SCHEDULES

SCHEDULE 1

Regulation 5

Further provisions for classification of medicinal products

PART 1

Descriptions of certain medicinal products to be available only on prescription

1. The following medicinal products shall be available only on prescription—

(a) a product for parenteral administration;

(b) a product that is a controlled drug **[**F1as defined in section 2(1)(a) of the Misuse of Drugs Act 1971**]**, unless it is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale;

(c) cyanogenic substances, other than preparations for external use;

(d) medicinal substances that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;

(e) a product that—

(i) is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and

(ii) consists of or contains aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules;

(f) a product that—

(i) is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and

(ii) consists of or contains (in any pharmaceutical form) pseudoephedrine salts or ephedrine base or salts; F2...

(g) a product that—

(i) is not covered by a marketing authorisation, and

(ii) is a prescription only medicine by virtue of articles 5 and 10 of, and Schedules 1 and 2 to, the Prescription Only Medicines (Human Use) Order 1997 M1**[**F3; and**]**

[F4(h) a product which is authorised by the licensing authority on a temporary basis under regulation 174, in circumstances where the licensing authority has attached a condition to that authorisation to the effect that, for the duration of the temporary authorisation, the product is classified as a prescription only medicine.**]**

Textual Amendments

F1 Words in Sch. 1 para. 1(b) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), **regs. 1(2)**, 10 and words in Sch. 1 para. 1(b) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **10**

F2 Word in Sch. 1 para. 1(f) omitted (6.11.2020) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(a)** and word in Sch. 1 para. 1(f) omitted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(a)**

F3 Word in Sch. 1 para. 1(g) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(b)** and word in Sch. 1 para. 1(g) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(b)**

F4 Sch. 1 para. 1(h) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(c)** and Sch. 1 para. 1(h) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(c)**

Marginal Citations

M1 S.I. 1997/1830, as amended by S.I. 1997/2044, S.I. 1998/108, S.I. 1998/1178, S.I. 1998/2081, S.I. 1999/1044, S.I. 1999/3463, S.I. 2000/1917, S.I. 2000/2899, S.I. 2000/3231, S.I. 2001/2777, S.I. 2001/3942, S.I. 2003/696 and S.I. 2006/915 and these Regulations. There are other amendments, but none is relevant.

2. In this Part "cyanogenic substances" means preparations which—

(a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17; or

(b) contain more than 0.1 per cent by weight of any substance having the formula either—

(i) alpha-Cyanobenzyl -6-O-Beta-d-glucopyranosyl -Beta-d-glucopyranoside, or

(ii) alpha-Cyanobenzyl -Beta-d-glucopyranosiduronic acid.

PART 2

Descriptions of certain medicinal products to be available only from a pharmacy

3. The following medicinal products shall be available only from a pharmacy—

(a) a product comprising eye ointment;

(b) a product that contains Vitamin A, Vitamin A acetate or Vitamin A palmitate, in each case with a maximum daily dose equivalent to more than 7500 international units of Vitamin A or 2250 micrograms of retinol;

(c) a product that contains Vitamin D with a maximum daily dose of more than 400 units of antirachitic activity **[**[F5]; and**]**

[[F6](d) a product which is authorised by the licensing authority on a temporary basis under regulation 174, in circumstances where the licensing authority has attached a condition to that authorisation to the effect that, for the duration of the temporary authorisation, it is only to be available from a pharmacy.**]**

Textual Amendments

F5 Word in Sch. 1 para. 3(c) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(3)(a)** and word in Sch. 1 para. 3(c) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(3)(a)**

F6 Sch. 1 para. 3(d) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(3)(b)** and Sch. 1 para. 3(d) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(3)(b)**

4. The following medicinal products shall be available only from a pharmacy unless they are the subject of a marketing authorisation or traditional herbal registration that classifies them as medicinal products subject to general sale—

(a) a product that is for use as an anthelmintic;

(b) a product that is for parenteral administration;

(c) a product that is for use as an enema;

(d) a product that is for use wholly or mainly for irrigation of—

(i) wounds, or

(ii) the bladder, vagina or rectum;

(e) a product that is for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

5. A medicinal product shall be available only from a pharmacy if it is a medicinal product of a kind specified in Schedule 15 but is not presented for sale in accordance with the requirements specified in that Schedule for a product of that kind to be subject to general sale.

SCHEDULE 2

Regulation 16

Supplementary provision relating to advisory bodies and expert advisory groups

Terms of appointment

1.—(1) The person appointed to chair an advisory body is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The person's term of office as chair of the advisory body is not to exceed the person's term of office as a member of the body.

(3) The person may resign from chairing the advisory body at any time by notice in writing to the Ministers.

2.—(1) A member of an advisory body, other than its chair, is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The term of an appointment may not exceed four years (but an appointment may be renewed).

(3) A member of an advisory body may resign from it at any time by notice in writing to the Ministers.

(4) Where a person ceases to be a member of an advisory body, the person also ceases to be a member of any expert advisory group appointed by the advisory body (including an expert advisory group appointed jointly with the other advisory body).

(5) But sub-paragraph (4) does not apply if—

(a) the person was a member of the advisory body only by virtue of being co-opted under regulation 13; or

(b) the person is immediately re-appointed to the advisory body.

3.—(1) The person appointed to chair an expert advisory group is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The person's term of office as chair of the expert advisory group is not to exceed the person's term of office as a member of the group.

(3) The person may resign from chairing the group at any time by notice in writing to the advisory body or bodies which appointed the group.

4.—(1) This paragraph applies to a member of an expert advisory group, other than a person appointed to chair an expert advisory group.

(2) The member is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (3) and (4)).

(3) The term of an appointment may not exceed four years (but an appointment may be renewed).

(4) The member may resign office at any time by notice in writing to the advisory body or bodies which appointed the group.

Facilities and proceedings

5. The Ministers must provide each advisory body with such staff, accommodation, services and other facilities as the Ministers think necessary or expedient for the proper performance of its functions.

6. The validity of any proceedings of an advisory body or expert advisory group is not affected by—

(a) a vacancy among its members; or

(b) a defect in the appointment of any member.

7.—(1) An advisory body may, subject to approval by the Secretary of State, make such provision as it thinks fit for the regulation of its own proceedings.

(2) The licensing authority may make provision for the regulation of the proceedings of an expert advisory group.

Payment and expenses

8. The Ministers may pay to the members of each advisory body and expert advisory group such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.

9. The Ministers must defray any expenses incurred with their approval by each advisory body and expert advisory group.

10. If an action is brought against a person arising out of an act performed as a member of an advisory body or expert advisory group, the Ministers may indemnify that person against any damages, costs or expenses incurred in that action.

11. Paragraphs 8 to 10 shall have effect in relation to an expert committee appointed by the licensing authority and to its members as if they were an advisory body or expert advisory group and its members.

Status

12. An advisory body or expert advisory group is not to be regarded—

(a) as a servant or agent of the Crown; or

(b) as enjoying any status, immunity or privilege of the Crown.

SCHEDULE 3

Regulation 21(1)

Applications for licences under Part 3

Manufacturer's licences

1.—(1) This paragraph applies to an application for a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the address of each of the premises where any operations to which the licence relates are to be carried out;

(d) the address of any premises not mentioned by virtue of paragraph (c) where—

(i) the applicant proposes to keep any living animals, from which a substance used in the production of the medicinal product to which the application relates is to be derived, or

(ii) materials of animal origin, from which a substance is to be derived as mentioned in sub-paragraph (i), are to be kept;

(e) the address of each of the premises where medicinal products are to be stored, or from which medicinal products are to be distributed;

(f) the name, address, qualifications and experience of the person ("S") whose duty it will be to supervise the manufacturing or assembling operations, and the name and job title of the person to whom S reports;

(g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products, a statement of that fact);

(h) the name, address and qualifications of the person to be responsible for any animals kept as mentioned in sub-paragraph (d)(i);

(i) the name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of medicinal products;

(j) the name, address and qualifications of the qualified person.

(3) The application must also contain—

(a) the pharmaceutical form of each medicinal product to be manufactured or assembled;

(b) details of the manufacturing or assembling operations to which the licence is to relate, including a statement of whether they include—

(i) the manufacture of medicinal products, or

(ii) the assembly of medicinal products;

(c) a statement of whether the medicinal products are to be manufactured or assembled for the purpose of—

(i) being administered to human beings in that form, or

(ii) as an ingredient in the preparation of another medicinal product;

(d) a statement of the facilities and equipment available at each of the premises where medicinal products are to be stored, or from which medicinal products are to be distributed;

(e) a separate statement, in respect of each of the premises mentioned in the application, of—

(i) the manufacturing or assembling operations capable of being carried out at those premises, and the class of medicinal products to which those operations relate, and

(ii) the equipment available at those premises for carrying out each stage of those operations;

(f) a statement of the authority conferred on the person mentioned in sub-paragraph (2)(g) to reject unsatisfactory medicinal products;

(g) a description of the arrangements for the identification and storage of materials and ingredients before and during manufacture or assembly and for the storage of medicinal products after manufacture or assembly;

(h) a description of the arrangements, at each of the premises where the applicant proposes to store medicinal products, for ensuring, so far as practicable, the turn-over of stocks of medicinal products;

(i) a description of the arrangements for maintaining—

(i) production records, and

(ii) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials used in manufacture, or of medicinal products, with the specification for such materials or medicinal products;

(j) a description of the arrangements for keeping reference samples of—

(i) materials used in the manufacture of medicinal products, and

(ii) medicinal products;

(k) where the application relates to an exempt advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow product traceability containing sufficient detail to enable the linking of a product to the patient who received it and vice versa; and

(l) details of—

(i) any manufacturing operations, other than those to which the licence is to relate, carried on by the proposed licence holder on or near the premises mentioned in sub-paragraph (2)(c), and

(ii) the substances or articles to which those operations relate.

Manufacturers' licence relating to import

2.—(1) This paragraph applies to an application for a manufacturer's licence relating to the import from a state other than an EEA State of medicinal products.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the name, pharmaceutical form, country of origin and marketing authorisation number of each imported medicinal product;

(d) the address of each set of premises where the importation operation is to take place;

(e) the address of each set of premises where any testing associated with the importation is to take place;

(f) the address of each set of premises where medicinal products are to be stored, or from which they are to be distributed;

(g) the name, address and qualifications of the qualified person; and

(h) the name, address, qualifications and experience of the person in charge of quality control.

(3) The application must also contain—

(a) details of the importation operations to which the licence is to relate;

(b) a statement of the facilities and equipment available at each set of premises where medicinal products are to be stored, or from which they are to be distributed;

(c) details of—

(i) any manufacturing of medicinal products carried on by the applicant on or near the premises mentioned in sub-paragraph (2)(d) to (f), and

(ii) the substances or articles manufactured or used in the manufacturing;

(d) a description of the arrangements for storage of the medicinal products after importation;

(e) a description of the arrangements at each set of premises for ensuring, so far as practicable, the turn-over of stocks of medicinal products;

(f) a description of the arrangements for maintaining—

(i) records of importation, and

(ii) records of analytical and other procedures applied in the course of importation; and

(g) a description of the arrangements for keeping reference samples of the medicinal products.

Wholesale dealer's licences

3.—(1) This paragraph applies to an application for a wholesale dealer's licence.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the address of each of the premises where medicinal products are to be stored, or from which they are to be distributed; and

(d) the name, address and qualifications of the responsible person.

(3) The application must also contain—

(a) details of the distribution by way of wholesale dealing to which the licence is to relate;

(b) a statement of whether the medicinal products to which the distribution relates are the subject of—

(i) a marketing authorisation,

(ii) a certificate of registration,

(iii) a traditional herbal registration, or

(iv) an Article 126a authorisation;

(c) a statement of whether the medicinal products to which the distribution relates are—

(i) prescription only medicines,

(ii) pharmacy medicines, or

(iii) medicines subject to general sale;

(d) a statement of whether the medicinal products to which the distribution relates are—

(i) special medicinal products, or

(ii) sold or supplied pursuant to regulation 174 (supply in response to spread of pathogenic agents etc);

(e) a statement of whether the medicinal products dealt in under the licence are to be used—

(i) for administration to human beings, or

(ii) as ingredients in the preparation of medicinal products for administration to human beings;

(f) an indication of the range of medicinal products to be stored at each of the premises mentioned in the application;

(g) a statement of the facilities and equipment available at those premises for storing and distributing medicinal products;

(h) a description of the arrangements at those premises for ensuring, so far as practicable, the turn-over of stocks of medicinal products (whether by the maintenance of records or by other means);

(i) details of an emergency plan which satisfies the requirements of regulation 43(7)(b), and

(j) a description of the arrangements for keeping records relating to products received or dispatched.

(4) In sub-paragraph (2)(d) "the responsible person" means the person who is to have responsibility, in relation to wholesale distribution activity carried out under the licence, for—

(a) ensuring that any conditions subject to which the licence is granted are complied with; and

(b) ensuring the quality of medicinal products being handled by the holder of the licence is being maintained in accordance with the requirements of the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applicable to those products.

All licences

4.—(1) If an application does not include information or other matters required under this Schedule, the application must state—

(a) why that information is not applicable; or

(b) any other reason for not including them.

(2) An application for a licence must be in English.

(3) The pages of an application for a licence must be serially numbered.

(4) The applicant must sign the application.

(5) If the application is made by another person on behalf of the applicant, that person must also sign the application.

SCHEDULE 4 Regulation 24

Standard provisions of licences under Part 3

PART 1

Manufacturer's licence relating to manufacture and assembly

1. The provisions of this Part are standard provisions of a manufacturer's licence relating to the manufacture or assembly of medicinal products.

2. The licence holder must place the quality control system referred to in Article 11(1) of the Good Manufacturing Practice Directive under the authority of the person notified to the licensing authority in accordance with paragraph 1(2)(g) of Schedule 3.

3. The licence holder may use a contract laboratory pursuant to Article 11(2) of the Good Manufacturing Practice Directive if the laboratory is operated by a person approved by the licensing authority.

4. The licence holder must provide such information as may be requested by the licensing authority—

(a) about the products currently being manufactured or assembled by the licence holder; and

(b) about the operations being carried out in relation to such manufacture or assembly.

5. The licence holder must inform the licensing authority of any change that the licence holder proposes to make to a person named in the licence as—

(a) the person whose duty it is to supervise the manufacturing or assembling operations;

(b) in charge of the animals from which are derived substances used in the production of the medicinal products being manufactured or assembled; or

(c) responsible for the culture of living tissues used in the manufacture of the medicinal products being manufactured or assembled.

6. The licence holder must—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of the Good Manufacturing Practice Directive; and

(b) permit the authorised person to take copies or make extracts from such documentation.

7. The licence holder must keep readily available for examination by a person authorised by the licensing authority the samples in each batch of finished medicinal product referred to in Article 11(4) of the Good Manufacturing Practice Directive.

8. Where the licence holder has been informed by the licensing authority that the strength, quality or purity of a batch of a medicinal product to which the licence relates has been found not to conform with—

(a) the specification for the finished product; or

(b) the provisions of these Regulations applicable to the medicinal product,

the holder must, if so directed, withhold the batch from distribution, so far as reasonably practicable, for a period (not exceeding six weeks) specified by the licensing authority.

9. The licence holder must ensure that tests for determining conformity with the standards and specifications applying to a product used in the manufacture of a medicinal product must, except so far as the conditions of the product specification for that product otherwise provide, be applied to

samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage of the manufacture as may be approved by the licensing authority.

10. Where the manufacturer's licence relates to the assembly of a medicinal product or class of product, and the licence holder supplies the product at such a stage of assembly that does not fully comply with the provisions of the product specification which relate to labelling, the licence holder must communicate the particulars of those provisions to the person to whom that product has been supplied.

11. Where—

(a) the manufacturer's licence relates to the assembly of a medicinal product;

(b) the medicinal product is not manufactured by the licence holder; and

(c) particulars of the name and address of the manufacturer of the product, or the person who imports the product, have been given by the licence holder to the licensing authority,

the licence holder must immediately notify the licensing authority in writing of any changes in the particulars.

12. The licence holder must keep readily available for examination by a person authorised by the licensing authority durable records of the details of the manufacture of intermediate products held by the licence holder for use in the manufacture of biological medicinal products, and the records must—

(a) be in such form as to ensure that the licence holder has a comprehensive record of all matters that are relevant to an evaluation of the safety, quality and efficacy of a finished biological medicinal product manufactured using those intermediate products; and

(b) not be destroyed without the consent of the licensing authority until the records of the details of manufacture of finished medicinal products which were or may be manufactured using those intermediate products may be destroyed in accordance with the requirements of these Regulations.

13. Where—

(a) animals are used in the production of medicinal products; and

(b) a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration contains provisions relating to them,

the manufacturer's licence holder must arrange for the animals to be housed in such premises, and managed in such a manner, as facilitates compliance with those provisions.

14. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided to the licensing authority is not false or misleading in any material particular if—

(a) it relates to a medicinal product which the licence holder manufactures or assembles; or

(b) it relates to any starting materials or intermediate products held by the licence holder which are for use in the manufacture of medicinal products.

PART 2

Manufacturer's licence relating to the import of medicinal products from a state other than an EEA State

15. The provisions of this Part are standard provisions of a manufacturer's licence relating to the import of medicinal products from a state other than an EEA State.

16. The licence holder must place the quality control system referred to in Article 11(1) of the Good Manufacturing Practice Directive under the authority of the person notified to the licensing authority in accordance with paragraph 2(2)(h) of Schedule 3.

17. The licence holder may use a contract laboratory pursuant to Article 11(2) of the Good Manufacturing Practice Directive if operated by a person approved by the licensing authority.

18. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal products which the licence holder imports.

19. The licence holder must—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of the Good Manufacturing Practice Directive; and

(b) permit the person authorised to take copies or make extracts from such documentation.

20. Where the licence holder has been informed by the licensing authority that the strength, quality or purity of a batch of a medicinal product to which the licence relates has been found not to conform with—

(a) the specification of the medicinal product in question; or

(b) those provisions of these Regulations that are applicable to the medicinal product,

the licence holder must, if so directed, withhold the batch from distribution, so far as reasonably practicable, for such a period (not exceeding six weeks) as may be specified by the licensing authority.

21. The licence holder must ensure that any tests for determining conformity with the standards and specifications applying to any ingredient used in the manufacture of a medicinal product must, except so far as the conditions of the product specification for that ingredient otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

22.—(1) Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from a state other than an EEA State—

(a) in response to an order which satisfies the requirements of regulation 167 (supply to fulfil special patient needs); and

(b) where the conditions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days before the day on which each importation of a special medicinal product takes place, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or the name of the manufacturer of the medicinal product;

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name, or where that constituent does not have any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in sub-paragraph (6); and

(e) the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported and, if the person who will supply the medicinal product for importation is not the manufacturer or assembler, the name and address of the supplier.

(3) The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in sub-paragraph (2), the licensing authority has notified the licence holder in writing that the product should not be imported.

(4) The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in sub-paragraph (3) that the product may be imported.

(5) Where the licence holder sells or supplies special medicinal products, the licence holder must, in addition to any other records which are required by the provisions of the licence, make and maintain written records relating to—

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

(b) details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware.

(6) The licence holder must not, on any one occasion, import more than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and must not, on any one occasion, import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder must not publish any advertisement, catalogue or circular relating to a special medicinal product or make any representations in respect of that product.

(8) The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(9) The licence holder must cease importing or supplying a special medicinal product if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

(10) In this paragraph—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia: lists of names);

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the European Pharmacopoeia or a foreign or international compendium of standards and "current" in this definition means current at the time the notice is sent to the licensing authority.

23. The licence holder must take all reasonable precautions and exercise due diligence to ensure that any information provided to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product for human use which is imported from a state other

than an EEA State, handled, stored or distributed under the licence is not false or misleading in a material particular.

PART 3

Manufacturer's licence relating to exempt advanced therapy medicinal products

24. The provisions of paragraphs 25 to 27 are incorporated as additional standard provisions of a manufacturer's licence relating to the manufacture and assembly of exempt advanced therapy medicinal products.

25. The licence holder must ensure that the immediate packaging of an exempt advanced therapy medicinal product is labelled to show the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the expiry date in clear terms including the year and month and, if applicable, the day;

(c) a description of the active substance, expressed qualitatively and quantitatively;

(d) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and of their specific origin;

(e) the pharmaceutical form and the contents by weight, volume or number of doses of the product;

(f) a list of excipients, including preservative systems;

(g) the method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated;

(h) any special storage precautions;

(i) specific precautions relating to the disposal of the unused product or waste derived from the product and, where appropriate, reference to any appropriate collection system;

(j) the name and address of the holder of the manufacturer's licence;

(k) the manufacturer's licence number;

(l) the manufacturer's batch number;

(m) the unique donation code referred to in Article 8(2) of Directive 2004/23/EC; and

(n) where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words “for autologous use only”.

26. The licence holder must ensure that the package leaflet of the exempt advanced therapy medicinal product shall include the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the intended effect of the medicinal product if correctly used, applied, administered or implanted;

(c) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and, where such cells or tissues are of animal origin, their specific origin;

(d) where the product contains a medical device or an active implantable medical device, a description of that device and, where that device contains cells or tissues of animal origin, their specific origin;

(e) any necessary instructions for use, including—

(i) the posology,

(ii) the method of use, application, administration or implantation and, if appropriate, the route of administration,

(iii) a description of symptoms of overdose,

(iv) action to be taken in the event of overdose, including any emergency procedures,

(v) action to be taken if one or more doses have been missed, and

(vi) a recommendation to consult the doctor or pharmacist for any clarification on the use of the product;

(f) where adverse reactions are known, a description of those which may occur under recommended conditions of use of the product and, if appropriate, an indication of action to be taken in such a case;

(g) an instruction that the patient report any adverse reaction not specified in the package leaflet to the doctor or pharmacist;

(h) the expiry date in clear terms and a warning against using the product after that date;

(i) any special storage precautions;

(j) a description of any visible signs of deterioration;

(k) a complete qualitative and quantitative composition;

(l) the name and address of the holder of the manufacturer's licence; and

(m) the date on which the package leaflet was last revised.

27. The licence holder must keep the data referred to in paragraph 8 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

PART 4

Wholesale dealer's licence

All wholesale dealer's licences

28. The provisions of this Part are standard provisions of a wholesale dealer's licence.

29. The licence holder must not use any premises for the handling, storage or distribution of medicinal products other than those specified in the licence or notified to the licensing authority from time to time and approved by the licensing authority.

30. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of medicinal products which the licence holder handles, stores or distributes.

31. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided by the licence holder to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product which the licence holder handles, stores or distributes is not false or misleading.

Wholesale dealer's licence relating to special medicinal products

32. The provisions of paragraphs 33 to 42 are incorporated as additional standard provisions of a wholesale dealer's licence relating to special medicinal products.

33. Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from another EEA State—

(a) in response to an order which satisfies the requirements of regulation 167, and

(b) where the conditions set out in paragraphs 34 to 41 are complied with.

34. No later than 28 days prior to each importation of a special medicinal product, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or the name of the manufacturer of the medicinal product;

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name, or where that constituent does not have any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in paragraph 38; and

(e) the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported and, if the person who will supply the medicinal product for importation is not the manufacturer or assembler, the name and address of the supplier.

35. The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in paragraph 34, the licensing authority has notified the licence holder in writing that the product should not be imported.

36. The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in paragraph 35, that the product may be imported.

37. Where the licence holder sells or supplies special medicinal products, the licence holder must, in addition to any other records which are required by the provisions of the licence, make and maintain written records relating to—

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

(b) details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware.

38. The licence holder must not, on any one occasion, import more than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and must not, on any one occasion, import more than the quantity notified to the licensing authority under paragraph 34(d).

39. The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

40. The licence holder must not publish any advertisement, catalogue, or circular relating to a special medicinal product or make any representations in respect of that product.

41. The licence holder must cease importing or supplying a special medicinal product if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

42. In this Part—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia- lists of names);

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the European Pharmacopoeia or a foreign or international compendium of standards, and "current" in this definition means current at the time the notice is sent to the licensing authority.

Wholesale dealer's licence relating to exempt advanced therapy medicinal products

43. The provisions of paragraph 44 are incorporated as additional standard provisions of a wholesale dealer's licence relating to exempt advanced therapy medicinal products.

44. The licence holder shall keep the data referred to in paragraph 16 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

SCHEDULE 5

Regulation 27; Schedule 11paragraphs 11(3), 13(3),23(4) and 30(4)

Review upon oral representations

Application of this Schedule

[F7 1.—(1) This Schedule applies if a person ("the applicant") mentioned in sub-paragraph (2) notifies the licensing authority that the applicant wishes the licensing authority to submit the proposal or as the case may be the decision to review upon oral representations under—

(a) regulation 27(3)(b);

(b) regulation 45H(3)(b);

(c) regulation 45R(3)(b);

(d) regulation 256J(4)(b); or

(e) Part 1, 2 or 3 of Schedule 11.

(2) Those persons are—

(a) in respect of notification under regulation 27(3)(b) the licence holder;

(b) in respect of a notification under regulation 45H(3)(b) the person registered as a broker;

(c) in respect of a notification under regulation 45R(3)(b) the person with an active substance registration;

(d) in respect of a notification under regulation 256J(4)(b) the person on the list in accordance with Part 12A; and

(e) in respect of a notification under Part 1, 2 or 3 of Schedule 11—

(i) an applicant for a UK marketing authorisation, certificate of registration or traditional herbal registration,

(ii) an applicant for the renewal of an authorisation, certificate or registration, and

(iii) the holder of an authorisation, certificate or registration.**]**

Textual Amendments

F7 Sch. 5 para. 1 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(a)**

Appointment of reviewers

2.—(1) The licensing authority must—

(a) appoint a panel of at least two persons ("the reviewers") to conduct the review; and

(b) provide facilities for the applicant to have the opportunity to appear before the reviewers.

(2) A person must not be appointed under sub-paragraph (1) if within the period of one year immediately preceding that time the person has been a member of—

(a) the Commission;

(b) an expert committee appointed by the licensing authority;

(c) an expert advisory group;

(d) the British Pharmacopoeia Commission or any of its sub-committees;

(e) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Medicines Act 1968; or

(f) the Herbal Medicines Advisory Committee formerly established under section 4 of the Medicines Act 1968.

(3) A person appointed under sub-paragraph (1) must not be an officer or servant of a Minister of the Crown, the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister.

Procedure before hearing

3.—(1) The applicant must supply the reviewers with a written summary of the oral representations that the applicant wishes to make and any documents on which the applicant wishes to rely in support of them before the end of the period of three months beginning with the date of the notification mentioned in paragraph 1.

(2) The reviewers may, at the request of the applicant and after consulting the licensing authority, extend the period mentioned in sub-paragraph (1) up to a maximum of six months beginning with the date of that notification.

(3) The applicant may submit additional written representations or documents after the end of the periods for doing so only with the permission of the reviewers.

(4) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the representations and documents referred to in paragraphs (1) and (3)—

(a) must not be based on any evidence or data that was not available to the licensing authority at the time that the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority; unless

(b) the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(5) The reviewers must notify the applicant and the licensing authority of the date of the hearing at least 28 days before that date, unless the applicant and the licensing authority agree to a shorter period of notice.

(6) The reviewers may establish at any stage of the procedures described in this Schedule a date by which all of those procedures, except for the hearing, must be completed, and notify this date to the applicant and to the licensing authority.

(7) The date established under sub-paragraph (6) must not be earlier than whichever is the earlier of—

(a) the first day after the end of the period of three months beginning with the date of the notification mentioned in paragraph 1; or

(b) the first day after the end of the period of 28 days beginning with the date on which the reviewers receive the written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1) and (3) of this paragraph,

and in any case not earlier than the first day after the period of seven days beginning on the day after the notification under sub-paragraph (6).

(8) A date established under sub-paragraph (6) may be varied or withdrawn on the application of the applicant or of the licensing authority.

(9) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the reviewers must not take into account any documents or other evidence, or any representations based on such documents or evidence, in the conduct of the hearing if it thinks that the data or evidence on which the documents or representations are based, or the evidence that is presented, were not available to the licensing authority at the time when the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority, unless the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(10) The reviewers may give such other directions as they think fit for the conduct of the hearing, including—

(a) the postponing or adjournment of the hearing for such period as it may decide; and

(b) establishing a list of documents that will be taken into account in the conduct of the hearing.

(11) If the applicant fails to comply with a time limit under sub-paragraph (1), (2) or (6)—

(a) the applicant may not appear before the reviewers; and

(b) the licensing authority must decide whether—

(i) to proceed with its proposal to revoke, vary or suspend the licence,

(ii) to confirm or alter its decision,

(iii) to refer the application to the Committee for Herbal Medicinal Products,

(iv) to grant or renew the UK marketing authorisation, certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application, [F8]...

(v) to revoke, vary or suspend the authorisation, certificate or registration,

[[F9](vi) to proceed to suspend, vary or remove the person's broker registration,

(vii) ro proceed to suspend, vary or remove the person's active substance registration, or

(viii) to proceed to suspend, vary or remove the person's entry on the list,**]**

as the case may be.

(12) The licensing authority must notify the applicant of its decision.

Textual Amendments

F8 Word in Sch. 5 para. 3(11)(b)(iv) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(i)**

F9 Sch. 5 para. 3(11)(b)(vi)-(viii) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(ii)**

Procedure at hearing

4.—(1) Both the applicant and the licensing authority may make representations at the hearing.

(2) The hearing must be in public if the applicant so requests.

(3) If the applicant fails to appear at the hearing, the reviewers may conduct the review on the basis of the applicant's written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1), (2) and (3) of paragraph 3.

Procedure following hearing

5.—(1) After the hearing the reviewers must provide a report to the licensing authority and to the applicant either—

(a) by the end of the period of 60 days beginning with the day after the conclusion of the hearing; or

(b) within such further period as the reviewers may notify to the licensing authority and to the applicant within that 60 day period.

(2) The licensing authority must take the report into account and decide whether—

(a) to proceed with its proposal to revoke, vary or suspend the licence;

(b) to confirm or alter its decision;

(c) to refer the application to the Committee for Herbal Medicinal Products;

(d) to grant or renew the UK marketing authorisation, certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application; [F10]...

[[F11](e) to revoke, vary or suspend the authorisation, certificate or registration;

(f) to proceed to suspend, vary or remove a person's broker registration;

(g) to proceed to suspend, vary or remove a person's active substance registration; or

(h) to proceed to suspend, vary or remove a person's entry on the list,**]**

as the case may be.

(3) The licensing authority must notify the applicant of its decision.

Textual Amendments

F10 Word in Sch. 5 para. 5(2)(d) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(i)**

F11 Sch. 5 para. 5(2)(e)-(h) substituted for Sch. 5 para. 5(2)(e) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(ii)**

SCHEDULE 6 Regulations 36(3) and 42(3)

Manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products

PART 1

Manufacturer's licences

1. The requirements in paragraphs 2 to 12 apply to a manufacturer's licence insofar as it relates to the manufacture and assembly of exempt advanced therapy medicinal products.

2. The licence holder must inform the licensing authority of any adverse reaction or suspected adverse reaction of which the holder is aware within the period of 15 days beginning on the day following the first day on which the holder knew about the reaction.

3. The licence holder must ensure, if using human cells or tissues in an exempt advanced therapy medicinal product, that the donation, procurement and testing of those cells or tissues is in accordance with Directive 2004/23/EC.

4. The licence holder must ensure that any human tissue or cell component imported into the United Kingdom and used by the holder as a starting material or raw material in the manufacture of an exempt advanced therapy medicinal product shall meet equivalent standards of quality and safety to those laid down in—

(a) Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells [M2]; and

(b) Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells [M3].

Marginal Citations

M2 OJ No L 38, 9.2.2006, p. 40.

M3 OJ No L 294, 25.10.2006, p. 32.

5. The licence holder must ensure that any blood or blood component imported into the United Kingdom and used by the manufacturer's licence holder as a starting material or raw material in the manufacture of an exempt advanced therapy medicinal product meets equivalent standards of quality and safety to those laid down in Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [M4].

Marginal Citations

M4 OJ No L 91, 30.3.2004, p. 25, as amended by Commission Directive 2011/38/EU, OJ No L 94, 12.4.2011, p. 28.

6. Where the holder of a manufacturer's licence distributes by way of wholesale dealing any exempt advanced therapy medicinal product manufactured or assembled pursuant to the licence that person must comply with—

(a) the requirements of paragraphs 15, 16, 18 and 19; and

(b) the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive;

as if that person were the holder of a wholesale dealer's licence.

7. The licence holder must, at the written request of the licensing authority, set up a risk management system designed to identify, characterise, prevent or minimise risks related to the exempt advanced therapy medicinal product.

8. The licence holder must establish and maintain a system ensuring that the exempt advanced therapy medicinal product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the establishment where the product is used.

9. The licence holder must, subject to paragraph 27 of Schedule 4, keep the data referred to in paragraph 8 for a minimum of 30 years after the expiry date of the exempt advanced therapy medicinal product.

10. The licence holder must secure that the data referred to in paragraph 8 will, in the event that—

(a) the licence is suspended, revoked or withdrawn; or

(b) the licence holder becomes bankrupt or insolvent,

be held available to the licensing authority by the holder of a manufacturer's licence for the period described in paragraph 9 or such longer period as may be required pursuant to paragraph 27 of Schedule 4.

11. The licence holder must, where an exempt advanced therapy medicinal product contains human cells or tissues, ensure that the traceability system established in accordance with paragraph 8 is complementary to and compatible with the requirements laid down in—

(a) Articles 8 and 14 of Directive 2004/23/EC as regards human cells and tissues other than blood cells, and

(b) as regards human blood cells, Articles 14 and 24 of Directive 2002/98/EC.

12. The licence holder must not import or export any exempt advanced therapy medicinal product.

PART 2

Wholesale dealer's licences

13. The requirements in paragraphs 14 to 20 apply to a wholesale dealer's licence insofar as it relates to exempt advanced therapy medicinal products.

14. The licence holder must obtain supplies of exempt advanced therapy medicinal products only from—

(a) the holder of a manufacturer's licence in respect of those products; or

(b) the holder of a wholesale dealer's licence in respect of those products.

15. The licence holder must distribute an exempt advanced therapy medicinal product by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence in respect of those products; or

(b) a person who—

(i) may lawfully administer those products, and

(ii) solicited the product for an individual patient.

16. The licence holder must establish and maintain a system ensuring that the exempt advanced therapy medicinal product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the establishment where the product is used.

17. The licence holder must inform the licensing authority of any adverse reaction to any exempt advanced therapy medicinal product supplied by the holder of the wholesale dealer's licence of which the holder is aware.

18. The licence holder must, subject to paragraph 44 of Schedule 4, keep the data referred to in paragraph 16 for a minimum of 30 years after the expiry date of the exempt advanced therapy medicinal product.

19. The licence holder must secure that the data referred to in paragraph 16 will, in the event that—

(a) the licence is suspended, revoked or withdrawn; or

(b) the licence holder becomes bankrupt or insolvent,

be held available to the licensing authority by the holder of a wholesale dealer's licence for the period described in paragraph 18 or such longer period as may be required pursuant to paragraph 44 of Schedule 4.

20. The licence holder must not import or export any exempt advanced therapy medicinal product.

SCHEDULE 7 Regulation 41

Qualified persons

PART 1

Qualification requirements for qualified person

1. A person must satisfy the requirements in paragraphs 2 and 8 or, alternatively, the requirements in paragraphs 7 and 8, of this Schedule before acting as a qualified person (but this is subject to Part 2).

2. The person must have a degree, diploma or other formal qualification which satisfies the requirements of this Part, in one of the following subjects—

(a) pharmacy;

(b) medicine;

(c) veterinary medicine;

(d) chemistry;

(e) pharmaceutical chemistry and technology; or

(f) biology,

but this paragraph is subject to paragraph 7.

3. A qualification satisfies the requirements of this Part if it is awarded on completion of a university course of study, or a course recognised as equivalent by the member State in which it is studied, which—

(a) satisfies the minimum requirements specified in paragraph 4; and

(b) extends over a period of at least four years of theoretical and practical study of a subject specified in paragraph 2 (but this is subject to paragraphs 5 and 6).

4.—(1) A course should include at least the following core subjects—

(a) experimental physics;

(b) general and inorganic chemistry;

(c) organic chemistry;

(d) analytical chemistry;

(e) pharmaceutical chemistry, including analysis of medicinal products;

(f) general and applied medical biochemistry;

(g) physiology;

(h) microbiology;

(i) pharmacology;

(j) pharmaceutical technology;

(k) toxicology; and

(l) pharmacognosy.

(2) The subjects mentioned in sub-paragraph (1) should be balanced in such a way as to enable the person to fulfil the obligations specified in Part 3 of this Schedule.

5. If the course referred to in paragraph 3 is followed by a period of theoretical and practical training of at least one year, including a training period of at least six months in a pharmacy open to the public and a final examination at university level, the minimum duration of the course is three and a half years.

6. If two university courses, or courses recognised as of university equivalent standard, co-exist, one of which extends over four years and the other over three years, the three-year course is to be treated as fulfilling the condition as to the duration of the course in paragraph 3, provided that the member State in which the courses take place recognises the formal qualifications gained from each course as being equivalent.

7. If the person's formal qualifications do not satisfy the requirements of this Part, the person may act as a qualified person if the licensing authority is satisfied, on the production of evidence, that the person has adequate knowledge of the subjects specified in paragraph 4(1).

8.—(1) The person must (subject to sub-paragraph (2)) have at least two years' practical experience in an undertaking authorised to manufacture medicinal products of—

(a) qualitative analysis of medicinal products;

(b) quantitative analysis of active substances; and

(c) the testing and checking necessary to ensure the quality of medicinal products.

(2) But—

(a) if the person has completed a university course lasting at least five years, the minimum period of practical experience under this paragraph is one year; and

(b) if the person has completed a university course lasting at least six years, the minimum period of practical experience under this paragraph is six months.

PART 2

Qualified persons with long experience

9.—(1) This paragraph applies to a person who has acted as a qualified person since the coming into force of Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [M5].

(2) A person to whom this paragraph applies may continue to act as a qualified person.

Marginal Citations

M5 OJ No L 147, 9.6.1975, p.13, no longer in force.

10.—(1) This paragraph applies to a person who—

(a) holds a degree, diploma or other formal qualification in a scientific discipline awarded on completion of a university course or course recognised as equivalent; and

(b) began the course before 21 May 1975.

(2) A person to whom this paragraph applies may act as a qualified person provided that sub-paragraph (3) (and, where applicable, paragraph 11) is satisfied.

(3) This sub-paragraph is satisfied if, for at least two years before 21 May 1985, the person has carried out one of the following activities in an undertaking authorised to manufacture medicinal products—

(a) production supervision;

(b) qualitative and quantitative analysis of active substances; or

(c) testing and checking, under the direct supervision of the qualified person in respect of the undertaking, to ensure the quality of the medicinal products.

11. If a person to whom paragraph 10 applies acquired the practical experience mentioned in paragraph 10(3) before 21 May 1965, the person must complete a further one year's practical experience of the kind specified in that paragraph immediately before the person may act as a qualified person.

PART 3

Obligations of qualified person

12. The qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in the United Kingdom has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products;[F12]...

(b) in the case of medicinal products imported from a non-EEA State, irrespective of whether the products have been manufactured in an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a

authorisation, certificate of registration or traditional herbal registration relating to those products; **[**[F13]and

(c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a third country, that the features specified in paragraph 18A of schedule 24 have been affixed on the packaging.**]**

Textual Amendments

F12 Word in Sch. 7 para. 12(a) omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(a)** and word in Sch. 7 para. 12(a) omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(a)**

F13 Sch. 7 para. 12(c) and preceding word inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(b)** and Sch. 7 para. 12(c) and preceding word inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(b)**

13.—(1) This paragraph applies where—

(a) a medicinal product which has undergone the controls referred to in paragraph 12 in another member State is imported to the United Kingdom; and

(b) each batch of the product is accompanied by control reports signed by another qualified person in respect of the medicinal product.

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph 12.

14.—(1) This paragraph applies where—

(a) medicinal products are imported from a country other than an EEA State; and

(b) appropriate arrangements have been made by the European Union with that country to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down by the European Union, and

(ii) the controls referred to in paragraph 12(b) have been carried out in that country.

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph 12.

15.—(1) The qualified person is responsible for ensuring, in relation to a medicinal product, that documentary evidence is produced that each batch of the product satisfies the requirements of paragraph 12.

(2) The documentary evidence referred to in sub-paragraph (1) must be kept up to date and must be available for inspection by the licensing authority for a period of at least five years.

[F14SCHEDULE 7A

Regulation 45N(5)(b)

Information to be provided for registration as an importer, manufacturer or distributor of active substances

Textual Amendments

F14 Sch. 7A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **33**

1. The name and address of the applicant.

2. The name and address of the person (if any) making the application on the applicant's behalf.

3. The address of each of the premises where any operations to which the registration relates are to be carried out.

4. The address of any premises not mentioned by virtue of the above requirement, where—

(a) the applicant proposes to keep any living animals, from which substance(s) used in the production of the active substance(s) to which the application relates are to be derived;

(b) materials of animal origin from which an active substance is to be derived, as mentioned in the above sub-paragraph, are to be kept.

5. The address of each of the premises where active substances are to be stored, or from which active substances are to be distributed.

6. The address of each of the premises where any testing associated with the manufacture or assembly of active substances to which the registration relates.

7. The name, address, qualifications and experience of the person whose duty it will be to supervise any manufacturing operations, and the name and job title of the person to whom they report.

8. The name, address, qualifications and experience of the person who will have responsibility for the quality control of active substances, and the name and job title of the person to whom they report.

9. The name, address, qualifications and experience of the person whose duty it will be to supervise any importation, storage or distribution operations, and the name and job title of the person to whom they report.

10. The name, address and qualifications of the person to be responsible for any animals kept as mentioned in paragraph 4(a).

11. The name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of an active substance.

12. For each active substance to be manufactured, imported, or distributed—

(a) the CAS registration number assigned to that active substance by the Chemical Abstracts Service, a division of the American Chemical Society;

(b) where applicable, the Anatomical Therapeutic Category code assigned to that active substance under the Anatomical Therapeutic Chemical Classification System used for the classification of drugs by the World Health Organisation's Collaborating Centre for Drug Statistics Methodology;

(c) either—

(i) the International Union of Pure and Applied Chemistry nomenclature, or

(ii) the common name; and

(d) the intended quantities of each active substance to be manufactured, imported or distributed.

13. Details of the operations to which the registration relates, including a statement of whether they include—

(a) the manufacture of active substances;

(b) the importation of active substances from third countries;

(c) the storage of active substances; or

(d) the distribution of active substances.

14. A statement of the facilities and equipment available at each of the premises where active substances are to be manufactured, stored or distributed.

15. A statement as to whether the particular active substances are intended for—

(a) use in a medicinal product with an EU marketing authorisation;

(b) use in a special medicinal product; or

(c) export to a third country.

16. A separate statement in respect of each of the premises mentioned in the application of—

(a) the manufacturing, storage or distribution operations carried out at those sites, and the specific active substances to which those activities relate; and

(b) the equipment available at those premises for carrying out those activities.

17. A statement of the authority conferred on the person responsible for quality control to reject unsatisfactory active substances.

18. A description of the arrangements for the identification and storage of materials before and during the manufacture of active substances.

19. A description of the arrangements for the identification and storage of active substances.

20. A description of the arrangements at each of the premises where the applicant proposes to store active substances for ensuring, as far as practicable, the turn-over of stocks of active substances.

21. A description of the arrangements for maintaining—

(a) production records, including records of manufacture and assembly;

(b) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials use in manufacture, or of active substances, with the specification for such materials or active substances;

(c) records of importation;

(d) records of storage and distribution.

22. A description of the arrangements for keeping reference samples of—

(a) materials used in the manufacture of active substances; and

(b) active substances.

23. Where the application relates to active substances intended for use in an advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow traceability containing sufficient detail to enable the linking of an active substance to the advanced therapy medicinal product it was used in the manufacture of and vice versa.

24. Details of—

(a) any manufacturing, importation, storage or distribution operations, other than those to which the application for registration relates, carried on by the applicant on or near each of the premises, and

(b) the substances or articles to which those operations relate.**]**

SCHEDULE 8 Regulation 50(1)

Material to accompany an application for a UK marketing authorisation

PART 1

General requirements

1. The name or corporate name and permanent address of the applicant and (where applicable) of the manufacturer of the medicinal product.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the marketing authorisation holder.

3. Qualitative and quantitative particulars of the constituents of the medicinal product, including—

(a) where there is an international non-proprietary name recommended by the World Health Organisation for a constituent, a reference to that name; or

(b) otherwise, a reference to the relevant chemical name.

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

5. A description of the methods of manufacturing the medicinal product.

6. The therapeutic indications and contra-indications for the medicinal product and the adverse reactions associated with it.

7. The posology and pharmaceutical form of the medicinal product, its method and route of administration and its expected shelf life.

8. The reasons for any precautionary and safety measures to be taken for—

(a) the storage of the medicinal product;

(b) the administration of the medicinal product to patients; and

(c) the disposal of the medicinal product and any waste products,

with an indication of the potential risks presented by the medicinal product for the environment.

9. A description of the control methods employed by the manufacturer.

[F15 9A. A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with the principles and guidelines of good manufacturing practice by conducting audits, in accordance with regulation 37(5)(a) and containing—

(a) information about the date of the audit; and

(b) a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.**]**

Textual Amendments

F15 Sch. 8 para. 9A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **34**

10. The results of the following in relation to the medicinal product and its constituent active substances—

(a) pharmaceutical (physico-chemical, biological or microbiological) tests;

(b) pre-clinical (toxicological and pharmacological) tests; and

(c) clinical trials.

11. A detailed summary of those results prepared and signed by an expert with appropriate technical or professional qualifications, which must be set out in a brief curriculum vitae.

12. A summary of the applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance;

(b) the member States in which the appropriately qualified person resides and carries out his or her tasks;

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.

13. The risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

14. Where any clinical trials have been carried out outside the European Union, a statement to the effect that the trials met the ethical requirements of the Clinical Trials Directive.

15. A summary of the product characteristics for the medicinal product in accordance with Part 2 of this Schedule.

16. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

17. A document showing that the manufacturer of the medicinal product is authorised to produce medicinal products in the manufacturer's own country.

18. Where an application for authorisation for the medicinal product to be placed on the market is under consideration in a member State or States—

(a) a list of the member State or States concerned; and

(b) in relation to each application, a copy of—

(i) the summary of the product characteristics proposed by the applicant, and

(ii) the package leaflet proposed by the applicant.

19. Where an authorisation for the medicinal product to be placed on the market has been granted by a member State or by a third country—

(a) a copy of that authorisation;

(b) a summary of the safety data, including the data contained in the periodic safety update reports, where available; and

(c) any suspected adverse reaction reports.

20. Where an authorisation for the medicinal product to be placed on the market has been granted by a member State in accordance with the 2001 Directive, a copy of—

(a) the summary of the product characteristics approved by the competent authority of the member State; and

(b) the package leaflet approved by that competent authority.

21. Where an authorisation for the medicinal product to be placed on the market has been refused by a member State or by a third country, details of that decision and of the reasons for it.

22. A copy of any designation of the medicinal product as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [M6] together with a copy of the relevant Agency opinion.

Marginal Citations

M6 OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.

PART 2

Summary of the product characteristics

The summary of the product characteristics must contain the following information in the following order—

(23) For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004, the statement "This medicinal product is subject to additional monitoring".

(24) The name of the medicinal product followed by its strength and pharmaceutical form.

(25) The qualitative and quantitative composition, using the usual common name or chemical description, of the medicinal product in terms of—

(a) the active substances; and

(b) those excipients of which knowledge is essential for proper administration of the medicinal product.

(26) The pharmaceutical form of the medicinal product.

(27) Clinical particulars in relation to the medicinal product, covering—

(a) therapeutic indications;

(b) posology and method of administration for adults and, where necessary, for children;

(c) contra-indications;

(d) special warnings and precautions for use and, in the case of immunological medicinal products any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient;

(e) interaction with other medicinal products and other forms of interactions;

(f) use during pregnancy and lactation;

(g) effects on ability to drive and to use machines;

(h) other undesirable effects; and

(i) information on overdose (including symptoms, emergency procedures and antidotes).

(28) The pharmacological properties of the medicinal product, covering—

(a) pharmacodynamic properties;

(b) pharmacokinetic properties; and

(c) pre-clinical safety data.

(29) Pharmaceutical particulars in relation to the medicinal product, covering—

(a) a list of excipients;

(b) major incompatibilities;

(c) shelf life after reconstitution of the medicinal product or when the immediate packaging is opened for the first time (as appropriate);

(d) special precautions for storage;

(e) nature and contents of container; and

(f) special precautions for disposal of the used medicinal product or waste materials derived from the medicinal product (as appropriate).

(30) The holder of the UK marketing authorisation.

(31) The number of the UK marketing authorisation.

(32) The date of the first UK marketing authorisation or, where the UK marketing authorisation has been renewed, the date of the last renewal.

(33) The date of any revisions of the text of the summary of the product characteristics.

(34) For radiopharmaceuticals, full details of internal radiation dosimetry.

(35) For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.

[F16SCHEDULE 8A

Regulation 50(1A)

Material to accompany an application for a parallel import licence

Textual Amendments

F16 Sch. 8A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **26** and Sch. 8A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **26**

1. The name or corporate name and permanent address of the applicant.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the parallel import licence holder.

3. Details of the product to be imported if requested by the licensing authority.

4. Details of the UK reference product.

5. If requested by the licensing authority, an evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

6. If requested by the licensing authority, a summary of the applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance;

(b) the member States in which the appropriately qualified person resides and carries out his or her tasks;

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.

7. If requested by the licensing authority, the risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

8. If requested by the licensing authority, a summary of the product characteristics for the medicinal product in accordance with Part 2 of Schedule 8.

9. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.]

SCHEDULE 9

Regulation 50(4)

Undertakings by non-EEA manufacturers

1. The manufacturer must provide and maintain such staff, premises and plant as are necessary for the carrying out in accordance with the marketing authorisation of such stages of the manufacture and assembly of the medicinal products to which the authorisation relates as are undertaken by the manufacturer.

2. The manufacturer must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products to which the marketing authorisation relates and which the manufacturer handles, stores or distributes as are necessary to avoid deterioration of the medicinal products.

3. The manufacturer must provide and maintain a designated quality control department having authority in relation to quality control and being independent of all other departments.

4. The manufacturer must conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products to which the marketing authorisation relates conform with the standards of strength, quality and purity applicable to them under the marketing authorisation.

5. The manufacturer must maintain an effective pharmaceutical quality assurance system involving the active participation of the management and personnel of the different services involved.

6. Where animals are used in the production of any medicinal product and the marketing authorisation contains provisions relating to them the manufacturer must arrange for the animals to be housed in premises of such a nature and to be managed in such a way as will facilitate compliance with such provisions.

7. The manufacturer must make such adequate and suitable arrangements as are necessary for carrying out in accordance with the marketing authorisation any tests of the strength, quality or purity of the medicinal products to which the marketing authorisation relates.

8. The manufacturer must inform the holder of the marketing authorisation of any material alteration in the premises or plant used in connection with the manufacture or assembly of the medicinal products to which the marketing authorisation relates or in the operations for which such premises or plant are so used, and of any change since the granting of the relevant marketing authorisation in respect of any person—

(a) responsible for supervising the production operations;

(b) responsible for quality control of the medicinal products to which the marketing authorisation relates;

(c) in charge of the animals from which are derived any substance used in the production of the medicinal products to which the marketing authorisation relates; or

(d) responsible for the culture of any living tissues used in the manufacture of the medicinal products to which the marketing authorisation relates.

9.—(1) The manufacturer shall keep readily available for inspection by a person authorised by the licensing authority durable records of—

(a) the details of manufacture and assembly of each batch of the medicinal product to which the marketing authorisation relates; and

(b) the tests carried out on the product,

in such a form that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is exported from the country where it has been manufactured or assembled.

(2) The manufacturer shall permit the person authorised to take copies of or make extracts from such records.

(3) Such records shall not be destroyed for a period of five years from the date of release of the batch concerned, or one year after the expiry date of the batch, whichever is the later.

10. The manufacturer must keep readily available for examination by a person authorised by the licensing authority samples of—

(a) each batch of finished products for at least a period of one year after their expiry date; and

(b) starting materials (other than solvents, gases or water) for at least a period of two years after release of the medicinal product of which those materials formed part,

except where the manufacturer is authorised by the licensing authority to destroy such samples earlier.

11.—(1) The manufacturer must implement a system for recording and reviewing complaints in relation to medicinal products to which a marketing authorisation relates, together with an effective system for recalling promptly and at any time the medicinal products in the distribution network.

(2) The manufacturer must record and investigate all complaints described in sub-paragraph (1) and must immediately inform the licensing authority of any defect which could result in a recall from sale, supply or export or in an abnormal restriction on such sale, supply or export.

12. The manufacturer must inform the holder of the marketing authorisation of any material change since the day upon which the authorisation was granted in respect of—

(a) the facilities and equipment available at each of the premises of the manufacturer for carrying out any stage of the manufacture or assembly of the medicinal products to which the marketing authorisation relates;

(b) the facilities and equipment available at each of the premises of the manufacturer for the storage of the medicinal products to which the marketing authorisation relates on, and the distribution of the products from or between, such premises;

(c) any manufacturing operations, not being operations in relation to the medicinal products to which the marketing authorisation relates, which are carried on by the manufacturer on or near any of the premises on which medicinal products to which the marketing authorisation relates are manufactured or assembled, and the substances or articles in respect of which such operations are carried on;

(d) the arrangements for the identification and storage of materials and ingredients before and during manufacture or assembly of the medicinal products to which the marketing authorisation relates and the arrangements for the storage of the products after they have been manufactured or assembled;

(e) the arrangements for ensuring a satisfactory turnover of stocks of medicinal products to which the marketing authorisation relates;

(f) the arrangements for maintaining production records and records of analytical and other testing procedures applied in the course of manufacture or assembly of the medicinal products to which the marketing authorisation relates; or

(g) the arrangements for keeping reference samples of materials used in the manufacture of the medicinal products to which the marketing authorisation relates and reference samples of the medicinal products themselves.

SCHEDULE 10

Regulations 50(6)(g) and 64(5)(b)

National homoeopathic products

Meaning of "national homoeopathic product"

1.—(1) In this Schedule "national homoeopathic product" means a homoeopathic medicinal product that—

(a) is not a registrable homoeopathic medicinal product; and

(b) is indicated for the relief or treatment of minor symptoms or minor conditions in human beings.

(2) For this purpose symptoms or conditions are minor if they can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

General requirements for application

2.—(1) An application for the grant of a UK marketing authorisation for a national homoeopathic product does not need be made in accordance with, and an applicant for such an authorisation does not need to comply with—

(a) paragraphs (b) and (c) of paragraph 10 of Schedule 8 (requirement to submit results of pre-clinical tests and clinical trials);

(b) the guidance referred to in paragraph (1) in the "Introduction and general principles" of Annex 1 to the 2001 Directive in so far as it relates to the requirement to submit the results of pre-clinical tests and clinical trials; or

(c) the following provisions of Part 1 of that Annex—

(i) sections 2.4 to 2.7 (non-clinical and clinical overview and non-clinical and clinical summaries),

(ii) section 4 (Module 4: non-clinical reports), or

(iii) section 5 (Module 5: clinical study reports).

(2) The applicant must submit with the application—

(a) particulars and documents relating to the safety of the product in accordance with paragraph 3 (subject to paragraph 4); and

(b) particulars and documents relating to the efficacy of the product in accordance with paragraph 5.

(3) References in Annex 1 to the 2001 Directive to non-clinical reports, non-clinical documentation and non-clinical data apply in relation to the application as if they were references to the particulars and documents referred to in paragraph 3.

(4) References in that Annex to clinical study reports, clinical documentation and clinical data apply in relation to the application as if they were references to the particulars and documents referred to in paragraph 5.

Requirement to submit safety data

3.—(1) The applicant must submit data as to the safety of the product unless paragraph 4 applies.

(2) The data must include information about the following aspects of the safety of the product—

(a) pharmacology;

(b) pharmacokinetics; and

(c) toxicology, including its toxicity, genotoxicity, reproductive and developmental toxicity and local tolerance.

(3) The data must be scientific data unless sub-paragraph (5) applies.

(4) For this purpose "scientific data" means—

(a) study reports in relation to the product;

(b) published scientific data; or

(c) a combination of data within paragraph (a) and data within paragraph (b).

(5) The applicant may submit other data in relation to an aspect of the safety of the product if having made reasonable attempts to obtain scientific data in relation to that aspect—

(a) the applicant is satisfied that no such scientific data is available; or

(b) the applicant thinks that such scientific data as is available may be inadequate to demonstrate an acceptable level of safety in relation to that aspect.

(6) The applicant must include with the data—

(a) a table of contents; and

(b) an evaluation of the scientific data, including an explanation of how it demonstrates an acceptable level of safety.

(7) If the applicant submits data other than scientific data, the applicant must include—

(a) a statement that sub-paragraph (5) applies; and

(b) an explanation of why an acceptable level of safety can be demonstrated despite the lack of scientific data.

Exceptions to requirement to submit safety data

4.—(1) The applicant does not need to submit data as to the safety of the product if—

(a) condition A, B or C is met; and

(b) the application is accompanied by a written statement that the condition is met.

(2) Condition A is that the product—

(a) is derived from a homoeopathic stock that is commonly present in food; and

(b) is intended to be administered orally.

(3) For this purpose "food" has the meaning given by Council Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [M7].

(4) Condition B is that—

(a) the product is derived from a homoeopathic stock from which is derived a medicinal product that has a marketing authorisation, certificate of registration or traditional herbal registration ("the source product");

(b) the source product is subject to general sale within the meaning of regulation 5(1); and

(c) the product has the same route of administration and the same degree of dilution as the source product.

(5) Condition C is that the product is derived from a homoeopathic stock that—

(a) is diluted to at least 1 in 10^{24} of the stock; and

(b) is not a material derived from a human or animal source.

Marginal Citations

M7 OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p. 14).

Requirement to submit efficacy data

5.—(1) The applicant must submit data as to the efficacy of the product.

(2) The data must consist of at least one the following—

(a) study reports in relation to the product;

(b) published scientific literature; or

(c) the results of investigations (commonly known as homoeopathic provings) consisting of the administration of a substance to a human subject to ascertain the symptoms it produces.

(3) The applicant must include with the data—

(a) a table of contents; and

(b) an evaluation of the data, including an explanation of how the data establishes that the product has a recognised level of efficacy in the therapeutic indication for which authorisation is sought.

SCHEDULE 11

Regulations 58(5);59(7); 60(11);66(8); 68(12); 104(4);105(9); 108(8); 110(9);130(11); 133(8); and 137

Advice and representations

PART 1

General procedures

Application of this Part

1.—(1) This Part of this Schedule applies to—

(a) an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration;

(b) an application to renew a UK marketing authorisation, certificate of registration or traditional herbal registration; and

(c) a proposal to revoke, vary or suspend a UK marketing authorisation, certificate of registration or traditional herbal registration (including variation by the variation or removal of a condition to which a UK marketing authorisation or a certificate of registration is subject) other than a proposal to vary the authorisation, certificate or registration on the application of or by agreement with its holder.

(2) This Part is subject to Part 4 of this Schedule.

Requirement to consult the appropriate committee

2.—(1) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety, quality or efficacy—

(a) to refuse to grant or renew a UK marketing authorisation or traditional herbal registration in response to the application; or

(b) to revoke, vary or suspend a UK marketing authorisation or traditional herbal registration.

(2) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety or quality—

(a) to refuse to grant or renew a certificate of registration in response to the application; or

(b) to revoke, vary or suspend a certificate of registration.

(3) This paragraph is subject to paragraphs 3 and 4 (exceptions to requirement to consult).

(4) In this Schedule "the appropriate committee" in relation to any function means whichever of the bodies listed in paragraph (5) the licensing authority considers to be the appropriate body to perform that function.

(5) Those bodies are—

(a) the Commission; and

(b) any expert committee appointed by the licensing authority.

Exceptions to requirement to consult

3.—(1) Paragraph 2 does not apply to a proposal to refuse to grant or renew a UK marketing authorisation, certificate of registration or traditional herbal registration if—

(a) the licensing authority has asked the applicant to supply information that the licensing authority thinks is relevant to enable the application to be determined; and

(b) the information has not been supplied to the authority within the relevant period.

(2) The relevant period is—

(a) where the licensing authority has completed its initial full assessment of the application, the period of six months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1); or

(b) where the licensing authority has completed its assessment of any supplemental information, the period of three months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1).

(3) The licensing authority may extend the relevant period if—

(a) the applicant asks it to do so;

(b) the applicant provides the grounds for that request; and

(c) the licensing authority thinks that the grounds are exceptional.

4.—(1) Paragraph 2 does not apply to a proposal to suspend a UK marketing authorisation, certificate of registration or traditional herbal registration if the licensing authority thinks that, in the interests of safety, it is necessary to suspend the authorisation, certificate or registration with immediate effect for not more than three months.

(2) In that event the licensing authority must report the suspension to the appropriate committee forthwith.

(3) Sub-paragraph (4) applies if, following a suspension to which this paragraph applies—

(a) the licensing authority thinks that the authorisation, certificate or registration should be further suspended, or varied or revoked; or

(b) the appropriate committee advises that the authorisation, certificate or registration should be further suspended, or varied or revoked.

(4) The provisions of this Part of this Schedule (including this paragraph) apply accordingly to the suspension, variation or revocation.

Provisional opinion against authorisation

5.—(1) If the appropriate committee is consulted under paragraph 2(1) it may give a provisional opinion that on grounds relating to safety, quality or efficacy—

(a) it may be unable to advise the licensing authority to grant or renew the UK marketing authorisation or traditional herbal registration;

(b) it may be unable to advise the licensing authority to grant the authorisation or registration unless—

(i) it contains terms other than those in the application, or

(ii) it is granted subject to conditions; or

(c) it may have to advise the licensing authority to revoke, vary or suspend the authorisation or registration.

(2) If the Commission is consulted under paragraph 2(2), it may give a provisional opinion that, on grounds relating to safety or quality—

(a) it may be unable to advise the licensing authority to grant or renew the certificate of registration;

(b) it may be unable to advise the licensing authority to grant the certificate unless—

(i) it contains terms other than those in the application, or

(ii) it is granted subject to conditions; or

(c) it may have to advise the licensing authority to revoke, vary or suspend the certificate.

(3) The appropriate committee must notify the applicant for the grant or renewal or (as the case may be) the holder of the authorisation, certificate or registration in writing of its provisional opinion.

Opportunity to make representations

6.—(1) An applicant or holder notified under paragraph 5 may, by notice in writing to the appropriate committee, request the opportunity to make written or oral representations to the appropriate committee.

(2) The applicant or holder must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

Written representations

7.—(1) If the applicant or holder requests the opportunity to make written representations, the applicant or holder must provide the appropriate committee with those representations and any documents on which the applicant or holder wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.

(2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.

(3) The applicant or holder may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

8.—(1) If the applicant or holder requests the opportunity to make oral representations, the applicant or holder must provide the appropriate committee with a written summary of those representations and any documents on which the applicant or holder wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.

(2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.

(3) The applicant or holder may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant or holder to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

9.—(1) This paragraph applies if the applicant or holder—

(a) does not request the opportunity to make written or oral representations to the appropriate committee within the period mentioned in paragraph 6;

(b) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(c) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

10.—(1) After receiving the appropriate committee's report under paragraph 7 or 8 or notification under paragraph 9 the licensing authority must—

(a) decide whether to grant or renew the UK marketing authorisation, certificate of registration or traditional herbal registration;

(b) decide whether to grant or renew the authorisation, certificate or registration in accordance with the application; or

(c) decide whether to proceed with its proposal to revoke, vary or suspend the authorisation, certificate or registration,

as the case may be.

(2) If the appropriate committee has given a report under paragraph 7 or 8, the licensing authority must take the report into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 10 notification

11.—(1) A person to whom a notification is given under paragraph 10 may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(2) The person must give the notification within the period of 28 days beginning with the day on which the notification under paragraph 10 is given or such longer period as the licensing authority may allow.

(3) The review must be conducted in accordance with Schedule 5.

(4) This paragraph does not apply if—

(a) the person has not made any representations in accordance with paragraph 7 or 8; and

(b) the decision of the licensing authority is in accordance with the advice of the appropriate committee.

Licensing authority decisions in other cases

12.—(1) This paragraph applies if the appropriate committee has not been consulted under paragraph 2(1) because the licensing authority proposes on grounds not relating to safety, quality or efficacy—

(a) to refuse to grant or renew a UK marketing authorisation or traditional herbal registration in response to the application;

(b) to grant or renew a UK marketing authorisation or traditional herbal registration otherwise than in accordance with the application; or

(c) to revoke, vary or suspend a UK marketing authorisation or traditional herbal registration.

(2) This paragraph also applies if, having been consulted under paragraph 2(1), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(1), and the licensing authority proposes—

(a) to determine the application for the UK marketing authorisation or traditional herbal registration in a way that differs from the appropriate committee's advice;

(b) to revoke, vary or suspend the authorisation or registration against such advice; or

(c) on grounds not relating to safety, quality or efficacy—

(i) to refuse to grant or renew the authorisation or registration,

(ii) to grant or renew the authorisation or registration otherwise than in accordance with the application, or

(iii) to revoke, vary or suspend the authorisation or registration.

(3) This paragraph also applies if the appropriate committee has not been consulted under paragraph 2(2) because the licensing authority proposes on grounds not relating to safety or quality—

(a) to refuse to grant or renew a certificate of registration in response to the application;

(b) to grant or renew a certificate of registration otherwise than in accordance with the application; or

(c) to revoke, vary or suspend a certificate of registration.

(4) This paragraph also applies if, having been consulted under paragraph 2(2), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2), and the licensing authority proposes—

(a) to determine the application for the certificate of registration in a way that differs from the appropriate committee's advice;

(b) to revoke, vary or suspend the authorisation against such advice; or

(c) on grounds not relating to safety or quality—

(i) to refuse to grant or renew the certificate,

(ii) to grant or renew the certificate otherwise than in accordance with the application, or

(iii) to revoke, vary or suspend the certificate.

(5) The licensing authority must notify the applicant for the grant or renewal or (as the case may be) the holder of the authorisation, certificate or registration in writing of its proposal.

(6) The notification must state—

(a) the reasons for the proposal; and

(b) any advice of the appropriate committee and any reasons it has given for that advice.

Right to review or representations after paragraph 12 notification

13.—(1) A person to whom a notification is given under paragraph 12 may—

(a) notify the licensing authority in writing that the person wishes the licensing authority to submit the proposal to review upon oral representations, or

(b) make representations in writing to the licensing authority with respect to the proposal.

(2) The person must give the notification or make the representations within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(3) A review in accordance with sub-paragraph (1)(a) must be conducted in accordance with Schedule 5.

(4) If the person makes written representations in accordance with sub-paragraph (1)(b) the licensing authority must take them into account before determining the matter.

PART 2

Type II variation applications, complex variation applications and new excipient variation applications

Application of this Part

14. This Part applies—

(a) to an application (a "Type II variation application") to vary a UK marketing authorisation if the variation is a major variation of Type II within the meaning of Article 2(3) of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [M8]; and

(b) to an application to vary a traditional herbal registration that is—

(i) a complex variation application, or

(ii) a new excipient variation application.

Marginal Citations

M8 OJ No L 334, 12.12.2008, p.7.

15.—(1) In paragraph 14(b)(i) "complex variation application" means an application by the holder of the registration to vary it so that one or more of the following changes can be made to the product to which it relates—

(a) a change in the product's active ingredients by the addition of an active ingredient from a new source;

(b) a change in the product's excipients by the addition of a TSE risk excipient from a new source; or

(c) a change by the addition of a vitamin or mineral from a new source, where no European Pharmacopoeia certificate of suitability for the vitamin or mineral is submitted with the application.

(2) For the purpose of sub-paragraph (1), an ingredient, vitamin or mineral is "from a new source" if its manufacturer as named in the application has not been named as its manufacturer in a marketing authorisation or traditional herbal registration granted for a medicinal product including the ingredient, vitamin or mineral.

(3) For the purpose of sub-paragraph (1), an excipient is a "TSE risk excipient from a new source" if—

(a) it has been manufactured from raw materials of ruminant origin or such raw materials have been used in its manufacture; and

(b) its manufacturer as named in the application has not been named as its manufacturer in a marketing authorisation or traditional herbal registration granted for a medicinal product that includes the excipient.

16.—(1) In paragraph 14(b)(ii) "new excipient variation application" means an application (other than a complex variation application) by the holder of the registration to vary it so that the formulation of the medicinal product to which it relates can be changed by the addition of a new excipient.

(2) For the purpose of sub-paragraph (1) "new excipient" means, subject to paragraphs (3) and (4), an ingredient of a medicinal product that is not an active ingredient and that has not been included in a medicinal product—

(a) intended to be administered by the same route as the product to which the application relates; and

(b) for which a marketing authorisation (other than a product licence of right) or traditional herbal registration has been granted.

(3) In the application of sub-paragraph (1) to a medicinal product intended to be administered orally, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in food or in a food product.

(4) In the application of sub-paragraph (1) to a medicinal product intended for external use only, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in a cosmetic product.

(5) In this paragraph "enactment" includes an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union.

17. This Part is subject to Part 4 of this Schedule.

Opportunity to make representations

18.—(1) This paragraph applies if the licensing authority notifies the applicant for a variation to which this Part applies that it has decided, on grounds relating to safety, quality or efficacy—

(a) to refuse to grant the application, or

(b) to grant it otherwise than in accordance with the application.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

19.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

20.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.

(3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

21.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

22.—(1) After receiving the appropriate committee's report under paragraph 19 or 20 or notification under paragraph 21 the licensing authority must confirm or alter its decision.

(2) If the appropriate committee gives a report under paragraph 19 or 20, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 22 notification

23.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 22—

(a) to refuse the application; or

(b) to grant it otherwise than in accordance with the application.

(2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 19 or 20.

PART 3

Referral to the Committee for Herbal Medicinal Products

Application of this Part

24.—(1) This Part applies if the licensing authority proposes to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive.

(2) This Part is subject to Part 4 of this Schedule.

Opportunity to make representations

25.—(1) The licensing authority must notify the applicant of the authority's proposal.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

26.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 25.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

27.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 24.

(3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the appropriate committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

28.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

29.—(1) After receiving the appropriate committee's report under paragraph 26 or 27 or notification under paragraph 28 the licensing authority must decide whether to proceed with its proposal.

(2) If the appropriate committee gives a report under paragraph 26 or 27, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 29 notification

30.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 29 to refer the applicant to the Committee on Herbal Medicinal Products as proposed.

(2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the licensing authority's notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 26 or 27.

PART 4

Exceptions to Schedule

31. This Schedule does not apply to an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration if, at any time during the period beginning with the date on which the application is made and ending with the date on which the licensing authority gives a decision on the application, there is an authorisation, certificate or registration in force in respect of the medicinal product in question in any EEA State.

32. This Schedule does not apply to an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration if the application has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive.

33. This Schedule ceases to apply if at any time the matter in question is referred to the Committee for Medicinal Products for Human Use or the Committee for Herbal Medicinal Products under Article 30 or 31 of the 2001 Directive for the application of the procedure laid down in Articles 32 to 34 of that Directive.

34. This Schedule does not apply to an application for a UK marketing authorisation or certificate of registration if—

(a) the licensing authority declines to assess the application on the ground that—

(i) an application for an authorisation or registration in respect of the same medicinal product is being examined in another EEA State, and

(ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or

(b) the licensing authority rejects the application on the ground that—

(i) the medicinal product in question has an authorisation or registration in another EEA State, and

(ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive.

35. This Schedule does not apply to an application for a traditional herbal registration in relation to which either of the conditions in Article 16d(1) of the 2001 Directive is met if—

(a) the licensing authority declines to assess the application on the ground that—

(i) an application for a registration in respect of the same medicinal product is being examined in another EEA State, and

(ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or

(b) the licensing authority rejects the application on the ground that—

(i) the medicinal product in question has a registration in another EEA State, and

(ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive.

36. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a UK marketing authorisation that—

(a) was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure);

(b) was granted before 1st January 1995 by member States in accordance with Article 4 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [M9]; or

(c) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorisation.

Marginal Citations

M9 OJ No L 15, 17.1.1987. p.38.

37. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a certificate of registration that was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure).

38. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a traditional herbal registration that—

(a) was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure); or

(b) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the registration.

39. This Schedule does not apply if—

(a) the licensing authority refuse to grant an application for a traditional herbal registration;

(b) the application was referred to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive; and

(c) the Committee for Herbal Medicinal Products did not support the grant of the application.

SCHEDULE 12 Regulation 128(1)

Material to accompany an application for a traditional herbal registration

PART 1

General requirements

1. The name or corporate name and permanent address of the applicant and (where applicable) of the manufacturer of the medicinal product.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the holder of the traditional herbal registration.

3. Qualitative and quantitative particulars of the constituents of the medicinal product, including—

(a) where there is an international non-proprietary name recommended by the World Health Organisation for a constituent, a reference to that name; or

(b) otherwise, a reference to the relevant chemical or botanical name.

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

5. A description of the methods of manufacturing the medicinal product.

6. The therapeutic indications and contra-indications for the medicinal product and the adverse reactions associated with it.

7. The posology and pharmaceutical form of the medicinal product, its method and route of administration and its expected shelf life.

8. The reasons for any precautionary and safety measures to be taken for—

(a) the storage of the medicinal product;

(b) the administration of the medicinal product to patients; and

(c) the disposal of the medicinal product and any waste products,

with an indication of the potential risks presented by the medicinal product for the environment.

9. A description of the control methods employed by the manufacturer.

10. Results of pre-clinical (toxicological and pharmacological) tests in relation to the medicinal product and its constituent active substances.

11. A detailed summary of those results prepared and signed by an expert with appropriate technical or professional qualifications, which must be set out in a brief curriculum vitae.

12. A summary of the product characteristics for the medicinal product in accordance with Part 2 of this Schedule.

13. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

14. A document showing that the manufacturer of the medicinal product is authorised to produce medicinal products in the manufacturer's own country.

15. Where the medicinal product consists of a combination of one or more herbal substances and one or more herbal preparations, or the medicinal product contains one or more vitamins or minerals—

(a) data on the traditional use of the medicinal product as a whole; and

(b) if any of the medicinal product's individual active ingredients are not sufficiently known, data on the traditional use of those active ingredients.

This covers (in particular)—

(c) evidence that the product is not harmful in the specified conditions of use; and

(d) evidence as to the pharmacological effects or efficacy of the product on the basis of long-standing use and experience.

16. Details of any authorisation or registration obtained by the applicant in another member State or a third country allowing the medicinal product to be placed on the market.

17. Details of any decision in another member State or a third country to refuse to grant an authorisation or registration allowing the medicinal product to be placed on the market, with the reasons for any such decision.

18. Bibliographical or expert evidence of the traditional use of the medicinal product or a product corresponding to the medicinal product.

For this purpose a product ("A") corresponds to a medicinal product ("B") if—

(a) product A has the same active ingredients as product B (regardless of the excipients used in either product);

(b) product A's intended purpose is the same as or similar to product B's intended purpose;

(c) product A has a strength and dosage equivalent to that of product B; and

(d) product A's route of administration is the same as or similar to product B's route of administration.

19. A bibliographic review of safety data.

20. An expert report on safety.

PART 2

Summary of the product characteristics

The summary of the product characteristics must contain the following information in the following order—

(21) For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004, the statement "This medicinal product is subject to additional monitoring".

(22) The name of the medicinal product followed by its strength and pharmaceutical form.

(23) The qualitative and quantitative composition, using the usual common name or chemical description, of the medicinal product in terms of—

(a) the active substances; and

(b) those excipients of which knowledge is essential for proper administration of the medicinal product.

(24) The pharmaceutical form of the medicinal product.

(25) The pharmacological properties of the medicinal product, covering—

(a) pharmacodynamic properties;

(b) pharmacokinetic properties; and

(c) pre-clinical safety data.

(26) Pharmaceutical particulars of the medicinal product, covering—

(a) a list of excipients;

(b) major incompatibilities;

(c) shelf life after reconstitution of the medicinal product or when the immediate packaging is opened for the first time (as appropriate);

(d) special precautions for storage;

(e) nature and contents of the container; and

(f) special precautions for disposal of the used medicinal product or waste materials derived from the medicinal product (as appropriate).

(27) The holder of the traditional herbal registration.

(28) The number of the traditional herbal registration.

(29) The date of the first traditional herbal registration or, where the traditional herbal registration has been renewed, the date of the last renewal.

(30) The date of any revisions of the text of the summary of the product characteristics.

SCHEDULE 13

Regulations 214(4) and 216(1)

Prescription only medicines for which community practitioner nurse prescribers are appropriate practitioners

Co-danthramer Capsules NPF

Co-danthramer Capsules Strong NPF

Co-danthramer Oral Suspension NPF

Co-danthramer Oral Suspension Strong NPF

Co-danthrusate Capsules

Co-danthrusate Oral Suspension NPF

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

Water for injections

In this Schedule "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

SCHEDULE 14

Regulation 215

Prescription etc by supplementary prescribers: particulars of clinical management plan

A clinical management plan must contain the following particulars—

(a) the name of the patient to whom the plan relates;

(b) the illnesses or conditions which may be treated by the supplementary prescriber;

(c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;

(d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;

(e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;

(f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;

(g) the arrangements for notification of—

(i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and

(ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and

(h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.

SCHEDULE 15

Regulation 221

Requirements for specific products subject to general sale

1. A medicinal product that contains aloxiprin, aspirin or paracetamol (or, where appropriate, any combination of those substances) and that is in the form specified in column 1 of the following table must be presented for sale in a separate and individual package containing not more than the amount of the product specified in the corresponding entry in column 2—

Column 1	***Column 2***
Effervescent tablets— (a) that do not contain aspirin, or (b) that do not contain more than 325 milligrams of aspirin per tablet.	30 tablets
Effervescent tablets— (a) that contain more than 325 milligrams of aspirin per tablet, but	20 tablets

(b) that do not contain more than 500 milligrams per tablet.	
Non-effervescent tablets— (a) that are enteric-coated, (b) that contain aspirin only, and (c) that do not contain more than 75 milligrams per tablet.	28 tablets
Other non-effervescent tablets	16 tablets
Powder or granules	10 sachets
Capsules	16 capsules
Liquid preparations of paracetamol intended for persons aged 12 years and over	160 millilitres
Liquid preparations of paracetamol intended for persons aged less than 12 years	Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses

2. A medicinal product that contains ibuprofen and that is in the form specified in column 1 of the following table must be presented for sale in a separate and individual package containing not more than the amount of the product specified in the corresponding entry in column 2—

Form of product	***Maximum amount***
Tablets	16 tablets
Capsules	16 capsules
Powder or granules	12 sachets
Liquid preparations of ibuprofen	Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses

SCHEDULE 16 Regulations 229, 230, 231,232, 233 and 234

Patient group directions

PART 1

Particulars to be included in a patient group direction

1. The period during which the direction is to have effect.

2. The description or class of medicinal product to which the direction relates.

3. The clinical situations which medicinal products of that description or class may be used to treat or manage in any form.

4. Whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions.

5. The clinical criteria under which a person is to be eligible for treatment.

6. Whether any class of person is excluded from treatment under the direction and, if so, what class of person.

7. Whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances.

8. The pharmaceutical form or forms in which medicinal products of that description or class are to be administered.

9. The strength, or maximum strength, at which medicinal products of that description or class are to be administered.

10. The applicable dosage or maximum dosage.

11. The route of administration.

12. The frequency of administration.

13. Any minimum or maximum period of administration applicable to medicinal products of that description or class.

14. Whether there are any relevant warnings to note and, if so, what warnings.

15. Whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances.

16. Arrangements for referral for medical advice.

17. Details of the records to be kept of the supply, or the administration, of products under the direction.

PART 2

Persons on whose behalf a patient group Direction must be signed

Column 1: Class of person by whom product is supplied	***Column 2: Person on whose behalf direction must be signed***
Common Services Agency	The Agency
Health authority	The health authority
Special health authority	The special health authority
NHS trust or NHS foundation trust	The trust
[F17Local authority	The Chief Executive or Director of Public Health of the local authority**]**
[F18Public Health England	The Chief Executive of Public Health England**]**
[F18Public Health Agency	The Public Health Agency**]**
F19	F19
...	...
A person who supplies medicinal products pursuant to an arrangement made with— (a) the Common Services Agency; (b) a health authority;	The Common Services Agency (where the arrangement has been made with the Agency); otherwise the— (a) health authority, (b) special health authority,

(c) a special health authority;

(d) an NHS trust;

[F20(da) a clinical commissioning group;

(db) the National Health Service Commissioning Board;

(dc) a local authority; F21...]

[F22(dd) Public Health England;

(de) Public Health Agency; or]

(e) an NHS foundation trust; F23...

F23(f) . . . . . .

(c) NHS trust,

[F24(ca) a clinical commissioning group,

(cb) the National Health Service Commissioning Board,

(cc) a local authority, F25...]

[F26(cd) Chief Executive of Public Health England,

(ce) Public Health Agency, or]

(d) NHS foundation trust, F27...

F27(e) . . . . . with which the arrangement has been made.

Textual Amendments

F17 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(a)** (with Sch. 3 para. 28)

F18 Words in Sch. 16 Pt. 2 added (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(a)** and words in Sch. 16 Pt. 2 added (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(a)**

F19 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(b)** (with Sch. 3 para. 28)

F20 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(c)(i)** (with Sch. 3 para. 28)

F21 Word in Sch. 16 Pt. 2 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(b)(i)** and word in Sch. 16 Pt. 2 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(b)(i)**

F22 Words in Sch. 16 Pt. 2 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(b)(ii)** and words in Sch. 16 Pt. 2 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(b)(ii)**

F23 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(c)(ii)** (with Sch. 3 para. 28)

F24 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(d)(i)** (with Sch. 3 para. 28)

F25 Word in Sch. 16 Pt. 2 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(c)(i)** and word in Sch. 16 Pt. 2 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(c)(i)**

F26 Words in Sch. 16 Pt. 2 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(c)(ii)** and words in Sch. 16 Pt. 2 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(c)(ii)**

F27 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(d)(ii)** (with Sch. 3 para. 28)

PART 3

Persons by whom or on whose behalf a patient group direction used as described in regulation 234 must be signed

Column 1: Force or service by whom or on whose behalf the health care is provided	***Column 2: Person by whom or on whose behalf direction must be signed***
A police force in England and Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996 M10)
A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1967 M11)
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(a) the Surgeon General, (b) a Medical Director General, or (c) a chief executive of an executive agency of the Ministry of Defence
[F28Contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency	Medical Director of the contractor carrying out search and rescue operations on behalf of the Maritime and Coastguard Agency**]**

Textual Amendments

F28 Words in Sch. 16 Pt. 3 added (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(3)** and words in Sch. 16 Pt. 3 added (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(3)**

Marginal Citations

M10 1996 c.16.
M11 1967 c.77.

PART 4

Classes of individuals by whom supplies may be made

Pharmacists.

Registered chiropodists and podiatrists.

Registered dental hygienist.

Registered dental therapist.

Registered dietitians.

Registered midwives.

Registered nurses.

Registered occupational therapists.

Registered optometrists.

Registered orthoptists.

Registered orthotists and prosthetists.

Registered paramedics.

Registered physiotherapists.

Registered radiographers.

Registered speech and language therapists.

SCHEDULE 17 Regulations 223(5)(b) and (c) 235,250(5) and 253(5)(d)

Exemption for sale, supply or administration by certain persons

PART 1

Exemption from restrictions on sale and supply of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***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 an institution concerned with educational 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, and (ii) the purpose for which the prescription only medicine is required, and (iii) the total quantity required; and

		(b) for the purpose of the education or research with which the institution is concerned.
2. Persons selling or supplying prescription only medicines to any of the following— (a) a public analyst appointed under section 27 of the Food Safety Act 1990 **M12** or article 27 of the Food Safety (Northern Ireland) Order 1991 **M13**; (b) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990 **M14**; (c) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989 **M15**; (d) an inspector acting under regulations 325 to 328; (e) a sampling officer within the meaning of Schedule 31.	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 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.
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 National Health Service Act 2006 **M16** , the National Health Service (Scotland) Act 1978 **M17** , the National Health Service (Wales) Act 2006 **M18** and the Health and Personal Social Services (Northern Ireland) Order 1972 **M19** , or under any subordinate legislation made under those Acts or that Order.	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 the prescription only medicine required; and (b) for the purposes of a scheme referred to in column 1 in this paragraph.
4. Registered midwives.	4. Prescription only medicines containing any of the following substances— (a) Diclofenac;	4. The sale or supply shall be only in the course of their professional practice.

	(b) Hydrocortisone Acetate; (c) Miconazole; (d) Nystatin; (e) Phytomenadione;	
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	5. Water for injection.	5. The sale or supply is to a person— (a) for a purpose other than parenteral administration; or (b) who has been prescribed dry powder for parenteral administration but has not been prescribed the water for injection that is needed as a diluent.
6. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	6. 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, (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,	6. The sale or supply shall be subject to the presentation of an order signed by— (a) a registered optometrist for a medicine listed under item (a) in column 2; (b) a registered chiropodist or podiatrist for a medicine listed under item (b) in column 2.

	(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.	
7. Registered optometrists.	7. Prescription only medicines listed in item (a) of paragraph 6 column 2.	7. The sale or supply shall be only— (a) in the course of their professional practice, and (b) in an emergency.
8. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	8. Medicinal products not for parenteral administration which are prescription only medicines by reason only that they contain any of the following substances— (a) Acetylcysteine, (b) Atropine sulphate, (c) Azelastine hydrochloride, (d) Diclofenac sodium, (e) Emedastine, (f) Homotropine hydrobromide, (g) Ketotifen, (h) Levocabastine, (i) Lodoxamide, (j) Nedocromil sodium, (k) Olopatadine, (l) Pilocarpine hydrochloride, (m) Pilocarpine nitrate, (n) Polymyxin B/bacitracin, (o) Polymyxin B/trimethoprim, (p) Sodium cromoglycate.	8. The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist.
9. Additional supply optometrists.	9. Prescription only medicines specified in paragraph 8 column 2.	9. The sale or supply shall be only— (a) in the course of their professional practice, and (b) in an emergency.
10. Holders of marketing authorisations, product licences or manufacturer's licences.	10. Prescription only medicines referred to in those authorisations 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. Registered chiropodists or podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicine specified in column 2.	11. 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.	11. The sale or supply shall be only in the course of their professional practice.
[F29 12. Persons selling or supplying prescription only medicines to a school.	12. **[**F30 Prescription only medicines comprising: (a) an inhaler containing salbutamol; or (b) an auto-injector containing adrenaline**]**	12. 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 **[**F31 or administering**]** the medicinal product to pupils at the school in an emergency.**]**

[F32 13 Registered orthoptists **[**F33 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**]**.	13 The following prescription only medicines– (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice.**]**

Textual Amendments

F29 Words in Sch. 17 Pt. 1 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(2)** and words in Sch. 17 Pt. 1 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(2)**

F30 Words in Sch. 17 Pt. 1 substituted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(a)(i)** and words in Sch. 17 Pt. 1 substituted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(a)(i)**

F31 Words in Sch. 17 Pt. 1 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(a)(ii)** and words in Sch. 17 Pt. 1 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(a)(ii)**

F32 Words in Sch. 17 Pt. 1 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(2)** and words in Sch. 17 Pt. 1 inserted (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(2)**

F33 Words in Sch. 17 Pt. 1 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(b)** and words in Sch. 17 Pt. 1 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(b)**

Marginal Citations

M12 1990 c.16. Section 27 was amended by the Local Government etc (Scotland) Act 1994 section 180(1) and Schedule 18 paragraph 163(3), the Food Standards Act 1999 section 40(1) and Schedule 5 paragraphs 7 and 8, the Local Government (Wales) Act 1994 section 22(3) and Schedule 9 paragraph 16(2), S.I. 1994/865 regulation 24, and the Local Government and Public Involvement in Health Act 2007 sections 22 and 241, Schedule 1 Part 2 paragraph 17, and Schedule 18 Part 1.

M13 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.

M14 1990 c.16.

M15 1989 No. 846 (N.I. 6).

M16 2006 c. 41.

M17 1978 c. 29.

M18 2006 c. 42.

M19 S.I. 1972/1265 (N.I. 14).

PART 2

Exemption from the restriction on supply of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***Conditions***
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines	1. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the exercise of the functions of the Institution.
2. The owner or master of a ship which does not carry a doctor on board as part of the ship's complement.	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the treatment of persons on the ship.
3. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 2001 **M20** or regulation 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 **M21** to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons employed or engaged in the provision of lawful drug treatment services.	4. Ampoules of sterile water for injection that contain no more than 2ml of water each.	4. The supply shall be only in the course of provisions of lawful drug treatment services.
[F34 4a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– (a) an NHS body; (b) a local authority; (c) Public Health England; or (d) Public Health Agency.	4a A prescription only medicine F35 ... containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only.	4a 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.**]**

5. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	5. Such prescription only medicines as may be specified in the relevant enactment.	5. The supply shall be— (a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and (b) subject to such conditions and such circumstances as may be specified in the relevant enactment.
6. Persons operating an occupational health scheme.	6. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	6. The supply of the prescription only medicine shall be— (a) in the course of operating an occupational health scheme, and (b) made by— (i) a doctor, or (ii) a registered nurse acting in accordance with the written directions of a doctor as to the circumstance in which such medicines are to be used in the course of an occupational health scheme.
[[F36]6a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	6b. 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 mentioned in entry 6a in response to an order in writing signed by a doctor or an occupational health vaccinator.	6c. The supply of the medicine is in the course of an occupational health scheme mentioned in entry 6a and is made, if not by a doctor, by an occupational health vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.**]**
7. The operator or commander of an aircraft.	7. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to an operator or commander of an aircraft in response to an order in writing signed by a doctor.	7. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
8. Persons employed as qualified first-aid personnel on off-shore installations.	8. All prescription only medicines.	8. The supply shall be only so far as is necessary for the

		treatment of persons on the installation.
9. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.	9. Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.	9. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.
10. Persons ("P") who are members of Her Majesty's armed forces.	10. All prescription only medicines.	10. The supply shall be— (a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and (b) where P is satisfied that it is not practicable for another person who is legally entitled to supply a prescription only medicine to do so; and (c) only in so far as is necessary— (i) for the treatment of a sick or injured person in a medical emergency, or (ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not supplied.
[F37 11. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	11. A prescription only medicinal product comprising an inhaler containing salbutamol.	11. 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.**]**
[F38 12 Registered midwives.	12 Prescription only medicines for parenteral administration that contain– (a) Diamorphine, (b) Morphine, (c) Pethidine hydrochloride.	12 The supply shall be only in the course of their professional practice.**]**

Textual Amendments

F34 Words in Sch. 17 Pt. 2 added (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **10(2)** and words in Sch. 17 Pt. 2 added (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **10(2)**

F35 Words in Sch. 17 Pt. 2 omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **18(a)** and words in Sch. 17 Pt. 2 omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **18(a)**

F36 Words in Sch. 17 Pt. 2 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(2)** and words in Sch. 17 Pt. 2 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(2)**

F37 Words in Sch. 17 Pt. 2 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(3)** and words in Sch. 17 Pt. 2 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(3)**

F38 Words in Sch. 17 Pt. 2 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(3)** and words in Sch. 17 Pt. 2 inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(3)**

Marginal Citations

M20 S.I. 2001/3998, to which there are amendments that are not relevant.

M21 S.R. 2002 No. 1, to which there are amendments that are not relevant.

PART 3

Exemptions from the restriction on administration of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***Conditions***
1. Registered 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.	1. Prescription only medicines for parenteral administration that contain— (a) Adrenaline, (b) Bupivacaine hydrochloride, (c) Bupivacaine hydrochloride with adrenaline where the maximum strength of adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride, (d) Levobupivacaine hydrochloride, (e) Lidocaine hydrochloride, (f) Lidocaine hydrochloride with adrenaline where the maximum strength of adrenaline does not exceed 1	1. The administration shall only be in the course of their professional practice and where the medicine includes a combination of substances in column 2, those substances shall not have been combined by the chiropodist or podiatrist.

	mg in 200 ml of lignocaine hydrochloride, (g) Mepivacaine hydrochloride, (h) Methylprednisolone, (i) Prilocaine hydrochloride, (j) Ropivacaine hydrochloride.	
2. Registered midwives and student midwives.	2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance that is classified as a product available on prescription only— (a) Adrenaline, (b) Anti-D immunoglobulin, (c) Carboprost, (d) Cyclizine lactate, (e) Diamorphine, (f) Ergometrine maleate, (g) Gelofusine, (h) Hartmann's solution, (i) Hepatitis B vaccine, (j) Hepatitis immunoglobulin, (k) Lidocaine hydrochloride, (l) Morphine, (m) Naloxone hydrochloride, (n) Oxytocins, natural and synthetic, (o) Pethidine hydrochloride, (p) Phytomenadione, (q) Prochloperazine, (r) Sodium chloride 0.9%.	2. The medicine shall— (a) in the case of Lidocaine and Lidocaine hydrochloride, be administered only while attending on a woman in childbirth, and (b) where administration is— (i) by a registered midwife, be administered in the course of their professional practice; (ii) by a student midwife— (aa) be administered under the direct supervision of a registered midwife; and (bb) not include Diamorphine, Morphine or Pethidine hydrochloride.
3. Persons who are authorised as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations 2001 **M22** or, regulations 8(3) or 9(3) of the Misuse of Drugs Regulations (Northern Ireland) 2002 **M23** , to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of the ship's complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.

5. Persons operating an occupational health scheme.	5. Prescription only medicines that are for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	5. The prescription only is administered in the course of an occupational health scheme, and the individual administering the medicine is— (a) a doctor, or (b) a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used.
[[F39]5a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	5b. 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 mentioned in entry 5a in response to an order in writing signed by a doctor or an occupational health vaccinator.	5c. The administration of the medicine is in the course of an occupational health scheme mentioned in entry 5a, and the individual administering the medicine is, if not a doctor, an occupational health vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.**]**
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of the doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons employed as qualified first-aid personnel on off-shore installations.	7. All prescription only medicines that are for parenteral administration.	7. The administration shall be only so far as is necessary for the treatment of persons on the installation.
8. Persons who are registered paramedics.	8. The following prescription only medicines for parenteral administration— (a) Diazepam 5 mg per ml emulsion for injection, (b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion, (c) medicines containing the substance Ergometrine Maleate 500 mcg per ml with Oxytocin	8. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

	5 iu per ml, but no other active ingredient, (d) prescription only medicines containing one or more of the following substances, but no other active ingredient— (i) Adrenaline Acid Tartrate, (ii) Adrenaline hydrochloride, (iii) Amiodarone, (iv) Anhydrous glucose, (v) Benzlypenicillin, (vi) Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution), (vii) Ergometrine Maleate, (viii) Furosemide, (ix) Glucose, (x) Heparin Sodium, (xi) Lidocaine Hydrochloride, (xii) Metoclopramide, (xiii) Morphine Sulphate, (xiv) Nalbuphine Hydrochloride, (xv) Naloxone Hydrochloride, (xvi) Ondansetron (xvii) Paracetamol, (xviii) Reteplase, (xix) Sodium Chloride, (xx) Streptokinase, (xxi) Tenecteplase.	
9. Persons who hold the advanced life support provider certificate issued by the Resuscitation Council (UK).	9. The following prescription only medicines for parenteral administration — (a) Adrenaline 1:10,000 up to I mg; and (b) Amiodarone.	9. The administration shall be only in an emergency involving cardiac arrest, and in the case of adrenaline the administration shall be intravenous only.
[[F40]10. Persons ("P") who are members of Her Majesty's armed forces.	10. All prescription only medicines.	10. The administration shall be— (a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and (b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine to do so; and (c) only in so far as is necessary—

		(i) for the treatment of a sick or injured person in an emergency, or (ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not administered.**]**
[[F41]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.**]**

Textual Amendments

F39 Words in Sch. 17 Pt. 3 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(3)** and words in Sch. 17 Pt. 3 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(3)**

F40 Words in Sch. 17 Pt. 3 added (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **11** and words in Sch. 17 Pt. 3 added (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **11**

F41 Words in Sch. 17 Pt. 3 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(3)** and words in Sch. 17 Pt. 3 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(3)**

Marginal Citations

M22 S.I. 2001/3998 as amended by S.I. 2007/2154. There are other amendments that are not relevant.

M23 S.R. 2002 No. 1, as amended by S.R. 2007 No. 348. There are other amendments that are not relevant.

PART 4

Exemptions from the restrictions in regulations 220 and 221 for certain persons who sell, supply, or offer for sale or supply certain medicinal products

Column 1 ***Persons exempted***	Column 2 ***Medicinal products to which exemption applies***	Column 3 ***Conditions***
1. Registered chiropodists and podiatrists.	1. Medicinal products on a general sale list which are for external use and are not veterinary drugs and the following pharmacy medicines for external use— (a) Potassium permanganate crystals or solution; (b) ointment of heparinoid and hyaluronidase; and (c) products containing, as their only active ingredients, any of the following substances, at a strength, in the case of each substance, not exceeding that specified in relation to that substance— (i) 9.0 per cent Borotannic complex (ii) 10.0 per cent Buclosamide (iii) 3.0 per cent Chlorquinaldol (iv) 1.0 per cent Clotrimazole (v) 10.0 per cent Crotamiton (vi) 5.0 per cent Diamthazole hydrochloride (vii) 1.0 per cent Econazole nitrate (viii) 1.0 per cent Fenticlor (ix) 10.0 per cent Glutaraldehyde (x) 1.0 per cent Griseofulvin (xi) 0.4 per cent Hydrargaphen (xii) 2.0 per cent Mepyramine maleate (xiii) 2.0 per cent Miconazole nitrate (xiv) 2.0 per cent Phenoxypropan-2-ol (xv) 20.0 per cent Podophyllum resin (xvi) 10.0 per cent Polynoxylin (xvii) 70.0 per cent Pyrogallol	

	(xviii) 70.0 per cent Salicylic acid (xix) 1.0 per cent Terbinafine (xx) 0.1 per cent Thiomersal.	
2. Registered chiropodists and podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines in column 2.	2. (a) 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 the 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 the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight; and (b) Ibuprofen, other than preparations of ibuprofen which are prescription only medicines.	2. The sale or supply shall be only in the course of their professional practice, and the medicinal product must have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied.
3. Registered optometrists.	3. All medical products on a general sale list, all pharmacy medicines and prescription only medicines which are not for parenteral administration and which— (a) are eye drops and are prescription only medicines by reason only that they contain not more than— (i) 30.0 per cent Sulphacetamide Sodium, or (ii) 0.5 per cent Chloramphenicol, or	3. The sale or supply shall be only— (a) in the case of medicinal products on a general sale list and pharmacy medicines, in the course of their professional practice; (b) in the case of prescription only medicines, in the course of their professional practice and in an emergency.

	(b) are eye ointments and are prescription only medicines by reason only that they contain not more than— (i) 30.0 per cent Sulphacetamide Sodium, or (ii) 1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any of the following substances— (i) Cyclopentolate hydrochloride, (ii) Fusidic acid, (iii) Tropicamide.	
4. Additional supply optometrists.	4. Medicinal products which are prescription only medicines by reason only that they contain any of the following substances— (a) Acetylcysteine, (b) Atropine sulphate, (c) Azelastine hydrochloride, (d) Diclofenac sodium, (e) Emedastine, (f) Homotropine hydrobromide, (g) Ketotifen, (h) Levocabastine, (i) Lodoximide, (j) Nedocromil sodium, (k) Olopatadine, (l) Pilocarpine hydrochloride, (m) Pilocarpine nitrate, (n) Polymyxin B/bacitracin, (o) Polymyxin B/ trimethoprim, (p) Sodium Cromoglycate.	4. The sale or supply shall be only in the course of their professional practice and only in an emergency.
5. Holders of manufacturer's licences where the licence in question contains a provision that the licence holder shall manufacture the medicinal product to which the licence relates only for a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.	5. Medicinal products on a general sale list which are for external use and are not veterinary drugs and pharmacy medicines which are for external use in the treatment of hair and scalp conditions and which contain any of the following— (a) not more than 5.0 per cent of Boric acid, (b) Isopropyl myristate or Lauryl sulphate,	5. The licence holder shall sell or supply the medicinal product in question only to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.

	(c) not more than 0.004 per cent Oestrogens, (d) not more than 1.0 per cent of Resorcinol, (e) not more than 3.0 per cent of Salicylic acid, (f) not more than 0.2 per cent of Sodium pyrithione.	
6. Persons selling or supplying medicinal products to universities, other institutions concerned with higher education or institutions concerned with research.	6. All medicinal products.	6. 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 the specified course of research stating— (i) the name of the institution for which the medicinal product is required, (ii) the purpose for which the medicinal product is required, and (iii) the total quantity required, and (b) for the purposes of the education or research with which the institution is concerned.
7. Persons selling or supplying medicinal products to organisations for research purposes.	7. All medicinal products.	7. The sale or supply is only for the purposes of research and shall be— (a) subject to the presentation of an order signed by the representative of the organisation concerned stating— (i) who requires the medicine, (ii) the purposes for which it is required, (iii) the quantity required, and (iv) the purposes of the research with which the organisation is concerned; and (b) not for administration to humans.
8. Persons selling or supplying medicinal products to any of the following— (a) a public analyst appointed under section 27 of the Food	8. All medicinal products.	8. The sale or supply is in connection with the exercise of any statutory function carried out by any person listed in sub-

Safety Act 1990 or under article 27 of the Food Safety (Northern Ireland) Order 1991; (b) an agricultural analyst appointed under section 67 of the Agriculture Act 1970 [M24], (c) a person duly authorised by an enforcement authority under regulations 325 to 328, (d) a sampling officer within the meaning a sampling officer within the meaning of Schedule 31.		paragraphs (a) to (d) of column 1 provided that— (a) the medicinal products are requested on an order signed by or on behalf of a person listed in sub-paragraph (a) to (d) of column 1, and (b) the order gives— (i) the status of the person signing it, (ii) the amount of medicinal product required.
9. Holders of a marketing authorisation, a certificate of registration or a manufacturer's licence.	9. Medicinal product referred to in the marketing authorisation, certificate of registration or manufacturer's licence.	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 medical product 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.
10. Registered dispensing opticians.	10. Pharmacy medicines for external use containing chloramphenicol at a strength not exceeding— (a) 0.5 per cent in eye drops; (b) 1 per cent in ointment.	10. The sale or supply shall only be in the course of their professional practice.
[[F42]11. Operator or commander of an aircraft.	11. All medicinal products on a general sale list.	11. The medicinal product must— (a) have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied; and (b) be stored in a part of the aircraft which the operator is able to close so as to exclude the public.**]**
[[F42]12. The operator of a train.	12. All medicinal products on a general sale list.	12. The medicinal product must— (a) have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied; and

		(b) be stored in a part of the train which the operator is able to close so as to exclude the public.**]**
[F43 13 Registered orthoptists **[**F44 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**]**.	13 All medicinal products on a general sale list, all pharmacy medicines and the following prescription only medicines– (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice.**]**

Textual Amendments

F42 Sch. 17 Pt. 4 Table Item 11, 12 inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **9**

F43 Words in Sch. 17 Pt. 4 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(4)** and words in Sch. 17 Pt. 4 inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(4)**

F44 Words in Sch. 17 Pt. 4 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(4)** and words in Sch. 17 Pt. 4 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(4)**

Marginal Citations

M24 1970 c.40: subsection (1) was amended by section 272(1) of and Schedule 30 to the Local Government Act 1972; section 16 of and Schedule 8 paragraph 15 to the Local Government Act 1985, and section 66(6) and (8) of, and Schedule 16 paragraph 38(5) and Schedule 18 to the Local Government (Wales) Act 1994. Subsection (1A) was inserted by section 66(6) of and Schedule 16 paragraph 38(5) to that Act. Subsection 2 was substituted by section 180(1) of and Schedule 13 paragraph 85(2) to the Local Government etc (Scotland) Act 1994, and subsection (7) was repealed by sections 1(1) and 194 of, and Schedule 1 paragraph 8 and Schedule 34 Part 1 to the Local Government, Planning and Land Act 1980.

PART 5

Exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products

Column 1 ***Persons exempted***	Column 2 ***Medicinal products to which exemption applies***	Column 3 ***Conditions***
1. Royal National Lifeboat Institution and certificated first aiders of the Institution.	1. All medicinal products.	1. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
2. British Red Cross Society and certificated first aid and certificated nursing members of the Society.	2. All pharmacy medicines and all medicinal products on a general sale list.	2. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
3. St John Ambulance Association and Brigade and certificated first aid and certificated nursing members of the Association and Brigade.	3. All pharmacy medicines and all medicinal products on a general sale list.	3. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
4. St. Andrew's Ambulance Association and certificated first aid and certificated nursing members of the Association.	4. All pharmacy medicines and all medicinal products on a general sale list.	4. The supply shall be only so far as is necessary for the treatment of sick and injured persons.
5. Order of Malta Ambulance Corps and certificated first aid and certificated nursing members of the Corps.	5. All pharmacy medicines and all medicinal products on a general sale list.	5. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
6. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 2001 or regulation 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	6. Such prescription only medicines and such pharmacy medicines as are specified in the licence.	6. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
7. Persons employed or engaged in the provision of lawful drug treatment services.	7. Ampoules of sterile water for injection that contain no more than 5ml of water each.	7. The supply shall be only in the course of provision of lawful drug treatment services.
[F45 7a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– (a) an NHS body;	7a **[**F46 A medicinal product containing naloxone hydrochloride but no other substance that is classified as a product available only on prescription or as a product available only from a pharmacy.**]**	7a 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.**]**

(d) a local authority;

(c) Public Health England; or

(d) Public Health Agency.

8. Persons requiring medicinal products for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	8. Such prescription only medicines and such pharmacy medicines as may be specified in the relevant enactment and medicinal products on a general sale list.	8. The supply shall be— (a) for the purpose of enabling compliance with any requirement made by or in pursuance of any such enactment, and (b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.
9. The owner or master of a ship which does not carry a doctor on board as part of the ship's complement.	9. All medicinal products.	9. The supply shall be only so far as is necessary for the treatment of persons on the ship.
10. Persons operating an occupational health scheme.	10. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines as are sold or supplied to a person operating an occupational health scheme in response to an order signed by a doctor or a registered nurse.	10. (a) The supply shall be in the course of an occupational health scheme. (b) The individual supplying the medicinal product, if not a doctor, shall be— (i) a registered nurse, and (ii) where the medicinal product in question is a prescription only medicine, acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of an occupational health scheme.
[[F47]10a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	10b. 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 mentioned in entry 10a in response to an order in writing signed by a doctor or an occupational health vaccinator.	10c. The supply of the medicine is in the course of an occupational health scheme mentioned in entry 10a, and the individual supplying the medicine is, if not a doctor, an occupational health vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.**]**
11. Persons carrying on the business of a school providing full-time education.	11. Pharmacy medicines that are for use in the prevention of	11. The supply shall be— (a) in the course of a school dental scheme, and

	dental caries and consist of or contain Sodium Fluoride.	(b) if to a child under 16 only where the parent or guardian of that child has consented to such supply.
12. Health authorities or Primary Health Trusts.	12. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.	12. The supply shall be in the course of— (a) a pre-school dental scheme, and the individual supplying the medicinal product shall be a registered nurse, or (b) a school dental scheme, and if to a child under 16 only where the parent or guardian of that child has consented to such supply.
13. The operator or commander of an aircraft.	13. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of an aircraft in response to an order in writing signed by a doctor.	13. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and, in the case of a prescription only medicine, shall be in accordance with the written instructions of a doctor as to the circumstances in which the prescription only medicines of the description in question are to be used on the aircraft.
14. Persons employed as qualified first-aid personnel on offshore installations.	14. All medicinal products.	14. The supply shall be only so far as is necessary for the treatment of persons on the installation.
15. A prison officer.	15. All medicinal products on the general sale list.	15. The supply shall only be so far as is necessary for the treatment of prisoners.
16. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.	16. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines which are sold or supplied to a person specified in column 1 of this paragraph in response to an order in writing signed by a doctor.	16. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.
17. Her Majesty's armed forces.	17. All medicinal products.	17. The supply shall be only so far as is necessary for the treatment of a sick or injured person or the prevention of ill-health.
[[F48]18. A person ("P") carrying on the business of a school	18. A prescription only medicinal product comprising	18. The supply shall be—

who is trained to administer the relevant medicine.	an inhaler containing salbutamol.	(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.**]**
[F49 19. Persons supplying medicinal products under an off-site emergency plan prepared under the **[**F50 Radiation (Emergency Preparedness and Public Information) Regulations 2019**].]**	**[**F49 19. Pharmacy medicines which contain any of the following substances but no other active ingredient— (a) Potassium Iodide; (b) Potassium Iodate.**]**	**[**F49 19. The supply shall be— (a) in accordance with the off-site emergency plan; and (b) only in the event that a radiation emergency has occurred or an event has occurred which could reasonably be expected to lead to a radiation emergency.**]**
[F49 20. A person or body listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies Act 2004.**]**	**[**F49 20. Pharmacy medicines which contain any of the following substances but no other active ingredient— (a) Potassium Iodide; (b) Potassium Iodate.**]**	**[**F49 20. The supply shall only be in response to the occurrence, or likely occurrence, of one of the following events— (a) an emergency within the meaning of section 1 of the Civil Contingencies Act 2004; (b) a **[**F51 radiation**]** emergency within the meaning of regulation 24 of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.**]**

Textual Amendments

F45 Words in Sch. 17 Pt. 5 added (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **10(3)** and words in Sch. 17 Pt. 5 added (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **10(3)**

F46 Words in Sch. 17 Pt. 5 substituted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **18(b)** and words in Sch. 17 Pt. 5 substituted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **18(b)**

F47 Words in Sch. 17 Pt. 5 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(4)** and words in Sch. 17 Pt. 5 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(4)**

F48 Words in Sch. 17 Pt. 5 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(4)** and words in Sch. 17 Pt. 5 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(4)**

F49 Words in Sch. 17 Pt. 5 inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **12(2)** and words in Sch. 17 Pt. 5 inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **12(2)**

F50 Words in Sch. 17 Pt. 5 substituted (E.W.S.) (22.5.2019) by The Radiation (Emergency Preparedness and Public Information) Regulations 2019 (S.I. 2019/703), reg. 1(1), **Sch. 10 para. 10(3)** (with reg. 3)

F51 Word in Sch. 17 Pt. 5 substituted (21.4.2019) by The Carriage of Dangerous Goods (Amendment) Regulations 2019 (S.I. 2019/598), regs. 1, **10**

SCHEDULE 18

Regulation 225

Substances that may not be sold or supplied by a pharmacist without a prescription in reliance on regulation 225

Ammonium bromide
Calcium bromide
Calcium bromidolactobionate
Embutramide
Fencamfamin hydrochloride
Fluanisone
Hexobarbitone
Hexobarbitone sodium
Hydrobromic acid
Meclofenoxate hydrochloride
Methohexitone sodium
Pemoline
Piracetam
Potassium bromide
Prolintane hydrochloride
Sodium bromide
Strychnine hydrochloride
Tacrine hydrochloride
Thiopentone sodium

SCHEDULE 19

Regulation 238

Medicinal products for parenteral administration in an emergency

Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis

Atropine sulphate and obidoxime chloride injection
Atropine sulphate and pralidoxime chloride injection
Atropine sulphate injection
Atropine sulphate, pralidoxime mesilate and avizafone injection
Chlorphenamine injection
Dicobalt edetate injection
Glucagon injection
Glucose injection
Hydrocortisone injection
Naloxone hydrochloride
Pralidoxime chloride injection
Pralidoxime mesilate injection
Promethazine hydrochloride injection
Snake venom antiserum
Sodium nitrite injection
Sodium thiosulphate injection
Sterile pralidoxime

SCHEDULE 20

Regulation 241

Herbal medicinal products specified for the purposes of regulation 241

PART 1

Botanical Source	***Common Name***
Apocynum cannabinum	Canadian hemp
Areca catechu	Areca
Artemisia cina	Santonica
Brayera anthelmintica	Kousso
Catha edulis	Catha
Chenopodium ambrosioides var anthelminticum	Chenopodium
Crotalaria berberoana	Crotalaria fulva
Crotalaria spectabilis	Crotalaria spect.
Cucurbita maxima	Cucurbita
Delphinium staphisagria	Stavesacre seeds
Dryopteris filix-mas	Male fern
Duboisia leichardtii	Duboisia

Duboisia myoporoides	
Ecballium elaterium	Elaterium
Embelia ribes Embelia robusta	Embelia
Erysimum canescens	Erysimum
Holarrhena antidysenterica	Holarrhena
Juniperus sabina	Savin
Mallotus philippinensis	Kamala
Pausinystalia yohimbe	Yohimbe bark
Punica granatum	Pomegranate bark
Rhus radicans	Poison ivy
Scopolia carniolica Scopolia japonica	Scopolia
Strophanthus courmonti Strophanthus emini Strophanthus gratus Strophanthus hispidus Strophanthus kombe Strophanthus nicholsoni Strophanthus sarmentosus	Strophanthus
Ulmus fulva Ulmus rubra	Slippery elm bark (whole or unpowdered)
Viscum album	Misletoe berry

PART 2

Column 1		Column 2	Column 3
Substance			
Botanical Source	**Common Name**	**Maximum dose and maximum daily dose**	**Percentage**
Aconitum balfourni Aconitum chasmanthum Aconitum deinorrhizum Aconitum lycoctonum Aconitum napellus Aconitum spicatum Aconitum stoerkianum Aconitum uncinatum var japonicum	Aconite		1.3 per cent
Adonis vernalis	Adonis vernalis	100 mg (MD) 300mg (MDD)	

Aspidosperma quebrachoblanco	Quebracho	50 mg (MD) 150 mg (MDD)	
Atropa acuminata Atropa belladonna	Belladonna herb, belladonna root	In the form of belladonna herb: 50 mg (MD) 150 mg (MDD); In the form of belladonna root: 30 mg (MD) 90 mg (MDD)	
Chelidonium majus	Celandine	2 g (MD) 6 g (MDD)	
Cinchona calisaya Cinchona ledgerana Cinchona micrantha Cinchona officinalis Cinchona succirubra	Cinchona bark	250 mg (MD) 750 mg (MDD)	
Colchicum autumnale	Colchicum corm	100 mg (MD) 300 mg (MDD)	
Conium maculatum	Conium fruits, conium leaf		7.0 per cent
Convallaria majalis	Convallaria	150 mg (MD) 450 mg (MDD)	
Datura innoxia Datura stramonium	Stramonium	50 mg (MD) 150 mg (MDD)	
Ephedra distachya Ephedra equisetina Ephedra gerardiana Ephedra intermedia Ephedra sinica	Ephedra	600 mg (MD) 1800 mg (MDD)	
Gelsemium sempervirens	Gelsemium	25 mg (MD) 75 mg (MDD)	
Hyoscyamus albus Hyoscyamus muticus Hyoscyamus niger	Hyoscyamus	100mg (MD) 300 mg (MDD)	
Lobelia inflata	Lobelia	200 mg (MD) 600 mg (MDD)	
Pilocarpus jaborandi Pilocarpus microphyllus	Jaborandi		5.0 per cent
Rhus toxicodendron	Poison oak		10.0 per cent
Senecio jacobaea	Ragwort		10.0 per cent

SCHEDULE 21 Regulation 242

Medicinal products at high dilutions

PART 1

Dilutions of unit preparations diluted to at least one part in a thousand (3x)

Agaricus muscarius
Ailanthus glandulosa
Apocynum cannabinum
Aurum lodatum
Belladonna
Bismuth Subgallate
Bryonia alba dioica
Calcium Fluoride
Cantharis
Cerium oxalicum
Chelidonium majus
Chenopodium oil
Cina
Colocynthis
Convallaria majalis
Gelsemium sempervirens
Hyoscyamus niger
Lycopodium
Manganese acetate
Ranunculus bulbosus
Terebinthinae oleum

PART 2

Dilutions of unit preparations diluted to at least one part in a million (6x)

Adonis vernalis
Agaricus bulbosus
Agaricus muscarius
Agnus castus
Ailanthus glandulosa
Alum
Amethyst
Ammonium Iodide
Amygdalae amarae

Apatite
Apocynum androsaemifolium
Apocynum cannabinum
Argentite
Argentum Chloride
Argentum Iodide
Arnica
Artemisia cina
Aspidium filix-mas
Aspidium anthelmintica
Aurum Sulphide
Balsamum copivae
Balsamum peruvianum
Barium Citrate
Barium Citrate
Barium Sulphate
Bismuth Metal
Bismuth Subgallate
Bismuth Subnitrate
Boletus laricis
Bovista
Cade Oil
Calcium Fluoride
Cantharis
Carduus marianus
Cedar Wood Oil
Cerium Oxalicum
Chalcocite
Chalcopyrite
Chelidonium majus
Chenopodium Oil
Colocynthis
Convallaria majalis
Copper Silicate, Nat.
Crotalus horridus
Cucurbita
Cucumis melo
Datura Stramonium
Derris
Diamond

Ephedra vulgaris
Ferric Acetate
Ferrous Iodide
Ferrous Oxalate
Ferrous Sulphide
Formic Acid
Gall
Gelsemium sempervirens
Gneiss
Granatum (Pomegranate) Bark
Harmamelis Virginiana
Hepar Sulfuris
Hyoscyamus niger
Iris florentine
Jaborandi
Juniperus sabina
Kalinite
Lachmanthus tinctoria
Lapis Albus
Lycopodium
Magnesium
Magnesium Acetate
Magnesium Chloride
Magnetite
Manganese Acetate
Nicotiana tabacum
Nicotiana tabacum oil
Oleander
Opuntia vulgaris
Oxalic Acid
Petroleum
Phellandrium aquaticum
Pix Liquida
Platinum
Platinum Chloride
Potassium Hydroxide
Potassium Silicate
Pyrethrum
Pyrolusite
Ranunculus acris

Ranunculus bulbosus
Ranunculus flammula
Ranunculus repens
Ranunculus sceleratus
Rhodium Oxynitrate
Rhododendron chrysanthemum
Rhus toxicodendron
Salicylic Acid
Scrophularia aquatica
Sodium Aluminium Chloride
Sodium Auro-chloride
Sodium Hypochlorite
Sodium Nitrate
Squill
Stannum Metal
Staphisagria
Sulphur Iodide
Tamus communis
Tannic Acid
Terebinthinae Oleum
Theridion
Thuja occidentalis
Topaz
Uric Acid
Zinc Hypophosphite
Zinc Isovalerate

PART 3

Dilutions of unit preparations diluted to at least one part in ten (1x)

Abies excelsa
Abies nigra
Abies nobilis
Acalpha indica
Agate
Alisma plantago Aq.
Alstonia scholaris
Aluminium
Amber (Succinum)
Ambra grisea

Ammonium Phosphate
Angostura vera
Anthoxanthum
Apis mellifera
Aqua Marina
Aqua Mellis
Aralia racemosa
Aranea diadema
Arum maculatum
Arum triphyllum
Asarum
Asperula odorata
Astacus fluviatillis
Auric Chloride
Badiaga
Beech (fagus sylvestris)
Bellis perennis
Berberis aquifolium
Borago officinalis
Butyric Acid
Calcium Metal
Calcium Chloride
Calcium Oxide
Calcium Sulphate
Castoreum
Ceanothus americanus
Cedron
Cerato (Ceratostigma Willmottiana)
Cherry Plum (Prunus cerasifera)
Chestnut, Red and Sweet
Cholesterinum
Chrysolite
Cistus canadensis
Clematis erecta
Conchae vera
Conchiolinum
Corallium Rubrum
Crab Apple
Crocus sativus
Erbium

Erigeron Canadense
Fuligo
Genista tinctoria
Geum urbanum
Glycogen
Gnaphalium leontopodium
Gold
Gorse (Ulex europaeus)
Graphites
Gratiola officinalis
Gymnocladus (American Coffee Tree)
Haematoxylon Campechianum
Hecla Lava (Ash from Mount Hecla)
Hedeoma pulegioides
Hedra helix
Heliotrope
Heracleum spondylium
Herniaria
Hornbeam (Carpinus betulus)
Iberis amara
Impatiens
Iris germanica
Iris pseudacorus
Jacaranda procera
Jatropha curcas
Juncus communis
Justica adhatoda
Lamium album
Laurus nobilis oil
Laurocerasus
Ledum palustre
Lilium tigrinum
Lonicera caprifolium
Lysimachia vulgaris
Magnesium Phosphate
Magnesite
Magnolia
Marum verum
Melilotus officinalis
Menispermum canadense

Pephitis putorius
Mercurialis perennis
Mimulus (Mimullis guttatus)
Moschus
Myrica gale
Myrtus communis
Ocimum basilicum
Olive
Oxalis acetosella
Pangamic Acid
Paullinia cupana
Penthorum sedoides
Pollen (mixed)
Polygonatum multiflorum
Polygonum aviculare
Polypodium vulgare
Primula vulgaris
Prunella vulgaris
Ptellea trifoliata
Ratanhia
Robinia pseudoacacia
Rubia tinctorum
Rumex acetosella
Sal Marina
Sarcolactic Acid
Sarracenia purpurea
Scleranthus (Scleranthus annuus)
Silica
Silphium laciniathum
Sodium Benzoate
Spongia marina
Star of Bethlehem (Ornithogalum umbellatum)
Ulmus campestris
Vine
Walnut (juglerus regia)
Water Violet (Hottonia palustris)
Wild Oat
Wild Rose

PART 4

Dilutions of unit preparations diluted to at least one part in ten (1x) for external use

Adonis vernalis
Agricus bulbosus
Agricus muscarius
Agnus castus
Allanthus glandulosa
Alum
Amethyst
Ammonium Iodide
Amygdalae amarae
Apatite
Apocynum androsaemifolium
Apocynum cannabinum
Argentite
Argentum Chloride
Argentum Iodide
Artemisia cina
Aspidium filix-mas
Aspidium anthelmintica
Aurum Sulphide
Balsamum copaivae
Balsamum peruvianum
Barium Citrate
Barium Sulphate
Bismuth Metal
Bismuth Subgallate
Bismuth Subnitrate
Boletus laricis
Bovista
Cade Oil
Calcium Fluoride
Carduus marianus
Cedar Wood Oil
Cerium Oxalicum
Chalcocite
Chalcopyrite
Chelidonium majus
Chenopodium Oil

Colocynthis
Convallaria majalis
Copper Silicate, Nat
Crotalus horridus
Cucurbita
Cucumis melo
Datura stramonium
Derris
Diamond
Ephedra vulgaris
Ferric Acetate
Ferrous Iodide
Ferrous Oxalate
Ferrous Sulphide
Formic Acid
Gall
Gelsemium sempervirens
Gneiss
Hamamelis virginiana
Hepar Sulfuris
Hyoscyamus niger
Iris florentine
Jaborandi
Juniperus sabina
Kaolinite
Lachmanthus tinctoria
Lapis Albus
Lycopodium
Magnesium
Magnesium Acetate
Magnesium Chloride
Magnetite
Manganese Acetate
Nicotiana tabacum
Nicotiana tabacum oil
Oleander
Opuntia vulgaris
Oxalic Acid
Petroleum
Phellandrium aquaticum

Pix Liquida
Platinum
Platinum Chloride
Potassium Hydroxide
Potassium Silicate
Pyrethrum
Pyrolusite
Ranunculus acris
Ranunculus bulbosus
Ranunculus flammula
Ranunculus repens
Ranunculus scelerantus
Rhodium Oxynitrate
Rhododendron chrysanthemum
Rhus toxicidendron
Salicylic Acid
Scrophularia aquatica
Sodium Aluminium Chloride
Sodium Auro-chloride
Sodium Hypochlorite
Sodium Nitrate
Squill
Stannum Metal
Sulphur Iodide
Tannic Acid
Terebinthinae Oleum
Topaz
Uric Acid
Zinc Hypophosphite
Zinc Isovalerate

SCHEDULE 22

Regulation 249

Classes of person for the purposes of regulation 249

Doctors

Dentists

Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.

Authorities or persons carrying on the business of—

(a) an independent hospital, independent clinic or independent medical agency,

(b) a hospital or health centre which is not an independent hospital or independent clinic, or

(c) in Northern Ireland, a nursing home.

Holders of wholesale dealer's licences or persons to whom the restrictions imposed by regulation 18(1) do not apply by virtue of an exemption in these Regulations.

Ministers of the Crown and Government departments.

Scottish Ministers.

Welsh Ministers.

A Northern Ireland Minister.

An NHS trust.

An NHS foundation trust.

[[F52]A local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006).**]**

Textual Amendments

F52 Words in Sch. 22 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(a)** (with Sch. 3 para. 28)

[[F53]Public Health England.**]**

Textual Amendments

F53 Words in Sch. 22 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(2)** and words in Sch. 22 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(2)**

[[F53]Public Health Agency.**]**

The Common Services Agency.

A health authority or a special health authority.

F54 . . . . . .

Textual Amendments

F54 Words in Sch. 22 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(b)** (with Sch. 3 para. 28)

A person other than an excepted person who carries on a business consisting (wholly or partly) of supplying medicinal products in circumstances corresponding to retail sale, or of administering such products, pursuant to an arrangement made with—

(a) an NHS trust or an NHS foundation trust;

(b) the Common Services Agency;

[[F55](ba) a clinical commissioning group; **]**

[[F55](bb) the National Health Service Commissioning Board;**]**

[F56(bc) a local authority;

(bd) Public Health England;

(be) Public Health Agency; or**]**

(c) a health authority or a special health authority; F57...

F57(d) . . . . . .

Textual Amendments

F55 Words in Sch. 22 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(c)(i)** (with Sch. 3 para. 28)

F56 Words in Sch. 22 substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(3)** and words in Sch. 22 substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(3)**

F57 Words in Sch. 22 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(c)(ii)** (with Sch. 3 para. 28)

A person other than an excepted person who carries on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of health care by or on behalf of, or under arrangements made by—

(a) a police force in England, Wales or Scotland;

(b) the Police Service of Northern Ireland;

(c) a prison service; F58...

[F59(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.**]**

Textual Amendments

F58 Word in Sch. 22 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(4)** and word in Sch. 22 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(4)**

F59 Words in Sch. 22 substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(5)** and words in Sch. 22 substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(5)**

In this Schedule "excepted person" means—

(a) a doctor or dentist; or

(b) a person lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.

SCHEDULE 23

Regulation 253

Particulars in pharmacy records

1. Paragraph 2 applies, subject to paragraph 3, where the sale or supply of a prescription only medicine is—

(a) in pursuance of a prescription given by—

(i) a doctor or dentist,

(ii) a supplementary prescriber,

(iii) a community practitioner nurse prescriber,

(iv) a nurse independent prescriber,

[F60(v) an optometrist independent prescriber,

(vi) a pharmacist independent prescriber,

(vii) a podiatrist independent prescriber,

(viii) a physiotherapist independent prescriber, F61...

(ix) a therapeutic radiographer independent prescriber; or**]**

[F62(x) a paramedic paramedic independent prescriber; or**]**

(b) under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription).

Textual Amendments

F60 Sch. 23 para. 1(a)(v)-(ix) substituted for Sch. 23 para. 1(a)(v)(vi) (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **17** and Sch. 23 para. 1(a)(v)-(ix) substituted for Sch. 23 para. 1(a)(v)(vi) (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **17**

F61 Word in Sch. 23 para. 1(a)(viii) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **13(2)(a)** and word in Sch. 23 para. 1(a)(viii) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **13(2)(a)**

F62 Sch. 23 para. 1(a)(x) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **13(2)(b)** and Sch. 23 para. 1(a)(x) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **13(2)(b)**

2. In such a case, the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine was sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address of the person giving the prescription;

(d) the name and address of the person for whom the prescription only medicine was prescribed;

(e) the date on the prescription; and

(f) in relation to the sale or supply of a prescription only medicine under regulation 224 the date on which the prescription relating to that sale or supply is received.

3. Where the sale or supply is in pursuance of a repeatable prescription and is not the first sale or supply in pursuance of that prescription, the particulars referred to in regulation 253(2)(a) are either—

(a) the date on which the prescription only medicine is sold or supplied and a reference to the entry in the record referred to in regulation 253(1) which was made in respect of the first sale or supply in pursuance of that prescription and which contains the particulars specified in paragraph 2; or

(b) the particulars specified in paragraph 2.

4. Where the sale or supply of a prescription only medicine is a sale or supply under regulation 225 (emergency sale etc by pharmacist: at patient's request), the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine was sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address of the person requiring the prescription only medicine; and

(d) the nature of the emergency.

5. Paragraph 6 applies where—

(a) the sale or supply of a prescription only medicine is by way of wholesale dealing and no order or invoice or copy of the order or invoice has been retained under regulation 224 or 225; or

(b) the sale or supply is one to which regulation 214(1) does not apply by reason of an exemption other than that in regulation 224 or 225.

6. In such a case, the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine is sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address and trade, business or profession of the person to whom the prescription only medicine is sold or supplied; and

(d) the purpose for which the prescription only medicine is sold or supplied.

SCHEDULE 24

Regulation 257

Packaging information requirements

PART 1

Outer and immediate packaging

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. A statement of the active substances in the product, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.

6. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

7. A list of—

(a) where the product is injectable or is a topical or eye preparation, all excipients; or

(b) in any other case, those excipients known to have a recognized action or effect and included in the guidance published pursuant to Article 65 of the 2001 Directive.

8. The method of administration of the product and if necessary the route of administration.

9. Where appropriate, space for the prescribed dose to be indicated.

10. A warning that the product must be stored out of the reach and sight of children.

11. Any special warning applicable to the product.

12. The product's expiry date (month and year), in clear terms.

13. Any special storage precautions relating to the product.

14. Any special precautions relating to the disposal of an unused product or part of a product, or waste derived from the product, and reference to any appropriate collection system in place.

15. The name and address of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product and, where applicable, the name of the holder's representative.

16. The number of the marketing authorisation, Article 126a authorisation or traditional herbal registration for placing the medicinal product on the market.

17. The manufacturer's batch number.

18. In the case of a product that is not a prescription only medicine, instructions for use.

[F63 18A. In the case of a medicinal product, other than a radiopharmaceutical, that is required by Article 54a of the 2001 Directive to bear safety features—

(a) a unique identifier which complies with the technical specifications set out in Chapter II of Commission Regulation 2016/161; and

(b) an anti-tampering device allowing verification of whether the packaging of the medicinal product has been tampered with.**]**

Textual Amendments

F63 Sch. 24 para. 18A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **19** and Sch. 24 para. 18A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **19**

PART 2

Immediate packaging: blister packs

19. The name of the medicinal product.

20. The strength and pharmaceutical form of the product.

21. Where appropriate, whether the product is intended for babies, children or adults.

22. Where the product contains up to three active substances, the common name of each active substance.

23. The name of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product.

24. The product's expiry date (month and year), in clear terms.

25. The manufacturer's batch number.

PART 3

Immediate packaging: small packages

26. The name of the medicinal product.

27. The strength and pharmaceutical form of the product.

28. Where appropriate, whether the product is intended for babies, children or adults.

29. Where the product contains up to three active substances, the common name of each active substance.

30. The method of administration of the product and if necessary the route of administration.

31. The product's expiry date (month and year), in clear terms.

32. The manufacturer's batch number.

33. The contents of the packaging by weight, by volume or by unit.

SCHEDULE 25

Regulation 258

Packaging requirements: specific provisions

PART 1

Medicines on prescription

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.

3. The date on which the product is sold or supplied.

4. Unless paragraph 5, applies, such of the following particulars as the appropriate practitioner who prescribed the product may specify—

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

5. This paragraph applies if the pharmacist, in the exercise of professional skill and judgement, is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 4 is inappropriate.

6. Where paragraph 5 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 4, as the pharmacist thinks appropriate.

PART 2

Transport, delivery and storage

7. Any special requirements for the storage and handling of the product.

8. The expiry date of the product.

9. The manufacturer's batch number.

PART 3

Pharmacy and prescription only medicines

10. Paragraph 11 applies if a pharmacy medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b), or

(d) distributed by way of wholesale dealing.

11. Where this paragraph applies, the capital letter "P" within a rectangle within which there is to be no other matter of any kind.

12. Paragraph 13 applies if a prescription only medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b); or

(d) distributed by way of wholesale dealing.

13. Where this paragraph applies, the capital letters "POM" within a rectangle within which there is to be no other matter of any kind.

PART 4

Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the outer and immediate packaging, the words "Contains paracetamol".

15. If the product contains paracetamol the words "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", which must appear adjacent to either the directions for use or the recommended dosage.

16. If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Do not take anything else containing paracetamol while taking this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Do not give anything else containing paracetamol while giving this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

18. If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position.

SCHEDULE 26 Regulations 3(13) and 4(5)

Packaging requirements: special provisions

PART 1

Supply by doctors, dentists, nurses and midwives

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.

3. The date on which the product is sold or supplied.

4. Such of the following particulars as the person under whose responsibility the product is sold or supplied considers appropriate—

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

PART 2

Pharmacy exceptions

5. Where the product is to be administered to a particular individual, the name of that individual.

6. The name and address of the person who sells or supplies the product.

7. The date on which the product is sold or supplied.

8. Where the product is prescribed by an appropriate practitioner, such of the following particulars as the appropriate practitioner who prescribed the product may specify, unless paragraph 9 applies —

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

9. This paragraph applies if a pharmacist, in the exercise of professional skill and judgement, is of the opinion that the inclusion of one or more of the particulars specified in paragraph 8 by the appropriate practitioner who prescribed the product is inappropriate.

10. Where paragraph 9 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 8, as the pharmacist thinks appropriate.

11. Where the product is not prescribed by an appropriate practitioner, directions for use of the product, but these may be omitted in circumstances where section 10(3) of the Medicines Act 1968 applies.

SCHEDULE 27 Regulation 260

Package leaflets

PART 1

General requirements

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. The pharmaco-therapeutic group, or type of activity, of the product, in terms easily comprehensible for the patient.

6. The product's therapeutic indications.

7. A list of—

(a) contra-indications;

(b) appropriate precautions for use;

(c) interactions with other medicinal products which may affect the action of the product;

(d) interactions with other substances, including alcohol, tobacco and foodstuffs, which may affect the action of the product; and

(e) special warnings, if any, relating to the product.

8. The list mentioned in paragraph 7 must—

(a) take into account the special requirements of particular categories of users (including, in particular, children, pregnant or breastfeeding women, the elderly and persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery; and

(c) list any excipients—

(i) if knowledge of the excipients is important for the safe and effective use of the product, and

(ii) the excipients are included in the guidance published pursuant to Article 65 of the 2001 Directive.

9. Instructions for proper use of the product including in particular—

(a) the dosage;

(b) the method and, if necessary, route of administration;

(c) the frequency of administration (including, if necessary, specifying times at which the product may or must be administered);

(d) the duration of treatment if this is to be limited;

(e) symptoms of an overdose and the action, if any, to be taken in case of an overdose;

(f) what to do if one or more doses have not been taken;

(g) an indication, if necessary, of the risk of withdrawal effects; and

(h) a specific recommendation to consult a doctor or pharmacist, as appropriate, for further explanation of the use of the product.

10. A description of the adverse reactions which may occur in normal use of the medicinal product and, if necessary, the action to be taken in such a case.

11. A reference to the expiry date printed on the packaging of the product with—

(a) a warning against using the product after that date;

(b) if appropriate, details of special storage precautions to be taken;

(c) if necessary, a warning concerning visible signs of deterioration;

(d) the full qualitative composition (in active substances and excipients), and the quantitative composition in active substances, using common names, of each presentation of the medicinal product;

(e) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;

(f) the name and address of the holder of the marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product and, if applicable, the name of the holder's appointed representative; and

(g) the name and address of the manufacturer of the product.

12. Where the product is authorised under different names in different member States in accordance with Articles 28 to 39 of the 2001 Directive, a list of the names authorised in each member State.

13. For medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the statement: "This medicinal product is subject to additional [F64]... monitoring".

Textual Amendments

F64 Word in Sch. 27 para. 13 omitted (E.W.S.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(2)** and word in Sch. 27 para. 13 omitted (N.I.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(2)**

[F65 14. A standardised text relating to adverse event reporting in accordance with the third sub-paragraph of Article 59(1) of the 2001 Directive.**]**

Textual Amendments

F65 Sch. 27 para. 14 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(3)** and Sch. 27 para. 14 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(3)**

15. The date on which the package leaflet was last revised.

PART 2

Paracetamol

16. If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

SCHEDULE 28

Regulation 264

Labelling requirements for registrable homoeopathic medicinal products

PART 1

Outer and immediate packaging

1. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

2. The name and address of the holder of the certificate of registration and, if different, the manufacturer.

3. The method and, if necessary, route of administration.

4. The product's expiry date (month and year), in clear terms.

5. The product's pharmaceutical form.

6. The contents of the presentation, specified by weight, volume or number of doses.

7. Special storage precautions, if any.

8. A special warning, if necessary in relation to the product.

9. The manufacturer's batch number.

10. The number of the certificate of registration.

11. The words “homoeopathic medicinal product without therapeutic indications”.

12. A warning advising the user to consult a doctor if symptoms persist.

PART 2

Blister packs etc contained in outer packaging

13. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

14. The name and address of the holder of the certificate of registration.

15. The product's expiry date (month and year), in clear terms.

16. The manufacturer's batch number.

17. The words “homoeopathic medicinal product without therapeutic indications”.

PART 3

Small immediate packaging

18. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

19. The name and address of the holder of the certificate of registration.

20. The method and, if necessary, route of administration.

21. The product's expiry date (month and year), in clear terms.

22. The contents of the presentation, specified by weight, volume or number of doses.

23. The manufacturer's batch number.

24. The words “homoeopathic medicinal product without therapeutic indications”.

SCHEDULE 29

Regulation 265

Labelling of traditional herbal medicinal products

PART 1

Traditional herbal medicinal products: general

1. A statement to the effect that the product is a traditional herbal medicinal product, for use for specific purposes by reason of long-standing use.

2. A statement that the user should consult a doctor or other health care practitioner if symptoms persist during use of the medicinal product, or if adverse effects not mentioned on the package or package leaflet occur.

PART 2

Traditional herbal medicinal products not subject to general sale

3. Subject to the provisions of regulation 265(2), paragraph 4 applies where a traditional herbal medicinal product that is a pharmacy medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b); or

(d) distributed by way of wholesale dealing.

4. Where this paragraph applies, the outer packaging and the immediate packaging of the product must be labelled to show the capital letter "P" within a rectangle, within which there is to be no other matter of any kind.

SCHEDULE 30

Regulations 294, 295 and 297

Particulars for advertisements to persons qualified to prescribe or supply

1. The number of the marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation for the medicinal product.

2. The name and address of the holder of **[**F66the temporary authorisation or**]** the marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation for the medicinal product or the business name and address of the part of the holder's business that is responsible for its sale or supply.

Textual Amendments

F66 Words in Sch. 30 para. 2 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(2)** and words in Sch. 30 para. 2 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(2)**

3. The classification of the medicinal product as—

(a) a product that is subject to general sale;

(b) a prescription only medicine; or

(c) a pharmacy medicine.

4. The name of the medicinal product.

5. A list of the active ingredients of the medicinal product that uses their common names and is placed immediately adjacent to the most prominent display of the name of the product.

6. One or more of the indications for the medicinal product consistent with the terms of the marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation for the product **[**F67or, in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174, the indications for the medicinal product consistent with the recommendation or requirement of the licensing authority as to the use of that product**]**.

Textual Amendments

F67 Words in Sch. 30 para. 6 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(3)** and words in Sch. 30 para. 6 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(3)**

7. **[**F68The entries or a**]** succinct statement of the entries (if any) in the summary of the product characteristics**[**F69, or in any equivalent summary published by the holder of a temporary authorisation,**]** relating to—

(a) adverse reactions, precautions and relevant contra-indications;

(b) dosage and method of use so far as relevant to the indications shown in the advertisement, and

(c) where this is not obvious, method of administration so far as relevant to those indications.

Textual Amendments

F68 Words in Sch. 30 para. 7 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **29** and words in Sch. 30 para. 7 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **29**

F69 Words in Sch. 30 para. 7 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(4)** and words in Sch. 30 para. 7 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(4)**

8. The cost excluding value added tax of—

(a) a specified package of the medicinal product; or

(b) a specified quantity or recommended daily dose of the medicinal product calculated by reference to a specified package of the medicinal product.

This paragraph does not apply to an advertisement inserted in a publication that is printed in the United Kingdom but that has a circulation outside the United Kingdom of more than 15 per cent of its total circulation.

9.—(1) The particulars specified in paragraph 7 must be printed in a clear and legible manner.

(2) Those particulars must be placed in such a position in the advertisement that their relationship to the claims and indications for the product can readily be appreciated by the reader.

SCHEDULE 31

Regulation 328(3)

Sampling

Modifications etc. (not altering text)

C1 Sch. 31 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Introductory

1.—(1) This Schedule has effect where a person authorised by an enforcement authority (in this Schedule referred to as a "sampling officer") obtains a sample of a substance or article—

(a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority ("the relevant enforcement authority") must or may enforce by virtue of regulations 323 and 324; or

(b) otherwise for a purpose connected with the performance of the relevant enforcement authority of its functions under these Regulations.

(2) This Schedule has effect whether the sample is obtained by purchase or in exercise of a power conferred by regulation 327.

(3) In this Schedule "medicines control laboratory" means a laboratory that is—

(a) designated by the licensing authority in accordance with Article 111(1) of the 2001 Directive for the purpose of the analysis of samples of one or more types of medicinal product; and

(b) is so designated in relation to a particular medicinal product that is submitted to it for analysis.

Division of sample

2. The sampling officer must as soon as practicable—

(a) divide the sample into three parts;

(b) mark each part;

(c) seal or fasten each part; and

(d) deal with the parts in accordance with paragraphs 3 to 10.

3. If the sample was purchased by the sampling officer otherwise than from a vending machine the officer must supply one part of the sample to the seller.

4. If the sampling officer obtained the sample from a vending machine—

(a) if a person's name and an address in the United Kingdom are stated on the machine as being the name and address of the owner of the machine, the sampling officer must supply one part of the sample to that person; and

(b) in any other case, the sampling officer must supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

5. If the sample is a sample of goods consigned from outside the United Kingdom, and was taken by the sampling officer before delivery to the consignee, the sampling officer must supply one part of the sample to the consignee.

6. If, in a case not falling within any of paragraphs 3 to 5 of this Schedule, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer must supply one part of the sample to the seller.

7. If, in a case not falling within any of paragraphs 3 to 6 of this Schedule, the sample was taken in transit, the sampling officer must supply one part of the sample to the consignor.

8. In any case not falling within any of paragraphs 3 to 7 of this Schedule, the sampling officer must supply one part of the sample to the person appearing to the sampling officer to be the owner of the substance or article from which the sample was taken.

9. In every case falling within any of paragraphs 3 to 8 of this Schedule, the sampling officer must inform the person to whom the part of the sample in question is supplied that the sample has been obtained for the purpose of analysis or other examination.

10. Unless the sampling officer decides not to submit the sample for analysis or other examination the sampling officer must—

(a) retain one of the two remaining parts for future comparison; and

(b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.

11. If a sample consists of substances or articles in unopened containers, the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them if it appears to the sampling officer that—

(a) it is not reasonably practicable to open the containers and divide the contents into parts; or

(b) opening the containers and dividing the contents into parts might affect the composition or impede the analysis or other examination of the contents.

12. Regulation 343(1)(a) to (d) has effect in relation to supplying a part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.

13. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample should be supplied, the sampling officer may retain that part of the sample.

Notice to person named on container

14.—(1) This paragraph applies where the sampling officer has obtained a sample of a substance or article and it appears to the sampling officer that—

(a) the substance or article was manufactured in the United Kingdom by a person ("M") whose name and address in the United Kingdom are stated on its container or packaging; and

(b) M is not a person to whom a part of the sample must be supplied under the preceding provisions of this Schedule.

(2) Unless the sampling officer decides not to submit the sample for analysis or other examination, the sampling officer must give notice to M—

(a) stating that the sample has been obtained; and

(b) specifying the person from whom the sampling officer purchased it or, if it was obtained otherwise than by purchase, the place from which the sampling officer obtained it.

(3) Notice under sub-paragraph (2) must be given to M within the period of three days beginning immediately after the day on which the sample was obtained.

Analysis or other examination

15. Where the enforcing authority that authorises the sampling officer is the Secretary of State or the Minister for Health, Social Services and Public Safety, if the sampling officer decides to submit the sample for analysis the officer must do so—

(a) to a medicines control laboratory; or

(b) to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

16. Where any other enforcing authority authorises the sampling officer, if the sampling officer decides to submit the sample for analysis the officer must do so to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

17.—(1) Arrangements of the kind mentioned in paragraphs 15(b) and 16 made by an enforcement authority in England, Wales or Scotland other than the Secretary of State must be approved by the Secretary of State.

(2) Arrangements of the kind mentioned in paragraph 15(b) made by a district council in Northern Ireland must be approved by the Minister for Health, Social Services and Public Safety.

18. A laboratory to which a sample is submitted under paragraph 15 or 16 must analyse or examine the sample as soon as practicable,

19. A laboratory that has analysed or examined a sample submitted under the preceding provisions of this Schedule must issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

20. A person to whom a part of the sample is to be supplied in accordance with paragraphs 2 to 8 is entitled, on payment of the required fee, to be given a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19.

Provisions as to evidence

21.—(1) In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document unless sub-paragraph (2) applies.

(2) A party to proceedings, other than the party who produced the document mentioned in paragraph (1), may require that the person who issued the certificate be called as a witness.

(3) In proceedings in Scotland, if the person who issued the certificate is called as a witness, that person's evidence is to be sufficient evidence of the facts stated in the certificate.

22. In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings which has been supplied by another party to the proceedings as a copy of a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document.

23.—(1) If, in proceedings before a magistrates' court for an offence under these Regulations, a defendant intends to produce a certificate issued under paragraph 19, or to require that the person by whom a certificate was issued be called as a witness, the defendant must give notice of that intention and (where a certificate is to be produced) a copy of the certificate to the other party at least three clear days before the day on which the summons is returnable.

(2) If sub-paragraph (1) is not complied with the court may adjourn the hearing on such terms as it thinks fit.

(3) In Scotland, if in proceedings in the sheriff court for an offence under these Regulations the accused intends to produce a certificate under paragraph 19, or to require that the person by whom a certificate was issued be called as a witness, the accused must give notice of that intention and (where a certificate is to be produced) a copy of the certificate to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.

(4) If sub-paragraph (3) is not complied with the sheriff may adjourn the diet on such terms as the sheriff thinks fit.

Analysis under direction of court

24.—(1) This paragraph applies where proceedings for an offence under these Regulations relate to a substance or article of which a sample has been taken as mentioned in paragraph 1 of this Schedule.

(2) Where this paragraph applies, the part of the sample retained in pursuance of paragraph 10(a) is to be produced as evidence.

(3) The court must, if requested by a party to the proceedings, and may, in the absence of such a request, cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, to the Government Chemist in Northern Ireland) or to be sent for other examination to a laboratory specified by the court.

(4) If, in a case where an appeal is brought, no action has been taken under sub-paragraph (3), that sub-paragraph applies to the court by which the appeal is heard.

(5) A person or laboratory to whom or to which a part of a sample is sent under this paragraph for analysis or other examination must—

(a) analyse or examine it; and

(b) issue and give to the court a certificate specifying the results of the analysis or examination.

(6) A certificate under sub-paragraph (5)(b) is to be evidence (and, in Scotland, is to be sufficient evidence) of the facts stated in the certificate unless a party to the proceedings requires that the person by whom it was issued be called as a witness.

(7) In Scotland, if the person by whom a certificate is issued is called as a witness that person's evidence is sufficient evidence of the facts stated in the certificate.

25. The costs of analysis or examination under paragraph 24 are to be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

Proof by written statement

26.—(1) In relation to England and Wales section 9 of the Criminal Justice Act 1967 [M25] does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

(2) In relation to Northern Ireland any enactment corresponding to section 9 of the Criminal Justice Act 1967 does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

Marginal Citations

M25 1967 c.80.

Payment for sample taken under compulsory powers

27.—(1) Where a sampling officer takes a sample in the exercise of a power conferred by regulation 327, the officer must, if payment is required, pay the value of the sample to the person to whom a part of the sample is required to be supplied under paragraph 5, 7 or 8 (as the case may be) of this Schedule.

(2) If the sampling officer and the person mentioned in sub-paragraph (1) are unable to agree, the value of the sample is to be determined—

(a) by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question; or

(b) if they are unable to agree on an arbitrator, by the county court for the district (or in Northern Ireland the division) in which the sample was taken.

(3) In the application of this paragraph to Scotland for references to the county court there is to be substituted a reference to the sheriff.

SCHEDULE 32

Regulation 347

Transitional provisions and savings

Continuity of the law

1.—(1) This paragraph applies where any provision of these Regulations re-enacts (with or without modification) an enactment or instrument repealed or revoked by these Regulations.

(2) The repeal and re-enactment do not affect the continuity of the law.

(3) Anything done, or having effect as if done, under or for the purposes of the repealed provision that could have been done under or for the purposes of the corresponding provision of these Regulations, if in force or effective immediately before the commencement of that corresponding provision, has effect thereafter as if done under or for the purposes of that corresponding provision.

(4) Any reference (express or implied) in these Regulations or any other enactment, instrument or document to a provision of these Regulations is to be construed (so far as the context permits) as including, as respects times, circumstances or purposes in relation to which the corresponding repealed provision had effect, a reference to that corresponding provision.

(5) Any reference (express or implied) in any enactment, instrument or document to a repealed provision is to be construed (so far as the context permits), as respects times, circumstances and purposes in relation to which the corresponding provision of these Regulations has effect, as being or (according to the context) including a reference to the corresponding provision of these Regulations.

(6) This paragraph has effect subject to any specific transitional provision or saving in this Schedule.

Product licences

2.—(1) This paragraph applies to a marketing authorisation that—

(a) became a marketing authorisation on 1st January 1995 by virtue of paragraph 1 of Schedule 6 [M26] to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (conversion of existing product licences); and

(b) by virtue of paragraph 1 of this Schedule, has effect from the coming into force of these Regulations as a marketing authorisation granted under these Regulations.

(2) The following provisions do not apply in relation to the marketing authorisation—

(a) regulation 68(7) (revocation etc of marketing authorisation because the holder has ceased to be established in the EU); and

(b) regulation 258 (packaging requirements: specific provisions).

(3) Paragraph (4) applies if the marketing authorisation has not been renewed in the period beginning with 1st January 1995 and ending when these Regulations come into force.

(4) The Medicines (Labelling) Regulations 1976 [M27] and the Medicines (Leaflets) Regulations 1977 [M28] (and subsequent regulations amending those regulations) in so far as they relate to medicinal products continue to have effect in relation to the product to which the marketing authorisation relates until the marketing authorisation is renewed.

Marginal Citations

M26 S.I. 1994/3144, as amended by S.I. 2004/3224 and S.I. 2005/2759. There are other amendments to those regulations that are not relevant to this paragraph..

M27 S.I. 1976/1726, as amended by S.I. 1977/996 and 2168, S.I. 1978/41 and 1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558 and 2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104 and 3144, S.I. 2002/236, S.I. 2004/1031 and S.I. 2005/2745 and 2753.

M28 S.I. 1977/1055, as amended by S.I. 1992/3274, 1994/104 and 3144, and 2005/2753..

Product licences of right

3.—(1) This paragraph applies to a product licence of right.

(2) In this paragraph, "product licence of right" means a licence of right within the meaning of section 25(4) of the Medicines Act 1968 that—

(a) has been issued in relation to the requirements to hold a product licence contained in section 7(2) of that Act; and

(b) is in force immediately before the coming into force of these Regulations.

(3) A product licence of right shall continue in force, subject to the following sub-paragraphs.

(4) Parts 4 to 11, 13 and 14 of these Regulations shall not apply in relation to a medicinal product that is the subject of a product licence of right, except as provided in the following sub-paragraphs.

(5) A medicinal product to which a product licence of right relates shall—

(a) continue to be classified as a prescription only medicine, a medicinal product not subject to general sale, or a medicinal product subject to general sale, as the case may be, in accordance with the provisions of the Medicines Act 1968 and any statutory instrument made under that Act that was in force immediately before the coming into force of these regulations; and

(b) shall be treated as a prescription only medicine, a pharmacy medicine not subject to general sale, or a medicine subject to general sale respectively, as the case may be, for the purposes of Part 12 of these Regulations.

(6) The provisions listed in sub-paragraph (7), and any provisions to which they refer, shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to a product licence of right and to the product to which it relates.

(7) Those provisions are—

(a) section 28(1), (2) and (3)(a) to (e) and (g) to (j) (general power to suspend, revoke or vary licences) of the Medicines Act 1968 [M29];

(b) the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975 [M30];

(c) the Medicines (Labelling) Regulations 1976 [M31];

(d) the Medicines (Leaflets) Regulations 1977 [M32]; and

(e) the Medicines (Labelling and Advertising to the Public) Regulations 1978 [M33].

(8) Part 1 of Schedule 11 (advice and representations) shall have effect where the licensing authority proposes to exercise any power conferred by section 28 of the Medicines Act referred to in sub-paragraph 7(a) in relation to a product licence of right, as if that proposal concerned the suspension, revocation or variation of a UK marketing authorisation, certificate of registration or traditional herbal registration under these Regulations.

(9) Without prejudice to any requirement of Part 1 of Schedule 11 as to the service of notices, where in the exercise of any such power the licensing authority suspends, revokes or varies a product licence of right, it must serve a notice on the holder a notice giving particulars of the suspension, revocation or variation and of the reasons for its decision to suspend, vary or revoke the product licence of right.

(10) Regulations 268 (offences relating to packaging and package leaflets: holder of authorisation etc), 269 (offences relating to packaging and package leaflets: other persons) and 271 (offences: penalties) shall have effect in relation to the provisions in sub-paragraph (7)(d) as if—

(a) references to the holder of a marketing authorisation included reference to the holder of a product licence of right; and

(b) the provisions in sub-paragraph (7)(d) were requirements of Part 13.

(11) A product licence of right shall cease to be in force at the same time that a marketing authorisation, certificate of registration or traditional herbal registration is granted in respect of the product to which the product licence of right relates.

Marginal Citations

M29 Section 28(3) was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (1984 c.40), regulation 4(5) of S.I. 1977/1050, regulation 2(2) of S.I. 1975/1169, regulation 6(2) of S.I. 1994/276, regulation 2(a)(iii) of S.I. 2002/236 and paragraph 14 of Schedule 8 to S.I. 2006/2407.

M30 S.I. 1975/1326, as amended by S.I. 1979/1760 and S.I. 1994/1932.

M31 S.I. 1976/1726, as amended by S.I. 1977/996, S.I. 1977/2168, S.I. 1978/41, S.I. 1978/1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558, S.I. 1985/2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104S.I. 1994/3144, S.I. 2002/236, S.I. 2004/1031, S.I. 2005/2745 and S.I. 2005/2753.

M32 S.I. 1977/1055, as amended by S.I. 1992/3274, S.I. 1994/104, S.I. 1994/3144, and S.I. 2005/2753.

M33 S.I. 1978/41, as amended by S.I. 2004/1771.

Classification of UK marketing authorisation and certificate of registration

4.—(1) Sub-paragraph (3) applies to a UK marketing authorisation granted before 1st April 2002 if—

(a) the authorisation contains a statement that the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2); or

(b) the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2) by virtue of any enactment in force immediately before the coming into force of these Regulations.

(2) Those bases are that the product is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(3) It is a condition of the UK marketing authorisation that the product is only to be available on that basis or those bases.

Advanced therapy medicinal products

5. No provision of these Regulations that applies only to advanced therapy medicinal products shall apply until 30th December 2012 to advanced therapy medicinal products which—

(a) are tissue engineered products; and

(b) were legally on the market in the United Kingdom in accordance with United Kingdom or European Union legislation on 30th December 2008.

*Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (*S.I. 2010/1882*)*

6. Regulation 9 (amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004) of the Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 [M34] remains in force.

Marginal Citations

M34 S.I. 2010/1882.

Section 60 of the Medicines Act 1968 etc

7.—(1) Section 60 of the Medicines Act 1968 ("the Act") shall continue to have effect insofar as it relates to the making of, and continued operation of, the Medicines (Administration of Radioactive Substances) Regulations 1978 [M35] ("the 1978 Regulations").

(2) The following provisions of the Act shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to the following provisions of the 1978 Regulations—

(a) section 22A(2) to (9) and 10(b) (hearing before person appointed) of the Act, in relation to regulation 7 (hearings and written representations) of the 1978 Regulations;

(b) section 67(2) and (4) (offences under Part III) of the Act, as they relate to section 60 of the Act, in relation to regulation 8 (application of provisions of the Act) of the 1978 Regulations; and

(c) paragraphs 7, 8, 9(3) and 10 to 12 of Schedule 1A (provisions relating to Commission and committees) to the Act [M36], in relation to the committee established under regulation 3 (advisory committee) of the 1978 Regulations.

Marginal Citations

M35 S.I. 1978/1006, as amended by S.I. 1995/2147, S.I. 2005/2754. S.I. 2006/2407 and S.I. 2006/2806.

M36 1968 c.67. Schedule 1A was inserted by regulation 7(2) of S.I. 2005/1094.

SCHEDULE 33

Regulation 212

Transitional arrangements: pharmacovigilance

Pharmacovigilance system master file

1. Regulation 182(2)(b) (obligation to maintain and make available pharmacovigilance system master file) does not apply in respect of a medicinal product granted an authorisation or registration before 21st July 2012 until whichever is the earlier of—

(a) the day on which the authorisation or registration is renewed under regulation 66 (application for renewal of UK marketing authorisation) or 133 (application for renewal of traditional herbal registration) for the first time after Part 11 has come into force; or

(b) 21st July 2015.

2. Regulation 210(3)(b) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) does not apply in respect of a medicinal product granted an EU marketing authorisation before 21st July 2012 until whichever is the earlier of—

(a) the day on which the EU marketing authorisation is renewed under article 14 of Regulation (EC) No 726/2004 for the first time after Part 11 has come into force; or

(b) 21st July 2015

Post-authorisation safety studies

3. Regulations 198, 199, 200, 201 and 202 (provisions relating to post authorisation safety studies) do not apply to post authorisation safety studies commenced before 21st July 2012.

4. Regulation 210(3)(g) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) does not apply to post authorisation safety studies commenced before 21stJuly 2012.

Reporting obligations

5. Paragraphs 6 to 8 apply for the period—

(a) that begins on the day that Part 11 comes into force; and

(b) concludes at the end of the period of six months beginning on the day following the day on which the EMA announces that the functionalities of the Eudravigilance database for the purposes of Title IX of the 2001 Directive have been established.

6. The references to "the Eudravigilance database" in regulation 188(1)(a) and (d) (reporting obligations on holders) shall be read as follows—

(a) in regulation 188(1)(a) and (d) in relation to serious adverse reactions that occur within the EEA, as a reference to the competent authority of each EEA State in whose territory the reaction occurred; and

(b) in regulation 188(1)(a) and (d) in relation to serious adverse reactions that occur within a third country, as a reference to—

(i) the EMA, and

(ii) the relevant competent authorities insofar as each of those competent authorities has requested that serious adverse reaction reports for third countries are submitted to it.

7. The licensing authority must ensure that all reports and updated reports it receives under regulation 188(1)(a) and (d) that relate to serious adverse reactions in the United Kingdom are made available to the Eudravigilance database promptly and in any event before the end of the period of

fifteen days beginning on the day following the day on which the report or updated report is received by the licensing authority.

8. Regulations 186(1)(e) (reporting obligations on licensing authority in relation to non-serious suspected adverse reactions) and 188(1)(b) (reporting obligations on holders in relation to non-serious suspected adverse reactions) do not apply.

Periodic safety update reports

9. Paragraph 10 applies for the period—

(a) that begins on the day that Part 11 comes into force; and

(b) concludes at the end of the period of twelve months beginning on the day following the day on which the EMA announces it is ready to receive reports pursuant to Article 107b(1) of the 2001 Directive.

10. The reference to "the EMA" in regulations 191(1) (obligation on holder to submit periodic safety update reports: general requirements) and 192(3) (obligation on holder to submit periodic safety update reports: derogation from general requirements) should be read on both occasions as a reference to "the relevant competent authorities".

SCHEDULE 34 Regulation 348

Amendments to existing law

PART 1

The Medicines Acts 1968 and 1971

1. The Medicines Act 1968 is amended as follows.

2. For the text of section 1 (Ministers responsible for the administration of Act) substitute—

"**1.** In this Act, "the Ministers" has the meaning given by regulation 6(6) to (8) of the 2012 Regulations (but as if references in that regulation to those Regulations were references to this Act).".

3. In section 10 [M37] (exemptions for pharmacists)—

(a) in subsection (1) for "a practitioner" substitute " an appropriate practitioner ";

(b) in subsections (1) and (4) for "sections 7 and 8 of this Act" substitute " regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations ";

(c) in subsection (5) for "section 7 of this Act" substitute " regulation 46 of the 2012 Regulations ";

(d) in subsection (6) for "section 8(2) of this Act" substitute " regulation 17(1) of the 2012 Regulations ";

(e) omit subsection (7); and

(f) in subsection (8) for the words from "section 92" to the end of the subsection substitute " regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations ".

Marginal Citations

M37 1968, c.67. Section 10(1), 10(3) and 10(7A) were amended and 10(2) repealed by Part 1 paragraphs 1 and 10 of Schedule 8 to S.I. 2006/2407, section 10(1), 10(4) were amended and 10(5) to (7) and 10(8) inserted by article 3 of S.I. 1971/1445, section 10(1) was amended and section 10(9) inserted by paragraph 5 Schedule 1 to the Regulations of Care (Scotland) Act 2001, and section 10(7A) to (7C) were inserted by section 26(1) of the Health Act 2006.

4. In section 15 (provision for extending or modifying exemptions)—

(a) omit subsections (1) and (2); and

(b) in subsection (3) [M38] for "sections 9 to 14" substitute " section 10 ".

Marginal Citations

M38 Section 15(3) was amended by paragraphs 1 and 11(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

5. In section 58 [M39] (medicinal products on prescription only)—

(a) in subsection (1) for the words from the first occurrence of "for the purposes" to the end of the subsection substitute " as prescription only medicines ";

(b) omit subsections (1A), (2) and (3);

(c) in the opening words of subsection (4) for "the last preceding subsection" substitute " regulation 223(1) of the 2012 Regulations ";

(d) in subsection (4)(a)—

(i) for "paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs," substitute " regulation 214(1) or (2) of the 2012 Regulations ", and

(ii) for the words from "or, where" to "of this section" substitute " or, in the case of an appropriate practitioner, other than a doctor or dentist, ";

(e) in subsection (4)(b) for "paragraph (a) of that subsection" substitute " regulation 214(1) of the 2012 Regulations ";

(f) in subsection (4A) for "a person who is an appropriate practitioner by virtue of subsection (1)(d) or (e)" substitute " an appropriate practitioner, other than a doctor or dentist ";

(g) in subsection (4C) for "subsection (2)(a) or (b) of this section" substitute " regulation 214(1) or (2) of the 2012 Regulations "; and

(h) after subsection (6) insert—

"(7) In subsection (6) "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

Marginal Citations

M39 Section 58((1), (4) and (6) was amended by paragraph 29 of Part 1 of Schedule 8 to S.I. 2006/2407. Section 58(4) was amended by paragraph 2(b) of Schedule 5 to S.I. 2002/53. Section 58(4) was amended

by section 63(1 and (4) of, and section 58(4A) and (4C) inserted by section 63(1) and (5) of, the Health and Social Care Act 2001.

6. In section 58A(1) [M40] (requirement to specify certain products as prescription-only products)—

(a) omit paragraphs (a) and (b) and the word "and" following paragraph (b); and

(b) for the words following paragraph (c) to the end of the subsection substitute "is specified as a prescription only medicine".

Marginal Citations

M40 Section 58A was inserted by regulation 2 of S.I. 1992/3271, and the heading substituted by and subsection (1) amended by paragraph 30 Part 1 of Schedule 8 to S.I. 2006/2407.

7. In section 62 [M41] (prohibition of sale or supply, or importation, of medicinal products of specified description), after subsection (7) add—

"(8) In this section "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

Marginal Citations

M41 Section 62(7) was substituted by paragraph 12(5) of Schedule 1 to S.I. 2005/1094.

8. In section 64(5) (protection for purchasers of medicinal products) for "a practitioner" substitute " an appropriate practitioner ".

9.—(1) Section 67 [M42] (offences under Part III) is amended as follows.

(2) In subsection (1B)(a) for "by virtue of provision made under section 58(1) of this Act" substitute " within the meaning of regulation 214 of the 2012 Regulations ";

(3) in subsection (2)—

(a) for "52, 58, 63, 64 and 65", substitute " 63 and 64 "; and

(b) omit "any regulations made under section 60 or section 61 or".

(4) Omit subsection (3A).

(5) In subsection (4) for "subsection (1A), (1B), (2), (3) or (3A)" substitute " subsection (1A), (1B), (2) or (3) ".

(6) Omit subsections (5) and (6).

Marginal Citations

M42 Section 67(1B) was inserted by section 63(7) of the Health and Social Care Act 2001, and section 67(3A) inserted and section 67(4) amended by paragraph 8 of Schedule 5 to S.I. 2005/2789

10. In section 72 (representative of pharmacist in case of death or disability)—

(a) in paragraph (1)(c) [M43], for the words from "a committee" to the end of paragraph (c) substitute "a controller is appointed in his case under the Mental Health (Northern Ireland) Order 1986 [M44] "; and

(b) in paragraph (4)(c) for "committee" substitute " controller ".

Marginal Citations

M43 Section 72(1)(c) was amended by paragraph 12(a) of Schedule 5 to the Adults with Incapacity (Scotland) Act 2000 and paragraph 14(a) of Schedule 6 to the Mental Capacity Act 2005, and section 72(4)(c) by paragraph 14(d) of Schedule 6 to the Mental Capacity Act 2005.

M44 S.I. 1986/594 (N.I. 4).

11. In section 82(4) (pharmacies: procedure relating to disqualification) for "Pharmaceutical Society" substitute—

(a) in the first place it appears, "General Pharmaceutical Council or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland"; and

(b) in the second place it appears, "Council or the Society".

12. In section 87 [M45] (requirements as to containers)—

(a) in subsection (1) for "section 85(2) of this Act" substitute " subsection (3) "; and

(b) after subsection (2) insert—

"(3) The purposes mentioned in subsection (1) are—

(a) securing that medicinal products are correctly described and readily identifiable;

(b) securing that any appropriate warning or other appropriate instruction or information is given, and that false or misleading information is not given, with respect to medicinal products;

(c) promoting safety in relation to medicinal products."

Marginal Citations

M45 Section 87(1) was amended by paragraph 44 of Part 1 of Schedule 8 to S.I. 2006/2407.

13. In section 88(1) [M46] (distinctive colours, shapes and markings of medicinal products) for "section 85(2)" substitute " section 87(3) ".

Marginal Citations

M46 Section 88(1) was amended by paragraph 45 of Part 1 of Schedule 8 to S.I. 2006/2407.

14. In section 91 [M47] (offences under Part V, and supplementary provisions)—

(a) omit subsection (1);

(b) in subsection (2) omit "section 85(3), section 86(2) or"; and

(c) in subsection (3) for "sections 85 to" substitute " section ".

Marginal Citations

M47 Section 91(2) and (3) was amended by paragraph 48(b) and (c) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 91(2) was amended by section 32(2) of the Magistrates' Courts Act 1980.

15. In section 104 (application of Act to certain articles and substances)—

(a) in the heading to the section for "Act" substitute " the 2012 Regulations "; and

(b) in paragraph (1) for "this Act" substitute " the 2012 Regulations ".

16. In section 105 (application of Act to certain other substances which are not medicinal products)—

(a) in the heading to the section for "Act" substitute " the 2012 Regulations "; and

(b) in paragraph (1) for "this Act" substitute " the 2012 Regulations ".

17. In section 107 (validity of decisions and proceedings relating thereto)—

(a) in subsection (1)—

(i) omit "of the licensing authority under Part II of this Act or", and

(ii) for "licence or certificate granted or issued" substitute " certificate issued ";

(b) in subsection (4)—

(i) for "grant a licence or certificate" substitute " issue a certificate ",

(ii) for "licence or certificate granted" substitute " certificate issued ", and

(iii) for "grant of the licence or" substitute " issue of the ";

(c) in subsection (6) omit "of Justice".

18.—(1) Section 108 [M48] (enforcement in England and Wales) is amended as follows.

(2) In subsection (2)—

(a) in paragraph (a) for the words from "sections 64" to "and 89(2)" substitute " section 64 and sections 87(2) and 88(3) ";

(b) omit paragraphs (b) and (c); and

(c) in the words following those paragraphs—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ",

(ii) for "the Society" substitute " the Council ",

(iii) for "that Society" substitute " that Council "

(iv) for "paragraphs (a) and (b)" substitute " paragraph (a) ",

(v) for "those paragraphs" substitute " that paragraph ", and

(vi) omit the words from ", and the provisions" to the end of the subsection.

(3) Omit subsections (3) to (5).

(4) In subsection (6)—

(a) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ";

(b) omit paragraph (a); and

(c) in paragraph (b) omit "or section 61".

(5) In subsections (6A) and (6B) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ".

(6) Omit subsection (7).

(7) In subsection (9) for "(7)" substitute " (6D) ".

(8) In subsection (10)—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ", and

(ii) for the words from "or any" to "that duty" substitute " has in relation to any matter failed to perform a duty imposed on it by subsections (6A) or (6B) to enforce any provisions mentioned in those subsections ".

(9) In subsection (12) for paragraphs (a) and (b) substitute—

"(a) in relation to an area in England other than the City of London, the council of a non-metropolitan county, metropolitan district or London borough;

(b) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London; and

(c) in relation to an area in Wales, the council of a county or county borough.".

Marginal Citations

M48 Section 108(2) was amended and 108(12) inserted by paragraph 8 of Schedule 3 to the Food Safety Act 1990, section 108(6A) to (6D) was inserted and section 108(9) and (10) amended by section 31(1) of the Health Act 2006, section 108(9) was amended by paragraph 56(c), section 108(10) by paragraph 56(d) and section 108(11) by paragraph 56(e) of Part 1 of Schedule 8 to S.I. 2006/2407, and section . 108(12) was amended by paragraph 33 of Schedule 16 to the Local Government (Wales) Act 1994.

19. In section 109 [M49] (enforcement in Scotland)—

(a) in subsection (2)—

(i) for the words from "(2)" to "(10)" substitute " (2), (6) to (6D), (9) and (10) ", and

(ii) in paragraph (a) omit the words from "or" to "jointly"; and

(b) omit subsection (3).

Marginal Citations

M49 Section 109(2)(c) was repealed by paragraph 9(a) of Schedule 3 to the Food Safety Act 1990, and section 109(2)(d) was repealed by paragraph 57 of Part 1 of Schedule 8 to S.I. 2006/2407.

20. In section 110 [M50] (enforcement in Northern Ireland)—

(a) in subsection (1), for "Minister of Health and Social Services for Northern Ireland" substitute " Minister for Health, Social Services and Public Safety ";

(b) in subsection (2)—

(i) for "paragraphs (a) and (b)" substitute " paragraph (a) " in both places where it occurs,

(ii) for the words from "those paragraphs" to "subsection" substitute " that paragraph ",

(iii) for "area" substitute " district "[M51] ,

(iv) for "health authority" in both places where it occurs substitute " district council ",

(v) omit the words "and the provisions and regulations specified in the said paragraph (c)";

(c) omit subsection (3);

(d) in subsections (3A) and (3B), after "the Pharmaceutical Society" insert " of Northern Ireland ";

(e) in subsection (5)—

(i) for "Subsections (9) and (10)" substitute " Subsection (9) ",

(ii) in paragraph (a) for "(2) to (7)" substitute " (2) to (6D) ", and

(iii) omit paragraph (b) and the word "and" preceding that paragraph;

(f) omit subsections (6) and (7); and

(g) for subsection (8) substitute—

"(8) In this section "district council" means a council established under the Local Government Act (Northern Ireland) 1972 [M52]."."

Marginal Citations

M50 Section 110(1) was amended by paragraph 58(a) and section 110(5)(a) was amended by paragraph 58(c)(i) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 110(3A) and (3B) were inserted by section 31(3)(b) and section 110(5)(a) amended by section 31(3)(c) of the Health Act 2006. In relation to Northern Ireland,

M51 The amendments in paragraph 19(b)(iii) and (iv), (f) and (g) reproduce amendments already made with effect in Northern Ireland by article 2 and the Schedule to S.R. (NI) 1973 No 211.

M52 1972 c. 9 (N.I.).

21. In section 111 [M53] (rights of entry)—

(a) in subsection (1) omit paragraph (aa) except for the word "or";

(b) in subsection (2) omit paragraph (a);

(c) omit subsection (3);

(d) in subsection (6) omit—

(i) "aircraft," in both places where it occurs, and

(ii) ", commander"; and

(e) for subsection (9) substitute—

"(9) References in this section to a justice of the peace—

(a) in relation to England, include a reference to a district judge (magistrates' courts);

(b) in relation to Scotland, are to be read as references to a sheriff, stipendiary magistrate or justice of the peace, and

(c) in relation to Northern Ireland, are to be read as references to a lay magistrate or a district judge (magistrates' courts).".

Marginal Citations

M53 Section 111(1)(aa) was inserted by paragraph 9 of Schedule 5 to S.I. 2005/2789.

22. In section 113(1) (application of sampling procedure to substance or article seized under section 112), omit the words from "(including" to the end of the subsection.

23. In section 114(1) (supplementary provisions as to rights of entry and related rights), omit—

(a) "aircraft," in both places where it occurs; and

(b) ", commander".

24. In section 121(4) [M54] (contravention due to default of other person), for the words from "63" to "96" substitute " 63, 64, 87 and 88 ".

Marginal Citations

M54 Section 121(4) was amended by paragraph 61 of Part 1 of Schedule 8 to S.I. 2006/2407.

25. In section 122(2) [M55] (warranty as defence), for the words "section 63(b), sections 64 and 65, sections 85 to 88" substitute " sections 63(b), 64, 87 and 88 ".

Marginal Citations

M55 Section 122(2) was amended by paragraph 62 of Part 1 of Schedule 8 to S.I. 2006/2407.

26. In section 123(1)(b) (offences in relation to warranties and certificates of analysis), omit "section 115 of this Act, or under".

27. In section 125 [M56] (prosecutions)—

(a) in subsection (4)—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ", and

(ii) for "that Society" substitute " the Council ";

(b) in subsections (6) and (7) for "Minister of Health and Social Services for Northern Ireland" substitute " Minister for Health, Social Services and Public Safety ".

Marginal Citations

M56 Section 125(4) was amended by paragraph 63 of Part 1 of Schedule 8 to S.I. 2006/2407.

28. In section 126 [M57] (presumptions)—

(a) in subsection (1), omit paragraph (b) and the word "or" following it;

(b) in subsection (3), omit "subsections (3) and (5) of section 85,"; and

(c) omit subsection (4).

Marginal Citations

M57 Section 126(3) was amended by paragraph 64(c) of Part 1 of Schedule 8 to S.I. 2006/2407.

29. In section 128 (financial provisions)—

(a) in subsection (1), for the words from "any of" to "section 1(1) of this Act" substitute " either of the Ministers ";

(b) in subsections (4) and (5), for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council or (as the case may be) the Pharmaceutical Society of Northern Ireland ";

(c) in subsection (5), for "a Minister" substitute " either of the Ministers "; and

(d) in subsection (6), for the words from "any of the Ministers" to "Ireland" substitute " the Secretary of State ".

30. In section 129 [M58] (orders and regulations)—

(a) in subsection (2), omit the words from "or any regulations" to "section 120 of this Act";

(b) in subsection (3)—

(i) in paragraph (a), for the words from "13" to "and 130(5)(c)" substitute " 58, 62, 79 and 106 ", and

(ii) omit paragraph (b);

(c) in subsection (4) omit the words from ", other" to "69(3),", and

(d) in subsection (7)—

(i) omit "Part V or Part VI", and

(ii) for the words "a committee established under section 4 of this Act" substitute " an expert committee appointed by themselves, or by one of them acting alone ".

Marginal Citations

M58 Section 129(2) was amended by paragraph 65(a) of and section 129(3) was amended by paragraph 65(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

31. In section 130 [M59] (meaning of medicinal product and related expressions)—

(a) for subsection (1) substitute—

"(1) In this Act, "medicinal product" has the meaning given by regulation 2 of the 2012 Regulations."; and

(b) omit subsections (2) to (8) and (10).

Marginal Citations

M59 Section 130(1) was amended by paragraph 66(a) of Part 1 of Schedule 8 to S.I. 2006/2407.

32. In section 131(5) [M60] (meaning of "wholesale dealing", "retail sale" and related expressions) for "or the Health and Personal Social Services (Northern Ireland) Order1972" substitute " , the Health and Personal Social Services (Northern Ireland) Order 1972 or the Health and Social Care (Reform) Act (Northern Ireland) 2009 ".

Marginal Citations

M60 Section 131(5) was amended by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006, paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978 and paragraph 128(2) of Schedule 4 to the National Health Service Reorganisation Act 1973.

33. In section 132 (general interpretation provisions)—

(a) for subsection (1) substitute—

"(1) In this Act—

(a) unless the context otherwise requires, any expression defined by any provision of the 2012 Regulations, and not defined in this Act, has the same meaning as it has for the purposes of those Regulations; and

(b) "the 2012 Regulations" means the Human Medicines Regulations 2012.";

(b) omit subsections (2) and (3);

(c) in subsection (4) omit "licence or" in each place it appears; and

(d) omit subsection (5).

34. In Schedule 3 [M61] (sampling)—

(a) omit paragraphs 5 to 7;

(b) in paragraph 8 for "3 to 7" substitute " 3 or 4 ";

(c) in paragraph 9 for "3 to 8" substitute " 3, 4, or 8 "; and

(d) in paragraph 17, in the words following paragraph (c)—

(i) for the words "a health authority" substitute " the Pharmaceutical Society of Northern Ireland ", and

(ii) for "the Minister of Health and Social Services for Northern Ireland" substitute " the Minister for Health, Social Services and Public Safety ".

Marginal Citations

M61 Paragraph 17 of Schedule 3 was amended by paragraph 66 of Part 1 of Schedule 8 to S.I. 2006/2407.

35. In Schedule 4 [M62] (provisions relating to Northern Ireland)—

(a) for every reference to "the Minister of Health and Social Services for Northern Ireland" substitute " the Minister for Health, Social Services and Public Safety ";

(b) in paragraph 6 omit the words from "(except" to "Act)";

(c) in paragraph 8 omit the words from ", and every regulation made solely" to "this Act,"; and

(d) in paragraph 10 for "the Ministry of Health and Social Services for Northern Ireland" substitute " the Department of Health, Social Services and Public Safety ".

Marginal Citations

M62 Paragraphs 2 to 5, 7 and 9(b) and (c) and following words of Schedule 4 were omitted by paragraphs 69(a), (c) and (e)(iii) and (iv) of Part 1 of Schedule 8 to S.I. 2006/2407. Paragraph 6 was amended by paragraph 69(b), paragraph 8 by paragraph 69(d), paragraph 9 by paragraph 69(e) and paragraph 10 by paragraph 69(f) of that Part.

Medicines Act 1971

36.—(1) The Medicines Act 1971 [M63] shall have effect as follows.

(2) In section 1 (fees)—

(a) in subsection (1), the reference to any application in pursuance of the Medicines Act 1968 for a licence or certificate under Part II of that Act, or for the variation or renewal of such a licence or certificate, shall have effect as a reference to any application under Parts 3 to 8 of these Regulations for the grant, variation or renewal of—

(i) a manufacturer's licence,

(ii) a wholesale dealer's licence,

(iii) a marketing authorisation,

(iv) a certificate of registration,

(v) a traditional herbal registration, or

(vi) an Article 126a authorisation; and

(b) in subsection (2)(b), the reference to any licence or certificate under the Medicines Act 1968 shall have effect as a reference to a manufacturer's licence, a wholesale dealer's licence, a marketing authorisation, a certificate of registration, a traditional herbal registration, or an Article 126a authorisation under these Regulations.

(3) Paragraph (2) has effect in relation to references of the kind mentioned in that paragraph in regulations made under section 1.

Marginal Citations
M63 1971 c.69.

PART 2

Other primary legislation

Trade Descriptions Act 1968

37. In section 2(5)(b) (trade descriptions) of the Trade Descriptions Act 1968 [M64] for the words from "made under Part V" to "that Act)" substitute " of Chapter 1 of Part 13 of the Human Medicines Regulations 2012 ".

Marginal Citations
M64 1968 c.29. Paragraph (b) of section 2(5) was inserted by paragraph 16 of Schedule 5 to the Medicines Act 1968.

House of Commons Disqualification Act 1975

38. In Part II (bodies of which all members are disqualified) of Schedule 1 to the House of Commons Disqualification Act 1975 [M65] for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Marginal Citations
M65 1975 c.24.

Northern Ireland Assembly Disqualification Act 1975

39. In Part II (bodies of which all members are disqualified) of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 [M66] for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Marginal Citations
M66 1975 c.25.

Consumer Protection Act 1987

40. Section 19(1) (interpretation of Part II) of the Consumer Protection Act 1987 [M67] shall have effect as if, in the definition "licensed medicinal product", the reference to any medicinal product within the meaning of the Medicines Act 1968, in respect of which a product licence within the meaning of that Act is for the time being in force, included a reference to a medicinal product, in respect of which a marketing authorisation or a traditional herbal registration within the meaning of these Regulations is for the time being in force.

Marginal Citations

M67 1987 c.43. Section 19(1) was amended by paragraph 7 of Part 1 of Schedule 9 to S.I. 2006/2407; there are other amendments to that subsection, but none is relevant.

Environmental Protection Act 1990

41. In section 142(7) (powers to obtain information about potentially hazardous substances) of the Environmental Protection Act 1990 [M68], for the entry relating to the Medicines Act 1968 substitute " Parts 3 to 8 and 16 of the Human Medicines Regulations 2012 ".

Marginal Citations

M68 1990 c.43. Section 142(7) was amended by paragraph 8 of Schedule 4 to the Radioactive Substances Act 1993 (1993 c.12), in relation to England and Wales by paragraph 5(1) and (12) of Part 1 of Schedule 26 to S.I. 2010/675, and by paragraph 8 of Part 1 of Schedule 9 to S.I. 2006/2407.

Value Added Tax Act 1994

42. In Part II of Schedule 8 (zero-rating) to the Value Added Tax Act 1994 [M69]—

(a) in note (2B) to Group 12 (drugs, medicines, aids for the handicapped etc) for the words "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 "; and

(b) in note (11) to Group 15 (charities etc)—

(i) for paragraph (a) substitute—

"(a) "medicinal product" has the meaning assigned to it by regulation 2(1) of the Human Medicines Regulations 2012;", and

(ii) omit paragraphs (b) and (c).

Marginal Citations

M69 1994 c.23. In Part II of Schedule 8, note (2B) to Group 12 was inserted by S.I. 2009/2972, and note (11)(a) to Group 15 was amended by paragraph 10(a), and (11)(d) inserted by paragraph 10(b), of Schedule 9 to S.I. 2006/2407.

Health Act 1999

43. In section 60(2A)(c) (regulation of health care and associated professions) of the Health Act 1999 [M70], after "that Act" insert " or the Human Medicines Regulations 2012 ".

Marginal Citations

M70 1999 c.8. Subsection (2A) was inserted by paragraph 1 of Schedule 8 to the Health and Social Care Act 2008 (2008 c.14).

Communications Act 2003

44. In section 368R(1) (interpretation of Part 4A) of the Communications Act 2003 [M71], for the definition "prescription-only medicine" substitute the following definition—

""prescription-only medicine" means a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012;".

Marginal Citations

M71 2003 c.21. Section 368R was inserted by regulation 2 of S.I. 2009/2979.

Christmas Day and New Year's Day Trading (Scotland) Act 2007

45. In section 7 (interpretation) of the Christmas Day and New Year's Day Trading (Scotland) Act 2007 [M72]—

(a) omit the definition "appropriate person"; and

(b) for the definition "on prescription" substitute the following definition—

""on prescription" means in accordance with a prescription given by an appropriate practitioner, within the meaning of regulation 214(1) and (3) to (6) (sale or supply of prescription only medicines) of the Human Medicines Regulations 2012;".

Marginal Citations

M72 2007 asp 13.

PART 3

Northern Ireland Orders in Council

Health and Personal Social Services (Northern Ireland) Order 1972

46. The Health and Personal Social Services (Northern Ireland) Order 1972 [M73] is amended as follows—

(a) in article 2(2), in the definition "pharmacist" for "Medicines Act 1968" substitute " Human Medicines Regulations 2012 "; and

(b) in article 57D—

(i) in paragraphs (3) and (5) for "Community" substitute " EU ", and

(ii) in paragraph (5) for "regulation 1 of the Medicines for Human Use (Marketing Authorisations etc Regulations 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M73 S.I. 1972/1265 (N.I. 14). Article 57D was inserted by article 4 of the Primary Medical Services (Northern Ireland) Order 2004 (S.I. 2004/311 (N.I. 2))

Pharmacy (Northern Ireland) Order 1976

47. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976 [M74], in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M74 S.I. 1976/1213 (N.I. 22).

Poisons (Northern Ireland) Order 1976

48. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976 [M75]—

(a) in the definition "pharmacist" after "Medicines Act" insert " or the Human Medicines Regulations 2012 "; and

(b) in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M75 S.I. 1976/1214 (N.I. 23).

Diseases of Animals (Northern Ireland) Order 1981

49. In article 38 of the Diseases of Animals (Northern Ireland) Order 1981 [M76] in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M76 S.I. 1981/1115 (N.I. 22).

Waste and Contaminated Land (Northern Ireland) Order 1997

50. In article 33(6) of the Waste and Contaminated Land (Northern Ireland) Order 1997 [M77] for the entry relating to the Medicines Act 1968 substitute " Parts 3 to 8, 12 and 16 of the Human Medicines Regulations 2012 ".

Marginal Citations

M77 S.I. 1997/2778 (N.I. 19). Article 33(6) was amended by S.R. (NI) 2006 No 45.

Shops (Sunday Trading &c.) (Northern Ireland) Order 1997

51. In article 4(3) of the Shops (Sunday Trading &c.) (Northern Ireland) Order 1997 [M78] for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M78 S.I. 1997/2779 (N.I. 20).

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004 [M79] are amended as follows.

Marginal Citations
M79 S.I. 2004/1031, as amended by S.I. 2005/2754. There are other amendments, but none is relevant.

53. In regulation 2(1) (interpretation)—

(a) before the definition "the Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;";

(b) for the definition "appropriate committee" substitute—

""appropriate committee" for the purposes of any provision of these Regulations under which a function falls to be performed means whichever the licensing authority considers to be appropriate of—

(a) the Commission on Human Medicines; or

(b) an expert committee appointed by the licensing authority;";

(c) insert in the appropriate position in alphabetical order the following definition—

""the Commission on Human Medicines" means the Commission on Human Medicines within the meaning of regulation 9 of the 2012 Regulations;";

(d) in the definition "licensing authority" for "section 6 of the Act" substitute " regulation 6 of the 2012 Regulations ";

(e) for sub-paragraph (a) of the definition "marketing authorisation" substitute—

"(a) a UK marketing authorisation granted by the licensing authority under the 2012 Regulations,"; and

(f) for the definition "medicinal product" substitute—

""medicinal product" means a medicinal product within the meaning of regulation 2(1) of the 2012 Regulations."

54. In regulation 4(3) (responsibility for functions under the Directive) for "the Act" substitute " the 2012 Regulations ".

55. In regulation 19(10) (authorisation procedure for clinical trials involving medicinal products for gene therapy etc) omit "established by section 2A of the Act".

56. In regulation 46(2)(c) (labelling) for words from "Schedule 5" to the end of the sub-paragraph substitute " Part 13 of the 2012 Regulations that apply in relation to medicinal products sold or

supplied in accordance with a prescription given by a person who is an appropriate practitioner within the meaning of regulation 214(3) to (6) of those Regulations ".

57. In regulation 47 (application of enforcement provisions of the Act)—

(a) for "the Act" in the heading substitute " the 2012 Regulations "; and

(b) for paragraph (1) substitute—

"(1) Regulations 2, 8(1), 322, 323(1), 324(1), 325 to 330, 332 to 339, 343 and Schedule 31 of the 2012 Regulations ("those provisions") shall apply for the purposes of these Regulations as they apply for the purposes of the 2012 Regulations, but with the modifications specified in Schedule 9, and any reference in those provisions to the 2012 Regulations includes a reference to these Regulations."; and

(c) after paragraph (2) insert the following paragraph—

"(3) In those provisions as applying by virtue of paragraph (1), any reference to, or relating to, a requirement, a power, a function, a right, a duty, an entitlement, or a protection shall be read as a reference to, or relating to, that requirement, power, function, right, duty, entitlement, or protection as applied by this regulation.".

58. In regulation 48(5) (infringement notices) for "sections 108 to 110 of the Act" substitute " regulation 323(1) or 324(1) of the 2012 Regulations ".

59. In regulation 49(5) (offences) for "the Act" substitute " the 2012 Regulations ".

60. In regulation 53(3) (construction of references to specified publications) for "section 103(1) of the Act" substitute " regulation 321(1) of the 2012 Regulations ".

61. In paragraph 4(2) of Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

62. In Schedule 7 (standard provisions for manufacturing authorisations)—

(a) in Part 2—

(i) in paragraph 5 for "the Act" substitute " the 2012 Regulations ",

(ii) in paragraph 9 for "the Act or any regulations under the Act" substitute " or the 2012 Regulations ", and

(iii) in paragraph 13—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations "; and

(b) in Part 3—

(i) in paragraph 6 for "the Act" in the first place where it occurs substitute " the 2012 Regulations ", and

(ii) in paragraph 8—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations ".

63. In paragraph 5(2) of Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

64. For Schedule 9 substitute the following Schedule—

"SCHEDULE 9 Regulation 47(1)

MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE 2012 REGULATIONS SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

1. The modifications of the 2012 Regulations mentioned in regulation 47 are as follows.

2. In regulation 2 (medicinal products)—

(a) at the beginning of paragraph (1) insert " Subject to paragraph (3), "; and

(b) after paragraph (2) insert the following paragraph—

"(3) "Medicinal product" includes any investigational medicinal product.".

2. In regulation 8(1) (interpretation)—

(a) the definition "assemble" is substituted by the definition of that expression in regulation 2(1) of these Regulations; and

(b) there is inserted in the appropriate position in alphabetical order a definition "container" in the same terms as the definition of that expression in regulation 2(1) of these Regulations; and

(c) the definition "qualified person" is substituted by the definition of that expression in regulation 2(1) of these Regulations.

3. In regulation 322(1) (validity of decisions and proceedings) omit "or" and insert a comma before " 8 (Article 126a authorisations) ", and after those words insert " or the Clinical Trials Regulations ".

4. In regulation 325(1) (rights of entry) insert after sub-paragraph (b) the following sub-paragraph—

"(ba) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations;".

5.—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (b) omit "; or";

(b) after sub-paragraph (c) insert " ; or " and the following sub-paragraph—

"(d) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations.".

(3) After paragraph (2)(g) insert the following sub-paragraph—

"(h) information and documents relating to clinical trials".

(4) In paragraph (3)—

(a) omit "or" following sub-paragraph (a); and

(b) following paragraph (b) insert " ; or " and the following sub-paragraph—

"(c) a medicinal product used, or intended to be used, in a clinical trial".

(5) In paragraph (4)—

(a) after "require" insert " — (a) "; and

(b) after "control" insert " ; or " and the following sub-paragraph—

"(b) a person associated with a clinical trial to produce information or documents relating to the clinical trial which are in the person's possession or under the person's control".

(6) In paragraph (5)(a) for "(2)(f) or (g)" substitute " (2)(f), (g) or (h) ".

(7) After paragraph (9) insert the following paragraph—

"(10) In this regulation, "a person associated with a clinical trial means any of the following—

(a) the sponsor of a clinical trial (within the meaning of regulation 3 of the Clinical Trials Regulations);

(b) any person who, under arrangements made with the sponsor of a clinical trial, carries out functions of the sponsor of the trial;

(c) in investigator for a clinical trial (within the meaning of regulation 2(1) of the Clinical Trials Regulations);

(d) any person, other than an investigator, who conducts a clinical trial;

(e) any person occupying premises at which a clinical trial is being conducted; or

(f) any person who, in the course of employment with a person listed in any of sub-paragraphs (a) to (e), undertakes activities in connection with a clinical trial.".

(8) In regulation 335(6) (contravention due to fault of another person) omit "and" after sub-paragraph (e) and after sub-paragraph (f) insert " ; and " and the following sub-paragraph—

"(g) any obligation or prohibition under the Clinical Trials Regulations".

(9) In regulation 336(3) (warranty as defence) omit "and" after sub-paragraph (c) and after sub-paragraph (d) insert " ; and " and the following sub-paragraph—

"(e) regulation 46 of the Clinical Trials Regulations (labelling)"."

PART 5

Other United Kingdom, Scotland and Wales Secondary legislation

Medicines (Administration of Radioactive Substances) Regulations 1978

65. In regulation 8(1) of the Medicines (Administration of Radioactive Substances) Regulations 1978 [M80]—

(a) for "Section 6(2) of the Act" substitute "Regulation 6(3) of the Human Medicines Regulations 2012 ("the 2012 Regulations"); and

(b) for "by or under the Act" substitute " by the 2012 Regulations ".

Marginal Citations

M80 S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2407. There are other amendments, but none is relevant.

Importation of Animal Products and Poultry Products Order 1980

66. In the Schedule to the Importation of Animal Products and Poultry Products Order 1980 [M81], for "or the Medicines for Human Use (Marketing Authorisations Etc. Regulations) 1994" substitute " or the Human Medicines Regulations 2012 ".

Marginal Citations

M81 S.I. 1980/14, as amended by S.I. 1994/2920, S.I. 1994/3142 and S.I. 1994/3144.

Medicines Act (Hearings by Persons Appointed) (Scotland) Rules 1986

67. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986 [M82]—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "the appropriate Ministers as defined in section 1(2)" substitute " the Ministers as defined in regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012 ".

Marginal Citations

M82 S.I. 1986/1700. There are amendments, but none is relevant.

Medicines Act (Hearings by Persons Appointed) Rules 1986

68. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986 [M83]—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "section 1(1)" substitute " regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012 ".

Marginal Citations

M83 S.I. 1986/1761, as amended by S.I. 2006/2407. There are other amendments, but none is relevant.

Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989

69.—(1) The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989 [M84] is amended as follows.

(2) In article 1(2) insert after the definition " the 1987 Act " the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(3) In Schedule 1—

(a) in paragraph 1 omit ", II" and ", VI";

(b) after paragraph 1 insert the following paragraph—

"**1A.** Functions of the Ministers under the 2012 Regulations (except those under Part 15 (British Pharmacopeia) of those Regulations), subject to paragraph 11 below.".

(c) in paragraph 2 for "Part II of the 1968 Act " substitute "Parts 3 to 8 of the 2012 Regulations";

(d) for paragraph 3 substitute—

"**3.** Functions of the Commission on Human Medicines, whose continuation is provided for in regulation 9 of the 2012 Regulations (except those under Part 15 (British Pharmacopoeia) of those Regulations).";

(e) for paragraph 4 substitute—

"**4.** Functions of any expert committee appointed by the licensing authority under the 2012 Regulations.".

(f) for paragraph 8 substitute—

"**8.** Functions of reviewers appointed under the 2012 Regulations.".

(g) omit paragraphs 9A, 9C and 9D;

(h) in paragraph 10(c) for "and of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " and of the 2012 Regulations " and

(i) in paragraph 11—

(i) after "Paragraphs 1" insert " , 1A ", and

(ii) after "under it" insert " or under the 2012 Regulations ".

Marginal Citations

M84 S.I. 1989/684, as amended by S.I. 1995/871, S.I. 2004/1031 and S.I. 2005/2754. There are other amendments, but none is relevant.

Medical Devices (Consultation Requirements) (Fees) Regulations 1995

70. In regulation 1(2) of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 [M85]—

(a) in the definition "authorised medicinal product"—

(i) in sub-paragraph (b) before "under" insert " the Human Medicines Regulations 2012 or ", and

(ii) in sub-paragraph (c) for "those" substitute " the latter "; and

(b) in the definition "product licence of right" for "section 25(4) of that Act" substitute " paragraph 3(2) of Schedule 32 to the Human Medicines Regulations 2012 ".

Marginal Citations

M85 S.I. 1995/449

Prescription Only Medicines (Human Use) Order 1997

71.—(1) The Prescription Only Medicines (Human Use) Order 1997 [M86] is amended as follows.

(2) In article 1—

(a) in paragraph (2) omit all the defined expressions except "inhaler" and "maximum strength";

(b) for paragraph (2A) substitute—

"(2A) In this Order, unless the context otherwise requires, any expression defined by any provision of the Human Medicines Regulations 2012 has the same meaning as it has for the purposes of those Regulations.";

(c) in paragraph (5) for "Schedules 1, 2, 3A and 5" substitute " Schedules 1 and 2 "; and

(d) omit paragraphs (6) to (9).

(3) In article 5(1) for the words from the beginning of the paragraph until sub-paragraph (a) substitute "A medicinal product that is not the subject of a marketing authorisation is a prescription only medicine for the purposes of the Human Medicines Regulations 2012 if it, or a substance in it, is listed in column 1 of Schedule 1, unless there".

(4) In paragraphs (1) and (2) of article 10 for the words "The restrictions" to "administration of" substitute " A medicinal product is not a prescription only medicine for the purposes of the Human Medicines Regulations 2012 by virtue of Article 5(1) if it is ".

Marginal Citations

M86 S.I. 1997/1830, as amended by S.I. 1997/2044, S.I. 1998/108, S.I. 1998/1178, S.I. 1998/2081, S.I. 1999/1044, S.I. 1999/3463, S.I. 2000/1917, S.I. 2000/2899, S.I. 2000/3231, S.I. 2001/2777, S.I. 2001/3942, S.I. 2003/696, and S.I. 2006/915. There are other amendments, but none is relevant.

General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999

72. In rule 7B(b) of the Schedule to the General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999 [M87], for the words from "article" to the end of the paragraph substitute " regulation 215 (prescribing and administration by supplementary prescribers) " of the Human Medicines Regulations 2012.

Marginal Citations

M87 S.I. 1999/3267, as amended by S.I. 2005/1476. There are other amendments, but none is relevant.

National Health Service (Charges for Drugs and Appliances) Regulations 2000

73. The National Health Service (Charges for Drugs and Appliances) Regulations 2000 [M88] are amended as follows—

[F70](a) . . . . . .

(b) in regulation 6A(6) for the words from "the Medicines" to the end of the paragraph substitute " the Human Medicines Regulations 2012 ".

Textual Amendments

F70 Sch. 34 para. 73(a) revoked (E.) (1.4.2015) by The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570), reg. 1, **Sch. 3**

Marginal Citations

M88 S.I. 2000/620, as amended by S.I. 2000/3189 and S.I. 2009/1166. There are other amendments, but none is relevant.

Biocidal Products Regulations 2001

74. In Schedule 2 to the Biocidal Products Regulations 2001 [M89]—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations

M89 S.I. 2001/880, as amended by S.I. 2010/745. There are other amendments, but none is relevant.

Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001

75. In article 4(4) of the Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001 [M90], for the words following "marketing authorisation" to the end of the paragraph substitute " , certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. "

Marginal Citations

M90 S.I. 2001/1841, as amended by S.I. 2005/2750 and S.I. 2008/548.

Misuse of Drugs Regulations 2001

76. In regulation 2(1) of the Misuse of Drugs Regulations 2001 [M91]—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "pharmacist independent prescriber", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in the definitions "pharmacist" and "registered pharmacy" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M91 S.I. 2001/3998, as amended by S.I. 2003/2429, S.I. 2005/271, S.I. 2006/986, S.I. 2006/1450, S.I. 2007/2154 and 2012/973. There are other amendments, but none is relevant.

Medicines for Human Use (Kava-kava) (Prohibition Order) 2002

77. In paragraph (d) of article 3 of the Medicines for Human Use (Kava-kava) (Prohibition Order) 2002 [M92], for the words following "subject" to the end of the article substitute " of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. ".

Marginal Citations

M92 S.I. 2002/3170, as amended by S.I. 2005/2750 and S.I. 2008/548.

Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

78. In article 1(3) of the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 [M93] for "the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M93 S.I. 2003/1076, as amended by S.I. 2005/2061. There are other amendments, but none is relevant.

Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003

79. In the column "specified UK laws" of the Schedule to the Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003 [M94] for "the Medicines (Advertising) Regulations 1994" substitute " Chapters 1 and 2 of Part 14 (advertising) of the Human Medicines Regulations 2012 ".

Marginal Citations

M94 S.I. 2003/1374. There are amendments, but none is relevant.

Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003

80. In the Schedule to the Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003 [M95]—

(a) in the first column, insert in the appropriate position in alphabetical order " Human Medicines Regulations 2012 ";

(b) in the second column, insert adjacent to the entry " Human Medicines Regulations 2012 " in the first column "regulation 303 (advertising offences)"; and

(c) omit "Medicines (Advertising) Regulations 1994" in the first column and the adjacent entry "regulation 23 (offences)" in the second column.

Marginal Citations

M95 S.I. 2003/1376. There are amendments, but none is relevant.

Health Professions (Parts of and Entries in the Register) Order of Council 2003

81. In article 6 of the Health Professions (Parts of and Entries in the Register) Order of Council 2003 [M96]—

(a) for sub-paragraph (b) of paragraph (2), up to and including the word "analgesics", substitute—

"(b) referred to in the following provisions of Schedule 17 (exemption for sale, supply or administration by certain persons) to the Human Medicines Regulations 2012 —

(i) in Part 1 (exemption from restrictions on sale or supply of prescription only medicines), paragraph 11 (certificate of competence in the use of specified medicines), or

(ii) in Part 3 (exemptions from the restriction on administration of prescription only medicines), paragraph 1 (certificate in the use of analgesics),"; and

(b) in paragraph (3) for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M96 S.I. 2003/1571, as amended by S.I. 2006/1996. There are other amendments, but none is relevant.

Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

82.—(1) The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [M97] (interpretation) are amended as follows.

(2) In regulation 1(2)—

(a) omit the following definitions—

(i) "the 1994 Regulations", and

(ii) "herbal remedy";

(b) before the definition of "the appropriate committee" insert—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(c) for the definition of "the appropriate committee" substitute—

""the appropriate committee" means whichever the appropriate Minister considers to be the appropriate body of the following—

(a) the Commission; or

(b) an expert committee appointed by the appropriate Minister, or by the appropriate Ministers for Great Britain and for Northern Ireland acting jointly;";

(d) after the definition of "the appropriate Minister" insert—

""the Commission" means the Commission on Human Medicines continued in existence by regulation 9 of the 2012 Regulations;";

(e) for the definition of "excluded medicine" substitute—

""excluded medicine" means a medicinal product to which the restrictions in regulation 46 (requirement for authorisation) of the 2012 Regulations do not apply by virtue of regulation 3(6) (scope of these Regulations: special provisions) or 4(1) (special provisions for pharmacies etc) of those Regulations;";

(f) in the definition of "market" for the words from "have the same meaning" to the end substitute " are to be construed in accordance with the 2012 Regulations; ";

(g) for the definition of "medicinal product" substitute—

""medicinal product" has the meaning given by regulation 2 of the 2012 Regulations;"; and

(h) in the definition of "unlicensed product"—

(i) in paragraph (a)(i), for "the 1994 Regulations" substitute " the 2012 Regulations ",

(ii) omit paragraph (b) and the word "or" following it,

(iii) for paragraph (c) substitute—

"(c) no traditional herbal registration has been granted by the licensing authority under the 2012 Regulations;", and

(iv) after that paragraph insert the word " or " and the following paragraph —

"(d) no Article 126a authorisation has been granted by the licensing authority under those regulations;".

Marginal Citations

M97 S.I. 2003/1680, as amended by S.I. 2004/3224, S.I. 2005/2750 and S.I. 2005/2754.

National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004

83.—(1) The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 [M98] are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 ".

(3) In paragraph 41(2)(a) of Schedule 5—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M98 S.S.I. 2004/115, as amended by S.S.I. 2005/337. There are other amendments, but none is relevant.

National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004

84.—(1) The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 [M99] are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 ".

(3) In paragraph 13(2)(a) of Schedule 1—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M99 S.S.I. 2004/116, as amended by S.S.I. 2005/336. There are other amendments, but none is relevant.

National Health Service (General Medical Services Contracts) Regulations 2004

F71 85. . . . . . .

Textual Amendments

F71 Sch. 34 para. 85 revoked (E.) (7.12.2015) by The National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862), reg. 1(2), **Sch. 5** (with reg. 2)

National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

86.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 **M100** are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition "the POM Order"; and

(ii) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 "; and

(b) in paragraph (3) for "the POM Order" substitute " the Human Medicines Regulations 2012 ".

(3) In paragraph 43(2)(a) of Schedule 6—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M100 S.I. 2004/478, as amended by S.I. 2006/358 and S.I. 2010/1647. There are other amendments, but none is relevant.

National Health Service (Personal Medical Services Agreements) Regulations 2004

F72 87. . . . . . .

Textual Amendments

F72 Sch. 34 para. 87 revoked (E.) (7.12.2015) by The National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879), reg. 1(2), **Sch. 4** (with regs. 2, 88)

National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004

88. In Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 [M101] for "article 12F of the Prescription Only Medicines (Human Use) Order 1997 or article 8 of the Medicines (Pharmacy and General Sale-Exemptions) Order 1980", in both places where those words occur, substitute " regulation 247 (exemption for supply in the event or anticipation of pandemic disease) of the Human Medicines Regulations 2012 ".

Marginal Citations

M101 S.I. 2004/1022, as amended by S.I 2005/366 and S.I. 2009/1977. There are other amendments, but none is relevant.

Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004

89.—(1) The Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004 [M102] is amended as follows.

(2) In article 2(1)—

(a) omit the definition "the 1994 Regulations"; and

(b) after the definition "the 2003 Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(3) In article 7—

(a) in paragraph (1) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations "; and

(b) in paragraph (2)—

(i) for "the 1994 Regulations" substitute " the 2012 Regulations ", and

(ii) for the words from "the following" to the end of the paragraph substitute " regulation 314 of the 2012 Regulations ".

(4) In article 8(3)(d) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations ".

(5) In article 11—

(a) in paragraph (2) for "the 1994 Regulations" substitute " the 2012 Regulations "; and

(b) in paragraph (3)—

(i) for "section 1(1)(a) of the Medicines Act 1968" substitute " regulation 6(6) of the 2012 Regulations ", and

(ii) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations ".

Marginal Citations
M102 S.I. 2004/1975.

General Optical Council (Registration Rules) Order of Council 2005

90. In the Table in rule 10 of the Schedule to the General Optical Council (Registration Rules) Order of Council 2005 [M103]—

(a) in entry B column 3—

(i) in paragraph (a) for "paragraph 6A of Schedule 5 to the Prescription Only Medicines (Human Use) Order 1997" substitute " paragraph 8 of Part 1 of Schedule 17 of the Human Medicines Regulations 2012 ", and

(ii) in paragraph (b) for "6B" substitute " 9 ";

(b) in entry C column 3 for "article 3B of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(c) in entry D column 3 for "article 3 of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations
M103 S.I. 2005/1478, as amended by S.I. 2008/1940. There are other amendments, but none is relevant.

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

91.—(1) The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 [M104] are amended as follows.

(2) In regulation 2(1) omit the definition of "the POM Order".

(3) In regulation 2(2A) for "the POM Order" substitute " the Human Medicines Regulations 2012 ".

(4) In regulation 7(2) for the words from "the Medicines" to the end of the regulation substitute " the Human Medicines Regulations 2012 ".

(5) In regulation 7A(1)(b) for the words from "article 12F" to the end of the regulation substitute " regulation 247 of the Human Medicines Regulations 2012 ".

Marginal Citations
M104 S.I. 2007/121, as amended by S.I. 2009/1175 and S.I. 2010/1647. There are other amendments, but none is relevant.

Human Tissue (Quality and Safety for Human Application) Regulations 2007

92. In regulation 2(3) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 [M105]—

(a) omit sub-paragraph (a); and

(b) for sub-paragraph (b) substitute—

"(b) the Human Medicines Regulations 2012;".

Marginal Citations

M105 S.I. 2007/1523.

Legislative and Regulatory Reform (Regulatory Functions) Order 2007

93.—(1) The Schedule to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007 [M106] is amended as follows.

(2) In Part 2 under the heading "Medicines"—

(a) omit the entries—

"Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994",

"Medicines (Advertising) Regulations 1994",

"Medicines (Monitoring of Advertising) Regulations 1994",

"Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994",

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005", and

"Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012".

(3) In Part 3 under the heading "Public health and safety"—

(a) omit the entries—

"Medicines (Advertising) Amendment Regulations 2004", and

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(4) In Part 6—

(a) omit the entry—

"Medicines (Advertising) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(5) In Part 8—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(6) In Part 13—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Marginal Citations

M106 S.I. 2007/3544, as amended by S.I. 2009/2981. There are other amendments, but none is relevant.

Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008

94. In paragraph (d) of article 3 of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 [M107], for the words following "subject" to the end of the article substitute " of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. ".

Marginal Citations

M107 S.I. 2008/548.

Specified Animal Pathogens Order 2008

95. In article 5(2) of the Specified Animal Pathogens Order 2008 [M108]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 "; and

(b) omit sub-paragraph (c).

Marginal Citations

M108 S.I. 2008/944. There are amendments, but none is relevant.

Specified Animal Pathogens (Wales) Order 2008

96. In article 5(2) of the Specified Animal Pathogens (Wales) Order 2008 [M109]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 "; and

(b) omit sub-paragraph (c).

Marginal Citations
M109 S.I. 2008/1270. There are amendments, but none is relevant.

Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008

97. In regulation 1(2) of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008 [M110] in the definition "prescription only medicine", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M110 S.I. 2008/3258. There are amendments, but none is relevant.

Specified Animal Pathogens (Scotland) Order 2009

98. In article 5(2) of the Specified Animal Pathogens (Scotland) Order 2009 [M111]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;" substitute " the Human Medicines Regulations 2012. "; and

(b) omit sub-paragraph (c).

Marginal Citations
M111 S.S.I. 2009/45. There are amendments, but none is relevant.

National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

99.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 [M112] are amended as follows.

(2) In regulation 2(1)—

(a) in the definition "clinical management plan" for the words from "article" to the end of the definition substitute " regulation 8(1) of the Human Medicines Regulations 2012 ";

(b) in the definition "non-proprietary name"—

(i) for "section 103(5) of the 1968 Act" in both places where it occurs substitute "regulation 321(3) of the Human Medicines Regulations 2012, and

(ii) for "section 100 of that Act" substitute " regulation 318 of those Regulations ";

(c) in the definition "Patient Group Direction" for the words from "Article" to the end of the definition substitute " regulation 213 of the Human Medicines Regulations 2012 "; and

(d) in the definition "supply form" for the words from "Article" to the end of the definition substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012 ".

(3) In Schedule 1—

(a) in paragraph 4—

(i) in sub-paragraph (23) for "Article 12C of the Prescription Only Medicines (Human Use) Order 1997 (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012 "; and

(ii) in sub-paragraph (29) for "paragraph (4) of article 8 of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 225 (emergency sale etc by pharmacist: at patient's request) of the Human Medicines Regulations 2012 "; and

(b) in paragraph 10(8) for "article 12C of the Prescription Only Medicines (Human Use) Order 1997, (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012, ".

Marginal Citations
M112 S.S.I. 2009/183.

Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009

100.—(1) The Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009 [M113] is amended as follows.

(2) In Part 1 of Schedule 1, to the entry "Medicines Act 1968 (section 109)" add "or Human Medicines Regulations 2012 (regulation 323)".

(3) In Part 2 of Schedule 1—

(a) omit the entry—

"Medicines (Advertising) Regulations 1994"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(4) In Part 4 of Schedule 1—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for human use) Regulations 2005"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(5) In Part 2 of Schedule 2—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Marginal Citations
M113 S.I. 2009/669. There are amendments, but none is relevant.

Single Use Carrier Bags Charge (Wales) Regulations 2010

101. In Schedule 1(3) to the Single Use Carrier Bags Charge (Wales) Regulations 2010 [M114]—

(a) in the definition "EEA health professional" for the words from "1(2)" to the end of the definition substitute " 213(1) of the Human Medicines Regulations 2012 ";

(b) in the definition "pharmacy medicine" for the words from "means" to the end of the definition substitute " has the meaning given in regulation 5(5) of the Human Medicines Regulations 2012 ";

(c) in the definition "prescription only medicine" for the words from "means" to the end of the definition substitute " has the meaning given in regulation 5(3) of the Human Medicines Regulations 2012 "; and

(d) in the definition beginning "supplementary prescriber" for "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations
M114 S.I. 2010/2880. There are amendments, but none is relevant.

PART 6

Northern Ireland statutory rules

Control of Pesticides Regulations (Northern Ireland) 1987

102. For regulation 3(2)(b)(i) of the Control of Pesticides Regulations (Northern Ireland) 1987 [M115] substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations
M115 S.R. (NI) 1987 No 414, as amended by S.R. (NI) 1997 No 469.

Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995

103. In rule 4 of the Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995 [M116]—

(a) omit the definition "the 1997 Order";

(b) in the definitions "nurse independent prescriber" and "pharmacist independent prescriber" for "article 1(2) of the 1997 Order" substitute " regulation 8(1) of the Human Medicines Regulations 2012 "; and

(c) in the definition "prescription only medicine" for "article 1(2) of the 1997 Order" substitute " regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations

M116 S.R. (NI) 1995 No 8, as amended by S.R. (NI) 2009 No 429. There are other amendments, but none is relevant.

Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996

104. In the Schedule to the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996 [M117] for "Medicines Act 1968" substitute " Human Medicines Regulations 2012 ".

Marginal Citations

M117 S.R. (NI) 1996 No 81.

Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997 [M118], in paragraph 2(12) for the words from "Articles" to the end of the paragraph substitute regulation 224 of the Human Medicines Regulations 2012".

Marginal Citations

M118 S.R. (NI) 1997 No 381, as amended by S.R. (NI) 1999 No 405. There are other amendments, but none is relevant.

Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998

106. In Schedule 1, Chapter 4, Section 4.8, Part C of the Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998 [M119], for the words from "means" to the end of the Part substitute " has the meaning given in regulation 2 of the Human Medicines Regulations 2012 ".

Marginal Citations

M119 S.R. (NI) 1998 No 28.

Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

107. The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998 [M120] are amended as follows—

(a) in regulation 10(1)(a) for "section 8 of the Medicines Act 1968" substitute " regulation 17 of the Human Medicines Regulations 2012 "; and

(b) in regulation 11(1) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M120 S.R. (NI) 1998 No 45, as amended by S.R. (NI) 2011 No 124.

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order (Northern Ireland) 1999 [M121] for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M121 S.R. (NI) 1999 No 433.

Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland) 2001 [M122]—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations
M122 S.R. (NI) 2001 No 422.

Misuse of Drugs Regulations (Northern Ireland) 2002

110.—(1) The Misuse of Drugs Regulations (Northern Ireland) 2002 [M123] are amended as follows.

(2) In regulation 2(2)—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in the definition "medicinal product" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 "

(3) In regulation 6A(1)(e) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

(4) In regulation 8(2)—

(a) in sub-paragraph (h) after the first occurrence of "the Medicines Act 1968" insert " or of Schedule 31 to the Human Medicines Regulations 2012 "; and

(b) in sub-paragraph (j) after "the Medicines Act 1968" insert " or of regulation 324 of the Human Medicines Regulations 2012 ".

(5) In regulation 9(2)—

(a) in sub-paragraph (f) after "the Medicines Act 1968" insert " or of Schedule 31 to the Human Medicines Regulations 2012 "; and

(b) in sub-paragraph (h) after "the Medicines Act 1968" insert " or of regulation 324 of the Human Medicines Regulations 2012 ".

(6) In regulation 11(1) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

(7) In regulation 17—

(a) after "the Medicines Act 1968" insert " or of the Human Medicines Regulations 2012 "; and

(b) after "that Act" insert " or of those Regulations ".

(8) In regulation 18 for paragraph (3) substitute—

"(3) In this regulation, "clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004.".

Marginal Citations

M123 S.R. (NI) 2002 No 1, as amended by S.R. (NI) 2003 No 324, S.R. (NI) 2003 No 420, S.R. (NI) 2005 No 119, S.R. (NI) 2005 No 564, S.R. (NI) 2006 No 214, S.R. (NI) 2006 No 264, and S.R. (NI) 2007 No 348.

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

111. In regulation 5(2)(c) of the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 [M124] for "section 58 of the Medicines Act 1968" substitute " regulation 214 of the Human Medicines Regulations 2012 ".

Marginal Citations

M124 S.R. (NI) 2003 No 34.

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management Licensing Regulations (Northern Ireland) 2003 [M125], in the definition "hazardous waste" for the words following " "medicinal product" means" to the end of the definition substitute " a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations

M125 S.R. (NI) 2003 No 493.

Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004

113.—(1) The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 [M126] are amended as follows.

(2) In regulation 2—

(a) in the definition "licensing authority" for "section 6(3) of the Medicines Act 1968" substitute " regulation 6 of the Human Medicines Regulations 2012 ";

(b) omit the definition "the POM Order" and

(c) in the definition "prescription only medicine" for the words from "referred" to the end of the definition substitute " within the meaning of regulation 5(3) of the Human Medicines Regulations 2012 ".

(3) In regulation 47(2) for the words from "Part 3" to the end of the regulation substitute " Part 12 of the Human Medicines Regulations 2012 ".

(4) In Schedule 5—

(a) in paragraph 11A(1) in the definition "Patient Group Direction" for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in paragraph 41(2)(a)—

(i) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(ii) for "that Order" substitute " those Regulations ".

Marginal Citations

M126 S.R. (NI) 2004 No 140, as amended by S.R. (NI) 2005 No 368.

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005 [M127] for "section 58 of the Medicines Act 1968" substitute " regulation 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations

M127 S.R. (NI) 2005 No 160.

Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005 [M128] for "section 58 of the Medicines Act 1968" substitute " regulation 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations

M128 S.R. (NI) 2005 No 161.

Children's Homes Regulations (Northern Ireland) 2005

116. In regulation 20(4)(b) of the Children's Homes Regulations (Northern Ireland) 2005 [M129], for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations
M129 S.R. (NI) 2005 No 176.

Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006

117. In regulation 3(1) of the Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006 [M130] in the definition "Pharmacist" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M130 S.R. (NI) 2006 No 478.

Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007

118. In regulation 71(3)(a) of the Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007 [M131], for "section 8(2) of the Medicines Act 1968" substitute " regulation 17 of the Human Medicines Regulations 2012 ".

Marginal Citations
M131 S.R. (NI) 2007 No 68.

Day Care Setting Regulations (Northern Ireland) 2007

119. In regulation 13(6)(b) of the Day Care Setting Regulations (Northern Ireland) 2007 [M132] for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations
M132 S.R. (NI) 2007 No 234.

Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern Ireland) 2007 [M133] for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations
M133 S.R. (NI) 2007 No 236.

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007

121. In regulation 3(1)(a) of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007 [M134] for "the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M134 S.R. (NI) 2007 No 420.

Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern Ireland) 2008 [M135] for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M135 S.R. (NI) 2008 No 336.

Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

123. In regulation 2(2) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 [M136], in the definition "retail pharmacy business" for "section 132 of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations
M136 S.R. (NI) 2009 No 225.

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern Ireland) 2009 [M137] for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M137 S.R. (NI) 2009 No 413.

SCHEDULE 35

Regulation 349

Repeals and revocations

Enactment or instrument	*Extent of repeal or revocation*
Medicines Act 1968 (c. 67)	Sections 2A to 9. Section 10(7). Sections 11 to 14. Section 15(1) and (2). Sections 16 to 57. Section 58(1A), (2) and (3). Sections 59 to 61. Sections 65 and 66. Section 67(3A), (5) and (6). Section 68. Sections 85 and 86. Section 89. Section 91(1). Sections 92 to 103. Section 108(3) to (5) and (7). Section 109(3). Section 110(3). Section 111(3). Section 112(7). Sections 115 and 116. Section 126(4). Section 130(2) to (8) and (10). Section 132(2), (3) and (5). Schedules 1A and 2. In Schedule 3, paragraphs 5 to 7.
Medicines (Extension to Antimicrobial Substances) Order 1973 (S.I. 1973/367)	The whole Order.
Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968)	The whole Order.
Medicines (Fluted Bottles) Regulations 1978 (S.I. 1978/40)	The whole of the Regulations.
Medicines (Medicines Act 1968 Amendment) Regulations 1983 (S.I. 1983/1724)	The whole of the Regulations.
Medicines (Products Other than Veterinary Drugs) (General Sale List) Amendment Order 1990 (S.I. 1990/1129)	The whole Order.
Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605)	The whole of the Regulations.
Medicines Act 1968 (Amendment) Regulations 1993 (S.I. 1993/834)	The whole of the Regulations.

Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994/105)	The whole of the Regulations.
Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1994 (S.I. 1994/899)	The whole of the Regulations.
Medicines (Advertising) Regulations 1994 (S.I. 1994/1932)	The whole of the Regulations.
Medicines (Monitoring of Advertising) Regulations 1994 (S.I. 1994/1933)	The whole of the Regulations.
Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144)	The whole of the Regulations.
Medicines Act 1968 (Amendment) Regulations 1995 (S.I. 1995/2321)	The whole of the Regulations.
Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1996 (S.I. 1996/482)	The whole of the Regulations.
Prescription Only Medicines (Human Use) Order 1997 (S.I. 1997/1830)	The whole of the Order except articles 1(1) to (5), 5 and 10 and Schedules 1 and 2.
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 1998 (S.I. 1998/3105)	The whole of the Regulations.
Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 (S.I. 1999/267)	The whole of the Regulations.
Medicines (Monitoring of Advertising) Amendment Regulations 1999 (S.I. 1999/784)	The whole of the Regulations.
Medicines (Codification Amendments Etc.) Regulations 2002 (S.I. 2002/236)	The whole of the Regulations
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2003 (S.I. 2003/1618)	The whole of the Regulations.
Medicines (Child Safety) Regulations 2003 (S.I. 2003/2317)	The whole of the Regulations.
Medicines (Advertising) Amendment Regulations 2004 (S.I. 2004/1480)	The whole of the Regulations.
Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765)	The whole Order.
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/768)	The whole of the Regulations.

Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094)	The whole of the Regulations except paragraph 12(1), (4) and (5) of Schedule 1, and regulation 8 as it relates to those paragraphs.
Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2005 (S.I. 2005/1520)	The whole of the Regulations.
Medicines (Provision of False or Misleading Information and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/1710)	The whole of the Regulations.
Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750)	The whole of the Regulations except paragraph 8(a)(i) and (b) of Schedule 7, and regulation 12 as it relates to those paragraphs.
Medicines (Advisory Bodies) (No 2) Regulations 2005 (S.I. 2005/2754)	The whole of the Regulations, except Schedule 3, and regulation 4 as it relates to that Schedule, and paragraphs 3 and 7(1) and (3) of Schedule 4, and regulation 5 as it relates to those paragraphs.
Medicines (Advertising Amendments) Regulations 2005 (S.I. 2005/2787)	The whole of the Regulations.
Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/2789)	The whole of the Regulations.
Medicines (Traditional Herbal Medicinal Products for Human Use) (Consequential Amendment) Regulations 2006 (S.I. 2006/395)	The whole of the Regulations.
Medicines for Human Use (National Rules for Homoeopathic Products) Regulations 2006 (S.I. 2006/1952)	The whole of the Regulations.
Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 (S.I. 2008/1692)	The whole of the Regulations.
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2008 (S.I. 2008/3097)	The whole of the Regulations.
Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (S.I. 2009/1164)	The whole of the Regulations, except regulation 3.
Medicines (Exemptions and Miscellaneous Amendments) Order 2009 (S.I. 2009/3062)	The whole Order.
Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882)	The whole of the Regulations.

Status:
Point in time view as at 19/12/2020.

Changes to legislation:
The Human Medicines Regulations 2012 is up to date with all changes known to be in force on or before 18 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.