other healthcare professions and to cooperate with colleagues to ensure patient benefit.

Support for these considerations is found in Standard 4 on the supply of prescribed medicines which says a licensed medicine should always be supplied, if available, in preference to an unlicensed one. The standard goes on to say that you should not substitute any

other product for what is prescribed, except in an emergency or with consent, but your key responsibility for the safety of the patient may mean that in these circumstances, the right thing to do might be to refuse to dispense the prescription. This is an important example of a situation in which, although you have obligations under NHS law to dispense the prescription, your duty to the patient might override them.

What professional knowledge do I have which applies here?

You will already know, and can check in reference books, much about the various uses of promethazine. You will want more information about which of these uses is in the mind of the doctor on this occasion and what other medicines might be in use for this or other conditions. You might want to know whether the child has had Phenergan Elixir before and whether it was well tolerated. Your position might depend upon whether the treatment was initiated by a paediatrician for a specific symptom (e.g. severe eczema that may be causing serious skin lesions through scratching) or prescribed more generally by the GP (e.g. for itching associated with chicken pox). GPs prescribe Phenergan as a sedative for a fractious child, although this is not recommended if the child is below two years of age.

Where can I look or who can I ask for help?

The obvious source of information is the prescribing doctor, but you cannot be satisfied from the details you already have that he or she has been properly advised of the position. Who was spoken to at the surgery? Were the consequences of prescribing an unlicensed medicine properly explained? Has the person responsible for the patient been informed? The Association of the British Pharmaceutical Industry *Compendium of Data Sheets and Summaries of Product Characteristics*, *Martindale: The Complete Drug Reference*, the *British National Formulary for Children* (launched September 2005) and a number of paediatric formularies prepared by specialist children's hospitals may give guidance on what doses may be suitable for a young child. Your local medicines information service or pharmacists and others at the local hospital pharmacy department may have experience of the use of promethazine in young children; your employer, the NPA or your defence organisation may offer some guidance.

Stage 2: prioritise and ascribe values

Patient, parents, carers

You will need to establish exactly who is presenting the prescription for dispensing and what relationship they have to the child. If he or she knows what condition the Phenergan Elixir has been prescribed for, you could use this information to judge the consequences of supplying or not supplying. You should consider the consequences too for the child's carer. You have a duty to ensure that the carer understands that this is an unlicensed use of Phenergan Elixir (which will be difficult to explain in layman's terms), but you must achieve this without undermining their faith in either the medicine or the prescriber. The more information you have on the circumstances of its use, the easier it will be.

Other healthcare professionals, your profession

This is the tricky bit, especially as your dispenser has already contacted the surgery once. The marketing authorisation for Phenergan Elixir used to permit prescribing by doctors for children from one year of age, although supply over the counter was restricted to those aged two and over. If you ask your experienced colleagues, they will probably tell you that Phenergan Elixir was often prescribed for infants, indeed was often bought over the counter, for sedation – to 'give the parents a good night's sleep'. But are there other ways in which this could be achieved?

Before approaching any prescriber with the prospect of passing comment on his or her prescribing, you should be confident of being able to make constructive suggestions for alternatives that achieve the prescriber's intentions. Perhaps you could supply an alternative brand that is licensed for younger children (if you stock it). Or perhaps you could discuss what side-effects to be aware of and what advice the prescriber gave to the patient's carer or how he or she would like the position to be explained to them now.

Your employer

As with emergency supplies, the solution to this kind of problem very much depends on your personal judgement and accountability as a pharmacist. Although there may be many other pharmacists that you can call on for advice, what you actually do and how you do it will be largely up to you.

Yourself

We have already said that your duty as a pharmacist is to maintain confidence in your profession, and yourself as a member of it, and confidence in other healthcare professionals while at the same time ensuring that no patient is put at risk by, or at the very least is unaware of, the risks associated with using a medicine outside its marketing authorisation specifications. Your skill as a competent pharmacist is to carry out this task without alarming the patient (or in this case the parent or carer) or antagonising the prescriber.

Stage 3: generate options**What could you do?**

1. Dispense the prescription with no further query or comment.
2. Check again with the surgery.

We think you will have little difficulty in recognising that you cannot just overlook this situation, so option 1 is not acceptable. Just take a little time to think about how the enquiries in option 2 should be made. You may get an indication of how urgent the prescription is by comparing the date on the prescription and the date it has been presented for dispensing. Should it be you or one of the staff who makes the enquiries? Will you settle for speaking to the receptionist or will you insist on the prescriber? What if he or she is not there? Will another doctor do? You will need the information about who has brought in the prescription as well. Is she the child's mother or a neighbour? If the latter, how will you ensure that the information is properly conveyed to the person who needs to know?

We think there are useful lessons here in planning how you are going to make your enquiries. Write down what information you need and tick it off when you get it. You'll want to avoid antagonising the doctor by asking the same questions about the same patients every month; could you check your patient medication record to see if any other pharmacist has recorded the response to similar enquiries. What adverse effects would you expect to see if promethazine were given to such a young child? Work out how you are going to ask the question – perhaps something like 'I haven't seen promethazine used in a child of this age before, could you please just confirm the background or rationale for choosing this particular drug and dose?'

So now you can generate some further options, provided you have ascertained what condition or symptoms are intended to be controlled and what alternatives (if any) you can suggest.

3. Attempt to persuade the prescriber to change the medication or agree to a modification in dose.

What if you cannot? You may need to demonstrate at some future stage that this phone call took place, so make a note of it in a permanent place and tell your colleagues that you have done so. In some situations you might even ask the prescriber to confirm in writing that he or she wants you to go ahead despite your advice. So there are more options:

4. Dispense the medication but explain to someone responsible for the patient about the situation and its consequences.
5. Refuse to dispense the medication but explain why to someone responsible for the patient.

Now let us consider the consequences of these last two options. The consequences of option 4 are unlikely, in this particular case, to be very serious. Phenergan Elixir has been used in very young children; you might consider supplying it and explaining to the child's parent or carer what you have done and why. Option 5 might be considered an overreaction taking account of the Code of Ethics stricture to bear in mind the relative harm (and not just to the patient) that may result from such a refusal.

Stage 4: choose an option

What should you do? We warned you in the introductory section on professional decision-making that sometimes several options may have little attraction but that you might have to consider which, of a number of unsatisfactory solutions, did the least harm. On this basis, therefore, we would choose option 4. Do you agree?

Discussion

Your choice of action could be entirely different if the facts were changed slightly. Consider the following situations and decide what you would do and why:

- the Phenergan Elixir is for a six-month-old infant
- the Phenergan Elixir is for an 18-month-old child to control vomiting associated with chemotherapy
- a customer comes to buy Phenergan Elixir for her 10-month-old child because the doctor has recommended she buy some to help her to cope after the birth of her second child.

7 PROBLEM

Responsibility for the supply of unlicensed medicines (2)

So far, we have looked at problems set in the community pharmacy practice sector. But the same laws and ethics apply just as well to hospital pharmacy practice. Pharmacy practice in hospitals must comply with the Medicines Act and the Misuse of Drugs Act and, of course, all pharmacists, wherever they work, are expected to comply with the profession's Code of Ethics. What is very different, however, is the application of internal NHS administrative instructions, sometimes statutory directions or guidance from the Department of Health, that constantly tell hospitals and other NHS bodies how they should carry out their work. Since the Health Act 1999 introduced a duty of quality for all NHS bodies, a whole performance assessment framework supported by healthcare assurance documents sets out in detail the quality objectives that should be reached within hospitals, with detailed audit and monitoring processes to ensure they are met. While these instructions do not always strictly have legal force, some do and in a managed service the expectation is that they will be followed and in some instances, such as the requirements for Patient Group Directions, they are in excess of what is strictly required in law.

We will now look at a similar problem to Problem 6, but in a hospital setting.



SCENARIOS

The midnight telephone call from the neonatal ward

You are a recently qualified pharmacist and were appointed two weeks ago to a resident pharmacist post in a teaching hospital. At about midnight one night you get a call from a nurse on the neonatal unit requesting an unlicensed drug for administration to a neonate. You have never encountered this drug before. What do you do?

What issues should I consider?

- More facts – How urgently needed is this supply? Who is the original prescriber and can s/he be contacted? What reference source did the prescriber use? Is this a new prescription or a repeat order?
- Medicines licensing requirements
- Exemptions from licensing requirements for pharmacists
- The law and Patient Group Directions
- Principles of negligence, joint liability
- Key responsibilities of a pharmacist in the Code of Ethics
- Ethical standards on Patient Group Directions
- Hospital policy in this situation
- Availability of alternative licensed medicines
- Hospital service policy on Patient Group Directions.

Where should I look in *Pharmacy Law and Ethics*?

Licensing of medicines (Chapter 3)

Exemptions from licensing for pharmacists (Chapter 3)

Patient Group Directions (Chapters 8 and 9)

Principles of negligence, joint liability (Chapter 23)

Code of Ethics (Chapter 23)

Hospital service directions (Chapter 26).

Stage 1: gather relevant facts**What criminal law applies here?**

This will be exactly as set out in Problem 6. You should also consider the possibility that the nurse may be making this request within an authorising Patient Group Direction. These may be used to authorise the supply of medicines ‘off-label’ in certain circumstances although this should be the exception rather than the rule. ‘Off-label’ is used to mean that the medicine has a marketing authorisation but the proposed conditions of use do not fall within the licensing conditions. A Patient Group Direction may not be used to authorise the supply of a medicine that has no licence at all.

What NHS law, including hospital service directions, applies here?

There are no explicit NHS legal provisions to cover this situation although there is a Health Service Circular (in England) or equivalent

setting out some additional conditions for Patient Group Directions. There should also be, within the hospital, policies and probably formularies on prescribing in neonatal or other practice or therapeutic areas in which the use of unlicensed medicines is commonplace. As an on-call resident pharmacist you would be expected to be familiar with these. You should also be aware of any Patient Group Directions for 'off-label' use in operation in the hospital.¹

What civil law applies here?

Again, your responsibilities and duty of care would be as in Problem 6. There is a further consideration that will have increasing impact on the quality expectations of pharmacy practice. The care and management of the neonate is generally recognised as a 'specialised' area, in which special expertise over and above the 'reasonably competent' practitioner might be expected. In deciding whether your duty of care had been met, a court might also ask whether there was a recognised specialist body that sought to bring together specialised skills and knowledge in this area of practice. The College of Pharmacy Practice has established faculties designed to promote good practice in specialised areas of practice. The Neonatal and Paediatric Pharmacists Group is now a faculty of the College; any standards that it promulgates will in due course become the standards normally expected in this area of practice. However, any such standards might take many years to become a practice norm and in any event, a 'generalist' on-call pharmacist could not be expected to have specialist expertise in every field where a query may arise.

What guidance does the Code of Ethics give here?

Your key responsibility is to use your knowledge for the well-being and safety of patients (see the Appendix). You must also ensure that your knowledge is up to date and relevant to your field of practice. Part 2 of the Code of Ethics, on the personal responsibilities you carry when offering a service, anticipates the development of specialised areas of practice by requiring you to comply with any accepted codes of practice applicable to your sphere of practice. The Code does not give any

¹ Patient Group Directions for neonatal use are rare and a pharmacist contemplating supply should contact a senior colleague first. In any event, the pharmacist should expect a copy of the Patient Group Directions to be held in the pharmacy, to be able to consult it personally and possibly consult with the pharmacist who authorised it.

specific additional guidance on prescribing for neonates, although in Standard 4 there are references to the use of licensed medicines wherever they are available and we have already referred to the specific standards for Patient Group Directions in Standard 23.

More significantly, in the general introduction to the service specifications, attention is drawn to the need for risk management and assessment procedures to be in place and followed and that adequate records are maintained to enable your service to be monitored. This is a restatement of the principles of clinical governance that require you to be able to 'know and to show' that your standards of patient care are high. Once again, these requirements mean that before starting work in this job, you should expect an induction process to make sure you are familiar with policies, procedures and documentation relating to the kind of on-call queries you may receive.

What professional knowledge do I have that applies here?

To respond properly to this request, you will need to draw on your existing knowledge of the management of neonates (which may be very limited) and supplement it by reference to the recognised paediatric and neonatal formularies (For example: *British National Formulary for Children*) and to *Martindale: The Complete Drug Reference*. As we said in Problem 6, you may want to contact the original prescriber or the neonatal nurse to discuss the reasons for this request and whether there are any alternatives. In the hospital setting, you may have access to the medical notes about the patient and this could inform your understanding of whether or not the supply of an unlicensed drug is the best course for the patient.

Where can I look or who can I ask for advice?

A key factor will be determining how urgent is the need for this medicine. If it is immediate then you have limited options. Is there another pharmacist or consultant who can be contacted for urgent advice at any time?² Is there an on-line source of medicines information that might be accessible? If the need is less urgent, or temporary

²A pharmacist contemplating an on-call position should expect to receive induction training, to have the opportunity to become familiar with the hospital's activities and operations before moving to 'on-call' and to have an 'on-call pharmacist's pack' listing sources of support, with names and contact numbers.

measures can be taken, could you contact your pharmacist or medical colleagues in the morning?

Stage 2: prioritise and ascribe values

Patient, parents, carers

Crucial to your considerations of the interests of the neonate patient will be the consequences of making the supply of an unlicensed medicine or not making such a supply. In either case, you may subsequently be called upon to defend your decision to parents, the hospital and even the wider world. You should at least consider what involvement the parents have had in this prescribing request, if any, and whether they are party to any decisions that may literally be matters of life or death for the neonate. While it may be somewhat remote to your considerations just now, you should be aware of how the hospital operates its consent arrangements in this controversial area of care. Are the parents aware of the consequences of the use of unlicensed medicines and are they comfortable with the measures that may be being proposed?

Other healthcare professionals, your profession

As in Problem 6, this could be a tricky area to address. However, if something went wrong you would be held liable for your part in overseeing the clinical appropriateness of this supply, just as the neonatal nurse and the consultant in charge of the case. Before challenging any request, you will want to marshal all your facts and be ready to substantiate your queries with evidence and to be prepared to suggest alternatives if necessary.

Your employer

We have briefly mentioned vicarious liability in Problem 4 and there is no question that if the worst should happen, your hospital will have in place arrangements to meet any claim for compensation from the patient's parents or other representatives. However, that does not mean you, or indeed your colleagues, would automatically avoid any sanctions in this event. Part of the relationship between employer and employee requires that the employee follows any reasonable policies and procedures put in place by the employer. There may still be a large element of professional discretion but there is an increasing expectation

that the NHS will operate within stated standards, clearly expressed, and monitored and audited accordingly. Of course, the employer must make sure that employees are aware of these policies etc. and in this case, your line manager should have anticipated such a situation and provided you with a second-line contact to a more senior or experienced pharmacist to contact if in difficulty. This process is part of the risk management approach: to anticipate where risks may arise, what could go wrong and develop strategies to respond to them.

Yourself

As in Problem 6, you have a duty to maintain confidence in your profession, and yourself as a member of it, and confidence in other healthcare professionals. However, you must also ensure that no patient is put at risk by the use of unlicensed medicines. Your skill as a competent pharmacist is to carry out this task without alarming the patient's parents or guardians and without antagonising the neonatal nurse or prescriber.

Stage 3: generate options

What *could* you do?

1. Do nothing
2. Supply without obtaining any further information or advice.

We think you will have little difficulty in recognising that neither of these options is acceptable. They represent the ends of the spectrum of choices and this problem would hardly be a dilemma at all if you could easily choose either option. So what else could you do?

3. Find out sufficient information to satisfy yourself of the clinical appropriateness and then supply.

This may, on the face of it, seem a reasonable option. Certainly, if you were very experienced in neonatal care and were familiar with the drug and neonatal pathophysiology, this may well be a defensible choice. If however, there were adverse consequences, then your accountability for them might be high.

It is worth adding that if, on the basis of evidence collated, you come to the conclusion that the treatment was inappropriate, then you may exercise professional judgement and refuse to supply. You should be prepared to defend yourself against the consequences of not supplying as well as supplying.

4. Find out sufficient information as in option 3, confirm your position with a senior colleague, and then supply.

We did say at the beginning that you should imagine you were a recently qualified and recently appointed pharmacist to this on-call position. As the law expects every practitioner to be competent at whatever professional activity they are performing (or more correctly not to undertake activities in which they are not competent), this may be a slightly safer option than 3, if you can secure the necessary confirmation. However, you may still retain some liability if you are wrong.

Stage 4: choose an option

What *would* you do? We think you should probably choose option 4. Do you agree? Obviously you will want to record what action you took before reaching this decision. Perhaps you could make a note of what references or medical records you checked, what facts you took into account and what colleagues you consulted before reaching your decision. Would you wish or be able to make a note in the patient's medical notes? Is there an agreed policy in the hospital on where such records should be made and in what form and detail? One consequence of working through this problem will be that you are now alerted to the need for risk assessment and working out what you would do on a general basis before the actual problems arise.

Discussion

This problem links an established problem area, the use of unlicensed medicines, with the development of specialised practice. What other areas of specialised practice can you identify, both within hospital and out in the community?

We list a few here and invite you to think how you would prepare to deal with 'unorthodox' or unusual requests in these areas:

- patients in the intensive care unit
- patients receiving palliative care
- patients receiving treatment for HIV infection
- oncology patients
- patients being treated for drug or substance abuse
- customers of a private travel health clinic employing pharmacists.

8 PROBLEM

The NHS contract, responsibilities of the superintendent

Try this problem but you should be aware that imminent changes may amend the duties of a superintendent under the Health Act 2006 (see p. 181).



SCENARIOS

The blizzard in the Yorkshire Dales

You are the superintendent pharmacist responsible for a company that owns three pharmacies, all in the Yorkshire Dales. It is February and a blizzard has trapped you in your home when you are supposed to be in charge of one of the pharmacies. Your senior counter assistant, Jean, has arrived, unlocked the pharmacy and telephones you to ask if she should stay, go or carry on without you. What are you going to do?

What issues should I consider?

- Ownership of pharmacies
- Meaning of personal control
- Legal definition of supervision
- Duties of a superintendent
- NHS Terms of Service, especially 'reasonable promptness' and hours of service
- Key responsibilities of a pharmacist in the Code of Ethics
- What local knowledge you might have in this situation
- What knowledge you might have of local healthcare professionals
- Needs of specific patients and the public at large.

Where should I look in *Pharmacy Law and Ethics*?

Ownership of pharmacies (Chapter 5)
 Meaning of personal control (Chapters 5, 24 and 27)
 Definition of supervision (Chapters 6 and 24)
 Duties of a superintendent (Chapters 5 and 24)
 NHS Terms of Service (Chapter 26)
 Key responsibilities of a pharmacist in the Code of Ethics (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

The Medicines Act specifies two conditions in relation to pharmacists and pharmacies. Firstly, a pharmacist must supervise the supply of pharmacy and prescription medicines (Chapter 6) and, secondly, the pharmacy must be under the personal control of a pharmacist (see p. 181 for discussion of changes that may amend the duties of a superintendent under the Health Act 2006). Failure to conduct a pharmacy properly in these two areas is a criminal offence and you as superintendent pharmacist would be personally liable to prosecution as well as the company concerned.

There have been many convictions of pharmacists for failing to supervise adequately, and cases relating to this and failure to exercise personal control have figured quite regularly in the work of the Statutory Committee. You might like to look now at Chapter 24 for examples.

What NHS law applies here?

We said in the introduction to this section that NHS law is administrative law that applies to pharmacy practice; breach attracts financial and administrative sanctions, but not prosecution. Your pharmacies will each have an NHS contract with the local health body that requires them to be open for specified minimum hours or otherwise as agreed with the authority (Chapter 26). Failure to be open for these hours, or indeed failure to supply medicines with ‘reasonable promptness’, would be a breach of your NHS Terms of Service.

What civil law applies here?

This is difficult to define as only when someone seeks goods or services from your pharmacy could a genuine duty of care be said to exist. Nevertheless, you certainly have a duty to care what happens in your absence and to ensure, as far as is reasonable, that potential patients and customers who would use your pharmacy are not put at risk. Your duties as a manager towards your staff mean that you should take reasonable steps to look after their interests as well.

What guidance does the Code of Ethics give here?

Your key responsibility as a pharmacist is to use your knowledge for the well-being of and safety of patients and public (see the Appendix). Part 2 of the Code sets out standards of professional performance. Initially these standards pick up the need to address the risk management aspects of clinical governance for all services. It is reasonable to expect that you, as superintendent, should anticipate that a pharmacist may be unable to attend at any of your pharmacies and to have some contingency procedures and guidance on what to do in this event. Further standards address your position as the pharmacist intending actually to provide professional services. If you were an employee, for example, you would have a duty to inform the pharmacy owner or some other responsible person as soon as you knew you were unable to honour a commitment to be in charge of a pharmacy.

What professional knowledge do I have which applies here? Where do I look or who can I ask for help?

We will take these together as it is a little difficult to separate what is technical knowledge from local knowledge. Here you would need to identify what alternative sources of pharmaceutical services were available near your pharmacy. Is your pharmacy the only one in that locality? If so, are there any other pharmacists whom you can call on to replace you, always assuming that they can reach your pharmacy in a reasonable amount of time? Can you move your pharmacists at the other two branches around if your replacement would find it easier to reach one of those rather than your pharmacy?

If there are other pharmacies reasonably close to the one where you were planning to be in charge, are they open and functioning with a pharmacist? Your key responsibilities in the Code of Ethics as a

pharmacist requires you to work in partnership with other health professionals for the benefit of the public, but we are sure you would anyway.

Can you conduct a pharmacy as a 'drug store' when the pharmacist is not there? The answer is no (but this may change in amendments to the Health Act 2006; see p. 181). There are plenty of cases that make this clear (Chapter 24), but someone ought to be at the premises to explain to those customers who do manage to call what alternative arrangements are in place.

What about the doctors in the area? They should be informed of your difficulty and emergency arrangements discussed. Medical practitioners can supply medicines to their own patients in most circumstances, and this may suffice for patients who need medicines for acute conditions (Chapter 9). Do not forget the police or the local hospital – they may be able to deal with urgent cases if necessary.

Finally you need to assess how long these difficulties may last, both at your home and at the pharmacy. Will facilities be needed to help the staff to get home, or stay overnight or share transport? These will be questions for you to handle in your capacity as manager as well as pharmacist.

Stage 2: prioritise and ascribe values

Patients, general public

It is important to ensure that patients and customers know what is going on. However, it is reasonable to assume that they, too, will have difficulty in getting about in the snow and the incidence of truly urgent need for medicines in the community is likely to be quite low, at least for one day's absence. The importance of these concerns will depend on how long it will be before you can resume a full service.

Other healthcare professionals, your profession

We have already covered most of the ground here when you were gathering relevant facts; your fellow professionals will all be expected to work together to sort out some solutions. Are there any contacts in your local RPSGB branch or Pharmaceutical Committee who can help? Is there a local 'cascade' system for circulating information to local pharmacies so that they know of your difficulties? The local radio stations can be very helpful in publicising arrangements in these situations.

Your employer, your staff, yourself

Although members of the public have a right to expect you to rate their interests highly, the safety and comfort of your staff, and indeed yourself, are also important. There is no point in any of them becoming a casualty themselves in an effort to help others.

Stage 3: generate options

What could you do?

1. Advise Jean to keep the shop open, but not to sell pharmacy medicines or dispense prescriptions.
2. Advise Jean to close the shop, with notices as to where to find the nearest pharmacy/services.
3. Advise Jean to keep the shop open but not to sell any medicines or dispense prescriptions until a relief pharmacist arrives.
4. Delay and seek further advice.

As always, we should consider risks and probability of the consequences of each action. You might have thought that option 1 was sensible, but it is not lawful (lack of personal control; but see p. 181) and puts the staff who are left in the pharmacy in an unenviable position. Option 2 is quite 'safe' from a criminal and civil law perspective but may create risks for some patients unless you have made alternative arrangements for an alternative source of pharmaceutical services that is easily accessible.

Option 3 is nearly as bad as 1 and might be worse for staff who have to explain why a pharmacy which appears to the public to be 'normal' cannot provide a service. The Medicines Act is somewhat perverse in allowing general sale list medicines to be sold from a greengrocer (provided they are in the manufacturer's original container; Chapter 7) without any control over their sale while stipulating that the same general sale list medicines can only be sold in a pharmacy when there is a pharmacist in personal control (this may change, see p. 181). Option 4 is a circular choice that will buy you time before choosing one of the others, but you will not have very long to decide. Option 4 would be acceptable if you could be confident that the staff would obey your instructions and that a pharmacist would be there within, say, an hour or two.

Note that all four options would be a breach of your Terms of Service, although we are unaware of any case being brought in such circumstances. In any event, you should also, as soon as practicable, advise your local health body of your position.

Stage 4: choose an option

What should you do? We think you should choose option 2 if there is a pharmacy nearby and option 4 if you are confident of having a pharmacist there within a couple of hours – provided that the pharmacist is not placed at undue risk and the staff are reasonably comfortable (i.e. warm and dry) in the process. Do you agree?

Discussion

Such situations might arise in a variety of ways, but the questions raised will be similar. You will be balancing the general risk to potential patients and customers against that run by yourself and your staff in struggling to maintain a service. The risk management aspects of clinical governance also mean that you should anticipate the non-availability of pharmacists and other key staff and have contingency plans as to what you would do.

Consider these other situations and decide what you would do and why.

- It is Saturday afternoon and drunken revellers from the local city carnival are invading your pharmacy. Should you close the pharmacy?
- Your pharmacy is a small unit within a large supermarket. Very few of the supermarket staff have made it to work although you have enough staff to cope. The supermarket manager wants to close the premises – what would you do?
- You have managed to open your pharmacy and your staff members have struggled through severe rain and gales to be there. Then the power supply fails, which disables your tills, fire and security alarms and your labelling and patient medication record system – what would you do?
- You are about to leave home for your pharmacy when you hear on the news that a bomb has exploded in the town centre shopping complex that includes your pharmacy. Your dispenser then phones you at home saying she is at the centre and the police will not let anyone near it. She asks you what she should do about the prescriptions, particularly for the three addicts who normally collect their daily instalments at 9.00 a.m. What will you say?

PROBLEM

Duty to protect the public, even from pharmacists

Sometimes your duties as a pharmacist can put you in an almost impossible position. Try this problem.



SCENARIOS

The locum and the bottle of whisky

Your cash supervisor, Anne, tells you that she saw your regular locum pharmacist, Mr W, who covers for your day off, sitting in his car at lunch time, drinking from a whisky bottle. She adds that, the same afternoon, the dispenser told her that Mr W had made a number of obvious errors when dispensing prescriptions for the nearby mental health day centre. Mr W is a friend of yours and is not associated with a locum agency. What are you going to do?

What issues should I consider?

- Nature and quality of the medicines supplied
- NHS Terms of Service: 'as so ordered'
- Principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Good practice: management of alcohol abuse
- Use of outside resources, e.g. your professional organisation.

Where should I look in *Pharmacy Law and Ethics*?

Nature and quality of medicines (Section 64 of the Medicines Act; Chapter 14)

NHS Terms of Service (Chapter 23)

Principles of negligence (Chapter 23)

Code of Ethics (Chapter 23).

First a cautionary note here. Some of the information you have been given is ‘hearsay’ – Anne is telling you what someone else has said to her. It would be unwise to take any action until you have some first-hand evidence yourself that there is a problem. You should certainly go back to the dispenser to hear her direct account and then see for yourself – perhaps you could drop in unexpectedly after lunch when Mr W is in charge.

Let us suppose that you are satisfied that there are grounds for concern.

Stage 1: gather relevant facts

What criminal law applies here?

It is not against the law to be ‘drunk in charge of a pharmacy’. Nor does Mr W cease to be a pharmacist in the eyes of the law just because he is drunk or, at least, has been seen to have been drinking. Mr W can still satisfy the legal requirements to supervise supplies of medicines and be in personal control of the pharmacy. You know, however, that Mr W drives a car, indeed was seen drinking while sitting in his car, so there would be concerns about his fitness to drive.

Mr W may, however, fail to prevent errors being made in dispensing. Supplying the wrong medicine is a breach of the Medicines Act legislation (Chapter 14), and a criminal offence, although prosecutions are rarely brought by the RPSGB. If such errors were the result of reckless or irresponsible behaviour (as in this case) rather than human error, then a prosecution might be somewhat more likely and if an error resulted in death, the pharmacist could be charged with manslaughter.

It is worth knowing that convictions of pharmacists are usually notified by the courts to the RPSGB, regardless of whether they occur in a pharmacy context or not (Chapter 24). Therefore, a conviction for drink driving could result in a reference to the Statutory Committee; such matters are for the discretion of the Committee chairman.

What NHS law applies here?

In the same way, the NHS Terms of Service do not include specific conditions about remaining sober, but dispensing a medicine that is not ‘as so ordered’ by the doctor is a breach (Chapter 23) and could lead to financial and administrative sanctions. The general requirements of

employment law are another form of administrative law where power to enforce the provisions rests with employment tribunals.

What civil law applies here?

There are serious civil liabilities incurred by you and Mr W in this situation. You and he have a duty of care towards the patients and customers who use your pharmacy. Any dereliction of that duty that causes injury or harm will render you both liable for compensation (damages) that reflects the extent of that harm. This may or may not be a higher risk for certain patients (say those with mental health problems) than others.

Set against this is the rather remoter possibility of defamation if you broadcast your suspicions about Mr W widely and they turn out to be without foundation.

What guidance does the Code of Ethics give here?

The Code of Ethics (see the Appendix) does not directly prohibit drunkenness or require pharmacists to exhibit sobriety, but the issue is implicit in your key responsibilities as a pharmacist; your duty is to act in the interests of patients and the public. Many cases that have come before the Statutory Committee justify this inference – you might like to look at these now.

Less compelling but still important are your key responsibilities to avoid any activity that would impair confidence in the profession or bring it into disrepute. You would also have obligations to help a fellow professional to cope with an apparently serious problem.

What professional knowledge do I have which applies here?

All of your training and experience will tell you that this is an unsafe situation that cannot be ignored. You should check back on the prescriptions that Mr W has dispensed and take reasonable steps to follow up those that have already been supplied to patients.

Where can I look or who can I ask for help?

The RPSGB has set up two helplines for pharmacists who have problems with drugs, alcohol or stress and for others who wish to get help for those with these problems (Chapter 22). The RPSGB also has its

local inspectors, who will probably have experience of this kind of situation and can give you some practical advice. Your employer or the NPA may be able to make some helpful suggestions. In any event, you will want to record your findings in an objective way so that you can justify whatever action you do decide to take. You may also want to take advice on the employment law implications of any action you take, particularly as Mr W is a regular locum who has not been provided by an agency.

Stage 2: prioritise and ascribe values

Patients, general public

Your first concern must always be protection of the public, if necessary from the actions of a drunken pharmacist. This is a serious but not necessarily urgent matter as you could simply not use Mr W for a while until you have decided what to do. But then you must consider the consequences of his working in other pharmacies in the same compromised condition and, further, the consequences for Mr W himself.

Other healthcare professionals, pharmacist colleagues

Whatever your sympathies and sensitivities in a case like this, you cannot allow them to overrule your duty of care to your patients. Nevertheless, this does not mean that you can declare to your professional colleagues that Mr W is a drunkard. Such an accusation would be unhelpful to him and dangerous to you. You would be wise to say nothing specific but to confine yourself to voicing discreet 'concern' while establishing the extent of the risk that is being created.

Your staff, your employer

Similar considerations will mean that you must be discreet in your observations to staff. You may need to take Anne and your dispenser into your confidence at least and ask them to make notes in writing of their knowledge of Mr W's behaviour and performance. If you are an employee, you will have to do the same thing for the benefit of your employer and, as we shall see, for your own protection should the position deteriorate. At the same time, you may want to remind them of their duty not to 'gossip' about this matter, particularly outside work.

Yourself

You may find that your loyalties are split if Mr W is well known to you or has been a friend to you in the past. Such considerations must not be allowed to obscure your first duty to prevent harm to patients, but it must be balanced against your duty to help Mr W deal with his problems. This is why you must be objective about his condition and make careful observation before jumping to any conclusions.

Stage 3: generate options

What could you do?

1. Do not use the services of Mr W again
2. As option 1, but tell the RPSGB's inspector about your suspicions.

Option 1 is clearly not a good one because Mr W may simply go and cause similar problems in another pharmacy. Option 2 is only slightly better, unless you know precisely where Mr W is going to be working, but is better than nothing. We could add a third option.

3. Keep observing Mr W and tell the RPSGB's inspector and helpline about Mr W.

This option has merit in that it allows the whereabouts of Mr W to be known and it anticipates both outcomes of this unfortunate case: either Mr W will continue to be compromised by his drinking and the RPSGB's inspectors will have to take action to protect the public or he will accept help, in which case you have alerted the people who can provide it. The inspectors may themselves pass information to the helplines, but details are never passed in the other direction.

There are other options that are worth exploring:

4. Confront Mr W with your suspicions.

We do not recommend this option unless you are very sure of your facts and have information that will support your accusations. It is a feature of alcohol abuse that sufferers often will not recognise that they have a problem, and if the response is a flat denial you have little room left for manoeuvre. Such a choice might just lead to a change in behaviour in Mr W, but it is more likely to become more covert and lead to Mr W simply ceasing to do your locums, which leaves you in the position envisaged in option 1.

Stage 4: choose an option

What should you do? Are you expecting us to give you an answer? Such situations are very difficult to deal with. Provided you do not unearth serious and frequent errors because of Mr W's condition, we think option 3 would be the best for all concerned. Do you agree? If you do uncover serious problems, you may have to take option 2 – dismiss Mr W but alert the RPSGB's inspector and perhaps the locum agency and local pharmacies as soon as you can.

Discussion

There are many variations on this scenario that you could consider. Here are a few:

- the report you have indicates that Mr W is abusing controlled drugs rather than alcohol
- you return to the pharmacy and find that Mr W is actually incapable and lying on the dispensary floor
- the report you have talks of Mr W staggering slightly and having slurred speech but there is no suggestion of alcohol or drug abuse.

10 PROBLEM

Duty to protect the public, even from pharmacists (2)

In Problem 8, we looked at the consequences of not having available a pharmacist at all to supervise the activities of a community pharmacy. The same issues of public and patient safety would arise in hospital practice if no pharmacist were present although the law is slightly different. Similar considerations to those in Problem 9 would arise if a pharmacist were available but there were doubts about his or her competence. Try this problem.



SCENARIOS

The European locum and the hospital staff

You are the pharmacist managing the pharmacy department in a small general hospital. Because of a national shortage of pharmacists, you have had to engage on a one-month trial period, a locum pharmacist, Mr V, to be the sole pharmacist in charge of the dispensary. Your Human Resources department says that occupational health have cleared him for employment and the locum agency has provided evidence that he is registered in Great Britain under reciprocal arrangements within the European Union. Two weeks after he starts, your senior pharmacy technician, Sheila, asks to see you. She says that she and other technicians have concerns about Mr V's ability to dispense accurately and to carry out proper clinical checks on prescriptions. Moreover, she says she now has a complaint from one of the medical staff and from several patients who say Mr V cannot converse adequately in English. What action are you going to take?

What issues should I consider?

- Offences under the Medicines Act
- Application of Medicines Act to hospital premises
- Registration of pharmacists and relevant byelaws
- Duty of quality (clinical governance) in hospitals
- Employment law
- Principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Professional knowledge about the medicines supplied.

Where should I look in *Pharmacy Law and Ethics*?

Offences under the Medicines Act (Chapter 2)

Application of the Medicines Act to hospital premises (Chapters 3, 9 and 26)

Registration of pharmacists and relevant byelaws (Chapter 22 and relevant Appendix)

Duty of quality (clinical governance) in hospitals (Chapter 26)

Employment law (Chapter 21)

Principles of negligence (Chapter 23)

Key responsibilities of a pharmacist in the Code of Ethics (Chapter 23).

First a cautionary note as in Problem 9. Some of the information you have been given is ‘hearsay’. As well as voicing her own opinions, Sheila appears to be telling you what someone else has told her. It would be unwise to take any action until you have first-hand evidence yourself that there is a problem. Check whether Sheila has some evidence and examples of Mr V’s alleged incompetence, or whether she has completed any of the hospital’s internal ‘error or incident’ report forms. See if the member of staff or the patients have made written complaints with specific details of when and what exactly is being complained about. Find out whether Mr V has already been made aware of these complaints and whether any explanations have already been offered. Finally, consider whether the complaints may be biased by a personality clash or cultural prejudices.

Let us suppose you are satisfied that there are grounds for concern.

Stage 1: Gather relevant facts.

What criminal law applies?

Your priority is firstly to establish the nature and seriousness of any alleged errors made by Mr V. Supplying an incorrectly dispensed medicine is a breach of the Medicines Act (Section 64) but more immediately you will want to make sure there is no risk to any patient.

In contrast to the situation in community pharmacy, there is no requirement in criminal law for a pharmacist to supervise the supply of medicines from a hospital pharmacy. However, any such transactions must be part of the business of the hospital and must be carried out in accordance with the directions of a doctor or dentist. For supplies of POM, these directions must be in writing. So, at least in terms of criminal sanctions, a hospital pharmacy can technically operate without a pharmacist. However, the preparation and assembly of medicines must be carried out under the supervision of a pharmacist to avoid the need for a marketing authorisation or manufacturer's licence. So in practice a hospital pharmacy cannot operate without a pharmacist.

The Pharmacy Act 1954 covers the registration of pharmacists in Great Britain (however, imminent changes to the Pharmacy and Pharmacy Technicians Order 2006 (when passed) will revoke the Pharmacy Act 1954; see p. 182) and you may like to look now at the relevant Chapter (22) and the byelaws (to be renamed rules) that govern the eligibility to practise in Great Britain of pharmacists from elsewhere in the world such as Mr V. The reciprocal arrangements with the European Union do not allow the Society to test for competence in the English language.

There is another statute that has some relevance to this case: the Public Interest Disclosure Act 1998. This Act aims to protect the right, and indeed duty, of public body employees to raise issues concerning patient or client care, sometimes called 'whistle blowing' (see also Problem 5 and Chapter 4 of this book). In the past, some individuals have suffered considerable criticism or even abuse for doing just that; in some instances they have found their job prospects halted or have even lost their jobs. While the proper place to raise concerns in the first instance will always be internally, every member of staff in a hospital has a duty to care for the interests of patients.

What NHS law, including hospital service directions, applies here?

The statutory duty of quality placed on trusts by the Health Act 1999 (Chapter 26) requires the trust to implement standards of healthcare

quality (determined by the Healthcare Commission) across a wide range of risk areas. The quality of staff will be a possible risk area and your human resources (personnel) department should have operational procedures to manage that risk. In this case, the checks they have carried out on health and registration appear to be part of those procedures as should be a period of induction training to cope with possibly unfamiliar surroundings. While any sanctions for failing to have adequate risk management controls within the trust may fall on the Chief Executive or other board level directors, you as a senior managerial pharmacist, might also be considered accountable for any other measures which you might reasonably be expected to have put in place.

A second area of healthcare quality is medicines management. A series of criteria to be monitored have been specified to demonstrate the safe and secure handling of medicines within a hospital. One of these requires that a pharmacist supervises pharmaceutical dispensing activities. This effectively mirrors the situation that applies statutorily outside the NHS.

The general requirements of employment law are another form of administrative law where power to enforce provisions rests with employment tribunals, both within and outside the NHS.

What civil law applies here?

You have a duty of care to ensure that patients and other users of your hospital dispensary are not put at risk. This duty of care will be heightened as it becomes the norm for hospital trusts to implement controls assurance processes. You also have a duty of care towards your staff to ensure that they are not required to take on responsibilities to which they have not agreed or for which they are not equipped. This may apply to your dispensing technicians, who should not have to effectively 'supervise' a pharmacist.

What guidance does the Code of Ethics give here?

The Code of Ethics (see the Appendix) states that your key responsibility is to use your knowledge for the well-being and safety of patients and public. In Part 2 of the Code, on standards of professional performance, Section A.1 places responsibilities on locums only to accept work where they have the relevant skills and fitness for the tasks to be performed. Moreover, they should disclose any factors that may affect their ability to provide services. Although this provision is most commonly invoked

in areas of conscience, it is equally valid if Mr V knew that his English was not adequate to cope with the colloquial English he might expect to encounter when dealing with patients. Furthermore, Section A.1 expects that if Mr V, or you in his place, considers that because of any mistakes or misunderstandings a patient may have received substandard care, there is an obligation to inform the patient and try to put things right.

You should also note that in Section A.2 you have an obligation as a manager to ensure that pharmacists (and other staff) are sufficiently competent in English and to ensure that the Society is informed of pharmacists whose professional competence or ability to practise may be impaired and put the public at risk.

What professional knowledge do I have which applies here? Where do I look or who can I ask for help?

Firstly, you will need to consider what medications Mr V has been supplying and the potential for risks to patients arising from errors. You will want to talk this through with Sheila and any other staff who have been working with Mr V. You may want to take advice from more senior colleagues and any member of the staff in the hospital who is generally accountable for risk management. At some stage you may want to contact the Society or the local inspector for their advice. You may consider it wise to take advice from your personnel department before tackling Mr V directly, particularly in respect of the conditions under which Mr V was engaged. We look at this in more detail in Stage 2.

You might also want to know if the locum agency that provided him is aware of any other problems associated with Mr V and what is their policy in dealing with such situations? Overarching all these questions will be the current availability of other pharmacists. Can you conceivably find a replacement for Mr V? Would the dispensary have to close if you could not? What other facilities for carrying out its activities might be available?

Stage 2: prioritise and ascribe values

Patients

Your first concern must always be the protection of patients. Are there likely to be any other errors made by Mr V which have not been made known to the patient? If you were able to find a replacement quickly for

Mr V, what might be the consequences for patients of any other pharmacy setting in which he might work?

Mr V himself

You should pause just a moment to consider whether any of the allegations or even evidence against Mr V might be unfair or even constitute defamation by libel (written) or slander (verbal). Although there are defences to such actions, you might want to establish what opportunity was Mr V given to raise any concerns he might have had about his competence or command of English? Did he ask for any support in carrying out his duties or did he claim to be fully competent from day one? Were the terms of his one-month trial put in writing to him and under what circumstances was it stated that his employment might be terminated?

Other healthcare professionals

The concerns of other healthcare professionals such as the hospital doctor should be acknowledged but you should be careful about rushing to confirm such concerns. So far, you have heard one side of the story; there may be a number of mitigating factors or exaggerations which will alter the picture quite radically on investigation.

Your staff, your employer

The same restraint upon jumping to conclusions should be exercised with your staff although you should always take their concerns seriously. It is important that they feel free to identify problems which may affect the quality of the service being given, provided they are prepared to support criticisms with objective evidence. The hospital authority too, will want to be able to show that concerns are noted and some investigation takes place (see reference to ‘whistle blowing’ in Stage 1).

Yourself

Your first duty is to prevent harm to patients but this must be balanced against your duty to be fair to Mr V and to deal objectively with the allegations. Dealing with personnel investigations can be stressful, even distressing for the investigators; you will want to ensure that you alone do not carry the whole burden particularly when issues of employment law are involved.

Stage 3: generate options

What *could* you do?

1. Terminate the use of Mr V's services immediately.

We think that you will readily recognise that this is an unsatisfactory option for at least three reasons. Firstly, it may mean that Mr V will work elsewhere, cause similar problems and be a risk to patient safety; secondly, this will not help Mr V, who may be unaware of his alleged shortcomings but could improve if they were made known to him. Finally such precipitate action unless carefully supported may render the hospital liable for a breach of Mr V's employment rights. You will also almost certainly have to explain to the locum agency why you took this action and this may reopen the whole situation once more.

2. After consultation with the locum agency and the hospital personnel department, terminate Mr V's employment.

This is clearly a better option, but the time needed to investigate and consult may not address urgent concerns about patient safety. This option also falls short of your duty to ensure that the Society is informed of pharmacists who may be incompetent to practise. So we could add a variation

3. As option 2, but consult with the Society as well.

In all three of these options, you are losing any opportunity of retaining Mr V's services at all. This may open up the prospect of closing down the dispensing facility altogether if you cannot find a replacement. Given the shortage of pharmacists, the cost of recruitment and induction and the possibility that Mr V may become competent if given some help, what other options might you have?

4. As option 3, but suspend Mr V's employment rather than terminate it.

This option has merit because it will ensure that the whereabouts of Mr V remain known and it provides an opportunity to set in place measures to rectify Mr V's shortcomings and keep the option of reinstating him at some time in the future. Any reinstatement may mean quite a lot of work for your staff and/or the locum agency and this may be a factor that will affect your chosen option. It also means that you will still have to find a replacement for Mr V or contemplate closure of the dispensary. Finally, don't forget that you will have to renegotiate Mr V's one-month trial to reflect the changed circumstances.

5. Talk to Mr V and get his version of events.

This might seem an obvious first option but we would urge you to be careful. Such a conversation needs to be carried out sensitively, using an exploratory approach with a view to clarification and support. An interview could easily become a confrontation and you might prepare for it to become a disciplinary procedure, in a formal interview setting with at least one other representative from the hospital present and a similar facility being offered to Mr V. Even if taking this option did not lead to difficulties under employment law, it may simply result in Mr V resigning immediately which will have all the drawbacks of option 1.

6. Bring in an additional pharmacist to support Mr V.

These might be worthwhile options if the availability of pharmacists permits it and you judge that Mr V's failings can be managed with further support. You will have to consider what benchmarks you need to establish that this support is effective and, as in option 4, Mr V's employment contract will have to be renegotiated. This option might fit well with the next, so that specialist pharmacists could be temporarily assigned to the dispensary whilst Mr V's difficulties are tackled.

7. Restrict Mr V's activities to those of least risk.

It might be reasonable to require that Mr V does not undertake outpatient or discharge medications but confines his activities to inpatient services. This should mean it is easier to offer support and intermediate safety checks by other health professionals. Alternatively, prescriptions for outpatients could temporarily be written on FP10(HP) or their equivalent for dispensing by community pharmacies.

Stage 4: choose an option

What *should* you do? We think the overriding factors are maintaining patient safety despite a shortage of pharmacists. All the options mean that you will have to find a replacement or an additional pharmacist in the short term. Given that, we think option 4, followed by options 5, 6 and 7 if practicable would be best. Do you agree?

Discussion

The importance of risk management – that is, the process of anticipating risk and having contingency plans to deal with it – is clearly demon-

strated in this problem. While this example relates to a locum pharmacist, any pharmacist or indeed any member of the support staff could develop signs of impaired competence and managers should have procedures to deal with that eventuality. When a shortage of essential personnel, such as pharmacists, is anticipated then decisions on what services are dispensable or could be delivered from elsewhere should be taken before the crisis arises rather than afterwards. This is yet another component of clinical governance.

What records could you make of this situation and where would such notes be held? Data protection law allows the subject to have access to most information that is held about them, including some parts of personnel data. Even if personnel records are partially protected, you should ensure that any comments or allegations of impaired competence are supported by objective evidence, just as you did before embarking on dealing with the allegations about Mr V.

Consider how you might assess risk and develop strategies to deal with the possibility of:

- a similar situation arising in your 'pharmacy shop' within the hospital, which dispenses outpatients prescriptions and sells a small range of over the counter medicines
- engaging a locum for ward cover on just one day
- coping with long-term sick leave in a regular full-time pharmacist.

11 PROBLEM

Duty to protect the public, even from other health professionals

As pharmacists take a more active part in the healthcare team and develop their own unique contribution to patient care, they may come into conflict with the judgements of other health professionals. The following problem is set in the primary care sector, in a GP surgery, but it could equally arise in hospital or community practice.



SCENARIOS

The contraindication and the confident practice nurse

You are an experienced community pharmacist who has recently started a clinical diploma. As part of the course work you need to carry out a medication review for a patient with diabetes. You ask the practice nurse at your local surgery, Liz, to select a patient. She suggests Mrs Cooper, an elderly lady who started on insulin a couple of months ago as her diabetes was not controlled by metformin alone.

While reviewing Mrs Cooper's case history, you see her creatinine levels indicate mild renal failure at the start of her treatment and that this has become worse although this is not mentioned in her notes. You give a copy of your case review to Liz, draw her attention to the contraindication and recommend that Mrs Cooper be managed on insulin alone. Liz responds by saying that Mrs Cooper can't possibly manage without the metformin and gives you a clear impression that your recommendation will not be acted upon. What will you do now?

What issues should I consider?

- Principles of negligence
- Clinical governance, statutory duty of quality
- Key responsibilities of a pharmacist under the Code of Ethics
- Professional indemnity insurance
- Vicarious liability
- Data Protection Act
- Reference sources for clinical advice.

Where should I look in *Pharmacy Law and Ethics*?

Principles of negligence (Chapter 23)

Key responsibilities of a pharmacist in the Code of Ethics (Chapter 23)

Clinical governance, statutory duty of quality (Chapters 23 and 26)

Professional indemnity insurance (Chapters 23 and 26)

Vicarious liability (Chapter 21)

Data Protection Act (Chapter 21).

Stage 1: gather relevant facts

Before any kind of legal or ethical analysis, you will want to be very sure of your clinical facts. Briefly, the use of metformin combined with insulin can be useful to prevent weight gain in obese patients. However, metformin is contraindicated in patients with renal failure because it can cause lactic acidosis. This is a rare side-effect but it can be fatal. So your first step may be to assemble references to support this clinical information.

What criminal law applies here?

None of the statutes we have so far looked at are at issue here. We should, however, consider the Data Protection Act, which is also discussed in later problems. There is an exemption in the Act that removes the need for patient consent if the information to be shared is necessary for patient care and is shared between health professionals (and any relevant staff) who 'owe a duty of confidentiality'. Strictly speaking, therefore, there is no statutory obligation to consult Mrs Cooper before undertaking the review but it is certainly desirable. This is in keeping with the philosophy of the Act to obtain consent to disclosure wherever possible.

We mentioned manslaughter in Problem 9. Where a patient's death can be attributed in any way to a failure of medical care, there is always the possibility of a police investigation to establish whether there are grounds for a prosecution for manslaughter arising from what is usually termed 'criminal negligence'. Such cases are rare but in 2000, a pharmacist was initially so charged for her part in a dispensing error associated with a death. In such cases, the police may wish to gather evidence that implicates anyone – preregistration pharmacist, dispenser, sales assistant – who may subsequently be judged to have contributed to the death by culpable negligence.

What NHS law applies here?

The Health Act 1999 (Chapter 26) introduced a statutory duty of continuous quality improvement on NHS bodies and services. This is usually termed *clinical governance* and places accountability for the quality of healthcare that professionals give directly or indirectly to NHS patients. In the primary care sector, the ultimate responsibility will rest with the Primary Care Trust Board in England or the equivalent body elsewhere. The individual health professionals, GPs, nurses or those working in association with them would also carry their own personal responsibilities and be accountable for their actions.

In addition, the same Act introduced a requirement for family health practitioners to hold approved indemnity cover, which now appears in the 2005 regulations covering the community pharmacy contract and is likely to be in the pending Pharmacists and Pharmacy Technicians Order 2006 (see p. 182).

What civil law applies here?

This situation has a fairly obvious potential to involve you in a medical negligence action. Mrs Cooper's GP would be regarded under the civil law as having the highest duty of care towards Mrs Cooper herself. However, he or she has delegated certain activities to Liz, the practice nurse. Provided the GP is sure that Liz is competent to carry out those delegated tasks, his or her duty of care may be proportionately diminished, but Liz will then acquire a clear duty of care to Mrs Cooper. Now that you as a pharmacist are involved, you will start to acquire a duty of care to Mrs Cooper too.

In a civil action for negligence, it is always arguable who exactly and in what proportion the various respondents may carry liability.

When dispensing prescriptions, case law now indicates that pharmacists will be held liable, albeit jointly with prescribers, if they fail to intervene when errors could potentially harm patients. It is very likely that the same liability will arise when pharmacists are providing advice on the use of medicines as well as supplying them.

What guidance does the Code of Ethics give here?

Your key responsibility as a pharmacist is to use your knowledge for the well-being and safety of patients (see the Appendix). This scenario is a clear example of where you have specialist knowledge that must be employed. The Code also says you must work in partnership with other health professions and respect patient's rights to be involved in decisions made about their care. Moreover, your key responsibilities also include an obligation to be up to date and to base your advice on evidence. In Part 2 of the Code on standards of professional performance, matching responsibilities are spelled out for both yourself and for your employer (if you are employed) to ensure that all the activities you undertake are covered by professional indemnity insurance.

Professional indemnity is similar to the 'third party' insurance for car drivers. It covers you for the costs of any damage to other persons arising from your faults. If you are employed, your employer will be vicariously liable for the consequences of your actions in the course of that employment. Your employer will normally carry an indemnity insurance arrangement for this purpose, but you should check. If you are self-employed, then you yourself should ensure you are appropriately insured. In this case, you will need to establish whether you are covered by your employment in community practice for this medication review or whether you are temporarily employed by the GP practice and covered by their insurance arrangements.

The Code of Ethics also has more to say on professional competence and confidentiality. In Part 2, paragraph B, guidance specific to your situation is given. Under Part 2, paragraph C emphasis is again placed on ensuring patient consent to disclosure or sharing of patient information except in closely defined circumstances as set out in the paragraph.

What professional knowledge do I have which applies here?

This is not a textbook on clinical pharmacy, so we will not attempt to give comprehensive advice here. The standard textbooks such as the

British National Formulary, Martindale: The Complete Drug Reference and the *Compendium of Data Sheets and Summaries of Product Characteristics* will contain ample supporting material for your advice. To this you may add national guidance such as (in England) National Service Frameworks and advice from NICE (or their equivalents) and any local formularies agreed at practice level or higher. Finally, there are many specialist textbooks on therapeutics which you can turn to.

Where can I look or who can I ask for help?

You could consult the lecturers on your clinical diploma for help in interpreting the facts and information you have found. We have said above that Mrs Cooper's GP carries the prime responsibility for her care so you might want to speak to him or her. Clearly this will be much easier if, at the start of your activities in the surgery, you had made yourself known to all the GPs and relevant staff working there. Ideally, an introduction at a suitable practice meeting would have given you an opportunity to explain your background, what your aims were and how you were going to carry them out.

Stage 2: prioritise and ascribe values

Patient

You should have no difficulty in recognising your first priority is Mrs Cooper. If this potential contraindication is not dealt with she could die.

Mrs Cooper's relatives or carers

You may have limited information about Mrs Cooper's personal circumstances but it is likely that she may have children or other relatives who will be anxious for her welfare. If her condition deteriorates because of a failure to institute avoiding action, then they may hold you accountable along with other health professionals involved in her care.

Other healthcare professionals, your profession

As we suggested in Problem 6 (unlicensed use of Phenergan Elixir), you should prepare carefully before speaking either to Liz or Mrs Cooper's GP. Do you have any alternatives to offer other than simply taking Mrs Cooper off metformin? Be prepared to recognise that they may know

more about Mrs Cooper than you and there may be some reasons which are not yet known to you as to why such a change is unwelcome. Be circumspect but firm bearing in mind your expertise and responsibility as an independent professional.

Employer

We have already said that you should check your position on professional indemnity insurance *before* commencing medication review or similar activities outside your normal employment. Your employer may not be willing to extend his accountability to activities that are completely outside his control.

Yourself

We think this is a good example of where you ‘owe it to yourself’ to intervene. You are acting as the patient’s advocate and seeking to ensure that no treatment that could conceivably cause more harm than good to Mrs Cooper remains uninvestigated. You may eventually reconsider your advice but you must pursue it as a matter of professional conscience.

Stage 3: generate options

What *could* you do?

1. Do nothing.

You might briefly consider this to be an acceptable option. Mrs Cooper seems to have been maintained so far on this treatment without obvious harm and may continue to be so. Any other patient might have been selected for your medication review and Mrs Cooper’s position might not have come to light. We think you should reject this option because once you know that there is a problem, you cannot simply pretend you didn’t know. How would you feel if Mrs Cooper did become seriously ill or die?

2. Put your advice in writing to Liz, the practice nurse, but do nothing more.

This might seem marginally safer than option 1 in that you have effectively passed the knowledge to Liz. In fact, it is probably a worse option because you could not subsequently deny that you knew there was a problem.

3. Fully document your advice to Liz and send a copy to Mrs Cooper's GP.

Now you are thinking defensively by involving all the partners in Mrs Cooper's care and ensuring that your advice is backed up by evidence.

4. Ask to see Mrs Cooper.

We have added this option because it highlights the need never to overlook the wishes and needs of the patient. We should always be wary of assuming that an 'elderly' person, or anyone else for that matter, is just a passive partner in their medical treatment. Mrs Cooper undoubtedly knows what her diabetes *feels* like better than anyone else. She may know why she 'can't' manage without metformin or be able to shed light on why Liz has formed this opinion.

Stage 4: choose an option

What *should* you do? We think we would choose option 3. Do you agree?

We have chosen option 3 because we think it is defensible to Mrs Cooper, to her relatives and carers and to the courts if necessary. You would probably add that you would be happy to discuss Mrs Cooper's case if needed and soften the challenge by thanking the practice for letting you undertake this review. Patient care is a partnership and you must do what is reasonable to ensure that your duty of care is properly discharged and that other health professionals have all the information necessary to meet their duties of care.

Discussion

An important aspect of continuing professional development is the value of *reflective practice* as part of the process of auditing your performance. In other words, to look over the events of the day or a longer period, consider what information and experiences were new to you, what you can learn from them and how you might use this new knowledge to inform your future practice. Most clinical diplomas and other postgraduate studies encourage the keeping of a diary or other record which documents this process. In the future, this will be part of the evidence pharmacist will need to show that they are undertaking continuing professional development and of demonstrating their commitment to clinical governance.

12

PROBLEM

Accountabilities of an employee; duties of a superintendent

As discussed at the beginning of this chapter (p. 181), imminent changes may amend to the duties of a superintendent under the Health Act 2006.



SCENARIOS

The non-pharmacist manager and the sales of codeine linctus

You are employed as a part-time pharmacist in a local community pharmacy – one of two owned by a limited company. A non-pharmacist director, Mr M, usually works on the medicines counter and in the rest of the shop. You are suspicious that he is selling large quantities of codeine linctus, especially during your lunch break. What can you do?

What issues should I consider?

- Law relating to ownership of pharmacies
- Liabilities of non-pharmacists
- Principles of negligence: remoteness of damage
- Good practice: management of drug abuse
- Key responsibilities and standards of professional performance in the Code of Ethics
- Interests of staff, colleagues and general public.

Where should I look in *Pharmacy Law and Ethics*?

Ownership of pharmacies (Chapter 5)
Liability of non-pharmacists (Chapter 24)
Negligence (Chapter 23)
Duties of superintendent (Chapters 5 and 24)
Code of Ethics (Chapter 23).

As in Problems 9 and 10, you need to gather some objective evidence before you can decide what to do. You might take note of how many bottles of codeine linctus are on the shelf or in the back before and after your lunch. You might ask the staff casually and discreetly about codeine sales and where the stock seems to have gone, although do not be surprised if they are very well aware of the situation! Let us assume that you have firm evidence to believe your suspicions are justified.

Stage 1: gather relevant facts

What criminal law applies here?

The Medicines Act lays down exactly who can own a pharmacy business (Chapter 5). If the owner is a company, then it must appoint a superintendent pharmacist who is accountable for the management of the business in so far as ‘it concerns the keeping, preparing, dispensing and supplying of medicinal products’ (this may change, see p. 181).

Codeine linctus, being a pharmacy medicine, should not be sold at all in your absence unless another pharmacist is present to supervise the sale. Such sales without supervision are criminal offences (Chapter 6) and could result in prosecutions for the company, the superintendent, you and Mr M. This is an unusual state of affairs, whereby Mr M is subject to the law in his capacity as a director and can be prosecuted as though he were a pharmacist (Chapter 24; but the disciplinary powers of the RPSGB may be changed following implementation of the Pharmacists and Pharmacy Technicians Order 2006; see p. 182).

What NHS law applies here?

None. The NHS contract refers only to pharmaceutical services, which do not, at present, include over the counter sales of medicines.

What civil law applies here?

The consequences of such uncontrolled sales causing injury or damage are significant, even though the purchasers are likely to be preexisting abusers of drugs. Many will be young people, and there is a real possibility that those near to the drug abuser – parents, relatives, friends – will regard such supplies as contributing to the continuing ill-health of the individual concerned or as a factor preventing him or her from overcoming the addiction. It is not unknown for abusers themselves to

contact the authorities and complain that a pharmacist is not properly restricting access to abusable drugs.

What guidance does the Code of Ethics give here?

The issue of how far pharmacists should go in helping drug abusers to manage their addiction has featured heavily in Statutory Committee cases over the years (Ch. 24; see the Appendix). You might like to look at these now and see how the profession does not generally expect a pharmacist alone to attempt such a task, other than by refusing to make supplies that are not authorised through a recognised drug rehabilitation programme.

This position is recognised in Standard 10 on the sales of pharmacy medicines, which says that you, as a pharmacist, must be aware of the abuse potential of certain over the counter products and should not supply where there are reasonable grounds for suspecting misuse. You should also be aware of Part 4 of the MEP guide, which provides guidance on improving pharmacy practice. There is also a section (4.3.42) called 'substances of misuse', which refers you to the RPSGB website to identify what kind of products can be abused and in what circumstances.

But this case is not about supply by a pharmacist. You have grounds to believe that Mr M is making the supplies illegally. As the pharmacist in charge at the material time you are responsible for those sales, even in your temporary absence.

Take a look at Part 2 of the Code, Sections A and B, which are concerned with the personal responsibilities of pharmacists and the particular responsibilities of the superintendent pharmacist. Together, you must ensure that persons who are not pharmacists, like Mr M, are not permitted to assume your responsibilities. This could lead to an uncommon but real dilemma where you have to consider whether you continue in this employment at all if it means compromising your professional judgement and accountability.

Finally, this situation should make you question how the superintendent pharmacist and other pharmacists in charge are complying with the requirements in Parts A and B to use trained counter assistants and comply with a protocol for selling non-prescription medicine. Has Mr M completed an approved training course? Does the protocol (if there is one) not make special provisions for sales of medicines liable to abuse? As the pharmacist in charge, you may modify any existing protocol, say by insisting that, in future, codeine linctus may only be sold

personally by you, although this might cause inconvenience for some bona fide purchasers.

What professional knowledge do I have which applies here?

As in Problem 2, you will know something of drug addiction and how it should be managed. You should know which drugs are likely to be used to supplement a habit and, equally important, which ones are 'fashionable' in the area in which you are working. You will know that consumption of codeine linctus in large quantities will have adverse effects on users, and that this might compromise any long-term supplies that he or she may be obtaining from a drug addiction clinic.

Moreover, such supplies may inhibit or avoid the need to attend such a clinic and leave the abusers to fend for themselves on the 'street', where the quality and safety of misused substances leave a lot to be desired.

Where can I look or who can I ask for help?

You could make discreet enquiries of the staff, who should be aware of what happens when you are out. You could ask other pharmacists who work in the pharmacy whether they share your concerns and you should make your worries known to the superintendent pharmacist. If you feel that such action does not go far enough, or you suspect that other pharmacists are failing to take this aspect of their responsibilities seriously, you might seek advice from the NPA, the RPSGB, your defence association or, in other circumstances, your 'head office'.

Stage 2: prioritise and assign values

Patients, contacts

Ultimately, you must do whatever is necessary to prevent patients or customers, including those who are misusing drugs, from being exposed to unnecessary harm. The supply of codeine linctus in an uncontrolled way is harmful, and you must do everything you can to remove your complicity in such activity and to persuade others to do the same. If necessary, you may have to write down your concerns and give reasons, so that you have put others on notice that matters cannot continue; this will serve also to show that you did not simply ignore or withdraw from the problem without trying to solve it.

Other healthcare professionals, your profession

Drug abuse is not, of itself, an offence in the UK, and there are teams of healthcare professionals who are well equipped and well able to minimise the harm that individual drug abusers face. Many drug abusers are not listed with family doctors and do not receive much of the general medical care they would otherwise have. When drug abusers attend a clinic, there is at least the opportunity to intervene in healthcare problems and to move abusers from the more harmful routes of abuse to others that cause less harm. Any failure to supervise adequately the sale of abused medicines is not simply a breach of the law; it may also bring, as in this case, disrepute upon the profession as a whole.

Your employer, staff and colleagues, yourself

Mr M is not, strictly speaking, your employer, but both he and your superintendent pharmacist function in a similar way in their dealings with you. If it is your 'employer' who is behaving improperly, then your responsibility towards him or her and your duty to protect his interests diminishes considerably. You will have a duty to do what you can to prevent the pharmacy staff being put in a difficult position and to encourage your pharmacist colleagues to take their own measures to discharge their responsibilities.

Stage 3: generate options

What could you do?

1. Do nothing and continue with your part-time work
2. Do nothing and seek other employment.

Of these, option 1 is not only unacceptable from the patients' point of view, in that it continues to place them at risk, but you are also compromised by going along with a situation that you know to be wrong. Option 2 removes the latter risk but is still inadequate where the patients' interests are concerned.

3. Confront Mr M. and insist that he stops.

This is not a bad idea if you are sure of your facts. It is just possible that he does not know what the law requires – although the superintendent pharmacist should have told him – and quite possible that he does not know what addicts use to supplement their drug habits. But this still

means that the superintendent and other pharmacists are either unaware of, or think they do not need to worry about, what has been happening.

4. As option 3, but also write down your position and the reasons for it and raise the matter formally with the superintendent pharmacist.

This is better than option 3 because you are protecting your position as well as trying to do something about the situation. Need you go further? What if others, such as staff or pharmacists elsewhere, have noticed illegal or excessive sales of codeine linctus and tell the RPSGB? This is not uncommon. We think that there is yet more you should do.

5. As option 4, but also contact the RPSGB and tell the RPSGB's inspector or the local drug squad officer what has been happening. You should be able to do this without the source of the information becoming publicly known.

In theory, this might be risky while you were still the pharmacist in charge of the pharmacy, because, if you go back to stage 1, under criminal law, offences that could be the subject of prosecution have been taking place. You must set against this risk your conscience as a pharmacist and the further risk that the offences may continue; you may then be involved at a later stage and asked to justify why you failed to take adequate steps to prevent this.

Stage 4: choose an option

What should you do? Not much difficulty here as we hope we have made the case for option 5. Do you agree?

Discussion

This case illustrates that, although liability to prosecution lies only with the owner of the pharmacy business and directors, professional liability applies to all pharmacists when they are in charge of a pharmacy, even though they might not be physically present during lunch times or tea breaks. Staff working in a pharmacy must understand the limits of what they are permitted to do in law, and that includes non-pharmacist directors. The superintendent pharmacist in particular must repeatedly make this clear to those affected.

There are many other 'irregularities' that you might come across. What might you do in situations such as the following:

- you become aware that a fellow employee pharmacist is helping himself to dispensary stock – you think that it includes diazepam and temazepam
- you discover a member of staff is regularly allowed to ‘borrow’ against her next prescriptions, which do not seem to arrive
- you become aware that several members of staff are supplying codeine linctus freely because (a) they are being threatened with violence and feel intimidated or (b) one of them has a boyfriend among the local drug users
- you become aware that a locum pharmacist seems to be ‘doctoring’ the ‘till receipts when she is working on the counter; you think she may be stealing money.

13 PROBLEM

A matter of confidentiality

With the almost universal use of computerised patient medication records and closer working relationships with other healthcare professionals, pharmacists are acquiring significant quantities of sensitive data that are related to identifiable individuals. Try this problem.



SCENARIOS

The suicide and his girlfriend

A young man and his girlfriend, Miss Wright, bought a house together on an endowment mortgage, but three years after moving in the young man committed suicide. Miss Wright notified the insurance company, which demanded further information about the man's medical history before agreeing to pay on the policy. She comes into your pharmacy, tells you all this and asks for a printout of her boyfriend's medicines for the last three years.

What issues should I consider?

- Data Protection Act 1998
- Access to Health Records Act 1990
- Ownership of NHS records
- Duty of confidentiality
- Principles of defamation
- Key responsibilities of a pharmacist in the Code of Ethics; specific guidance on confidentiality
- Pathology: consequences of disclosure
- Use of outside resources, e.g. employer, professional organisation
- Urgency of need.

Where should I look in *Pharmacy Law and Ethics*?

Data Protection issues (Chapter 21)

Confidentiality, defamation (Chapter 23)

Code of Ethics (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

The Data Protection Act (Chapter 21) covers all information, whether computerised or held on paper, that relates to an identifiable, living human being. It sets out eight principles, which cover the proper management of this ‘personal data’; breaches of which are criminal offences. In this instance, you have to be sure of who owns and, therefore, controls access to these data and that you can lawfully disclose the information requested. The Act makes clear the accountability of the person or organisations that process the data (i.e. the ‘data controller’).

In community pharmacy, patient medication records are the property of the pharmacist or pharmacy company that holds them. Contrast this with the hospital and GP service, where the medical records (which include medication details) are generally accepted to be the property of the local health body. The Act also defines the accountability of the ‘data processor’ – which is you.

Records relating to patients kept by pharmacists are additionally ‘health records’ as defined under the Access to Health Records Act (Chapter 21). Although this Act was mostly repealed by the 1998 Data Protection Act, it retained provisions relating to access to health records after the patient’s death for the executor or administrator of deceased person’s estate. The Data Protection Act no longer applies after the death of the data subject, but other obligations continue when the record is a health record.

What NHS law applies here?

There are no requirements in the Terms of Service to keep patient medication records. However, to qualify for certain payments under the NHS Terms of Service, there are some provisions in the Drug Tariff as to what they should contain.

What civil law applies here?

Disclosure, or failure to disclose, will not result in physical injury or damage to Miss Wright, still less to her boyfriend. But physical injury is not the only kind of damage. You still have a duty to care for the interests of your patient, even after death, which includes an obligation to keep confidential information that you have acquired about him in the course of your practice. The patient's family and close contacts may suffer distress and embarrassment if the records are freely disclosed – this can also be classed as 'damage', for which compensation can be sought. Miss Wright may suggest that she is incurring unnecessary costs for every month that she has to go on meeting the mortgage until the insurance company pays out. These costs may also be classed as 'damage'. Finally, although this is unlikely with pharmacy records, rude or personal comments that may have been kept in medical records for the information of the holder may be considered defamatory if disclosed. This may result in more grounds for claiming compensation.

What guidance does the Code of Ethics give here?

In the standards of professional performance (Part 2 of the Code of Ethics; see the Appendix), there is a special section spelling out your common law and professional obligations to protect the confidentiality of the records you hold. It goes much further in spelling out circumstances when you might disclose, the most obvious one being where you have the consent of the patient. It also says you can disclose to someone who has a statutory (legal) right to such information.

What professional knowledge do I have which can help here?

You should check the record to see if it discloses evidence of serious conditions, such as HIV infection or cancer, which may cause distress if disclosed. In this case, there might well be evidence of a mental health condition of which Miss Wright may be quite unaware. You should also assess whether there is evidence of prescribing or dispensing errors that, in other circumstances, may be the reason for the request. You should bear in mind the consequences for you and the recipient if this information is disclosed.

Where can I look or who can I ask for help?

If you are an employee, your employer may have a policy and procedures for dealing with requests such as this. Such data may also be commercially sensitive and covered by your general obligation as an employee not to give away your employer's commercial secrets. This is a tricky area and you may want to check with the RPSGB, the NPA or your defence association.

Stage 2: prioritise and ascribe values

Patient

You have a duty to act in the interests of your patient, even when dead. You may have known him well and had an understanding of what he might have wished to happen were he alive. More likely, you will have no insight into this area at all.

Patient's parents, next of kin

You may wish to know whether Miss Wright is the next of kin or whether the deceased's parents are still alive and may have a prior claim to this information. Have the patient's relatives consented to this disclosure? Who has a financial interest here and what would your position be if you contributed to some fraudulent claim under the insurance?

Other healthcare professionals, your profession

We have already hinted that you should be alert to the possibility that the records may be valuable evidence in a medical negligence case. Has the patient's doctor been approached with the same request? As we said in Problem 2, you have a duty not to be gullible and to at least consider the possibility that Miss Wright is not who she says she is or that she is not telling the truth. What evidence does she have of her identity and the truth of her story?

Your employer

In this case, the employer would have vicarious liability for your actions and would probably be considered to be the true owner of the patient medication records. You must, therefore, consider your employer's interests and involve them in your decision.

Yourself

As well as ensuring that you are not yourself at risk from your actions, you may have your own views on the propriety of this claim. Insurance claims are often invalidated by suicide; should this concern you? Do you think it fair that Miss Wright should collect the money? You might also want to think about the means of suicide. If it had been from an overdose, are there any implications for you as the supplier of the medicines or for the prescriber?

Stage 3: generate options

What could you do?

1. Refuse to supply the printout to Miss Wright
2. Require a court order before you will disclose to Miss Wright.

Both of these options, if unhelpful, may seem 'safe'. In fact, they could be unlawful because Miss Wright may have a legal right to see these records. Have a closer look at the requirements of the Access to Health Records Act and you will see that there is a provision whereby anyone who has a claim arising out of a patient's death can require access to the patient's health records. So we had better not choose options 1 or 2.

3. Require a request in writing from Miss Wright, stating authority for claim and precise details required
4. Require a request in writing from the insurance company giving precise details of what is required and why
5. Require a request in writing from the parents or next of kin authorising disclosure.

Now you are thinking hard! And you are thinking defensively, which is increasingly appropriate in modern pharmacy practice. But there is another option, which we said was always worth considering.

6. Delay and pass the query to your employer, head office or defence association, or seek direct legal advice.

Stage 4: choose an option

What should you do? We think you should choose option 6. Do you agree?

There is no great urgency to this request, and you need time to check the veracity of Miss Wright's story. You also need time to check

on your knowledge of the Access to Health Records Act – you may exclude disclosure of information that you consider to be irrelevant to the claim for access or which you think could cause serious harm to the physical and mental health of any individual. You do not even have to inform Miss Wright that you have done this although, of course, you could be challenged on your actions at a later stage.

This has some relevance to the form of information you might supply to Miss Wright. She asks for a printout; not every computer system can provide these, or let you make amendments. It would look very unprofessional if certain parts of the record had been manually obliterated because you thought they were unsuitable. It is probably a better idea to create a letter providing the information you have selected together with any clarifications that you feel are necessary. The legislation allows that the provision of information need not be immediate; you would expect to have time to make reasonable enquiries.

Finally, but importantly, options 3, 4 and 5 all suggest written requests for information.

Taking your time, asking plenty of questions and recording everything is the hallmark of the professional who can show that he or she is taking ‘all reasonable steps’ to discharge their responsibilities conscientiously (see p. 184).

14

PROBLEM

A matter of confidentiality (2)

The concept of confidentiality is far wider than the requirements of the Data Protection Act. It is a fundamental part of healthcare ethics and is now implicit in the provisions of the Human Rights Act 1998, which establish a legal right to respect for private and family life (Article 8). Providers of healthcare have always reasonably argued that patients will withhold sensitive but possibly vital information from their doctors, nurses, etc. if they cannot be confident that such details remain private.

While total privacy has to be balanced against certain statutory or public interest arguments for disclosure (see Chapter 6 of this book), the best rule in cases of uncertainty is to secure the patient's consent to disclosure. To be valid, the patient must be capable of understanding the implications of giving consent (known as having 'capacity' to give consent) and be given as much information as is needed to ensure this understanding ('informed consent'). There is no legal obligation to have written records of consent but in some instances this is a wise precaution.



SCENARIOS

The friend in hospital and her anxious mother

You are a clinical pharmacist working in a psychiatric hospital. On a routine ward visit you are surprised to see a long-standing friend, Emma, has been admitted. After chatting briefly you continue the ward round. As you are leaving about half an hour later, Emma's mother whom you also know confronts you outside the ward. Emma's mother is very agitated and demands to know what is wrong with Emma, what is she taking and when will she be well again? What will you do?

What issues should I consider?

- Data Protection Act
- Health Service circulars in the NHS
- Principles of negligence; breach of confidentiality
- Key responsibilities of a pharmacist in the Code of Ethics
- Nature of Emma's condition and treatment.

Where should I look in *Pharmacy Law and Ethics*?

Data Protection Act (Chapter 21)

Guidance and directions in the NHS (Chapter 26)

Principles of negligence; breach of confidentiality (Chapter 23)

Key responsibilities of a pharmacist in the Code of Ethics (Chapter 23).

Stage 1: gather relevant facts**What criminal law applies here?**

The Data Protection Act 1998 would apply to all data concerning Emma's condition, so her medical records, treatment details and care plan for example are clearly controlled by this Act. The Act also goes on to control consultation and use of such data, so even verbal communications using this information without consent could conceivably be a breach of the Act. The Data Protection Act provides an exemption whereby disclosure of information is permitted if it is necessary for medical purposes and is to a health or other professional or a member of their staff who is bound by a duty of confidentiality; this exemption would not extend to relatives.

What NHS law, including hospital service directions, applies here?

Hospitals and contractors providing NHS services are expected to operate within the Caldicott guidelines (Health Service Circular 2000/009). Your interview and particulars of employment should have included agreement to the maintenance of confidentiality. You should be aware of the NHS Code of Practice on confidentiality (see Chapter 6 of this book), what policies and procedures your hospital has in place over the confidentiality of patient information and what guidance, if any, is given to address this particular situation. This may be a useful source of defence if you decide that you cannot help Emma's mother.

What civil law applies here?

Disclosure of Emma's details to her mother may not result in physical injury to Emma but this is not the only kind of damage that can attract compensation for a breach of duty of care. Anxiety or distress caused by careless disclosure of patient's details could still be regarded as negligent. Even if disclosure without consent did not lead to an action of this nature, it might conceivably jeopardise Emma's progress or treatment and this could result in measurable injury. Finally don't forget that 'damage' can also include financial loss such as loss of earnings caused by delay in Emma's return to work.

What guidance does the Code of Ethics give here?

Your key responsibilities as a pharmacist explicitly include reference to respect for patients' confidentiality and patients' rights to participate in decisions about their care. In addition, a specific section, Part 2, Section C, of the Code of Ethics (see the Appendix) gives detailed guidance of just when the law or public interest might be presumed to override the usual absolute need to ensure the consent of the patient to any disclosure of information about them. Interestingly, this section does not include the fairly obvious situation where patient information needs to be shared between health professionals or carers who need this information to provide their contribution to the overall care of the patient. This may be because of the exemption referred to under the criminal law described above.

What professional knowledge do I have which can help here?

In your position as a clinical ward pharmacist, you will have knowledge of Emma's condition and treatment. You may also have specialised knowledge of the pharmaceutical care of psychiatric patients but this would not increase your duty of confidentiality. This would not vary with the amount of information you have, only its nature. Contrast this with the heightened duty of care you would have in the care of neonates mentioned in Problem 7.

Where can I look or who can I ask for help?

We have already mentioned the probability that your hospital has procedures governing the disclosure and sharing of sensitive patient

information. You will have colleagues on the medical and nursing teams who may be able to provide background or respond to Emma's mother's demands for information.

You may also have access to Emma's full medical record, although this may depend on the hospital's policy.

Stage 2: prioritise and ascribe values

Patient

Quite clearly, it is Emma whose interests and wishes which must prevail in this situation. She has capacity to give consent; you know this because you have talked to her. So there is no reason why she cannot be consulted.

Patient's parents, carers, friends

In some ways your professional knowledge might be a handicap in dealing with her mother's demands since you may be aware that Emma has perhaps a serious condition with a poor prognosis. Your instincts may tell you that her mother should be similarly aware so that she can help and support Emma. However, these sentiments should be resisted since Emma is an adult and competent before the law to manage her own affairs. Nevertheless, you should consider what support you could give her mother short of actually disclosing details about Emma's condition. Perhaps you can offer her a chair and a cup of tea and try to establish what exactly her fears are and how much she knows already.

Other healthcare professionals, your profession

The consultant and other doctors or nurses caring for Emma may already know how much or how little information Emma wants her mother to have. You might expect to discuss Emma's case with your colleagues but bear in mind that such sharing of information must be within the bounds of the Data Protection Act exemption. It would not be appropriate to discuss the case at home with your spouse, for example.

Your employer

Your trust hospital would be vicariously liable if your actions led to a civil action. Hospitals and other bodies in the public eye are vulnerable

to criticism by the media so you will want to be sure that your actions are defensible to a wider world, as well as within the hospital itself.

Yourself

You may find yourself in a true dilemma because of your wish to do as Emma wishes and to relieve her mother's distress. You now have enough facts and priorities to decide what to do.

Stage 3: generate options

What *could* you do?

1. Tell Emma's mother what you know.

We think we have established why this simply is not a defensible option. It would be a breach of confidentiality, a breach of your professional ethics and the law and could have serious consequences for yourself and the hospital, and possibly for Emma.

2. Tell Emma's mother you cannot discuss the matter at all.

This option is certainly safe but is hardly a proper response for a pharmacist. Emma's mother is distressed and you should try to address that as we suggested in stage 2.

3. Take time to sit with Emma's mother and explain why you can't divulge the information she wants, and then decide what further action to take.

Stage 4: choose an option

What *should* you do? We think this is a fairly easy choice to select option 3. Do you agree?

There are various follow-up actions that may result. You might suggest that Emma's mother speaks to the consultant in charge but this may just shift the dilemma away from yourself. The consultant may not know Emma's wishes and Emma's mother may become even more distressed by a second refusal to respond to her. Emma's mother may also have tried to secure this information from the consultant before.

You might suggest that Emma's mother should speak to Emma herself about her concerns. Unfortunately this may cause distress to Emma if she is already struggling with a difficult diagnosis or coming to terms with her condition. Moreover, not all daughters get on with their

mothers and vice versa, so you may just be precipitating some conflict that may make matters worse.

You might volunteer to talk to Emma on her mother's behalf. This is somewhat similar to the 'buy time' option that we suggest you always consider. There is no true urgency to provide this information; it will not change in matter of hours. The urgency is to deal with the mother's distress. You will also have to prepare Emma's mother for the possibility that Emma will not give consent to reveal any more information.

Discussion

Would you think this incident is worth recording and, if so, where? If you believe an incident may have later repercussions or will be needed by other professionals dealing with Emma's care, (and we think both are likely) you should make a signed, dated and timed entry chronologically in Emma's notes. This might be particularly important if you find that although Emma does not want her illness discussed with her mother, she subsequently becomes unable to manage her treatment and suffers adverse events which her mother might have been able to prevent had she been given more information about Emma's condition.

You might like to consider what other options and issues might arise:

- if the patient is under 16
- if the patient has just been told she has terminal cancer
- if the patient is incapacitated through mental illness.

15

PROBLEM

Private beliefs and patients' needs

Pharmacists in community practice do not often have to grapple with their private beliefs in the course of their everyday practice. As medical practice, and the pharmaceutical practice that complements it, makes progress, issues surrounding the concepts of the beginning and end of life are increasingly likely to be raised and actions called into question. Try this problem.



SCENARIOS

The adolescent girl and the Levonelle

Your pharmacy is in the heart of a major city and is open for long hours, seven days a week. You do the late shifts and many of your regular customers are 'clubbers' whom you have got to know personally. It is Good Friday, it is 7.00 p.m. and one of your regulars, who calls herself Deedee, comes in to ask if you can supply her with some Levonelle tablets. She has had them before from the sexual health clinic within the local hospital. She tells you she had a wild night with a group of boys last night, had unprotected sex and the clinic does not open until Easter Tuesday. What will you do?

What issues should I consider?

- Criteria for making an 'emergency supply'
- Use of Patient Group Directions
- The principles of negligence
- Key responsibilities of a pharmacist in the Code of Ethics
- Personal responsibilities when providing professional services
- Action, uses and conditions of marketing authorisation for Levonelle
- Use of outside resources, e.g. reference books, local support services.

Where should I look in *Pharmacy Law and Ethics*?

'Emergency supply' (Chapter 8)

Patient Group Directions (Chapters 8 and 9)

Negligence (Chapter 23)

Code of Ethics (Chapter 23).

Before embarking on this problem, you should ensure you know about the two presentations of Levonelle. At the time of writing (August 2006), this medicine existed in two forms: Levonelle 1500, a POM and Levonelle One Step, a pharmacy medicine. Look up their details to see how the conditions of marketing vary. One crucial piece of information will be Deedee's age. She eventually tells you that she is 14.

Stage 1: gather relevant facts**What criminal law applies here?**

We have covered the requirements for 'emergency' supply in Problems 1 and 2. Provided that you could establish from your patient medication record or by some other means that Deedee has previously had Levonelle prescribed, and you know the dose, you could decide that the 'emergency' supply provisions apply, but this does not seem likely in this case. Much more likely, however, is that this is not a simple question of whether to make an 'emergency supply' of a POM. Deedee probably received Levonelle 1500 without a prescription under the terms of a Patient Group Direction at the hospital.

We have seen in Problem 6 and 7 that, if a pharmacy medicine is supplied for use in circumstances outside its marketing authorisation, the product will be controlled as a POM. To knowingly supply Levonelle One Step, which is authorised only for supply to patients of 16 or over, to a young girl who is under 16 could be an offence under the Medicines Act.

What NHS law applies here?

It is also possible that a Patient Group Direction may be in place locally setting out how emergency hormonal contraception might be supplied from certain pharmacies. If this were the case, then any pharmacist who makes such supplies does so within the terms of a contract with the local

health body that drew up the Patient Group Direction. This has implications for liability if the pharmacist goes outside the terms of the Direction but also gives scope to supply Levonelle 1500 free of charge within the NHS (where a prescription levy would not apply) and also under the wider marketing authorisation conditions of Levonelle 1500.

What civil law applies here?

You have a duty of care towards all your patients, including Deedee, regardless of their lifestyle or how they came to be in need of your help. However, that is some way from saying that if you do not help you could be liable for the consequences. Rather more likely, unfortunately, is that you may be held liable for any adverse effects arising from the use of Levonelle if you do supply it. One issue to consider is Deedee's age. In Scotland, the law on the age at which minors (young people) can give consent to treatment is taken to be when in the opinion of a qualified medical practitioner the patient is capable of understanding the nature and possible consequences of the procedure or treatment.

A similar position was reached in England and Wales in a test case brought by a Mrs Gillick against a health authority; this is now usually referred to as demonstrating 'Gillick competence' or applying the 'Fraser ruling' – (Lord Fraser being one of the judges hearing the case; see p. 127). This interpretation has come to apply to the judgement of any health professional who is involved in dealing with young people. Do you think that Deedee is likely to continue to have unprotected sex and/or that her health might suffer if she does? Do you think she will understand any advice that you give her? Do you think she can be persuaded to tell her parents of her difficulties? These are some of the questions you should consider when assessing Deedee's competence to make best use of Levonelle.

What guidance does the Code of Ethics give here?

The Code of Ethics (see the Appendix) anticipates that some pharmacists may have religious or personal convictions that direct them not to be involved in the supply of products for the control of pregnancy, conception or termination of pregnancy. In Part 2 of the Code, on standards of professional performance, there are matching obligations for individual pharmacists and their managers. You will see that pharmacists are expected to make known to their employer or manager if any such reservations may affect their willingness to undertake certain services

and their employer or manager must make arrangements to accommodate those reservations. However, the Code makes it clear that, even if this does apply to you, you must make every effort to help individuals who need such products, including advising them of an alternative source of supply if necessary.

Moreover, this must be done in a discreet and non-condemnatory manner that fully protects the patient's right to confidentiality. Remember that Part 2C of the Code also makes it clear that you should not normally disclose any patient information to others without consent.

Additionally, the Code has a specific standard, 11, which applies to the supply of emergency hormonal contraception. This makes it clear that you should deal with the request personally and should offer advice on regular methods of contraception, disease prevention and sources of help.

What professional knowledge do I have which applies here? Where can I look or who can I ask for advice?

Levonelle is not a product with serious side-effects but it is not intended as a method of regular contraception. This is a supply over which you must take particular care and you must make a record of the care that you took if you do decide to supply. A detailed briefing on the practice aspects of supply of emergency hormonal contraception is available from RPSGB (2004b).

You will want to ask Deedee if she is taking other medication and, if so, assess whether this will compromise the effectiveness of the Levonelle. You will know that Levonelle should be taken as soon as possible after coitus but will be effective for up to 72 hours afterwards. You may be aware of the availability of doctors over the Easter holiday period who will be better equipped than you to deal with the request if Deedee has some medical contraindication. If Levonelle is contraindicated, one option might be the temporary fitting of an intrauterine device. Even if the surgeries are closed, many local family planning clinics offer emergency helplines and emergency clinics, especially in the major conurbations.

Stage 2: prioritise and assign values

Patient, dependants

It is probably very important to Deedee that she does not become pregnant but she must be fully involved in the decision to use Levonelle and

encouraged to understand the limitations and precautions involved. You must explain the possible consequences and ensure that they are understood.

Your duty as a pharmacist is to do that which is in the interest of the patient, but to do this properly you will have to spell out the limitations on what you can do and be sure that Deedee understands these and the possible consequences, say, if she is already pregnant or if the Levonelle fails and an ectopic pregnancy results.

Patient contacts

You may think it right to enquire as to what method of protection Deedee uses and explore what risks she and her contacts may incur.

Other healthcare professionals, your profession

Given the special nature of this request, you could suggest to Deedee that she should consider consulting her doctor or a clinic that can provide any supporting supplies or advice. If Deedee does not want anyone else informed, including her parents, you must respect that wish.

Yourself

The guidance from the Society does not require you to keep records of supply of Levonelle One Step as a pharmacy medicine, although supplies under a Patient Group Direction may do so. You should consider whether, in this case, you should take steps to protect your own position by writing down what you have done and why, and, ideally, getting written confirmation from Deedee that she has understood and accepts the matters you have discussed. If you decide to supply outside the marketing authorisation you may be liable for the consequences unless you can point to the steps you took to do your best for the patient (see Problems 6 and 7).

We have not yet contemplated the likelihood that you may not think it right to supply Levonelle products to individuals such as Deedee, or even to supply it at all. As we said above, such a position would be covered by your personal responsibilities under Part 2 of the Code of Ethics, which says that if you are of this mind you must nevertheless make every effort to ensure that Deedee receives the help she needs.

Stage 3: generate options

What could you do?

1. Say that you cannot supply the Levonelle
2. Delay and seek advice.

At first sight, this might seem a little unhelpful, as speed is important if Deedee is to be helped. What we are thinking of is a short delay for you to make arrangements to speak to Deedee quietly and calmly, and that might involve asking her to come back in, say, half an hour when you are less busy and have time to ensure that she fully understands the situation, go through the patient leaflet with her and advise on contraception methods. You yourself may also need this time to find out which local pharmacies, if any, are trained and prepared to supply Levonelle under a Patient Group Direction. But you will still have to decide what to do then. We think that you have two further options left:

3. Do everything you can to arrange for Deedee to be seen by a doctor or at the sexual health clinic.

This could be a valid option if Deedee has some medical contraindication to using Levonelle. But we think this is rather unlikely and in any event would have to be balanced against the importance of using Levonelle within 72 hours of unprotected intercourse to be confident that it will be effective.

4. Supply Levonelle and keep full written records of what you explained and confirmation of Deedee's understanding.

Stage 4: choose an option

What should you do? We think that option 4 may well be the best option for Deedee but you would have to be prepared to defend your decision. Do you agree? You should certainly try option 3 as well and do your best to persuade Deedee to be seen by a doctor or in a clinic; perhaps you might offer to help her make the appointment.

Discussion

There are some thought-provoking variations to this scenario:

- what if you suspect that the person seeking the Levonelle has been coerced into having sex or is showing other signs of sexual abuse (see Chapter 6 p. 127)?
- what if you have already made similar supplies to Deedee in the recent past?
- what if a young man comes in making a similar request for his girlfriend?
- what if a request is made in anticipation of unprotected sex?
- what if you think that there is a widespread problem in the area with the clubs and the effect they have on young people's behaviours?

In the last example, should the RPSGB's inspector or the police be informed? Or the local family planning service or sexual health clinic? What about the implications for the spread of sexually transmitted diseases?

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Appendix

Code of Ethics

The Code of Ethics published in this appendix was published by the Royal Pharmaceutical Society of Great Britain in August 2007. Readers should consult the Society's website (www.rpsgb.org) for the most up to date version of the Code of Ethics and its supporting professional standards and guidance documents.

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Code of Ethics for Pharmacists and Pharmacy Technicians

About this document

Registration as a pharmacist or pharmacy technician carries obligations as well as privileges. It requires you to:

- develop and use your professional knowledge and skills for the benefit of those who seek your professional services,
- maintain good professional relationships with others, and
- act in a way that promotes confidence and trust in the pharmacy professions.

The Code of Ethics sets out the principles that you must follow as a pharmacist or pharmacy technician. The Code is the Society's core guidance on the conduct, practice and professional performance expected of you. It is designed to meet our obligations under The Pharmacists and Pharmacy Technicians Order 2007 and other relevant legislation. The principles of the Code are intended to guide and support the work you do and the decisions you make. They also inform the general public of the standards of behaviour that can be expected from the pharmacy professions. The Code underpins all

other standards and guidance we issue. We will review the Code in the light of changes within the professions or healthcare environment.

The Code is founded on seven principles which express the values central to the identity of the pharmacy professions. The seven principles and their supporting explanations encapsulate what it means to be a registered pharmacist or pharmacy technician. Making these principles part of your professional life will maintain patient safety and public confidence in the professions.

As well as the Code of Ethics, we have produced supporting standards and guidance documents that expand on aspects of the Code, or provide more detailed guidance on specific areas of pharmacy practice. You can download these documents and more copies of the Code from our website at www.rpsgb.org, or you can telephone us on 020 7735 9141.

Status of the Code of Ethics

The principles of the Code of Ethics are mandatory. As a registered pharmacist or pharmacy technician your professional and personal conduct will be judged against the Code. You must abide by its principles irrespective of the job you do. Disreputable behaviour, even if it is not directly connected to your professional practice, or failure to comply with the principles identified in the Code could put your registration at risk. The Society's fitness to practise committees will take account of the Code in considering cases that come before them but are not limited solely to the matters mentioned in it. They will consider the circumstances of an individual case when deciding whether or not action should follow.

The Seven Principles

As a pharmacist or pharmacy technician you must:

1. MAKE THE CARE OF PATIENTS YOUR FIRST CONCERN
2. EXERCISE YOUR PROFESSIONAL JUDGEMENT IN THE INTERESTS OF PATIENTS AND THE PUBLIC
3. SHOW RESPECT FOR OTHERS
4. ENCOURAGE PATIENTS TO PARTICIPATE IN DECISIONS ABOUT THEIR CARE
5. DEVELOP YOUR PROFESSIONAL KNOWLEDGE AND COMPETENCE

6. **BE HONEST AND TRUSTWORTHY**
7. **TAKE RESPONSIBILITY FOR YOUR WORKING PRACTICES**

Applying the principles

Pharmacists have overall responsibility for the provision of pharmaceutical services. Pharmacy technicians undertake work to support, develop or provide these services. Every registered pharmacy professional is responsible for their own actions.

It is your responsibility as a pharmacist or pharmacy technician to apply the principles of the Code of Ethics to your daily work, whether or not you routinely treat or care for patients. You must be able to show that you are aware of the Code and have followed the principles it lays down.

You are professionally accountable for your practice. This means that you are answerable for your acts and omissions, regardless of advice or directions from your manager or another professional. You are expected to use your professional judgement in the light of the principles of the Code and must be prepared to justify your actions if asked to do so.

Users of pharmaceutical services include patients, customers and clients. The Code uses the term patient(s) to encompass any individuals or groups who access or are affected by your professional pharmacy services or advice. If you offer veterinary pharmacy services, the term patient also extends to the animals you provide services for.

The work of pharmacists and pharmacy technicians takes many different forms and accordingly not all of the principles will be applicable to every situation you find yourself in. The seven principles are of equal importance. Each principle is supported by a series of statements that explain the types of action and behaviour expected of you when applying the principles in practice. These are not exhaustive. In meeting the principles of the Code you are expected to comply with other accepted standards and take account of guidance issued by the Society or other relevant organisations.

From time to time you may be faced with conflicting professional obligations or legal requirements. In these circumstances you must consider fully the options available to you, evaluate the risks and benefits associated with possible courses of action and determine what is most appropriate in the interests of patients and the public.

1. MAKE THE CARE OF PATIENTS YOUR FIRST CONCERN

The care, well-being and safety of patients are at the centre of every-day professional practice. They must be your primary and continuing concern when practising, irrespective of your field of work. Even if you do not have direct contact with patients your actions or behaviour can still impact on their care or safety. You must:

- 1.1 Provide a proper standard of practice and care to those for whom you provide professional services.
- 1.2 Take steps to safeguard the well-being of patients, particularly children and other vulnerable individuals.
- 1.3 Promote the health of patients.
- 1.4 Seek all relevant information required to assess an individual's needs and provide appropriate treatment and care. Where necessary, refer patients to other health or social care professionals or other relevant organisations.
- 1.5 Seek to ensure safe and timely access to medicines and take steps to be satisfied of the clinical appropriateness of medicines supplied to individual patients.
- 1.6 Encourage the effective use of medicines and be satisfied that patients, or those who care for them, know how to use their medicines.
- 1.7 Be satisfied as to the integrity and quality of products to be supplied to patients.
- 1.8 Maintain timely, accurate and adequate records and include all relevant information in a clear and legible form.
- 1.9 Ensure you have access to the facilities, equipment and materials necessary to provide services to professionally accepted standards.
- 1.10 Undertake regular reviews, audits and risk assessments to improve the quality of services and minimise risks to patient and public safety.

2. EXERCISE YOUR PROFESSIONAL JUDGEMENT IN THE INTERESTS OF PATIENTS AND THE PUBLIC

The need to balance the requirements of individuals with society as a whole and manage competing priorities and obligations is a feature of professional life. Guidelines, targets and financial constraints need to be taken into account, but they must not be allowed to compromise your ability to make an informed professional judgement on what is appropriate for patients in specific situations. When acting in your professional capacity you must:

- 2.1 Consider and act in the best interests of individual patients and the public.
- 2.2 Make sure that your professional judgement is not impaired by personal or commercial interests, incentives, targets or similar measures.

- 2.3 Make best use of the resources available to you.
- 2.4 Be prepared to challenge the judgement of colleagues and other health or social care professionals if you have reason to believe that their decisions could compromise the safety or care of others.
- 2.5 Conduct research and development with integrity and obtain any necessary permissions from the appropriate regulatory authorities.
- 2.6 In an emergency take appropriate action to provide care and reduce risks to patients and the public, taking into account your competence and other options for assistance or care available.

3. SHOW RESPECT FOR OTHERS

Demonstrating respect for the dignity, views and rights of others is fundamental in forming and maintaining professionally appropriate relationships with patients, their carers, colleagues and other individuals with whom you come into contact with. In your professional practice you must:

- 3.1 Recognise diversity and respect the cultural differences, values and beliefs of others.
- 3.2 Treat others politely and considerately.
- 3.3 Make sure your views about a person's lifestyle, beliefs, race, gender, age, sexuality, disability or other perceived status do not prejudice their treatment or care.
- 3.4 Ensure that if your religious or moral beliefs prevent you from providing a particular professional service, the relevant persons or authorities are informed of this and patients are referred to alternative providers for the service they require.
- 3.5 Respect and protect the dignity and privacy of others. Take all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information and ensure that you do not disclose confidential information without consent, apart from where permitted to do so by the law or in exceptional circumstances.
- 3.6 Obtain consent for the professional services, treatment or care you provide and the patient information you use.
- 3.7 Use information obtained in the course of professional practice only for the purposes for which it was given or where otherwise lawful.
- 3.8 Take all reasonable steps to ensure appropriate levels of privacy for patient consultations.
- 3.9 Maintain proper professional boundaries in the relationships you have with patients and other individuals that you come into contact with during the course of your professional practice, taking special care when dealing with vulnerable individuals.

4. ENCOURAGE PATIENTS TO PARTICIPATE IN DECISIONS ABOUT THEIR CARE

Patients have a right to be involved in decisions about their treatment and care. They should be encouraged to work in partnership with you and other members of the professional team to manage their healthcare needs. Successful partnership working requires effective communication and an ability to identify the individual needs of patients. Where patients are not legally capable of making decisions about their care you must seek the authority of persons who are empowered to make decisions on their behalf. You must:

- 4.1 When possible, work in partnership with patients, their carers and other healthcare professionals to manage the patient's treatment and care. Explain the options available and help individuals to make informed decisions about whether they wish to use particular services or treatment options.
- 4.2 Listen to patients and their carers and endeavour to communicate effectively with them. Ensure that, whenever possible, reasonable steps are taken to meet the particular communication needs of the patient.
- 4.3 Take all reasonable steps to share information that patients or their carers want or need in a way that they can understand, and make sure that the information you provide is impartial, relevant and up to date.
- 4.4 Subject to paragraph 3.5, ensure that information is shared appropriately with other health and social care professionals involved in the care of the patient.
- 4.5 Respect a patient's right to refuse to receive treatment, care or other professional services.
- 4.6 Consider and whenever possible take steps to address factors that may prevent or deter individuals from obtaining or taking their treatment.
- 4.7 Ensure that when a patient is not legally competent, any treatment or care you provide is in accordance with the appropriate legal requirements.

5. DEVELOP YOUR PROFESSIONAL KNOWLEDGE AND COMPETENCE

At all stages of your professional working life you must ensure that your knowledge, skills and performance are of a high quality, up to date and relevant to your field of practice. You must:

- 5.1 Maintain and improve the quality of your work by keeping your knowledge and skills up to date, evidence-based and relevant to your role and responsibilities.
- 5.2 Apply your knowledge and skills appropriately to your professional responsibilities.
- 5.3 Recognise the limits of your professional competence; practise only in those areas in which you are competent to do so and refer to others where necessary.

- 5.4 Undertake and maintain up-to-date evidence of continuing professional development relevant to your field of practice.
- 5.5 Respond constructively to the outcomes of assessments, appraisals and reviews of your professional performance and undertake further training where necessary.
- 5.6 Practise only if you are fit and competent to do so. Promptly declare to the Society, your employer and other relevant authorities any circumstances that may call into question your fitness to practise or bring the pharmacy professions into disrepute, including ill health that impairs your ability to practise, criminal convictions and findings by other regulatory bodies or organisations.

6. BE HONEST AND TRUSTWORTHY

Patients, colleagues and the public at large place their trust in you as a pharmacy professional. You must behave in a way that justifies this trust and maintains the reputation of your profession. You must:

- 6.1 Uphold public trust and confidence in your profession by acting with honesty and integrity.
- 6.2 Ensure you do not abuse your professional position or exploit the vulnerability or lack of knowledge of others.
- 6.3 Avoid conflicts of interest and declare any personal or professional interests to those who may be affected. Do not ask for or accept gifts, inducements, hospitality or referrals that may affect, or be perceived to affect, your professional judgement.
- 6.4 Be accurate and impartial when teaching others and when providing or publishing information to ensure that you do not mislead others or make claims that cannot be justified.
- 6.5 Adhere to accepted standards of personal and professional conduct.
- 6.6 Comply with legal requirements, mandatory professional standards and accepted best practice guidance.
- 6.7 Honour commitments, agreements and arrangements for the provision of professional services.
- 6.8 Respond honestly, openly and courteously to complaints and criticism.

7. TAKE RESPONSIBILITY FOR YOUR WORKING PRACTICES

Team working is a key feature of everyday professional practice and requires respect, co-operation and communication with colleagues from your own and other professions. When working as part of a team you remain accountable for your own decisions, behaviour and any work done under your supervision. You must:

- 7.1 Communicate and work effectively with colleagues from your own and other professions and ensure that both you and those you employ or supervise have sufficient language competence to do this.
- 7.2 Contribute to the development, education and training of colleagues and students, sharing relevant knowledge, skills and expertise.
- 7.3 Take responsibility for all work done by you or under your supervision. Ensure that individuals to whom you delegate tasks are competent and fit to practise and have undertaken, or are in the process of undertaking, the training required for their duties.
- 7.4 Be satisfied that appropriate standard operating procedures exist and are adhered to, and that clear lines of accountability and verifiable audit trails are in place.
- 7.5 Ensure that you are able to comply with your legal and professional obligations and that your workload or working conditions do not compromise patient care or public safety.
- 7.6 Make sure that your actions do not prevent others from complying with their legal and professional obligations, or present a risk to patient care or public safety.
- 7.7 Ensure that all professional activities undertaken by you, or under your control, are covered by appropriate professional indemnity arrangements.
- 7.8 Be satisfied that there is an effective complaints procedure where you work and follow it at all times.
- 7.9 Raise concerns if policies, systems, working conditions, or the actions, professional performance or health of others may compromise patient care or public safety. Take appropriate action if something goes wrong or if others report concerns to you.
- 7.10 Co-operate with investigations into your or another healthcare professional's fitness to practise and abide by undertakings you give or any restrictions placed on your practice.

Guidance that Supports the Code of Ethics

Supporting standards and guidance documents that expand on aspects of the Code, or provide more detailed guidance on specific areas of pharmacy practice are available on the Society's website at www.rpsgb.org. You can also telephone us on 020 7735 9141 or e-mail us at enquiries@rpsgb.org.

Other Sources of Advice

Further advice on the Code, or other professional or legal obligations, can be obtained by contacting our legal and ethical advisory service on 020 7572 2308.

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