Statutory Document No. 2005/0011

Medicines Act 2003

PRESCRIPTION ONLY MEDICINES (HUMAN USE) REGULATIONS 2005[1]

Approved by Tynwald: *17 January 2006*
Coming into Operation: *1 February 2006*

In exercise of the powers conferred on the Department of Health and Social Security by sections 2 and 52 of the Medicines Act 2003[1] and of all other enabling powers, the following Regulations are hereby made: —

1 Citation and commencement

These Regulations may be cited as the Prescription Only Medicines (Human Use) Regulations 2005, and shall come into operation on the 1st February 2006.

2 Application of UK prescription-only orders

The provisions of —

(a) the Prescription Only Medicines (Human Use) Order 1997[2]

(b) the orders amending that Order specified in Schedule 1; and,

(c) any order made after the making of these Regulations and amending that Order,

being orders made under the provisions of the Medicines Act 1968 (An Act of Parliament)[3] corresponding to section 2 of the Medicines Act 2003, shall apply to the Island subject to the modifications specified in Schedule 2.

3 Revocations

The Prescription Only Medicines (Human Use) Order 1997[4] is revoked.

MADE **9 DECEMBER 2005**

[1] 2003 c.4
[2] SI 1997/1830
[3] 1968 c.67
[4] SD 486/97

SCHEDULE 1

AMENDING ORDERS APPLIED TO THE ISLE OF MAN

[Regulation 2]

Reference	*Title*
SI 997/2044	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1997
SI 1998/108	Prescription Only Medicines (Human Use) Amendment Order 1998
SI 1998/1178	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1998
SI 1998/2081	Prescription Only Medicines (Human Use) Amendment (No.3) Order 1998
SI 1999/1044	Prescription Only Medicines (Human Use) Amendment Order 1999
SI 1999/3463	Prescription Only Medicines (Human Use) Amendment (No.2) Order 1999
SI 2000/1917	Prescription Only Medicines (Human Use) (Amendment) Order 2000
SI 2000/2899	Prescription Only Medicines (Human Use) Amendment (No.2) Order 2000
SI 2000/3231	Prescription Only Medicines (Human Use) Amendment (No.3) Order 2000
SI 2001/2777	Prescription Only Medicines (Human Use) Amendment Order 2001
SI 2001/2889	Prescription Only Medicines (Human Use) (Electronic Communications)Order 2001
SI 2001/3942	Prescription Only Medicines (Human Use) Amendment (No.2) Order 2001
SI 2002/549	Prescription Only Medicines (Human Use) (Amendment) Order 2002
SI 2003/696	Prescription Only Medicines (Human Use) (Amendment) Order 2003
SI 2003/2915	Prescription Only Medicines (Human Use) (Amendment) (No.2) Order 2003
SI 2004/2	Prescription Only Medicines (Human Use) (Amendment) Order 2004
SI 2004/1189	Prescription Only Medicines (Human Use) (Amendment) (No,2) Order 2004
SI 2004/2693	Prescription Only Medicines (Human Use) Amendment (No.3) Order 2004
SI 2005/765	The Medicines for Human Use (Prescribing) Order 2005

SCHEDULE 2[2]

[Regulation 2]

MODIFICATIONS SUBJECT TO WHICH THE ORDERS APPLY TO TIIE ISLAND

PART 1 - GENERAL MODIFICATIONS

(1) For any reference to a matter specified in column 1 of the following table, substitute a reference to the corresponding matter specified in column 2 of that table:

Column 1	*Column 2*
the Medicines Act 1968[5] (of Parliament)	the Medicines Act 2003
[Revoked][3]	[Revoked][4]
section 58(2) of the Medicines Act 1968[5]	section 5(2) of the Medicines Act 2003[6]
section 58(2)(a) of the Medicines Act 1968[6][7]	section 5(2)(a) of the Medicines Act 2003[8]
section 58(2)(b) of the Medicines Act 1968[9]	section 5(2)(b) of the Medicines Act 2003[10]
section 69 of the Medicines Act 1968	Section 35 of the Medicines Act 2003
the Misuse of Drugs Act 1971[7] (of Parliament)	the Misuse of Drugs Act 1976
[Revoked][11]	[Revoked][12]
the National Health Service Act 1977 (of Parliament)[8]	the National Health Service Act 2001
[Revoked][13]	[Revoked][14]
any mention of the following: (i) NHS Trust; (ii) NHS Foundation Trust; (iii) Health Authority; (iv) Local Health Board; (v) Primary Care Trust; (vi) Special Health Authority; (vii) Secretary of State	the Department
nurse independent prescriber	independent nurse prescriber
nursing home	adult care home
police force	Isle of Man Constabulary
relevant manager	registered manager

(2) Unless otherwise specified, any reference to an enactment is to be read as an enactment of Tynwald.

[5] 1968 c.67
[6] 1968 c.67
[7] 1971 c.38
[8] 1977 c.49

(3) Omit any reference to, and if applicable, any definitions for, —

(a) "police service" and "police service of Northern Ireland";

(b) the "Common Services Authority";

(c) "(restrictions on sale, supply and administration)" where it appears after "section 58(2)";

(d) "(restriction on sale and supply)" where it appears after "section58(2)(a)";

(e) the "Common Services Agency";

(f) the "ministers".

PART 2

SPECIFIC MODIFICATIONS

1 Article 1 modified

(1) In article 1(2) (citation, commencement and interpretation) at the appropriate place insert —

"**adult care home**" has the same meaning as in section 16 of the Regulation of Care Act 2013;";

"**appropriate practitioner**" has the same meaning as in article 2;";

"**care service**" has the same meaning as in Part 1 of the Regulation of Care Act 2013;";

"**chiropractor**" means a registered chiropractor;" ;

"**coronavirus**" means severe acute respiratory syndrome coronavirus 2 (SARSCoV-2);";

"**health care professional**" means —

(a) a health care professional regulated by the Health Care Professionals Act 2014;

(b) a dentist;

(c) a registered dental care professional, as defined in section 11 of the Dental Act 1985;

(d) a pharmacist;";

"**the Health and Care Professions Council register**" means the register established and maintained by the Health and Care Professions Council under article 5 (establishment and maintenance of register) of the Health and Social Work Professions Order 2001 (of Parliament)[9];";

[9] SI 2002/254

"**independent care service**" has the same meaning as in section 10 of the Regulation of Care Act 2013 ;";

"**independent nurse prescriber**" means a person —

(a) who is a nurse or a midwife; and

(b) is noted in the Nursing and Midwifery Register as qualified to order drugs, medicines and appliances as an independent nurse prescriber or an nurse independent/ supplementary prescriber and is also recorded in that register;";

"**midwife**" means a registered midwife;";

"**NHS Act 2001**" means the National Health Service Act 2001;";

"**nurse**" means a registered nurse;";

"**Nursing and Midwifery Register**" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 (of Parliament)[10];";

"**occupational health vaccinator**" means a health care professional who is employed or engaged by a person operating an occupational health scheme who is, —

(a) a nurse or midwife;

(b) an operating department practitioner, a paramedic or a physiotherapist; or

(c) a pharmacist;";

"**operating department practitioner**" means a registered operating department practitioner;";

"**paramedic independent prescriber**" means a person, —

(a) who is a paramedic; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;";

"**physiotherapist**" means a registered physiotherapist;";

"**physiotherapist independent prescriber**" means a person —

(a) who is a physiotherapist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;";

"**podiatrist**" means a registered podiatrist;";

[10] SI 2002/0253

"**podiatrist independent prescriber**" means a person, —

(a) who is a podiatrist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a podiatrist independent prescriber;";

"**radiographer**" means a registered radiographer;";

"**the registered manager**" is someone who is registered under Part 3 of the Regulation of Care Act 2013;";

"**registered medical practitioner**" has the same meaning as in the Health Care Professionals Act 2014;";

"**school**" means a school or a nursery school within the meaning of section 59(1) of the Education Act 2001;";

"**serious shortage protocol**" means a written protocol that, —

(a) is issued by the Department if the Island is, in the opinion of the Department, experiencing or may experience a serious shortage of, —

(i) a prescription only medicine; or

(ii) any other specified drug or appliance;

(b) provides for the supply by a pharmacist of a different quantity, strength or pharmaceutical form of the prescription only medicine to that which is ordered on a prescription form or repeatable prescription, subject to any conditions which may be specified in the protocol; and

(c) specifies the period for which the protocol is to have effect;";

"**SSP**" means serious shortage protocol;";

"**special medical prescription**" means a prescription for any substance or product for the time being specified in schedules 1, 2 or 3 to the Misuse of Drugs Regulations;";

"**temporary authorisation**" means an authorisation granted by the UK licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc) of the Human Medicines Regulations 2012 (of Parliament)[11];";

"**therapeutic radiographer independent prescriber**" means a person, —

(a) who is a radiographer; and

(b) against whose name is recorded in the relevant register, —

[11] SI 2012/1916

(i) an entitlement to use the title "**therapeutic radiographer**"; and

(ii) an annotation signifying that the person is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;"; and

"**UK licensing authority**" means either or both of the United Kingdom Secretary of State and the Minister for Health, Social Services and Public Safety responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under the Human Medicines Regulations 2012 (of Parliament)[12];".

(2) In article 1(2) (citation, commencement and interpretation) for the definition of —

(a) "health prescription" substitute —

"health prescription" means a prescription issued by a prescriber under, or by virtue of, the NHS Act 2001;";

(b) "health record" substitute —

"health record" means a record which, —

(a) consists of data concerning health; and

(b) has been made by or on behalf of a health care professional in connection with the diagnosis, care or treatment of the natural person to whom the data relates;";

(c) "independent clinic" substitute —

"independent clinic" has the same meaning as in section 26 of the Regulation of Care Act 2013;";

(d) "independent hospital" substitute —

"independent hospital" has the same meaning as in section 27 of the Regulation of Care Act 2013;";

(e) "independent medical agency" substitute —

"independent medical agency" has the same meaning as in section 28 of the Regulation of Care Act 2013;";

(f) "IRME practitioner" substitute —

"IRME practitioner" means in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2019[13];";

(g) "master" substitute —

[12] SI 2012/1916

[13] SD 2019/0282

"master" has the same meaning as in section 78 of the Merchant Shipping Registration Act 1991;";

(h) "medical exposure" substitute —

"medical exposure" means the exposure to ionising radiation of any of the following persons —

(a) patients as part of their own medical diagnosis or treatment;

(b) individuals as part of health screening programmes;

(c) patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) carers or comforters;

(e) asymptomatic individuals; and

(f) individuals undergoing non-medical imaging using medical radiological equipment;";

(i) "Misuse of Drugs Regulations" substitute —

"the Misuse of Drugs Regulations" means the Misuse of Drugs Regulations 2001 (of Parliament)[14] as applied to the Island[15];";

(j) "offshore installation" substitute —

"offshore installation" means any installation which is or has been maintained, or is intended to be established, for the carrying on of any activity to which the Mineral Workings (Offshore Installations) (Isle of Man) Act 1974 applies;";

(k) "operator" substitute —

"operator" —

(a) in relation to an aircraft, means the person for the time being having management of the aircraft; and

(b) for the purposes of article 7B, means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated, medical physics experts and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training;";

(l) "prison service" substitute —

"prison service" means the exercising of functions in relation to prisons and prisoners by the Department of Home Affairs under the Custody Act 1995;";

[14] SI 2001/3998

[15] SD 0310/13 (as amended by SD 2016/0254)

(m) "registered dietitian" substitute —

"dietitian" means a registered dietitian;";

(n) "registered ophthalmic optician" substitute —

"optometrist" means a registered optometrist whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989 (of Parliament)[16];";

(o) "registered orthoptist" substitute —

"orthoptist" means a registered orthoptist;";

(p) "orthotist and prosthetist" substitute —

"orthotist and prosthetist" means a registered orthotist and prosthetist;";

(q) "registered provider" substitute —

"registered provider" means a person who carries on an independent care service the and is registered under Part 3 of the Regulation of Care Act 2013;";

(r) the "relevant register" substitute —

"relevant register" means, —

(a) in relation to a pharmacist, —

(i) Part 1 of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010 (of Parliament)[17], or

(ii) in Northern Ireland, the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976[18];

(b) in relation to a nurse or midwife, the Nursing or Midwifery Register;

(c) in relation to an optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989 (of Parliament)[19]; and

(d) in relation to a chiropodist or podiatrist, a dietitian, a physiotherapist, an orthoptist, a paramedic or a radiographer, the applicable part of the Health and Care Professions Council register relating to, —

(i) chiropodists and podiatrists;

(ii) physiotherapists;

[16] 1989 c.44

[17] SI 2010/231 as amended

[18] SI 2010/1213 (N.I. 22) as amended

[19] 1989 c.44

(iii) radiographers;

(iv) orthoptists;

(v) dietitians; or

(v) paramedics,

as the case may be;";

(s) "registered speech and language therapist" substitute —

""speech and language therapist" means a registered speech and language therapist;";

(t) "sell" substitute —

""sell" means sell by retail as defined in section 53 of the Act and "sale" has a corresponding meaning;";

(u) "state registered chiropodist" substitute —

""chiropodist" means a registered chiropodist;";

(v) "state registered paramedic" substitute —

""paramedic" means a registered paramedic;";

(w) "supplementary prescriber" substitute —

""supplementary prescriber" means a person who is noted in the relevant register as qualified to order drugs, medicines and appliances as a supplementary prescriber (or, in the case of a nurse or midwife, as a nurse independent /supplementary prescriber) and is, —

(a) a pharmacist;

(b) a midwife;

(c) a nurse;

(d) a chiropodist, podiatrist, physiotherapist, paramedic or radiographer;

(e) an optometrist; or

(f) a dietitian;";

(x) for "supply" substitute —

""supply" means supply in circumstances corresponding to retail sale as defined in section 53 of the Act;"; and

(y) for "marketing authorization" substitute —

""marketing authorization" includes a reference both to a UK authorization and to a Community authorization;".

(3) In article 1(2) (citation, commencement and interpretation) —

(a) in the definition of "community practitioner nurse prescriber"—

(i) omit "registered" where it appears before "nurse" and before "midwife"; and

(ii) for "professional register" substitute "Nursing and Midwifery Register";

(b) in the definition of "dental care professionals register", after "Dentists Act 1984" insert "(of Parliament)[20]";

(c) in the definition of "homoeopathic certificate of registration", after "Regulations 1994" insert "(of Parliament)[21]"; and

(d) omit the following definitions —

(i) "Health Authority";

(ii) "Local Health Board";

(iii) "medicinal product";

(iv) "NHS Trust";

(v) "nurse independent prescriber";

(vi) "nursing Home";

(vii) "Primary Care Trust";

(xi) "professional register";

(xii) "relevant manager"; and

(xiii) "Special Health Authority.".

(4) After article 1(4) (citation, commencement and interpretation), insert —

"(4A) Unless the context otherwise requires, a term not otherwise defined in this Order has the meaning given in the Act.".

2 Article 2 substituted

For article 2 (appropriate practitioners) substitute —

"**2 Appropriate practitioners**

(1) For the purposes of section 5(2)—

(a) in relation to the descriptions and classes of medicinal products specified in article 3, —

(i) a doctor,

(ii) a dentist,

(iii) a supplementary prescriber,

(iv) an independent nurse prescriber, and

(v) a pharmacist independent prescriber

are appropriate practitioners;

[20] 1984 c.24

[21] SI 1994/105

(b) a community practitioner nurse prescriber is an appropriate practitioner in relation to a prescription only medicine specified in Schedule 3;

(c) an optometrist independent prescriber is an appropriate practitioner in relation to the descriptions and classes of medicinal products specified in article 3 other than, —

(i) a medicinal product that is a product subject to special medical prescription, or

(ii) a medicinal product that is for parenteral administration;

(d) a podiatrist independent prescriber is an appropriate practitioner in relation to the descriptions and classes of medicinal products specified in article 3 unless that medicinal product contains a product subject to special medical prescription other than, —

(i) Dihydrocodeine, or

(ii) Temazepam;

(e) a physiotherapist independent prescriber is an appropriate practitioner in relation to the descriptions and classes of medicinal products specified in article 3 unless that medicinal product contains a product subject to special medical prescription other than, —

(i) Dihydrocodeine,

(ii) Fentanyl,

(iii) Morphine,

(iv) Oxycodone, or

(v) Temazepam;

(f) a therapeutic radiographer independent prescriber is an appropriate practitioner in relation to the descriptions and classes of medicinal products specified in article 3 unless that medicinal product contains a product subject to special medical prescription other than, —

(i) Codeine,

(ii) Fentanyl,

(iii) Midazolam,

(iv) Morphine,

(v) Oxycodone,

(vi) Temazepam, or

(vii) Tramadol; and

(g) a paramedic independent prescriber is an appropriate practitioner in relation to the descriptions and classes of

medicinal products specified in article 3 unless that medicinal product contains a product subject to special medical prescription other than, —

(i) Codeine,

(ii) Fentanyl,

(iii) Midazolam, or

(iv) Morphine.

(2) This article is subject to the exemptions set out in this Order.".[15]

3 Article 3 modified

(1) In article 3 (medicinal products on prescription only) for "section 58" substitute "article 2".

(2) After paragraph (h), insert —

"(i) a product with a temporary authorisation, in circumstances where the UK licensing authority has attached a condition to the effect that, for the duration of the temporary authorisation, the product is classified as a prescription only medicine."

4 Article 7 modified

In article 7 (exemption for parenteral administration in an emergency to human beings of certain prescription only medicines) —

(a) omit "Dextrose Injection Strong B.P.C.", "Cobalt Edetate Injection" and "Diphenhydramine Injection";

(b) after "Pralidoxime mesilate injection" insert —

"Chlorphenamine injection

Dicobalt Edetate injection

Glucose injection;" ; and

(c) after "Hydrocortisone Injection" insert —

"Naloxone Hydrochloride".

5 Article 7A modified

(1) Article 7A (exemptions for administration of smallpox vaccine) is modified as follows.

(2) In paragraph (1) after "(restriction on administration)" insert "of the Medicines Act 1968 (of Parliament)[22]".

(3) For paragraph (2)(a), substitute —

[22] 1968 c.67

"(a) the vaccine has been supplied by, or on behalf of, or under arrangements made by the Department; and".

(4) In paragraph (2)(b), for "United Kingdom" substitute "Isle of Man".

(5) Omit paragraph (4).

6 Article 7B modified

(1) Article 7B (exemption for administration by operators) is modified as follows.

(2) In paragraph (2)(a), for "regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000" substitute "regulation 7(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2019[23]".

(3) In paragraph (2)(c), for "certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978" substitute "licence issued under the Ionising Radiation (Medical Exposure) Regulations 2019".

7 Article 8 modified

(1) Article 8 (exemptions for emergency sale or supply) is modified as follows.

(2) For paragraph (1) substitute —

"(1) Section 5(2)(a) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy where the conditions specified in paragraph (2) are satisfied.".[16]

(3) For sub paragraphs (a)-(e) of paragraph (2) substitute —

"(a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by an appropriate practitioner who by reason of an emergency is unable to furnish a prescription immediately;

(b) that the appropriate practitioner has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;

(c) that the prescription only medicine is sold or supplied in accordance with the directions of an appropriate practitioner requesting it;

(d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations; and

(e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous

[23] SD 2019/0282

Provisions) Regulations 1980 (of Parliament)[24] as applied to the Island[25] within the time specified in that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.".

(4) For paragraph 4(a)(ii) substitute —

"(ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by an appropriate practitioner for the person requesting it; and".

(5) For paragraph (6)(b)(i) substitute —

"(i) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by an appropriate practitioner for the person to be treated with it; and".

8 Article 11 modified

In article 11 (exemptions for certain persons) after paragraph (2) insert —

"(3) The following entries in Schedule 5 (exemption for certain persons from section 5(2) of the Medicines Act 2003) cease to have effect on 1 April 2026 —

(a) in Part II (exemptions from the restrictions on supply), entry 5a; and

(b) in Part III (exemptions from restrictions on administration), entry 5a..".[17]

9 Article 12 modified

In article 12(2)(c) (exemption for sale and supply in hospitals), omit "(other than a veterinary surgeon or veterinary practitioner)".

10 Article 12A modified

(1) Article 12A (exemptions for the supply and administration of prescription only medicines) is modified as follows.

(2) For paragraph (1) substitute —

"(1) The restrictions imposed by sections 5(2)(a) and 5(2)(b) do not apply to the supply of a prescription only medicine by —

(a) the Department; or

[24] SI 1980/1923

[25] Applied by SD 12/05

(b) a person, other than an excepted person, pursuant to an arrangement made with the Department for the supply of prescription only medicines,

where the medicine is supplied for the purpose of being administered to a particular person in accordance with the written directions, which need not satisfy the conditions specified in article 15(2), of a doctor or dentist relating to that person.".

(3) For paragraph (2), substitute, —

"(2) The restrictions imposed by sections 5(2)(a) and 5(2)(b) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by, —

(a) the Department; or

(b) a person, other than an excepted person, pursuant to an arrangement made with the Department for the supply of prescription only medicines,

where the medicine is supplied for the purpose of being administered or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (3) are satisfied.".

(4) In paragraph 3(c), for "person specified in column 2 of the Table in Part II of Schedule 7 to this Order ("the authorising person") against the entry in column 1 of that Table" substitute "the Department".

(5) In paragraph 3(e) after "is administered," insert "a temporary authorisation,".[18]

11 Article 12B modified

(1) Article 12B (exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist doctors or dentists in providing national health services) is modified as follows.

(2) In paragraph (2)(d)(ii), for "health authority" substitute "Department".

(3) In paragraph (2)(f), after "is administered," insert "a temporary authorisation,".

(4) Omit paragraph (3).

12 Article 12C modified

(1) Article 12C (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction) is modified as follows.

(2) In paragraph (1)(a)(i)(aa), for "a body referred to in article 12A(a) to (d)" substitute "the Department, or".

(3) In paragraph (1)(a)(i)(bb)—

(a) for "a force or service" substitute "a body"; and

(b) omit "or", being the last word of the provision.

(4) Omit paragraph 1(a)(i)(cc).

(5) In paragraph (2)(c)(i), for "with a body referred to in article 12A(a) to (d), on behalf of that body" substitute "made with the Department, on behalf of the Department".

(6) In paragraph (2)(c)(iii), for " a prison service, by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that service" substitute "the prison service, by or on its behalf".

(7) In paragraph (2)(c)(iv), for "a police force or the Police Services of Northern Ireland" substitute "the Isle of Man Constabulary".

(8) In paragraph (2)(c)(iv)(a), for "the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service" substitute "the Chief Constable".

(9) In paragraph (2)(c)(iv)(b), for "any police force or the Police Service of Northern Ireland" substitute "the Isle of Man Constabulary".

(10) In paragraph (2)(c)(v)—

(a) immediately after "by or on behalf of", insert "—"; and

(b) for "a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces" substitute —

"(aa) the Surgeon General;

(bb) a Medical Director General; or

(cc) a chief executive of an executive agency of the Ministry of Defence;".

(11) In paragraph (2)(cc)(i), for "a body referred to in article 12A(a) to (d), on behalf of that body" substitute "the Department, or on behalf of the Department".

(12) In paragraph (2)(cc)(iii), for "a force or service referred to in article 12E(1)(a)(i) to (iii), by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service" substitute "the prison service or the Isle of Man Constabulary".

(13) In paragraph (2)(cc)(iv) for "column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces" substitute "paragraph (2)(c)(v)".

(14) In paragraph (2)(d) after "is administered," insert "a temporary authorisation,".

13 Article 12D modified

(1) Article 12D (exemption for the supply and administration of prescription only medicines by independent hospitals, clinics and agencies) is modified as follows.

(2) In paragraph (1)(d), for "in Northern Ireland, a nursing home" substitute "an adult care home".

(3) In paragraph (2)(e), after "is administered," insert "a temporary authorisation,".

14 Article 12E[26] modified

(1) Article 12E (exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces) is modified as follows.

(2) In paragraph (1)(a)(i), for "a police force in England, Wales or Scotland" substitute "the Isle of Man Constabulary".

(3) Omit paragraph (1)(a)(ii).

(4) In paragraph (2)(a), for "police force or service" substitute "Isle of Man Constabulary".

(5) For paragraph (2)(d) substitute —

> "(d) the Patient Group Direction is signed by or on behalf of the Isle of Man Constabulary, the prison service or a person specified in article 12C(2)(c)(v) for Her Majesty's Forces by whom, or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care;".

15 Article 12F modified

(1) Article 12F (exemption for the supply of prescription only medicines in the event or anticipation of pandemic disease) is modified as follows.

(2) For paragraph (b)(i), substitute —

> "(i) is approved by the Department; and".

(3) In paragraph (b)(ii)(aa), for "symptoms of, and" substitute "how the medicinal product is to be used for the prevention of, or".

[26] Article inserted by SI 2003/696

16 New article 12G

(1) After article 12F insert —

"12G Protocols relating to coronavirus and influenza vaccinations and immunisations

(1) Section 5(2) does not apply to the supply or administration of a medicinal product —

(a) for parenteral administration; and

(b) used for vaccination or immunisation against coronavirus or influenza virus (of any type),

that meets the following conditions.[19]

(2) Condition A is that the supply is made, or the medicinal product is administered, while a disease (which may be neither coronavirus nor influenza) is, or in anticipation of a disease being imminently —

(a) pandemic; and

(b) a serious risk or potentially serious risk to human health.

(3) Condition B is that the supply or administration is in accordance with the requirements of a protocol that is approved by the Department.

(4) Condition C is that the protocol specifies (amongst other matters) —

(a) the classes of persons permitted to administer medicinal products under the protocol;

(b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer medicinal products under the protocol; and

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers a medicinal product under the protocol.

(5) Condition D is that when the medicine is supplied, there is in force in relation to it —

(a) a temporary authorisation;

(b) a Community authorisation; or

(c) a UK authorisation.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this article has effect, the Department must —

(a) review the operation of this article with a view to evaluating whether there has been any adverse consequences for the

market in prescription only medicines or for patient safety as a consequence of the operation of this article;

(b) set out the conclusions of the review in a report; and

(c) publish the report.".

17 Article 13A[27] modified

(1) Article 13A (exemptions relating to prescriptions given by certain health professionals) is modified as follows.

(2) In paragraph 1, omit "registered" where it appears before "nurse" and "midwife".

(3) In paragraph (1)(d), after "(iii) radiographers: diagnostic or therapeutic, or", insert —

"(iv) paramedics; or

(e) optometrists,".

18 Article 15 modified

(1) Article 15 is modified as follows.

(2) In paragraph (2)(b), for "for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations" substitute "a special medical prescription".

(3) For paragraph (2)(c)(iii), substitute "an indication of the kind of appropriate practitioner giving it".

(4) For paragraph (2)(c)(iv), substitute "the name and address of the person for whose treatment it is given; and",

(5) For paragraph (2)(c)(v), substitute "if that person is under 12, that person's age;".

(6) In paragraph (3), for "health prescription for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations or is given by a veterinary surgeon or a veterinary practitioner" substitute "special medical prescription".

(7) For paragraph (4), substitute —

"(4) The conditions referred to in paragraph (3) are that the prescription shall be, —

(a) created in electronic form;

(b) signed with an advanced electronic signature; and

[27] Article inserted by SI 2002/549

(c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries)".

(8) In paragraph (7) for the definition of, —

(a) "advanced electronic signature" substitute —

"electronic signature" has the meaning given by section 5 of the Electronic Transactions Act 2000;

(b) "electronic communication" substitute —

"electronic communication" has the meaning given by section 12 of the Electronic Transactions Act 2000;

19 New article 15A

(1) After article 15 insert —

"

15A Sale etc. by a pharmacist in accordance with a serious shortage protocol

(1) Section 5(2)(a) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if the conditions in paragraph (2) are met.[20]

(2) The conditions referred to in paragraph (1) are —

(a) the prescription only medicine is sold or supplied for the purpose of being supplied to a person in accordance with a serious shortage protocol (SSP);

(b) the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the prescription only medicine may be sold or supplied; and

(c) the sale or supply of the prescription only medicine is by or under the supervision of a pharmacist who is of the opinion, in the exercise of the pharmacist's professional judgement, that the sale or supply of a different strength, quantity or pharmaceutical form of the prescription only medicine ordered by the prescriber is reasonable and appropriate.".

20 Schedule 5 modified

(1) Schedule 5 (exemption for certain persons from section 58(2) of the Act) is modified as follows.

(2) For the table in Part I (exemption from restrictions on sale or supply) substitute —

"

Column 1	*Column 2*	*Column 3*

Persons exempted	*Prescription only medicines to which the exemption applies*	*Conditions*
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines	1. The sale or supply shall be, —
		(a) subject to the presentation of an order signed by the principal of the institution concerned with education or research or the appropriate head of department in charge of a specified course of research stating-
		(i) the name of the institution for which the prescription only medicine is required,
		(ii) the purpose for which the prescription only medicine is required, and
		(iii) the total quantity required, and
		(b) for the purposes of the education or research with which the institution is concerned.
2. Persons selling or supplying prescription only medicines to any of the following-	2. All prescription only medicines.	2. The sale or supply shall be subject to the presentation of an order signed by or on behalf of any person listed in column 1 of this paragraph stating the status of the person signing it and the amount of prescription only medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.
(1) a public analyst (as defined in the schedule of the Interpretation Act 2015;		
(2) an authorised officer within the meaning of section 46 of the Food Act 1996;		
(3) a person duly authorised by the Department under		

Part 4 of the Act;		
(4) a sampling officer within the meaning of Schedule 1 of the Act.		
3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the NHS Act 2001.	3. All prescription only medicines.	3. The sale or supply shall be-
		(a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only medicine required, and
		(b) for the purposes of a scheme referred to in column 1 in this paragraph.
4. Midwives.	4. Prescription only medicines containing any of the following substances, — (a) Diclofenac; (b) Hydrocortizone Acetate; (c) Miconazole; (d) Nystatin; (e) Phytomenadione.	4. The sale or supply shall be only in the course of their professional practice.
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 35.	5. Items which are, — (a) prescription only medicines which are not for parenteral administration and which, — (i) are eye drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent of Chloramphenicol, or (ii) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or (iii) are prescription only medicines by reason only that they contain any of the following substances, — (aa) Cyclopentolate hydrochloride;	5. The sale or supply shall be subject to the presentation of an order signed by, — (a) an optometrist for a medicine listed under item 5(a) in column 2; (b) a chiropodist or podiatrist for a medicine listed under item 5(b) in column 2.

	(bb) Fusidic Acid; (cc) Tropicamide; (b) the following prescription only medicines, — (i) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight; (ii) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in lacquer does not exceed 5 per cent by weight in volume; (iii) Amoxicillin; (iv) Co-Codamol; (v) Co-dydramol 10/500 tablets; (vi) Codeine Phosphate; (vii) Erythromycin; (viii) Flucloxacillin; (ix) Silver Sulfadiazine; (x) Tioconazole 28%; (xi) Topical hydrocortisone where the maximum strength of hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	
6. Optometrists.	6. Prescription only medicines listed in column 2 of paragraph 5.	6. The sale or supply shall be only-
		(a) in the course of their professional practice and
		(b) in an emergency.
7. Persons lawfully conducting a retail pharmacy business within the meaning of section 35.	7. Medicinal products not for parenteral administration, which are prescription only medicines by reason only that they contain any of the following substances: Acetylcysteine Atropine sulphate Azelastine hydrochloride Dicofenac sodium Emedastine Homotropine hydrobromide Ketotifen Levocabastine Lodoxamide Nedocromil sodium Olopatadine Pilocarpine hydrochloride Pilocarpine nitrate Polymyxin B/bacitracin	7. The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist.

	Polymyxin B/trimethoprim Sodium cromoglycate.	
8. Additional supply optometrists.	8. Prescription only medicines specified in column 2 of paragraph 7.	8. The sale or supply shall be only — (a) in the course of their professional practice, and (b) in an emergency.
9. Persons selling or supplying prescription only medicines to the British Standards Institution.	9. All prescription only medicines.	9. The sale or supply shall be-
		(a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and
		(b) only for the purpose of testing containers of medicinal products or determining the standards for such containers.
10. Holders of marketing authorizations, product licences or manufacturer's licences.	10. Prescription only medicines referred to in the authorizations or licences.	10. The sale or supply shall be only-
		(a) to a pharmacist,
		(b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and
		(c) of no greater quantity than is reasonably necessary for that purpose.
11. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 2 (regulation of sale of poisons) or section 3 (exclusion of sales by wholesale and certain other sales) of the Poisons	11. Amyl nitrite.	11. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.

Act 1979.		
12. Chiropodists or podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.	12. The following prescription only medicines, — (a) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight; (b) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in lacquer does not exceed 5 per cent by weight in volume; (c) Amoxicillin; (d) Co-Codamol; (e) Co-dydramol 10/500 tablets; (f) Codeine Phosphate; (g) Erythromycin; (h) Flucloxacillin; (i) Silver Sulfadiazine; (j) Tioconazole 28%; (k) Topical hydrocortisone where the maximum strength of hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	12. The sale or supply shall be only in the course of their professional practice.
13. Persons selling or supplying prescription only medicines to a school.	13. Prescription only medicines comprising: (a) an inhaler containing salbutamol; or (b) an auto-injector containing adrenaline.	13. The sale or supply shall be, — (a) subject to the presentation of an order signed by the principal or head teacher at the school concerned stating, — (i) the name of the school for which the medicinal product is required, (ii) the purpose for which that product is required, and (iii) the total quantity required, and (b) for the purpose of supplying or administering the medicinal product to pupils at the school in an emergency.
14. Orthoptists against whose names are recorded in the relevant register annotations signifying that they are qualified to sell or supply the medicine specified in column 2.	14. The following prescription only medicines — (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol,	14. The sale or supply shall be only in the course of their professional practice.

	(i) Fusidic acid.	
15. Persons lawfully conducting a retail pharmacy business within the meaning of section 35.	15. water for injection	15. The sale or supply is to a person — For a purpose other than parenteral administration; or Who has been prescribed dry powder for parenteral administration but has not been prescribed the water for injection that is needed as a diluent.

”

(3) In Part II (exemptions from the restrictions on supply), in item 5 in the table omit every instance of “registered” where it appears before “nurse”.

(4) In Part II after item 5 in the table insert —

“

5a. The Department operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	5a. A prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	5a. The supply of the medicine is in the course of an occupational health scheme and is made, if not by a doctor, by an occupational health scheme vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.

”[21]

(5) In Part II, item 8 in the table, column 1, after “England and Wales, or” insert “Northern Ireland”.

(6) In Part II, after item 9 in the table insert —

“

10. A person (“P”) carrying on the business of a school who is trained to administer the relevant medicine.	10. A prescription only medicinal product comprising an inhaler containing salbutamol.	10. The Supply shall be, — (a) in the course of P carrying on the business of a school; (b) where supply is to a pupil at that school who is known to suffer from asthma; and (c) where the pupil requires the medicinal product in an emergency.
11. Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by the Department.	11. (a) a prescription only medicine containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only; and (b) Ampoules of sterile water for injection containing not more than 2 mg of sterile water.	11. The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.
12. Persons employed or engaged in the	12. Ampoules of sterile water for injection containing not more than 2	12. The supply shall be only in the course of provisions of lawful drug

provision of drug treatment services provided by, on behalf of or under arrangements made by the Department.	mg of sterile water.	treatment services.
13. Midwives.	13. Prescription only medicines for parenteral administration that contain — (a) Diamorphine, (b) Morphine, (c) Pethidine hydrochloride.	13. The supply shall be only in the course of their professional practice.

”

(7) In Part III (exemptions from restrictions on administration), in item 1 in the table omit “registered” where it appears before “chiropodists”.

(8) In Part III, in item 2 in the table omit every instance of the word “registered” where it appears before “midwife” and “midwives”.

(9) In Part III, in item 5 in the table omit every instance of “registered” where it appears before “nurse”.

(10) In Part III, after item 5 in the table insert —

“

5a. The Department operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	5a. A prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	5a. The administration of the medicine is in the course of an occupational health scheme and the individual administering the medicine is, if not a doctor, an occupational health scheme vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.

”[22]

(11) In Part III, in item 9 in the table —

(a) For column 1, substitute, —

“9 Persons who are paramedics.”; and

(b) in column 2, omit “Bretylium Tosylate”, “Lignocaine Hydrochloride” and “Polygeline” and at the appropriate place insert —

“Lidocaine Hydrochloride”;

“Ondansteron”; and

“Paracetamol”.

(12) In Part III, after paragraph 10, insert —

“

11. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	**11.** A prescription only medicine comprising an auto-injector containing adrenaline.	**11.** The administration shall be, — (a) in the course of P carrying on the business of a school; (b) where administration is to a pupil at that school who is known to be at risk of anaphylaxis; and (c) where the pupil requires the medicinal product in an emergency.

"

21 Schedule 7 modified

(1) Schedule 7 is modified as follows.

(2) Omit Part II (persons on whose behalf a patient group direction must be signed) and Part IIA (persons by whom or on whose behalf a patient group direction used in the provision of health care by or on behalf of the police, the prison service or the armed forces must be signed).

(3) In Part III (classes of individual by whom prescription only medicines may be supplied or administered) for the list of individuals by whom prescription only medicines may be supplied or administered substitute —

"Pharmacists

Chiropodists and podiatrists

Dental hygienist

Dental therapist

Dietitians

Midwives

Nurses

Occupational therapists

Optometrists

Orthoptists

Orthotists and prosthetists

Paramedics

Physiotherapists

Radiographers

Speech and language therapists"

ENDNOTES

Table of Endnote References

[1] The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.

[2] Sch 2 substituted by SD2020/0471.

[3] Entry revoked by SD2021/0127.

[4] Entry revoked by SD2021/0127.

[5] Entry amended by SD2021/0127.

[6] Entry substituted by SD2021/0127.

[7] Entry inserted by SD2021/0127.

[8] Entry inserted by SD2021/0127.

[9] Entry inserted by SD2021/0127.

[10] Entry inserted by SD2021/0127.

[11] Entry revoked by SD2021/0127.

[12] Entry revoked by SD2021/0127.

[13] Entry revoked by SD2021/0127.

[14] Entry revoked by SD2021/0127.

[15] Para 2 substituted by SD2021/0127.

[16] Substituted para (1) amended by SD2021/0127.

[17] Inserted text substituted by SD2024/0085.

[18] Para 10 substituted by SD2021/0127.

[19] Inserted para (1) amended by SD2021/0127.

[20] Inserted para (1) amended by SD2021/0127.

[21] Subpara (4) substituted by SD2022/0148.

[22] Subpara (10) substituted by SD2022/0148.