SCHEDULES

SCHEDULE 1

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, 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; and
   (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(1).

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.

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

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**

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

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 nonproprietary 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 nonproprietary 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 11 paragraphs 11(3), 13(3), 23(4) and 30(4)

Review upon oral representations

Application of this Schedule

1.—(1) This Schedule applies if a person (“the applicant”) mentioned in sub-paragraph (2) notifies the licensing authority—
(a) under regulation 27(3)(b) in respect of a proposal by the licensing authority; or
(b) under Part 1, 2 or 3 of Schedule 11 in respect of a decision or a proposal by 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.

(2) Those persons are—
(a) in respect of notification under regulation 27(3) the licence holder; and
(b) in respect of 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.

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, or

(v) to revoke, vary or suspend the authorisation, certificate or registration, as the case may be.
(12) The licensing authority must notify the applicant of its decision.

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; or
   (e) to revoke, vary or suspend the authorisation, certificate or registration,
as the case may be.
(3) The licensing authority must notify the applicant of its decision.

SCHEDULE 6

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—


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(4).

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.

(3) OJ No L 294, 25.10.2006, p. 32.
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

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(5).

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

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; and
   (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.

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.

SCHEDULE 8

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.

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—
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) 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.

(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.

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.


   (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.

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.

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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(8); 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.

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(9); 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.

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

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.


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—

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effervescent tablets—</td>
<td>30 tablets</td>
</tr>
<tr>
<td>(a) that do not contain aspirin, or</td>
<td></td>
</tr>
<tr>
<td>(b) that do not contain more than 325 milligrams of aspirin per tablet.</td>
<td></td>
</tr>
<tr>
<td>Effervescent tablets—</td>
<td>20 tablets</td>
</tr>
<tr>
<td>(a) that contain more than 325 milligrams of aspirin per tablet, but</td>
<td></td>
</tr>
<tr>
<td>(b) that do not contain more than 500 milligrams per tablet.</td>
<td></td>
</tr>
<tr>
<td>Non-effervescent tablets—</td>
<td>28 tablets</td>
</tr>
<tr>
<td>(a) that are enteric-coated,</td>
<td></td>
</tr>
<tr>
<td>(b) that contain aspirin only, and</td>
<td></td>
</tr>
<tr>
<td>(c) that do not contain more than 75 milligrams per tablet.</td>
<td></td>
</tr>
<tr>
<td>Other non-effervescent tablets</td>
<td>16 tablets</td>
</tr>
<tr>
<td>Powder or granules</td>
<td>10 sachets</td>
</tr>
<tr>
<td>Capsules</td>
<td>16 capsules</td>
</tr>
<tr>
<td>Liquid preparations of paracetamol intended for persons aged 12 years and over</td>
<td>160 millilitres</td>
</tr>
<tr>
<td>Liquid preparations of paracetamol intended for persons aged less than 12 years</td>
<td>Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses</td>
</tr>
</tbody>
</table>
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—

<table>
<thead>
<tr>
<th>Form of product</th>
<th>Maximum amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>16 tablets</td>
</tr>
<tr>
<td>Capsules</td>
<td>16 capsules</td>
</tr>
<tr>
<td>Powder or granules</td>
<td>12 sachets</td>
</tr>
<tr>
<td>Liquid preparations of ibuprofen</td>
<td>Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Column 1: Class of person by whom product is supplied</th>
<th>Column 2: Person on whose behalf direction must be signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Services Agency</td>
<td>The Agency</td>
</tr>
<tr>
<td>Health authority</td>
<td>The health authority</td>
</tr>
<tr>
<td>Special health authority</td>
<td>The special health authority</td>
</tr>
<tr>
<td>NHS trust or NHS foundation trust</td>
<td>The trust</td>
</tr>
<tr>
<td>Primary Care Trust</td>
<td>The Trust</td>
</tr>
<tr>
<td>A person who supplies medicinal products pursuant to an arrangement made with—</td>
<td>The Common Services Agency (where the arrangement has been made with the Agency); otherwise the—</td>
</tr>
<tr>
<td>(a) the Common Services Agency;</td>
<td>(a) health authority,</td>
</tr>
<tr>
<td>(b) a health authority;</td>
<td>(b) special health authority,</td>
</tr>
<tr>
<td>(c) a special health authority;</td>
<td>(c) NHS trust,</td>
</tr>
<tr>
<td>(d) an NHS trust;</td>
<td>(d) NHS foundation trust, or</td>
</tr>
<tr>
<td>(e) an NHS foundation trust; or</td>
<td>(e) Primary Care Trust, with which the arrangement has been made.</td>
</tr>
<tr>
<td>(f) a Primary Care Trust</td>
<td></td>
</tr>
</tbody>
</table>

PART 3

Persons by whom or on whose behalf a patient group direction used as described in regulation 234 must be signed

<table>
<thead>
<tr>
<th>Column 1: Force or service by whom or on whose behalf the health care is provided</th>
<th>Column 2: Person by whom or on whose behalf direction must be signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>A police force in England and Wales</td>
<td>The chief officer of police for that police force (within the meaning of the Police Act 1996(10))</td>
</tr>
<tr>
<td>A police force in Scotland</td>
<td>The chief constable of that police force (within the meaning of the Police (Scotland) Act 1967(11))</td>
</tr>
<tr>
<td>The Police Service of Northern Ireland</td>
<td>The Chief Constable of the Police Service of Northern Ireland</td>
</tr>
</tbody>
</table>

(10) 1996 c.16.
(11) 1967 c.77.
<table>
<thead>
<tr>
<th>Column 1: Force or service by whom or on whose behalf the health care is provided</th>
<th>Column 2: Person by whom or on whose behalf direction must be signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>The prison service in England and Wales</td>
<td>The governor of the prison in relation to which the health care in question is being provided</td>
</tr>
<tr>
<td>The prison service in Scotland</td>
<td>The Scottish Prison Service Management Board</td>
</tr>
<tr>
<td>The prison service in Northern Ireland</td>
<td>The Northern Ireland Prison Service Management Board</td>
</tr>
</tbody>
</table>
| 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 |

**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

Exemption for sale, supply or administration by certain persons

PART 1

Exemption from restrictions on sale and supply of prescription only medicines

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.</td>
<td>1. All prescription only medicines.</td>
<td>1. The sale or supply shall be—&lt;br&gt;(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—&lt;br&gt;(i) the name of the institution for which the prescription only medicine is required, and&lt;br&gt;(ii) the purpose for which the prescription only medicine is required, and&lt;br&gt;(iii) the total quantity required; and&lt;br&gt;(b) for the purpose of the education or research with which the institution is concerned.</td>
</tr>
<tr>
<td>2. Persons selling or supplying prescription only medicines to any of the following—&lt;br&gt;(a) a public analyst appointed under section 27 of the Food Safety Act 1990(12) or</td>
<td>2. All prescription only medicines.</td>
<td>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 medicines.</td>
</tr>
</tbody>
</table>

---

(12) 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
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>article 27 of the Food Safety (Northern Ireland) Order 1991(13);</td>
<td></td>
<td>medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.</td>
</tr>
<tr>
<td>(b) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990(14);</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989(15);</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) an inspector acting under regulations 325 to 328;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) a sampling officer within the meaning of Schedule 31.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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(16), the National Health Service (Scotland) Act 1978(17), the National Health Service (Wales) Act 2006(18) and the Health and Personal Social Services (Northern Ireland) Order 1972(19), or under any subordinate legislation made under those Acts or that Order.</td>
<td>3. All prescription only medicines</td>
<td>3. The sale or supply shall be —</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) for the purposes of a scheme referred to in column 1 in this paragraph.</td>
</tr>
<tr>
<td>4. Registered midwives.</td>
<td>4. Prescription only medicines containing any of the following substances—</td>
<td>4. The sale or supply shall be only in the course of their professional practice.</td>
</tr>
<tr>
<td></td>
<td>(a) Diclofenac;</td>
<td></td>
</tr>
</tbody>
</table>

---


(13) 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.
(14) 1990 c.16.
(15) 1989 No. 846 (N.I. 6).
(16) 2006 c. 41.
(17) 1978 c. 29.
(18) 2006 c. 42.
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>(b) Hydrocortisone Acetate;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Miconazole;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) Nystatin;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) Phytomenadione;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. 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 are—

   (i) eye drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent of Chloramphenicol, or

   (ii) 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,

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.

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.
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>(bb) Fusidic Acid, (cc) Tropicamide; (b) the following prescription only medicines— (i) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight, (ii) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in lacquer does not exceed 5 per cent by weight in volume, (iii) Amoxicillin, (iv) Co-Codamol, (v) Co-dydramol 10/500 tablets, (vi) Codeine Phosphate, (vii) Erythromycin, (viii) Flucloxacillin, (ix) Silver Sulfadiazine, (x) Tioconazole 28%, (xi) Topical hydrocortisone where the maximum strength of hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
</tbody>
</table>
| 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. |
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
</tbody>
</table>
| 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. |

**PART 2**

Exemption from the restriction on supply of prescription only medicines

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>1. Royal National Lifeboat Institution and certified first aiders of the Institution.</td>
<td>1. All prescription only medicines</td>
<td>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.</td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>---------</td>
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</tr>
<tr>
<td>Persons exempted</td>
<td>Prescription only medicines to which the exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>2. The owner or master of a ship which does not carry a doctor on board as part of the ship’s complement.</td>
<td>2. All prescription only medicines.</td>
<td>2. The supply shall be only so far as is necessary for the treatment of persons on the ship.</td>
</tr>
<tr>
<td>3. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 2001(20) or regulation 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002(21) to supply a controlled drug.</td>
<td>3. Such prescription only medicines, being controlled drugs, as are specified in the licence.</td>
<td>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.</td>
</tr>
<tr>
<td>4. Persons employed or engaged in the provision of lawful drug treatment services.</td>
<td>4. Ampoules of sterile water for injection that contain no more than 2ml of water each.</td>
<td>4. The supply shall be only in the course of provisions of lawful drug treatment services.</td>
</tr>
<tr>
<td>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.</td>
<td>5. Such prescription only medicines as may be specified in the relevant enactment.</td>
<td>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.</td>
</tr>
<tr>
<td>6. Persons operating an occupational health scheme.</td>
<td>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.</td>
<td>6. The supply of the prescription only medicine shall be— (a) in the course of operating an occupational health scheme, and (b) (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</td>
</tr>
</tbody>
</table>

(20) S.I. 2001/3998, to which there are amendments that are not relevant.
(21) S.R. 2002 No. 1, to which there are amendments that are not relevant.
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>7. The operator or commander of an aircraft.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>8. Persons employed as qualified first-aid personnel on off-shore installations.</td>
<td>8. All prescription only medicines.</td>
<td>8. The supply shall be only so far as is necessary for the treatment of persons on the installation.</td>
</tr>
<tr>
<td>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.</td>
<td>9. Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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
### Column 1

**Persons exempted**

### Column 2

**Prescription only medicines to which the exemption applies**

### Column 3

**Conditions**

- is a risk that a person would suffer ill-health if the prescription only medicine is not supplied.

---

### PART 3

Exemptions from the restriction on administration of prescription only medicines

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
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</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
</tbody>
</table>
| 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 mg in 200 ml of lignocaine hydrochloride,
   (g) Mepivacaine hydrochloride,
   (h) Methylprednisolone,
   (i) Prilocaine hydrochloride,
   (j) Ropivacaine hydrochloride. | 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. |
<p>| 2. Registered midwives and student midwives. | 2. Prescription only medicines for parenteral administration | 2. The medicine shall— |</p>
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td></td>
<td>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) Prochlorperazine, (r) Sodium chloride 0.9%</td>
<td>(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.</td>
</tr>
</tbody>
</table>

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(22) or, regulations 8(3) or 9(3) of the Misuse of Drugs Regulations (Northern Ireland) 2002(23), 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.

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(22) S.I. 2001/3998 as amended by S.I. 2007/2154. There are other amendments that are not relevant.

(23) S.R. 2002 No. 1, as amended by S.R. 2007 No. 348. There are other amendments that are not relevant.
<table>
<thead>
<tr>
<th>Column 1</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Prescription only medicines to which the exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>5. Persons operating an occupational health scheme.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>6. The operator or commander of an aircraft.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>7. Persons employed as qualified first-aid personnel on off-shore installations.</td>
<td>7. All prescription only medicines that are for parenteral administration.</td>
<td>7. The administration shall be only so far as is necessary for the treatment of persons on the installation.</td>
</tr>
<tr>
<td>8. Persons who are registered paramedics.</td>
<td>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 5 iu per ml, but no other active ingredient, (d) prescription only medicines containing one</td>
<td>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.</td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
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</tr>
<tr>
<td>Persons exempted</td>
<td>Prescription only medicines to which the exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>or more of the following substances, but no other active ingredient—</td>
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<td></td>
</tr>
<tr>
<td>(i) Adrenaline Acid Tartrate,</td>
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<tr>
<td>(ii) Adrenaline hydrochloride,</td>
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<td></td>
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<tr>
<td>(iii) Amiodarone,</td>
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<tr>
<td>(iv) Anhydrous glucose,</td>
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<tr>
<td>(v) Benzylpenicillin,</td>
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</tr>
<tr>
<td>(vi) Compound Sodium Lactate Intravenous Infusion (Hartmann’s Solution),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(vii) Ergometrine Maleate,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(viii) Furosemide,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ix) Glucose,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(x) Heparin Sodium,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(xi) Lidocaine Hydrochloride,</td>
<td></td>
<td></td>
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<tr>
<td>(xii) Metoclopramide,</td>
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<td></td>
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<tr>
<td>(xiii) Morphine Sulphate,</td>
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<tr>
<td>(xiv) Nalbuphine Hydrochloride,</td>
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<td></td>
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<tr>
<td>(xv) Naloxone Hydrochloride,</td>
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<tr>
<td>(xvi) Ondansetron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(xvii) Paracetamol,</td>
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</tr>
<tr>
<td>(xviii) Reteplase,</td>
<td></td>
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<tr>
<td>(xix) Sodium Chloride,</td>
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<tr>
<td>(xx) Streptokinase,</td>
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<td></td>
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<tr>
<td>(xxi) Tenecteplase.</td>
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<td></td>
</tr>
</tbody>
</table>

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 1 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.
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

<table>
<thead>
<tr>
<th>Column 1</th>
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<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Medicinal products to which exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
</tbody>
</table>
| 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 | |
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>(xii) 2.0 per cent</td>
<td>Mepyramine maleate</td>
<td>(xii) 2.0 per cent</td>
</tr>
<tr>
<td>(xiii) 2.0 per cent</td>
<td>Miconazole nitrate</td>
<td>(xiii) 2.0 per cent</td>
</tr>
<tr>
<td>(xiv) 2.0 per cent</td>
<td>Phenoxypropan-2-ol</td>
<td>(xiv) 2.0 per cent</td>
</tr>
<tr>
<td>(xv) 20.0 per cent</td>
<td>Podophyllum resin</td>
<td>(xv) 20.0 per cent</td>
</tr>
<tr>
<td>(xvi) 10.0 per cent</td>
<td>Polynoxylin</td>
<td>(xvi) 10.0 per cent</td>
</tr>
<tr>
<td>(xvii) 70.0 per cent</td>
<td>Pyrogallol</td>
<td>(xvii) 70.0 per cent</td>
</tr>
<tr>
<td>(xviii) 0.0 per cent</td>
<td>Salicylic acid</td>
<td>(xviii) 0.0 per cent</td>
</tr>
<tr>
<td>(xix) 1.0 per cent</td>
<td>Terbinafine</td>
<td>(xix) 1.0 per cent</td>
</tr>
<tr>
<td>(xx) 0.1 per cent</td>
<td>Thiomersal.</td>
<td>(xx) 0.1 per cent</td>
</tr>
</tbody>
</table>

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.

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,

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.
<table>
<thead>
<tr>
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<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>(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</td>
<td>(b) Ibuprofen, other than preparations of ibuprofen which are prescription only medicines.</td>
<td></td>
</tr>
</tbody>
</table>

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  
- (b) are eye ointments and are prescription only medicines by reason only that they contain not more than—  
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.
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>(i) 30.0 per cent Sulphacetamide Sodium, or</td>
<td>(i) Cyclopentolate hydrochloride,</td>
<td>(c) are prescription only medicines by reason only that they contain any of the following substances—</td>
</tr>
<tr>
<td>(ii) 1.0 per cent Chloramphenicol, or</td>
<td>(ii) Fusidic acid,</td>
<td>(i) Cyclopentolate hydrochloride,</td>
</tr>
<tr>
<td>(c) are prescription only medicines by reason only that they contain any of the following substances—</td>
<td>(iii) Tropicamide.</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Medicinal products to which exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>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.</td>
<td>(a) not more than 5.0 percent of Boric acid, (b) Isopropyl myristate or Lauryl sulphate, (c) not more than 0.004 percent Oestrogens, (d) not more than 1.0 percent of Resorcinol, (e) not more than 3.0 percent of Salicylic acid, (f) not more than 0.2 percent of Sodium pyrithione.</td>
<td>his own judgement as to the treatment required.</td>
</tr>
<tr>
<td>6. Persons selling or supplying medicinal products to universities, other institutions concerned with higher education or institutions concerned with research.</td>
<td>6. All medicinal products.</td>
<td>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.</td>
</tr>
<tr>
<td>7. Persons selling or supplying medicinal products to organisations for research purposes.</td>
<td>7. All medicinal products.</td>
<td>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</td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>---------</td>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>representative of the organisation concerned stating—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(i) who requires the medicine,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(ii) the purposes for which it is required,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(iii) the quantity required, and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(iv) the purposes of the research with which the organisation is concerned; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) not for administration to humans.</td>
</tr>
</tbody>
</table>

8. Persons selling or supplying medicinal products to any of the following—

(a) a public analyst appointed under section 27 of the Food 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 (24),

(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.

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-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 only—

(a) to a pharmacist,

(b) so as to enable that pharmacist to prepare

(24) 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(3) 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.
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td></td>
</tr>
<tr>
<td>1. Royal National Lifeboat Institution and certificated first aiders of the Institution.</td>
<td>1. All medicinal products.</td>
<td>1. The supply shall be only so far as is necessary for the treatment of sick or injured persons.</td>
</tr>
<tr>
<td>2. British Red Cross Society and certificated first aid and certificated nursing members of the Society.</td>
<td>2. All pharmacy medicines and all medicinal products on a general sale list.</td>
<td>2. The supply shall be only so far as is necessary for the treatment of sick or injured persons.</td>
</tr>
<tr>
<td>3. St John Ambulance Association and Brigade and certificated first aid and certificated nursing members of the Association and Brigade.</td>
<td>3. All pharmacy medicines and all medicinal products on a general sale list.</td>
<td>3. The supply shall be only so far as is necessary for the treatment of sick or injured persons.</td>
</tr>
<tr>
<td>4. St. Andrew’s Ambulance Association and certificated first aid and certificated nursing members of the Association.</td>
<td>4. All pharmacy medicines and all medicinal products on a general sale list.</td>
<td>4. The supply shall be only so far as is necessary for the treatment of sick and injured persons.</td>
</tr>
</tbody>
</table>

**PART 5**

Exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons exempted</td>
<td>Medicinal products to which exemption applies</td>
<td></td>
</tr>
<tr>
<td>10. Registered dispensing opticians.</td>
<td>10. Pharmacy medicines for external use containing chloramphenicol at a strength not exceeding—</td>
<td>10. The sale or supply shall only be in the course of their professional practice.</td>
</tr>
<tr>
<td></td>
<td>(a) 0.5 per cent in eye drops;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(b) 1 per cent in ointment.</td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Medicinal products to which exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>5. Order of Malta Ambulance Corps and certificated first aid and certificated nursing members of the Corps.</td>
<td>5. All pharmacy medicines and all medicinal products on a general sale list.</td>
<td>5. The supply shall be only so far as is necessary for the treatment of sick or injured persons.</td>
</tr>
<tr>
<td>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.</td>
<td>6. Such prescription only medicines and such pharmacy medicines as are specified in the licence.</td>
<td>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.</td>
</tr>
<tr>
<td>7. Persons employed or engaged in the provision of lawful drug treatment services.</td>
<td>7. Ampoules of sterile water for injection that contain no more than 5ml of water each.</td>
<td>7. The supply shall be only in the course of provision of lawful drug treatment services.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>9. The owner or master of a ship which does not carry a doctor on board as part of the ship’s complement.</td>
<td>9. All medicinal products.</td>
<td>9. The supply shall be only so far as is necessary for the treatment of persons on the ship.</td>
</tr>
<tr>
<td>10. Persons operating an occupational health scheme.</td>
<td>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.</td>
<td>10. (a) The supply shall be in the course of an occupational health scheme. 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</td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Medicinal products to which exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>11. Persons carrying on the business of a school providing full-time education.</td>
<td>11. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.</td>
<td>11. The supply shall be— in the course of 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
</tr>
<tr>
<td>12. Health authorities or Primary Health Trusts.</td>
<td>12. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.</td>
<td>12. The supply shall be in the course of— a pre-school dental scheme, and the individual supplying the medicinal product shall be a registered nurse, or 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
</tr>
<tr>
<td>13. The operator or commander of an aircraft.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Persons employed as qualified first-aid personnel on offshore installations.</td>
<td>14. All medicinal products.</td>
<td>14. The supply shall be only so far as is necessary for the treatment of persons on the installation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. A prison officer.</td>
<td>15. All medicinal products on the general sale list.</td>
<td>15. The supply shall only be so far as is necessary for the treatment of prisoners.</td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>---------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Persons exempted</strong></td>
<td><strong>Medicinal products to which exemption applies</strong></td>
<td><strong>Conditions</strong></td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>17. Her Majesty’s armed forces.</td>
<td>17. All medicinal products.</td>
<td>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.</td>
</tr>
</tbody>
</table>

**SCHEDULE 18**

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

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

Herbal medicinal products specified for the purposes of regulation 241

PART 1

<table>
<thead>
<tr>
<th>Botanical Source</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apocynum cannabinum</td>
<td>Canadian hemp</td>
</tr>
<tr>
<td>Areca catechu</td>
<td>Areca</td>
</tr>
<tr>
<td>Artemisia cina</td>
<td>Santonica</td>
</tr>
<tr>
<td>Brayera anthelmintica</td>
<td>Kousso</td>
</tr>
<tr>
<td>Catha edulis</td>
<td>Catha</td>
</tr>
<tr>
<td>Chenopodium ambrosioides var anthelminticum</td>
<td>Chenopodium</td>
</tr>
<tr>
<td>Crotalaria berberaana</td>
<td>Crotalaria fulva</td>
</tr>
<tr>
<td>Crotalaria spectabilis</td>
<td>Crotalaria spect.</td>
</tr>
<tr>
<td>Cucurbita maxima</td>
<td>Cucurbita</td>
</tr>
<tr>
<td>Botanical Source</td>
<td>Common Name</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Delphinium staphisagria</td>
<td>Stavesacre seeds</td>
</tr>
<tr>
<td>Dryopteris filix-mas</td>
<td>Male fern</td>
</tr>
<tr>
<td>Duboisia leichardtii</td>
<td>Duboisia</td>
</tr>
<tr>
<td>Duboisia myoporoides</td>
<td></td>
</tr>
<tr>
<td>Ecballium elaterium</td>
<td>Elaterium</td>
</tr>
<tr>
<td>Embelia ribes</td>
<td>Embelia</td>
</tr>
<tr>
<td>Embelia robusta</td>
<td></td>
</tr>
<tr>
<td>Erysimum canescens</td>
<td>Erysimum</td>
</tr>
<tr>
<td>Holarrhena antidysenterica</td>
<td>Holarrhena</td>
</tr>
<tr>
<td>Juniperus sabina</td>
<td>Savin</td>
</tr>
<tr>
<td>Mallotus philippinensis</td>
<td>Kamala</td>
</tr>
<tr>
<td>Pausinystalia yohimbe</td>
<td>Yohimbe bark</td>
</tr>
<tr>
<td>Punica granatum</td>
<td>Pomegranate bark</td>
</tr>
<tr>
<td>Rhus radicans</td>
<td>Poison ivy</td>
</tr>
<tr>
<td>Scopolia carniolica</td>
<td>Scopolia</td>
</tr>
<tr>
<td>Scopolia japonica</td>
<td></td>
</tr>
<tr>
<td>Strophanthus courmonti</td>
<td>Strophanthus</td>
</tr>
<tr>
<td>Strophanthus emini</td>
<td></td>
</tr>
<tr>
<td>Strophanthus gratus</td>
<td></td>
</tr>
<tr>
<td>Strophanthus hispidus</td>
<td></td>
</tr>
<tr>
<td>Strophanthus kombe</td>
<td></td>
</tr>
<tr>
<td>Strophanthus nicholsoni</td>
<td></td>
</tr>
<tr>
<td>Strophanthus sarmentosus</td>
<td></td>
</tr>
<tr>
<td>Ulmus fulva</td>
<td>Slippery elm bark (whole or unpowdered)</td>
</tr>
<tr>
<td>Ulmus rubra</td>
<td></td>
</tr>
<tr>
<td>Viscum album</td>
<td>Mistletoe berry</td>
</tr>
</tbody>
</table>
## PART 2

<table>
<thead>
<tr>
<th>Botanical Source</th>
<th>Common Name</th>
<th>Maximum dose and maximum daily dose</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aconitum balfourni</td>
<td>Aconite</td>
<td>1.3 per cent</td>
<td></td>
</tr>
<tr>
<td>Aconitum chasmanthum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum deinorrhizum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum lycoctonum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum napellus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum spicatum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum stoerkianum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aconitum uncinatum var japonicum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adonis vernalis</td>
<td>Adonis vernalis</td>
<td>100 mg (MD) 300mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Aspidosperma quebrachoblanco</td>
<td>Quebracho</td>
<td>50 mg (MD) 150 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Atropa acuminata</td>
<td>Belladonna herb, belladonna root</td>
<td>In the form of belladonna herb: 50 mg (MD) 150 mg (MDD); In the form of belladonna root: 30 mg (MD) 90 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Atropa belladonna</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chelidonium majus</td>
<td>Celandine</td>
<td>2 g (MD) 6 g (MDD)</td>
<td></td>
</tr>
<tr>
<td>Cinchona calisaya</td>
<td>Cinchona bark</td>
<td>250 mg (MD) 750 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Cinchona ledgerana</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cinchona micrantha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cinchona officinalis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cinchona succirubra</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance</td>
<td>Common Name</td>
<td>Maximum dose and maximum daily dose</td>
<td>Percentage</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------</td>
<td>-------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Colchicum autumnale</td>
<td>Colchicum corm</td>
<td>100 mg (MD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>300 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Conium maculatum</td>
<td>Conium fruits, conium leaf</td>
<td>7.0 per cent</td>
<td></td>
</tr>
<tr>
<td>Convallaria majalis</td>
<td>Convallaria</td>
<td>150 mg (MD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>450 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Datura innoxia</td>
<td>Stramonium</td>
<td>50 mg (MD)</td>
<td></td>
</tr>
<tr>
<td>Datura stramonium</td>
<td></td>
<td>150 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Ephedra distachya</td>
<td>Ephedra</td>
<td>600 mg (MD)</td>
<td></td>
</tr>
<tr>
<td>Ephedra equisetina</td>
<td></td>
<td>1800 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Ephedra gerardiana</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ephedra intermedia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ephedra sinica</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gelsemium sempervirens</td>
<td>Gelsemium</td>
<td>25 mg (MD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>75 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Hyoscyamus albus</td>
<td>Hyoscyamus</td>
<td>100 mg (MD)</td>
<td></td>
</tr>
<tr>
<td>Hyoscyamus muticus</td>
<td></td>
<td>300 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Hyoscyamus niger</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lobelia inflata</td>
<td>Lobelia</td>
<td>200 mg (MD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>600 mg (MDD)</td>
<td></td>
</tr>
<tr>
<td>Pilocarpus jaborandi</td>
<td>Jaborandi</td>
<td>5.0 per cent</td>
<td></td>
</tr>
<tr>
<td>Pilocarpus microphyllus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhus toxicodendron</td>
<td>Poison oak</td>
<td>10.0 per cent</td>
<td></td>
</tr>
<tr>
<td>Senecio jacobaea</td>
<td>Ragwort</td>
<td>10.0 per cent</td>
<td></td>
</tr>
</tbody>
</table>
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 secelerantus
Rhodium Oxynitrate
Rhododendron chrysanthemum
Rhus toxicidendron
Salicylic Acid
Scrofularia 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

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.
The Common Services Agency.
A health authority or a special health authority.
A Primary Care Trust.

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;
(c) a health authority or a special health authority; or
(d) a Primary Care Trust.

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; or
(d) Her Majesty’s Forces.

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

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,
(v) an optometrist independent prescriber, or
(vi) a pharmacist independent prescriber; or

(b) under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription).

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.
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
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”.

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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

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

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 safety monitoring”.

14. The statement: “Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.”.

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

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

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 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.

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.

7. A succinct statement of the entries (if any) in the summary of the product characteristics 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.
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

Sampling

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 taken 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(25) 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.

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(25) 1967 c.80.
(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.

**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**

**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(26) 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(27) and the Medicines (Leaflets) Regulations 1977(28) (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.

**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—

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(26) 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.


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(29);  
(b) the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975(30);  
(c) the Medicines (Labelling) Regulations 1976(31);  
(d) the Medicines (Leaflets) Regulations 1977(32); and  
(e) the Medicines (Labelling and Advertising to the Public) Regulations 1978(33).

(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.

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)


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(35) (“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(36), in relation to the committee established under regulation 3 (advisory committee) of the 1978 Regulations.

SCHEDULE 33

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—

(34) S.I. 2010/1882.
(36) 1968 c.67. Schedule 1A was inserted by regulation 7(2) of S.I. 2005/1094.
(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.


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

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(37) (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”.

4. In section 15 (provision for extending or modifying exemptions)—
(a) omit subsections (1) and (2); and
(b) in subsection (3)(38) for “sections 9 to 14” substitute “section 10”.

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(37) 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.

(38) 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(39) (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.”.

6. In section 58A(1)(40) (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”.

7. In section 62(41) (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.”.

8. In section 64(5) (protection for purchasers of medicinal products) for “a practitioner” substitute “an appropriate practitioner”.

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(39) 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.

(40) 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.

(41) Section 62(7) was substituted by paragraph 12(5) of Schedule 1 to S.I. 2005/1094.
9.—(1) Section 67(42) (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).
10. In section 72 (representative of pharmacist in case of death or disability)—
   (a) in paragraph (1)(c)(43), 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(44)”; and
   (b) in paragraph (4)(c) for “committee” substitute “controller”.
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(45) (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.”
13. In section 88(1)(46) (distinctive colours, shapes and markings of medicinal products) for “section 85(2)” substitute “section 87(3)”.
14. In section 91(47) (offences under Part V, and supplementary provisions)—
   (a) omit subsection (1); and
   (b) in subsection (2) omit “section 85(3), section 86(2) or”; and
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(48) (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”.

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(48) 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.
(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.”.

19. In section 109 (49) (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).

20. In section 110 (50) (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 “that paragraph ”,
(iii) for “area” substitute “district”(51),
(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

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(49) 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.

(50) 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,

(51) 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.
(g) for subsection (8) substitute—

“(8) In this section “district council” means a council established under the Local Government Act (Northern Ireland) 1972(52).”.

21. In section 111(53) (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).”.

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)(54) (contravention due to default of other person), for the words from “63” to “96” substitute “63, 64, 87 and 88”.

25. In section 122(2)(55) (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”.

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(56) (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”.

28. In section 126(57) (presumptions)—

(52) 1972 c. 9 (N.I.).
(53) Section 111(1)(aa) was inserted by paragraph 9 of Schedule 5 to S.I. 2005/2789.
(54) Section 121(4) was amended by paragraph 61 of Part 1 of Schedule 8 to S.I. 2006/2407.
(55) Section 122(2) was amended by paragraph 62 of Part 1 of Schedule 8 to S.I. 2006/2407.
(56) Section 125(4) was amended by paragraph 63 of Part 1 of Schedule 8 to S.I. 2006/2407.
(57) Section 126(3) was amended by paragraph 64(c) of Part 1 of Schedule 8 to S.I. 2006/2407.
(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).

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(58) (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”.

31. In section 130(59) (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).

32. In section 131(5)(60) (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”.

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

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(58) 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.
(59) Section 130(1) was amended by paragraph 66(a) of Part 1 of Schedule 8 to S.I. 2006/2407.
(60) 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.
(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(61) (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”.

35. In Schedule 4(62) (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”.

Medicines Act 1971

36.—(1) The Medicines Act 1971(63) 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.

(61) Paragraph 17 of Schedule 3 was amended by paragraph 66 of Part 1 of Schedule 8 to S.I. 2006/2407.
(62) 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.
(63) 1971 c.69.
(3) Paragraph (2) has effect in relation to references of the kind mentioned in that paragraph in regulations made under section 1.

PART 2
Other primary legislation

Trade Descriptions Act 1968

37. In section 2(5)(b) (trade descriptions) of the Trade Descriptions Act 1968(64) for the words from “made under Part V” to “that Act)” substitute “of Chapter 1 of Part 13 of the Human Medicines Regulations 2012”.

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(65) 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.”.

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(66) 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.”.

Consumer Protection Act 1987

40. Section 19(1) (interpretation of Part II) of the Consumer Protection Act 1987(67) 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.

Environmental Protection Act 1990

41. In section 142(7) (powers to obtain information about potentially hazardous substances) of the Environmental Protection Act 1990(68), for the entry relating to the Medicines Act 1968 substitute “Parts 3 to 8 and 16 of the Human Medicines Regulations 2012”.

(64) 1968 c.29. Paragraph (b) of section 2(5) was inserted by paragraph 16 of Schedule 5 to the Medicines Act 1968.
(65) 1975 c.24.
(66) 1975 c.25.
(67) 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.
(68) 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(69)—

(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”;

(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;”;

(ii) omit paragraphs (b) and (c).

Health Act 1999

43. In section 60(2A)(c) (regulation of health care and associated professions) of the Health Act 1999(70), after “that Act” insert “or the Human Medicines Regulations 2012”.

Communications Act 2003

44. In section 368R(1) (interpretation of Part 4A) of the Communications Act 2003(71), 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;”.

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(72)—

(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;”.

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(73) is amended as follows—

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(69) 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.

(70) 1999 c.8. Subsection (2A) was inserted by paragraph 1 of Schedule 8 to the Health and Social Care Act 2008 (2008 c.14).

(71) 2003 c.21. Section 368R was inserted by regulation 2 of S.I. 2009/2979.

(72) 2007 asp 13.

(73) 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))
(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”.

Pharmacy (Northern Ireland) Order 1976

47. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976(74), 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”.

Poisons (Northern Ireland) Order 1976

48. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976(75)—

   (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”.

Diseases of Animals (Northern Ireland) Order 1981

49. In article 38 of the Diseases of Animals (Northern Ireland) Order 1981(76) 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”.

Waste and Contaminated Land (Northern Ireland) Order 1997

50. In article 33(6) of the Waste and Contaminated Land (Northern Ireland) Order 1997(77) for the entry relating to the Medicines Act 1968 substitute “Parts 3 to 8, 12 and 16 of the Human Medicines Regulations 2012”.

Shops (Sunday Trading &c.) (Northern Ireland) Order 1997

51. In article 4(3) of the Shops (Sunday Trading &c.) (Northern Ireland) Order 1997(78) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004(79) are amended as follows.

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(74) S.I. 1976/1213 (N.I. 22).
(75) S.I. 1976/1214 (N.I. 23).
(76) S.I. 1981/1115 (N.I. 22).
(78) S.I. 1997/2779 (N.I. 20).
(79) 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”.

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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”;

(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

(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

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(80)—

(a) for “Section 6(2) of the Act” substitute “Regulation 6(3) of the Human Medicines Regulations 2012 (“the 2012 Regulations”); and

(80) S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2407. There are other amendments, but none is relevant.
(b) for “by or under the Act” substitute “by the 2012 Regulations”.

**Importation of Animal Products and Poultry Products Order 1980**

66. In the Schedule to the Importation of Animal Products and Poultry Products Order 1980(81), for “or the Medicines for Human Use (Marketing Authorisations Etc. Regulations) 1994” substitute “or the Human Medicines Regulations 2012”.

**Medicines Act (Hearings by Persons Appointed) (Scotland) Rules 1986**

67. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986(82)—

(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”.

**Medicines Act (Hearings by Persons Appointed) Rules 1986**

68. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986(83)—

(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”.

**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(84) is amended as follows.

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(82) S.I. 1986/1700. There are amendments, but none is relevant.  
(83) S.I. 1986/1761, as amended by S.I. 2006/2407. There are other amendments, but none is relevant.  
(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 Pharmacopeia) 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”.

Medical Devices (Consultation Requirements) (Fees) Regulations 1995

70. In regulation 1(2) of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(85)—
(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”.

Prescription Only Medicines (Human Use) Order 1997

71.—(1) The Prescription Only Medicines (Human Use) Order 1997(86) is amended as follows.
(2) In article 1—

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(85) S.I. 1995/449
(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 ”.

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(87), 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.

National Health Service (Charges for Drugs and Appliances) Regulations 2000

73. The National Health Service (Charges for Drugs and Appliances) Regulations 2000(88) are amended as follows—

(a) in regulation 5(3B)(b) for the words from “article 12F” to the end of the paragraph substitute “regulation 247 (exemption for supply in the event or anticipation of pandemic disease) of the Human Medicines Regulations 2012”; and

(b) in regulation 6A(6) for the words from “the Medicines” to the end of the paragraph substitute “the Human Medicines Regulations 2012”.

Biocidal Products Regulations 2001

74. In Schedule 2 to the Biocidal Products Regulations 2001(89)—

(a) omit entry (f); and

(b) for entry (i) substitute—
   “(i) the Human Medicines Regulations 2012;”.

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(90), for the words following “marketing authorisation” to the end of the paragraph substitute “, certificate

(87) S.I. 1999/3267, as amended by S.I. 2005/1476. There are other amendments, but none is relevant.
(88) S.I. 2000/620, as amended by S.I. 2000/3189 and S.I. 2009/1166. There are other amendments, but none is relevant.
(89) S.I. 2001/880, as amended by S.I. 2010/745. There are other amendments, but none is relevant.
of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012.”

**Misuse of Drugs Regulations 2001**

76. In regulation 2(1) of the Misuse of Drugs Regulations 2001**(91)**—

(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”.

**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**(92)**, 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.”.

**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**(93)** for “the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

**Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003**


**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**(95)**—

(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)”;

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**(93) S.I. 2003/1076**, as amended by S.I. 2005/2061. There are other amendments, but none is relevant.

**(94) S.I. 2003/1374**. There are amendments, but none is relevant.

**(95) S.I. 2003/1376**. There are amendments, but none is relevant.
(c) omit “Medicines (Advertising) Regulations 1994” in the first column and the adjacent entry “regulation 23 (offences)” in the second column.

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(96)—

(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”.

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 (97) (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—

(96) S.I. 2003/1571, as amended by S.I. 2006/1996. There are other amendments, but none is relevant.

“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;”;

(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;”.

National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004

83.—(1) The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(98) 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”.

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(99) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition “the POM Order”; and

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(98) S.S.I. 2004/115, as amended by S.S.I. 2005/337. There are other amendments, but none is relevant.  
(99) S.S.I. 2004/116, as amended by S.S.I. 2005/336. There are other amendments, but none is relevant.  

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(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”.

National Health Service (General Medical Services Contracts) Regulations 2004

85.—(1) The National Health Service (General Medical Services Contracts) Regulations 2004(100) 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 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”.

National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

86.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(101) 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”.

(100) S.I. 2004/291, as amended by S.I. 2005/893. There are other amendments, but none is relevant.
(101) 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

87.—(1) The National Health Service (Personal Medical Services Agreements) Regulations 2004(102) 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 42(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”.

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(103) 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”.

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(104) 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—

(102) S.I. 2004/627, as amended by S.I. 2005/893. There are other amendments, but none is relevant.
(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”.

**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((105))—

(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”.

**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((106)) 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”.

**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((107))—

(a) omit sub-paragraph (a); and

(b) for sub-paragraph (b) substitute—

“(b) the Human Medicines Regulations 2012;”.

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((105))S.I. 2005/1478, as amended by S.I. 2008/1940. There are other amendments, but none is relevant.

((106))S.I. 2007/121, as amended by S.I. 2009/1175 and S.I. 2010/1647. There are other amendments, but none is relevant.

((107))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\(^{(108)}\) 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

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\(^{(108)}\)S.I. 2007/3544, as amended by S.I. 2009/2981. There are other amendments, but none is relevant.
(b) add the entry—

“Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations”.

**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 (109), 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.”.

**Specified Animal Pathogens Order 2008**

95. In article 5(2) of the Specified Animal Pathogens Order 2008(110)—

(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).

**Specified Animal Pathogens (Wales) Order 2008**

96. In article 5(2) of the Specified Animal Pathogens (Wales) Order 2008(111)—

(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).

**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(112) in the definition “prescription only medicine”, for “the Prescription Only Medicines (Human Use) Order 1997” substitute “the Human Medicines Regulations 2012”.

**Specified Animal Pathogens (Scotland) Order 2009**

98. In article 5(2) of the Specified Animal Pathogens (Scotland) Order 2009(113)—

(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).

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(109)S.I. 2008/548.
(110)S.I. 2008/944. There are amendments, but none is relevant.
(111)S.I. 2008/1270. There are amendments, but none is relevant.
(112)S.I. 2008/3258. There are amendments, but none is relevant.
(113)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(114) 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,”.

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(115) 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—

(114) S.S.I. 2009/183.
(115) S.I. 2009/669. There are amendments, but none is relevant.
“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”.

Single Use Carrier Bags Charge (Wales) Regulations 2010

101. In Schedule 1(3) to the Single Use Carrier Bags Charge (Wales) Regulations 2010(116)—

(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”.

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(117) substitute—

“(i) the Human Medicines Regulations 2012;”. 

(116) S.I. 2010/2880. There are amendments, but none is relevant.

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(118)—

(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”.

Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996


Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997(120), in paragraph 2(12) for the words from “Articles” to the end of the paragraph substitute regulation 224 of the Human Medicines Regulations 2012”.

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(121), 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”.

Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

107. The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998(122) 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”.

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order (Northern Ireland) 1999(123) for “the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

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(118) S.R. (NI) 1995 No 8, as amended by S.R. (NI) 2009 No 429. There are other amendments, but none is relevant.
(120) S.R. (NI) 1997 No 381, as amended by S.R. (NI) 1999 No 405. There are other amendments, but none is relevant.
(123) S.R. (NI) 1999 No 433.
Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland) 2001(124)—

(a) omit entry (f); and

(b) for entry (i) substitute—

“(i) the Human Medicines Regulations 2012;”.

Misuse of Drugs Regulations (Northern Ireland) 2002

110.—(1) The Misuse of Drugs Regulations (Northern Ireland) 2002(125) 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.”.

(124) S.R. (NI) 2001 No 422.

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(126) for “section 58 of the Medicines Act 1968” substitute “regulation 214 of the Human Medicines Regulations 2012”.

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management Licensing Regulations (Northern Ireland) 2003(127), 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”.

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(128) 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”; and
(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”.

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(129) for “section 58 of the Medicines Act 1968” substitute “regulation 214 or 215 of the Human Medicines Regulations 2012”.

(126) S.R. (NI) 2003 No 34.
(127) S.R. (NI) 2003 No 493.
Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(130) for “section 58 of the Medicines Act 1968” substitute “regulation 214 or 215 of the Human Medicines Regulations 2012”.

Children’s Homes Regulations (Northern Ireland) 2005


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(132) in the definition “Pharmacist” for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

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(133), for “section 8(2) of the Medicines Act 1968” substitute “regulation 17 of the Human Medicines Regulations 2012”.

Day Care Setting Regulations (Northern Ireland) 2007


Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern Ireland) 2007(135) for “section 58 of the Medicines Act 1968” substitute “regulations 214 or 215 of the Human Medicines Regulations 2012”.

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(136) for “the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

(133) S.R. (NI) 2007 No 68.
(135) S.R. (NI) 2007 No 236.
Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern Ireland) 2008(137) for “the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

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(138), in the definition “retail pharmacy business” for “section 132 of the Medicines Act 1968” substitute “regulation 8(1) of the Human Medicines Regulations 2012”.

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern Ireland) 2009(139) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

SCHEDULE 35

Repeals and revocations

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<td>The whole Order.</td>
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<tr>
<td>Prescription Only Medicines (Human Use) Order 1997 (S.I. 1997/1830)</td>
<td>The whole of the Order except articles 1(1) to (5), 5 and 10 and Schedules 1 and 2.</td>
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<td>Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094)</td>
<td>The whole of the Regulations except paragraph 12(1), (4) and (5) of Schedule 1, and regulation 8 as it relates to those paragraphs.</td>
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