Statutory Document No. 2005/0009

*Medicines Act 2003*

# MEDICINES FOR 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, Commencement and interpretation

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

(2) In these regulations —

"the Act" means the Medicines Act 2003;

"EU authorisation" has the meaning given in section 1(3) of the Act;[2]

"health care professional" means —

(a) a health 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; or

(d) a pharmacist;[3]

"manufacturing licence" has the meaning given in paragraph (d) of the definition of "UK authorisation" in section 1(3) of the Act;[4]

"relevant medicinal product" means a medicinal product for human use intended to be placed on the market and either prepared industrially or manufactured by a method involving an industrial process[5];

"temporary authorisation" means an authorisation granted by the UK licensing authority on a temporary basis under regulation 174 (supply in response

[1] 2003 c.4

to spread of pathogenic agents etc.) of the Human Medicines Regulations 2012 (of Parliament)[2];[6]

"UK authorisation" has the meaning given in section 1(3) of the Act; and[7]

"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)[3].[8]

(3) For the purposes of the definition of relevant medicinal product" in paragraph (2) a medicinal product which is a herbal remedy is not industrially produced if the process to which the plant or plants are subjected in producing the product consists only of drying, crushing or comminuting.

(4) [Revoked][9]

(5) [Revoked][10]

## 2 Placing on the Market and Wholesale Dealing

(1) Subject to paragraphs 1 and 3 of Schedule 1 —

(a) no relevant medicinal product shall be placed on the market; and

(b) no such product shall be distributed by way of wholesale dealing,

unless a UK authorisation or EU authorisation in respect of that product is for the time being in force in accordance with those provisions.[11]

(2) Schedule 1 shall have effect for the purpose of making certain exceptions or exemptions from paragraph (1), and for imposing certain obligations in connection with such exceptions and exemptions.

## 3 Borderline Products

(1) Where the Department is of the opinion that a product without a marketing authorisation is a relevant medicinal product, they may, by a notice in writing (referred to in this regulation as a "provisional determination notice") served on any person who has placed or who in the opinion of the Department may place the product on the market —

(a) inform the person that they are minded to determine that the product is a relevant medicinal product (referred to in this regulation as "the provisional determination") and of the reasons why they are so minded; and

(b) advise the person that if they disagree with the provisional determination, they may request that the Department review their

[2] SI 2012/1916

[3] SI 2012/1916

provisional determination, provided that within four weeks of the date on which the provisional determination notice was served (referred to in this regulation as "the date of the provisional determination") the person makes that request, and

(i) within such period (being not less than six weeks from the date of the provisional determination) as may be specified in the provisional determination notice, the person furnishes the Department with written representations explaining why the person considers that the product is not a relevant medicinal product, or

(ii) within four weeks of the date of the provisional determination, the person informs the Department in writing that they wish to make oral representations to a review panel, appointed by the Department, explaining why the person considers that the product is not a relevant medicinal product.

(2) Where the Department has been informed, pursuant to paragraph (1)(b)(ii), that a person wishes to make oral representations to a review panel, they shall, after consultation with that person, set a date for the oral hearing (at which the Department may also make oral representations to the panel) and, subject to paragraph (3), that date shall be the date fixed for the oral hearing.

(3) Where the Department considers that, because of either exceptional circumstances or the nature and complexity of the issues, additional time is needed —

(a) for the preparation of written representations in a case where the Department has not been informed, pursuant to paragraph (l)(b)(ii), that the person on whom the provisional determination notice was served wishes to make oral representations, the Department may alter the period specified in the notice within which written representations are to be furnished to a different period, and then that different period shall be the period within which the written representations are to be furnished;

(b) for preparation for the oral hearing, they may alter the date set for the hearing to a different date, and then that different date shall be the date fixed for the oral hearing;

and they shall inform the person on whom the relevant provisional determination notice was served of the alteration and the reasons for it.

(4) Where a person on whom a provisional determination notice has been served —

(a) has not requested that the Department review their provisional determination within four weeks of the date of the provisional determination; or

(b) has made such a request but has not availed themselves of the opportunities afforded to them under the procedure set out in this regulation to make representations explaining why they consider that the product in respect of which the provisional determination has been made is not a relevant medicinal product,

the Department shall, after further consideration of the matter, determine whether or not the product is a relevant medicinal product and shall inform that person in writing of their determination and their reasons for it.

(5) If a person on whom a provisional determination notice was served —

(a) has made written representations to the Department pursuant to paragraph (l)(b)(i), read with paragraph (3)(a), the Department shall —

(i) put those written representations before a review panel, appointed by the Department, together with any written representations which the Department may make to the panel on the matter, and

(ii) after further consideration of the matter, and in particular after having considered the advice of the review panel arising out of those representations and any other evidence considered by the review panel,

determine whether or not the product is a relevant medicinal product;

(b) has made oral representations to a review panel at an oral hearing arranged pursuant to paragraph (2), read with paragraph (3)(b), the Department shall, after further consideration of the matter and in particular after having considered the advice of the review panel arising out of —

(i) the oral representations made and any other evidence submitted to the panel at the hearing by that person,

(ii) any oral representations made and any other evidence submitted to the panel at the hearing by the Department; and

(iii) any other evidence considered by the review panel,

determine whether or not the product is a relevant medicinal product, and shall inform that person in writing of their determination and their reasons for it, and if the Department makes a determination which is contrary to the advice of the review panel, they shall also give their reasons for disagreeing with the advice of the review panel.

(6) In respect of any product which the Department determines, in accordance with paragraph (4) or (5), to be a relevant medicinal product, the Department may, by a notice in writing served on any person who has

placed or who in the opinion of the Department may place the product on the market, require that they shall —

(a) stop marketing the product from a date specified in the notice; or

(b) not place the product on the market,

unless or until a marketing authorisation is granted in respect of that product.

(7) Nothing in this regulation precludes a determination by the Department that a product is a relevant medicinal product otherwise than in accordance with this regulation in appropriate circumstances.

## 4 Obligations of holders of marketing authorisations and offences by holders of marketing authorisations and other persons

(1) Every holder of an EU authorisation for a relevant medicinal product shall comply with all obligations which relate to them by virtue of the EC code.[12]

(1A) Every holder of a UK authorisation for a relevant medicinal product shall comply with all obligations which relate to them by virtue of the Human Medicines Regulations 2012 (of Parliament)[4].[13]

(2) Schedule 2 shall have effect to create certain criminal offences in connection with the obligations of applicants for, and holders of, UK authorisations and EU authorisations and other persons.[14]

## 4A Immunity from civil liability

(1) This regulation applies where the UK licensing authority or the Department makes a recommendation or requirement to which paragraph (2) applies in response to the suspected or confirmed spread of —

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.

(2) This paragraph applies to a recommendation or requirement —

(a) for the use of a medicinal product without a UK authorisation; or

(b) for the use of a medicinal product with a UK authorisation, but for a therapeutic indication that is not permitted under the authorisation.

(3) The use of the medicinal product referred to in paragraph (2) is not in accordance with a recommendation or requirement of the UK licensing authority for the purposes of this regulation if—

[4] SI 2012/1916

(a) a condition attached to a temporary authorisation of its sale or supply is breached; and

(b) any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person (with an interest in placing medicinal products on the market) would regard the breach as sufficiently serious to justify the licencing authority setting aside the recommendation or requirement.

(4) Notwithstanding paragraph (3), the persons mentioned in paragraph (5) are not subject to any civil liability resulting from a use of that medicinal product that was (but for the operation of that paragraph) in accordance with the recommendation or requirement of the UK licensing authority, if those persons were not wholly or partly responsible for the breach in question.

(5) None of the following are to be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement —

(a) any holder of a UK authorisation for the product;

(b) if there is no holder of a UK authorisation for the product but the sale or supply of the product is authorised by the UK licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012 (of Parliament)[5], the person responsible for placing the product on the market;

(c) any manufacturer of the product;

(d) any officer, servant, employee or agent of a person within subparagraph (a), (b) or (c);

(e) any health care professional; or

(f) any person not being a health care professional, who administers the product in accordance with a protocol of the type mentioned in —

(i) regulation 8A of the Medicines (Pharmacy and General Sale List – Exemption) Order 1980[6] (of Parliament) as it applies to the Island[7]; and

(ii) regulation 12G of the Prescription Only Medicines (Human Use) Order 1997[8] (of Parliament) as it applies to the Island[9].

(6) This regulation does not apply in relation to liability under section 1 (liability for defective products) of the Consumer Protection Act 1991.**[15]**

[5] SI 2012/1916

[6] SI 1980/1924

[7] SI 1980/1924 was applied to the Island by SD 13/05

[8] SI 1997/1830

[9] SI 1997/1830 was applied to the Island by SD 11/05

## 5 Application of enforcement provisions of the Act

(1) Subject to paragraph (2) below, the provisions of Part 4 of the Act (which provides for enforcement of the Act), shall apply for the purposes of these Regulations as they apply for the purposes of the Act.

(2) Those provisions as so applied shall have effect —

(a) with the modifications specified in Schedule 2 to these Regulations; and

(b) as if all relevant medicinal products were medicinal products for the purposes of the Act (whether or not they would otherwise be so).

## 6 Other Schedules to have effect

Schedules 3 and 4 shall have effect

## 7 Revocation

The Orders in Schedule 5 are revoked to the extent specified in column 3 of that Schedule.

**MADE 9 DECEMBER 2005**

## SCHEDULE 1

## EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 2

[Regulation 2]

1. Regulation 2(1) shall not apply to a relevant medicinal product supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor or dentist and for use by his individual patients on his direct personal responsibility, but such supply shall be subject to the conditions specified in paragraph 2.

2. The conditions mentioned in paragraph 1 are that —

(a) the relevant medicinal product is supplied to a doctor or dentist or for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist, in accordance with paragraph 1;

(b) no advertisement or representation relating to the relevant medicinal product is issued with a view to it being seen generally by the public in the Isle of Man and that no advertisement relating to that product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order;

(c) the manufacture or assembly of the relevant medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that the product is of the character required by and meets the specifications of the doctor or dentist who requires it;

(d) written records as to the manufacture or assembly in accordance with sub- paragraph (c) are made and maintained and are available to the Department on request by them;

(e) the relevant medicinal product is manufactured, assembled or imported by the holder of a manufacturing licence which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; and[16]

(f) the relevant medicinal product is distributed by way of wholesale dealing by the holder of a wholesale dealer's licence.

3. (1) Subject to the following sub-paragraphs, regulation 2(1) shall not apply to anything done —

(a) by a doctor or dentist which relates to a relevant medicinal product specially prepared by them, or to their order, for administration to

one or more of their patients or, where that doctor or dentist is a member of a group of doctors or dentists working together to provide general medical or dental services, to one or more patients of any other doctor or dentist of that group, and consists of procuring the manufacture or assembly of a stock of the product with a view to administering the product to such patients; or

(b) in a registered pharmacy, a hospital or health centre and is done there by or under the supervision of a pharmacist, and consists of procuring the manufacture or assembly of a stock of relevant medicinal products with a view to dispensing them in accordance with paragraph 1.

(2) The exemption conferred by sub-paragraph (1) shall not apply to procuring the manufacture of relevant medicinal products unless those products are to be manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture or assembly of relevant medicinal products to which paragraph 1 applies.

(3) The exemption conferred by sub-paragraph (1) shall not apply to anything done by a doctor or dentist in relation to a stock held by them of such relevant medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all relevant medicinal products to which that sub-paragraph relates.

4. (1) Regulation 2(1) shall not apply to the placing on the market by way of supplying of any relevant medicinal product to which this paragraph relates if the conditions of sub-paragraph (3) are satisfied.

(2) The relevant medicinal products to which this paragraph relates are relevant medicinal products which are for use by being administered to one or more human beings and which may be lawfully sold by retail or supplied in circumstances corresponding to retail sale, otherwise than in accordance with a prescription by a doctor or dentist.

(3) The conditions referred to in sub-paragraph (1) are —

(a) that the relevant medicinal product is sold or supplied to a person exclusively for use by them in the course of a business carried on by them for the purposes of administering it or causing it to be administered to one or more human beings otherwise than by selling it;

(b) that, if sold or supplied through the holder of a wholesale dealer's licence, the relevant medicinal product is sold or supplied to such a person, and for such use by them, as is described in 4(3)(a) above;

(c) that, where the manufacture or assembly of the relevant medicinal product is procured, it is procured by such a person, and for such use by them, as is described in 4(3)(a) above;

(d) that no advertisement or representation relating to the relevant medicinal product is issued with a view to it being seen generally by the public in the Isle of Man and that no advertisement relating to that product, by means of any catalogue, price list or circular

letter, is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order;

(e) that the relevant medicinal product is prepared by or under the supervision of a pharmacist; and

(f) that the relevant medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of relevant medicinal products to which paragraph 1 applies.

5. (1) Regulation 2(1) shall not apply to a radiopharmaceutical product for human use —

(a) which is prepared at the time at which it is intended to be administered; and

(b) which is prepared, in accordance with the manufacturer's instructions and by the person by whom it is to be administered, exclusively from a kit, generator or precursor (or from more than one of these) in respect of which a UK authorisation is in force; and

(c) the administration of which is not or will not be a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978[10].

(2) In this paragraph —

"generator'' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical product;

"kit" means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical product, usually prior to its administration;

"precursor'' means a radionuclide produced for the radio-labelling of another substance prior to its administration, other than a radionuclide which is incorporated in or produced from a generator or is included in a radiopharmaceutical product;

"radiopharmaceutical product" means any relevant medicinal product which when ready for use contains one or more radionuclides included for a medicinal purpose.

6. Any person who sells or supplies a relevant medicinal product in accordance with any of paragraphs 1 to 4 shall maintain, and keep for a period of at least 5 years, a record showing —

[10] SI 1978/1006

(a) the source from which that person obtained that product;

(b) the person to whom and the date on which the sale or supply was made;

(c) the quantity of each sale or supply;

(d) the batch number of the batch of that product from which the sale or supply was made; and

(e) details of any suspected adverse reaction to the product so sold or supplied of which they are aware.

7. A person required to maintain the records mentioned in paragraph 6 shall —

(a) notify the Department of any suspected adverse reaction such as is mentioned in heading (e) of that paragraph which is a serious adverse reaction; and

(b) make available for inspection at all reasonable times by the Department the records mentioned in that paragraph.

8. (1) Regulation 2(1) does not apply to the sale or supply of a relevant medicinal product where the conditions specified as conditions A to C in this paragraph are met.

(2) Condition A is that there is a temporary authorisation in force with respect to the relevant medicinal product.

(3) Condition B is that the sale or supply of the relevant medicinal product is—

(a) as required or recommended by the UK licensing authority; and

(b) in accordance with any conditions attached to the temporary authorisation by the UK licensing authority.

(4) Condition C is that the Department has determined that the product may be sold or supplied in response to the suspected or confirmed spread of —

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.[17]

## SCHEDULE 2

## OFFENCES, PENALTIES ETC.

[Regulation 4(2)]

*Offences*

1. Any person who, in breach of the EC code or of these Regulations, places a relevant medicinal product on the market without holding an EU authorisation in respect of that product, or otherwise than in accordance with the terms of such an authorisation, shall be guilty of an offence. Any person who, in breach of the Human Medicines Regulations 2012 (of Parliament)[11] or of these Regulations, places a relevant medicinal product on the market without holding a UK authorisation in respect of that product or otherwise than in accordance with the terms of such an authorisation shall be guilty of an offence. In respect of any product which is a relevant medicinal product, where, following a determination under regulation 3(4) or (5), the Department may serve a notice in respect of that product on any person under regulation 3(6) requiring them —

(a) to stop marketing the product from a date specified in the notice unless or until a marketing authorisation is granted in respect of that product, if after the date specified

(i) they place that product on the market, or

(ii) in the course of a business carried on by them, they sell or supply to a member of the public or procures for sale or for supply to a member of the public that product,

without a marketing authorisation having been granted in respect of that product, they shall be guilty of an offence;

(b) not to place the product on the market unless or until a marketing authorisation is granted in respect of that product, if they thereafter places the product on the market without a marketing authorisation having been granted in respect of that product, they shall be guilty of an offence.[18]

2. Any person who, in the course of a business carried on by them, sells, supplies, manufactures or assembles, or procures the sale, supply, manufacture or assembly of, a relevant medicinal product, or who has in his possession a relevant medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to paragraph 1 shall be guilty of an offence.

3. Without prejudice to any other sanction which may be available for the enforcement of conditions attaching to marketing authorisations, any holder of a UK authorisation or EU authorisation for a relevant medicinal product who contravenes any condition of the authorisation shall be guilty of an offence.[19]

[11] SI 2012/1916

4. Any holder of a UK authorisation who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorisation relates —

(a) which does not comply with the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[12] for packaging and package leaflets relating to medicinal products; or

(b) which is not accompanied by a package leaflet when one is required by virtue of the Human Medicines Regulations 2012 (of Parliament)[13],

shall be guilty of an offence.[20]

4A. Any holder of an EU authorisation who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorisation relates —

(a) which does not comply with the applicable requirements of the EC code for packaging and package leaflets relating to medicinal products; or

(b) which is not accompanied by a package leaflet when one is required by virtue of the EC code,

shall be guilty of an offence.[21]

5. Where, in relation to a relevant medicinal product —

(a) the labelling of the product, or any package leaflet accompanying the product, does not comply with the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[14]; or

(b) the product is not accompanied by a package leaflet required to be provided by virtue of the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[15],

any person, other than the holder of the UK authorisation for that product, who in the course of a business carried on by them, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.[22]

5A. Where, in relation to a relevant medicinal product —

(a) the labelling of the product, or any package leaflet accompanying the product, does not comply with the applicable requirements of the EC code; or

[12] SI 2012/1916
[13] SI 2012/1916
[14] SI 2012/1916
[15] SI 2012/1916

(b) the product is not accompanied by a package leaflet required to be provided by virtue of the applicable requirements of the EC code,

any person, other than the holder of the EU authorisation for that product, who in the course of a business carried on by them, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.[23]

6. Any person who fails to keep any record required under paragraph 6 of Schedule 1, or to give notice or make it available for inspection as and when required under paragraph 7 of that Schedule, shall be guilty of an offence.

*Penalties*

8. Any person guilty of an offence under any of the preceding paragraphs shall be liable-

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

*Miscellaneous*

9. Where an offence is committed under any of paragraphs 8, 9 or 10 by a person mentioned in those paragraphs who is acting as the employee or agent of another person, the employer or principal of that person shall be guilty of the same offence.

10. Where the holder of a UK authorisation is charged with an offence under these Regulations in respect of anything which has been manufactured or assembled to his order by another person and had been so manufactured or assembled as not to comply with the provisions of that authorisation, it shall be a defence for them to prove —

(a) that they had communicated the provisions relating to the authorisation to that other person; and

(b) that they did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with.

## SCHEDULE 3

## LABELS

[Regulation 6]

*Interpretation*

1. In this Schedule, unless the context otherwise requires —

"dispensed relevant medicinal product" means a relevant medicinal product prepared or dispensed in accordance with a prescription given by a practitioner;

"relevant medicinal product on a general sale list" means a relevant medicinal product of a description, or falling within a class, specified in an order under section 4 of the Act which is for the time being in force;

"requirements" includes restrictions;

"retail sale" has the same meaning as in section 53 of the Act; and

"supply in circumstances corresponding to retail sale" has the same meaning as in section 53 of the Act.

*Introductory*

2. The requirements of this Schedule supplement those of the Human Medicines Regulations 2012 (of Parliament)[16] relating to:

(a) special warnings necessary for particular medicinal products;

(b) the legal status for supply to the patient, in accordance with the Human Medicines Regulations 2012 (of Parliament)[17], and;

(c) identification and authenticity.

*Dispensed relevant medicinal products*

3. (1) Subject to the following provisions of this Schedule, where a relevant medicinal product is a dispensed relevant medicinal product the container of that product shall be labelled to show the following particulars —

(a) the name of the person to whom the product is to be administered;

(b) the name and address of the person who sells or supplies the product;

(c) the date on which the product is dispensed;

(d) where the relevant medicinal product has been prescribed by a practitioner, such of the following particulars as they may request —

[16] SI 2012/1916

[17] SI 2012/1916

(i) the name of the relevant medicinal product or its common name;

(ii) directions for use of the relevant medicinal product; and

(iii) precautions relating to the use of the relevant medicinal product,

or where a pharmacist, in the exercise of his professional skill and judgement, is of the opinion that any of such particulars are inappropriate and has taken such steps as in all the circumstances are reasonably practicable to consult with the practitioner but has been unable to do so, particulars of the same kind as those requested by the practitioner as appear to the pharmacist to be appropriate.

(2) Where the container of a dispensed relevant medicinal product is enclosed in a package immediately enclosing that container the particulars set out in sub-paragraph (1) may be omitted from the container if that package is labelled to show such particulars.

(3) Where a number of containers or packages, or of containers and packages, of dispensed relevant medicinal products all of the same description are enclosed in a package, sub-paragraph (1)(d) shall be deemed to have been complied with if such of the particulars referred to in that sub-paragraph as would, apart from this sub-paragraph, be required to be shown on each container or package, or on each container and package so enclosed, are shown on either one or more such containers or packages or such containers and packages as the case may be.

*Delivery and storage*

4. (1) Subject to the following provisions of this Schedule, where for the purposes of transport, delivery or storage a number of packages of relevant medicinal products all of the same description, not being relevant medicinal products to which paragraph 1 of Schedule 1 applies, are enclosed in a package, such package shall be labelled to show the following particulars —

(a) any special requirements for the storage and handling of the product;

(b) the expiry date of the product; and

(c) the manufacturer's batch number.

(2) Sub-paragraph (1) does not apply to any package in the form of a packing case, crate or other covering used solely for the purposes of transport or delivery (but not storage) of containers and packages of relevant medicinal products each of which is labelled in accordance with the provisions of this Schedule.

*Relevant medicinal products on a general sale list*

5. (1) Subject to the following provisions of this Schedule, where a relevant medicinal product on a general sale list, not being a dispensed relevant medicinal product, is sold by retail, or supplied in circumstances corresponding to retail sale or by

means of an automatic machine or is in the possession of any person for the purpose of such sale or supply, every container and every package immediately enclosing a container of such product, being a product described in any of the following sub-paragraphs, shall be labelled to show the words and particulars set out in such sub-paragraph or sub-paragraphs —

(a) if the product contains aloxiprin, aspirin or paracetamol, the words "If symptoms persist consult your doctor'' and, except where the product is for external use only, the recommended dosage;

(b) if the product contains aloxiprin, the words "Contains an aspirin derivative";

(c) if the product contains aspirin, except where the product is for external use only or where the name of the product includes the word "aspirin" and appears on the container or package, the words "Contains aspirin";

(d) if the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the container or package, the words "Contains paracetamol";

(e) if the product contains paracetamol, the words "Do not exceed the stated dose";

(f) if the product contains paracetamol, unless it is wholly or mainly intended for children who are twelve years old or younger, the words "Do not take with any other paracetamol - containing products", and

(i) if a package leaflet accompanying the product displays the words set out in quotation marks in paragraph 1 of Schedule 4, the words "Immediate medical advice should be sought in the case of an overdose, even if you feel well", or

(ii) if no package leaflet accompanies the product or the package leaflet does not display the words in paragraph 1 of Schedule 4, the words "Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage";

(g) if the product contains aspirin or aloxiprin, the words "Do not give to children aged under 16 years, unless on the advice of a doctor.".

(2) Where a container or package is required by this paragraph to show —

(a) words set out in more than one of sub-paragraphs (b), (c) and (d) of sub- paragraph (1), there may be substituted for those words other words showing that the product contains more than one of the substances aloxiprin, aspirin and paracetamol and naming the substances so contained, except that in the case of aloxiprin the words "aspirin derivative" shall appear and the word "aloxiprin" need not appear;

(b) words set out in one or more of those sub-paragraphs, such words shall appear in a prominent position and shall be within a rectangle within which there shall be no other matter of any kind, except that where words set out in more than one of the said sub- paragraphs appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

(3) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall appear adjacent to either the directions for use, where such directions appear on the container or package, or the recommended dosage, where such recommendation appears on the container or package.

(4) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall not be required to be shown if, by virtue of paragraph 6, the words set out in sub-paragraph (2)(a) of that paragraph are required to be, and are, shown.

(5) Without prejudice to the operation of sub-paragraph (1), where a relevant medicinal product, not being a dispensed medicinal product, is —

(a) sold by retail; or

(b) supplied in circumstances corresponding to retail sale; or

(c) in the possession of a person for the purpose of such sale or supply; or

(d) sold by way of wholesale dealing,

then, if the product is a product referred to in regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 19803 which is not presented for sale in the manner described in relation to that product in that regulation, every container and every package immediately enclosing a container of that relevant medicinal product shall be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

*Relevant medicinal products not on a general sale list*

6. (1) Subject to the following provisions of this Schedule, where a relevant medicinal product to which any of the restrictions imposed by section 2 of the Act (sale or supply of medicinal products not on general sale list) apply is sold by retail, or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such a product —

(a) shall be labelled in accordance with the provisions of paragraph 5 as if such provisions applied to such containers and packages as they apply to containers and packages of relevant medicinal products on a general sale list;

(b) shall, if the product is described in sub-paragraph (2), be labelled to show the words and particulars set out in that sub-paragraph,

except that where words set out in more than one of headings (a), (b) and (c) of that sub-paragraph appear on the container or package then the word "Warning" need not appear more than once, and where the product is a dispensed relevant medicinal product then the words set out in those headings need not appear;

(c) shall, unless any of the provisions of paragraph 7 apply to such container or package or the product is a dispensed relevant medicinal product, be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

(2) The descriptions and words referred to in sub-paragraph (1) are-- —

(a) if the product would be subject to restrictions imposed under section 2 of the Act but for an exemption from any such restrictions conferred by an order made. under that section by reason of the proportion or level in such product of any substance, except where the product is for external use only or contains any of the substances described in (c) of this sub-paragraph the words "Warning. Do not exceed the stated dose";

(b) if the product is for the treatment of asthma or other conditions associated with bronchial spasm or contains ephedrine or any of its salts, except where the product is for external use only, the words "Warning. Asthmatics should consult their doctor before using this product";

(c) if the product contains an antihistamine or any of its salts or molecular compounds, except where the product is for external use only or where the UK authorisation contains no warning relating to the sedating effect of the product in use, the words "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink";

(d) if the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, the words "For external use only";

(e) if the product contains hexachlorophane, either the words "Not to be used for babies" or a warning that the product is not to be administered, except on medical advice, to a child under two years.

(3) The requirement of sub-paragraph (1)(c) shall apply to every container and every package immediately enclosing a container of a relevant medicinal product which is sold by way of wholesale dealing and which is not a relevant medicinal product on a general sale list.

(4) Where a container or package is required by this paragraph to be labelled to show any of the words or particulars specified in sub-paragraph (2) (a) to (e), such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in more than one heading of that sub- paragraph appear on the container or package then any of them may be together within a rectangle within which there shall be no other matter of any kind.

*Prescription only relevant medicinal products*

7. Subject to the following provisions of this Schedule, every container and every package immediately enclosing a container of a relevant medicinal product which is subject to restrictions imposed under section 5 of the Act (relevant medicinal products on prescription only) shall, if the product is described in sub-paragraph (2) (d) or (e) of paragraph 6, be labelled to show the words and particulars set out in that heading and shall, except where the product is sold by retail or supplied in circumstances corresponding to retail sale or is the subject of an exemption, by virtue of the provisions of section 58(4) (a), from any of the restrictions imposed by section 5 of the Act, be labelled to show the letters "POM" in capital letters within a rectangle within which there shall be no other matter of any kind.

*Exemptions*

8. Nothing in this Schedule shall require the labelling of —

(a) any package in the form of a transparent wrapping or cover to a container and package of a relevant medicinal product or any package the whole or part of which is transparent or open if the particulars shown on the labelled container enclosed in that package are clearly visible;

(b) any package in the form of a wrapping paper, paper bag or similar covering in which the container and package of a relevant medicinal product labelled in accordance with the provisions of this Schedule is placed when such relevant medicinal product is sold by retail or supplied in circumstances corresponding to retail sale; or

(c) any container or package immediately enclosing the container of a relevant medicinal product which is for export any container which is —

(i) an ampoule or other container of not more than 10 millilitres nominal capacity which is immediately enclosed in a package which is labelled in accordance with those provisions of paragraphs 5 to 7 which apply to such package;

(ii) in the form of a wrapper consisting of paper, film, plastic material, metal foil or other sheet or strip material or in the form of a bubble, blister or other sealed unit consisting of such sheet or strip material, enclosing one or more dosage units of a relevant medicinal product and such container is immediately enclosed in a package which is labelled in accordance with those provisions of paragraphs 5 to 7 which apply to such package;

(iii) where the package immediately enclosing such a container as is described in (ii) above is itself in the form of a bubble,

blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages and is required to be labelled to show any of the words, particulars or letters referred to in paragraphs 5 to 7, such requirements shall be deemed to have been complied with if the said words, particulars or letters, as the case may be, are displayed at frequent intervals on the said sheet or strip of such packages.

## SCHEDULE 4[24]

## SCHEDULE 5

## REVOCATIONS

[Regulation 7]

| *Reference* | *Title* | *Extent of revocation* |
|---|---|---|
| GC 13/78 | The Medicines Subsidiary Legislation (Application) Order 1978 | In Schedule 1, Part II and Part VI |
| GC 157/78 | The Medicines Subsidiary Legislation (Application no.2) Order 1978 | In Schedule 1, Part IV and Part V |
| GC 200/79 | The Medicines Subsidiary Legislation (Application no.3) Order 1979 | In Schedule 1, Part I, items 3, in Part II, items 1, 2, 3 and 4. |
| GC 63/85 | The Medicines Subsidiary Legislation (Application no.8) Order 1985 | In Schedule 1, Part II, items 11 and 13, |
| GC 330/87 | The Medicines Subsidiary Legislation (Application no.10) Order 1987 | In Schedule 1, Part II, item 7 |
| GC 299/88 | The Medicines Subsidiary Legislation (Application no.12) Order 1988 | In Schedule 1, Part II, item 7 |

## 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] Definition of "EU authorisation" inserted by SD2019/0102.

[3] Definition of "health care professional" inserted by SD2020/0470.

[4] Definition of "manufacturing licence" inserted by SD2019/0102.

[5] Definition of "relevant medicinal product" substituted by SD2019/0102.

[6] Definition of "temporary authorisation" inserted by SD2020/0470.

[7] Definition of "UK authorisation" substituted by SD2019/0102.

[8] Definition of "UK licensing authority" inserted by SD2020/0470.

[9] Para (4) revoked by SD2019/0102.

[10] Para (5) revoked by SD2019/0102.

[11] Para (1) substituted by SD2019/0102.

[12] Para (1) amended by SD2019/0102.

[13] Para (1A) inserted by SD2019/0102.

[14] Para (2) amended by SD2019/0102.

[15] Reg 4A inserted by SD2020/0470.

[16] Para (e) substituted by SD2019/0102.

[17] Para 8 inserted by SD2020/0470.

[18] Para 1 amended by SD2019/0102.

[19] Para 3 amended by SD2019/0102.

[20] Para 4 substituted by SD2019/0102.

[21] Para 4A inserted by SD2019/0102.

[22] Para 5 substituted by SD2019/0102.

[23] Para 5A inserted by SD2019/0102.

[24] Sch 4 revoked by SD2019/0102.