STATUTORY INSTRUMENTS

2005 No. 2789

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 and shall come into force on 30th October 2005.

(2) In these Regulations—

"the Act" means the Medicines Act 1968(**1**);

"the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**2**);

"the Applications Regulations" means the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**3**);

"the Standard Provisions Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**);

"BCG" means the bacillus of Calmette and Guerin;

"BCG vaccine" means a vaccine that is a preparation of the bacteria in a living pure culture of a strain of the bacillus of Calmette and Guerin;

"biological medicinal product" means a medicinal product, the active substance of which is a biological substance;

"biological substance" means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control;

"blood" means whole human blood;

"blood component" means a therapeutic constituent of blood (red cells, white cells, platelets and plasma);

"blood product" means any industrially prepared medicinal product for human use derived from human blood or human plasma and includes but is not limited to albumin, coagulation factors and immunoglobulins of human origin, but does not include blood or blood components;

"Commission Directive 2003/94/EC" means Commission Directive 2003/94/EC(**5**) laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and for investigational medicinal products for human use;

(**1**) 1968 c. 67.
(**2**) S.I. 1994/ 3144 as amended by S.I.1998/3105, 200/292, 2001/795, 2002/236, 2002/542, 2003/2321, 2004/3224 and 2005/768.
(**3**) S.I. 1971/974 as amended by S.I.1977/1052, 1978/1140, 1983/1725, 1993/832 and 2002/236.
(**4**) S.I. 1971/972, as amended by S.I. 1974/1523, 1977/675, 1983/1730, 1992/2846, 1999/4, 2002/236, 2003/2321, 2004/1031 and 2005/1710.
(**5**) OJ No. L262, 14.10.2003, p.22.

"the Directive" means Directive 2001/83/EC, of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**6**), as amended by—

(a) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**7**),

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**8**),

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**9**) and

(d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**10**);

"EEA State" means a member State, Norway, Iceland or Liechtenstein;

"exempt relevant medicinal product" means a relevant medicinal product to which paragraph 1 of Schedule 1 to the 1994 Regulations or any equivalent legislation in any EEA State other than the United Kingdom applies;

"the guidelines on good distribution practice" means the Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C63/03) published by the European Commission pursuant to Article 84 of the Directive(**11**);

"intermediate product" means a substance, other than a starting material, which—

(e) has been manufactured for use in the manufacture of medicinal products, and

(f) is intended for further processing by a manufacturer of such products;

"marketing authorization" means—

(a) a marketing authorization granted by the licensing authority under the 1994 Regulations;

(b) a marketing authorization issued by the competent authority of an EEA state, other than the United Kingdom, in accordance with the Directive;

(c) a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93(**12**) or Regulation (EC) No. 726/2004(**13**);

(d) a traditional herbal registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**14**); or

(e) a certificate of registration granted by the licensing authority under the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994(**15**);

"the principles and guidelines of good manufacturing practice" means the principles and guidelines of good manufacturing practice set out in Commission Directive 2003/94/EC(**16**);

"qualified person" means—

(**6**) OJ No. L311, 28.11.2001, p67
(**7**) OJ No. L33, 8.2.2003, p30.
(**8**) OJ No L159, 27.6.2003, p 46.
(**9**) OJ No L 136, 30.4. 2004, p.85.
(**10**) OJ No. L136, 30.4.2004, p.85.
(**11**) OJ No. C63 1.3.1994.
(**12**) OJ No. L214, 24.8.1993, p.1.
(**13**) OJ No L136, 30.4.2004, p.1.
(**14**) S.I. 2005/2750.
(**15**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.
(**16**) OJ No. L 262 14.10.2003, p 22.

(a) a person whose qualifications and experience satisfy the requirements of Article 49 or 50 of the Directive, or

(b) insofar as the activities of the qualified person are limited to traditional herbal medicinal products, a person who, without satisfying the requirements referred to in paragraph (a) —

(i) has been engaged in activities equivalent to those to be performed in accordance with Article 51 of the Directive in respect of traditional herbal medicinal products on or before 30th April 2011; and

(ii) has, whilst they continue to be engaged in activities equivalent to those to be performed in accordance with Article 51 of the Directive, been named as a qualified person in an application for a manufacturer's licence which is made in accordance with the requirements of the Applications Regulations and before 30th April 2013;

"relevant medicinal product" means a medicinal product for human use to which the provisions of the Directive apply;

"serum" means a fluid fraction of coagulated blood;

"smallpox vaccine" means a vaccine that is a preparation of an infective vaccinia virus;

"toxins" means substances used in the diagnosis, prevention or treatment of disease consisting wholly or partly of poisonous substances derived from specific micro-organisms, plants or animals;

"traditional herbal medicinal product" has the meaning given by Article 1(29) of the Directive;

"vaccines" means antigenic substances which consist wholly or partly of—

(a) any micro-organisms, viruses or other organisms in any state,

(b) any toxins of microbial origin which have been detoxified (toxoids), or

(c) any extracts or derivatives of any micro-organisms or of any viruses,

being substances which, when administered to human beings are used for the treatment of specific diseases.

(3) Expressions used in these Regulations which are used in any provision of the Act have the meaning which they bear in the Act.

Requirement that manufacturer's licence holders comply with certain obligations in relation to the manufacture and assembly of relevant medicinal products

2.—(1) In relation to the manufacture and assembly of relevant medicinal products, a manufacturer's licence holder shall—

(a) comply with the principles and guidelines of good manufacturing practice;

(b) comply with the requirements of paragraph (3); and

(c) subject to paragraph (2), use active substances as starting materials only where those active substances have been manufactured or assembled in accordance with the principles and guidelines of good manufacturing practice applicable to starting materials;

(2) A manufacturer's licence holder shall not be required to comply with the requirement of paragraph (1)(c) in relation to the manufacture or assembly of relevant medicinal products pursuant to his manufacturer's licence, insofar as such activity is limited to the manufacture or assembly of exempt relevant medicinal products.

(3) The requirements of this paragraph are that the manufacturer's licence holder shall—

(a) maintain such staff, premises, equipment and facilities as are necessary for such stages of the manufacture and assembly of relevant medicinal products as are undertaken by him in accordance with the requirements of—

(i) his licence, and

(ii) the marketing authorizations of the relevant medicinal products in question;

(b) maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of the relevant medicinal products which he handles, stores and distributes under his licence, as are necessary to maintain the quality of those medicinal products;

(c) ensure that any arrangements he makes with any person for the control, storage and distribution of the relevant medicinal products are adequate to maintain the quality of those products;

(d) not carry out any manufacture or assembly of relevant medicinal products other than—

(i) the manufacture or assembly of those classes of relevant medicinal product specified in his licence, and

(ii) at the premises specified in his licence;

(e) not use any premises for the handling, control, storage or distribution of relevant medicinal products other than those specified in his licence as approved by the licensing authority for that purpose, or approved by the licensing authority for that purpose from time to time;

(f) inform the licensing authority before making any material alteration to the premises or facilities used under his licence, or in the operations for which they are used;

(g) inform the licensing authority of any change that he proposes to make to any personnel named in his licence as responsible for quality control of the medicinal products being manufactured or assembled by him, including the person named as the qualified person for the purposes of regulation 4;

(h) for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(i) for suspending, revoking or varying any licence granted under Part II of the Act; or

(ii) suspending or terminating any licence in accordance with the provisions of Part II of the Act,

permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence**;**

(i) ensure that any blood or blood component imported into the United Kingdom and used by him as a starting material or raw material in the manufacture of a relevant medicinal product shall meet equivalent standards of quality and safety to those laid down in Commission Directive 2004/33/EC, implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components; and

(j) shall, where he distributes by way of wholesale dealing, any relevant medicinal product manufactured or assembled pursuant to his licence, comply with the requirements of regulations 8(1)(a) and (b) and (2), and 9 (2) and (3), as if he was the holder of a wholesale dealer's licence.

Requirement that manufacturer's licence holders comply with certain obligations in relation to the import from a third country of relevant medicinal products

3. In relation to the import from a third country of any relevant medicinal product, a manufacturer's licence holder shall—

(a) comply with the principles and guidelines of good manufacturing practice insofar as they are relevant to the import of relevant medicinal products;

(b) comply with the guidelines on good distribution practice;

(c) ensure that any relevant medicinal products (other than exempt relevant medicinal products) imported by him from a third country use active substances as starting materials only where those active substances have been manufactured in accordance with the principles and guidelines of good manufacturing practice applicable to starting materials;

(d) maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of the relevant medicinal products which he handles, stores and distributes under his licence, as are necessary to maintain the quality of those medicinal products;

(e) ensure that any arrangements he makes with any person for the storage and distribution of the medicinal products are adequate to maintain the quality of those products;

(f) not use any premises for the handling, control, storage or distribution of relevant medicinal products other than those specified in his licence as approved by the licensing authority for that purpose, or approved by the licensing authority for that purpose from time to time;

(g) inform the licensing authority before making any material alteration in the premises or facilities used under his licence, or in the operations for which they are used;

(h) inform the licensing authority of any change that he proposes to make to any personnel named in his licence as responsible for quality control of the medicinal products being imported by him including the person named as the qualified person for the purposes of regulation 4;

(i) for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(i) for suspending, revoking or varying any licence granted under Part II of the Act; or

(ii) suspending or terminating any licence in accordance with the provisions of Part II of the Act,

permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence**;** and

(j) where he distributes by way of wholesale dealing, any relevant medicinal product manufactured or assembled pursuant to his licence, comply with the requirements of regulations 8(1)(a) and (b) and (2), and 9 (2) and (3), as if he was the holder of a wholesale dealer's licence.

Requirements as to qualified persons

4.—(1) Subject to paragraphs (7) and (8), where a manufacturer's licence relates to the manufacture, assembly or importation of relevant medicinal products, a manufacturer's licence holder shall ensure that he has at all times at his disposal the services of at least one qualified person who is responsible for carrying out, in relation to those products, the duties specified in Article 51 of the Directive in respect of relevant medicinal products manufactured, assembled or imported by him.

(2) If a licence holder satisfies the requirements as to qualifications and experience specified in the definition of "qualified person" in regulation 1(2), he may act as the qualified person in accordance with paragraph (1) for the purposes of that licence.

(3) For the purposes of this paragraph, but without prejudice to paragraph (4) below, the licence holder may regard a person as satisfying the provisions of Article 49 or 50 of the Directive as respects formal qualifications if he produces evidence that—

(a) he is a member of—

(i) the Institute of Biology,

(ii) the Pharmaceutical Society,

(iii) the Royal Society of Chemistry, or

(iv) such other body as may appear to the licensing authority to be an appropriate body for the purpose of this paragraph; and

(b) he is regarded by the body of which he is a member as so satisfying those provisions.

(4) The licence holder—

(a) shall notify the licensing authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of qualified person;

(b) shall notify the licensing authority of any change to the qualified person; and

(c) shall not permit any person to act as qualified person other than the person named in his licence as qualified person or, subject to paragraph (5), any other such person whose name is notified to the licensing authority.

(5) Where, after giving the licence holder and the person acting as a qualified person the opportunity of making representations to them (orally or in writing), the licensing authority is of the opinion that—

(a) the person so acting does not satisfy—

(i) the provisions of Articles 49 and 50 of the Directive as respects qualifications and experience, or

(ii) the requirements as to qualifications and experience specified in paragraph (b) of the definition of "qualified person" in regulation 1(2); or

(b) he is failing to carry out the duties referred to in paragraph (1) adequately or at all,

and has notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a qualified person.

(6) Subject to paragraph (7), the licence holder shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to paragraph (1), to carry out the duties referred to in that subsection.

(7) A licence holder shall not be required to meet the requirements of this regulation in relation to any activity carried out pursuant to his licence which consists of the manufacture, assembly or import from a third country of relevant medicinal products pursuant to a manufacturer's licence insofar as such activity is limited to the manufacture, assembly or importation of —

(a) exempt relevant medicinal products; or

(b) products which may be placed on the market in any EEA State without a marketing authorization by virtue of legislation adopted by that State under Article 5(2) of the Directive.

(8) Where the conditions specified in paragraph 2 of Article 51 of the Directive are satisfied, a qualified person shall not be required to meet the requirements of point (b) of the first sub-paragraph

of paragraph 1 of Article 51 of the Directive in respect of the import of any relevant medicinal product from a third country.

Offence relating to the sale and supply of starting materials for use in the manufacture of relevant medicinal products

5.—(1) Any person who, in the course of a business carried on by him, sells or supplies any active substance in circumstances where the active substance —

(a) has not been manufactured in accordance with the principles of good manufacturing practice applicable to starting materials; and

(b) is intended to be used by the person to whom it is sold or supplied in the manufacture of a relevant medicinal product other than an exempt relevant medicinal product,

shall be guilty of an offence.

(2) It shall be a defence to an offence under paragraph (1) for the person who sells or supplies the relevant medicinal product in question to show that he could not, by reasonable diligence have discovered that it was not manufactured in accordance with the principles of good manufacturing practice applicable to starting materials.

(3) A person guilty of an offence under paragraph (1) shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both; or

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

Standard provisions for manufacturer's licences

6. The standard provisions, for the purposes of Part II of the Act, for manufacturer's licences, insofar as those licences relate to relevant medicinal products shall be—

(a) those provisions set out in Schedule 1, insofar as those licences relate to the manufacture and assembly of relevant medicinal products; and

(b) those provisions set out in Schedule 2, insofar as those licences relate to the import from a third country of relevant medicinal products.

Additional standard provisions for manufacturers licences which relate to vaccines, toxins and sera

7.—(1) In addition to the standard provisions for manufacturer's licences set out in Schedules 1 and 2, there shall be the following additional standard provisions for manufacturer's licences, insofar as those licences relate to relevant medicinal products which are vaccines for human use—

(a) for all vaccines, including smallpox and BCG vaccines, those provisions set out in Part 1 of Schedule 3;

(b) for smallpox vaccine, those provisions set out in Part 2 of Schedule 3; and

(c) for BCG vaccine, those provisions set out in Part 3 of Schedule 3.

(2) In addition to the standard provisions for manufacturer's licences set out in Schedules 1 and 2, there shall be the following additional standard provisions for manufacturers licences relating to relevant medicinal products which are toxins and sera for human use—

(a) for toxins, those provisions set out in Part 4 of Schedule 3; and

(b) for sera, those provisions set out in Part 5 of Schedule 3.

Requirement that holders of wholesale dealer's licences comply with certain obligations

8.—(1) The holder of a wholesale dealer's licence, insofar as that licence relates to relevant medicinal products, shall—

(a) comply with the guidelines on good distribution practice;

(b) ensure, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale so that the needs of patients in the United Kingdom are covered;

(c) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the relevant medicinal products which he handles, stores or distributes under his licence as are necessary to maintain the quality of, and ensure proper distribution of the medicinal products which he handles, stores or distributes pursuant to his licence;

(d) inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or premises which have been approved from time to time by the licensing authority.

(2) Subject to paragraph (3), the holder of a wholesale dealer's licence shall not sell or offer for sale or supply any relevant medicinal product unless—

(a) there is a marketing authorization for the time being in force in respect of that product; and

(b) the sale or offer for sale is in conformity with the provisions of that authorisation.

(3) The restriction in paragraph (2) shall not apply to—

(a) the sale or offer for sale of any exempt relevant medicinal product; and

(b) the export to an EEA State, or supply for the purposes of such export, of a relevant medicinal product which may be placed on the market in that State without a marketing authorization by virtue of legislation adopted by that State under Article 5(2) of the Directive.

(4) The holder of a wholesale dealer's licence shall—

(a) keep such documents relating to the sale of medicinal products to which his licence relates as will facilitate the withdrawal or recall from sale of relevant medicinal products in accordance with paragraph (b);

(b) have in place an emergency plan which will ensure effective implementation of the recall from the market of any relevant medicinal products where such recall is—

(i) ordered by the licensing authority or by the competent authority of any other EEA State; or

(ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorization for, the product in question;

(c) keep such records, which may be in the form of purchase and sales invoices, or on a computer or in any other form, which give, as a minimum, where any relevant medicinal products are received or dispatched, the following information—

(i) the date of receipt or, as the case may be, dispatch,

(ii) the name of the relevant medicinal product,

(iii) the quantity of relevant medicinal product received or, as the case may be, dispatched, and

(iv) the name and address of, as may be applicable in each case, the person from whom the products are received or to whom they are sold or supplied.

(5) Where the holder of a wholesale dealer's licence imports from another EEA State any relevant medicinal product in respect of which he is not either—

(a) the marketing authorization holder in respect of that product; or

(b) acting on behalf of the marketing authorization holder in importing that product,

he shall notify the marketing authorization holder and the licensing authority of his intention to import it.

(6) The licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any licence granted under Part II of the Act; or

(b) suspending or terminating any licence in accordance with the provisions of Part II of the Act,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence.

Requirement that wholesale dealers deal only with specified persons

9.—(1) The holder of a wholesale dealer's licence shall obtain supplies of relevant medicinal products only from either—

(a) a manufacturer's licence holder or wholesale dealer's licence holder in respect of such products; or

(b) a person who holds an authorisation granted by another EEA State authorizing the manufacture of such products or their distribution by way of wholesale dealing.

(2) The holder of a wholesale dealer's licence shall distribute relevant medicinal products by way of wholesale dealing only to—

(a) a holder of a wholesale dealer's licence relating to those products;

(b) a holder of an authorization granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing;

(c) any person who may lawfully sell those products by retail or who may lawfully supply them in circumstances corresponding to retail sale; or

(d) any person who may lawfully administer those products.

(3) Where any relevant medicinal product is supplied to any person pursuant to paragraph (2)(c), the licence holder shall enclose with the product a document which makes it possible to ascertain—

(a) the date on which the supply took place;

(b) the name and pharmaceutical form of the product supplied;

(c) the quantity of product supplied; and

(d) the names and addresses of the person or persons from whom the products were supplied to the licence holder.

(4) The licence holder shall—

(a) keep a record of the information supplied pursuant to paragraph (3) for a minimum period of five years after the date on which it is supplied; and

(b) ensure, during that period, that that record is available to the licensing authority for inspection.

Requirement as to responsible persons

10.—(1) Where a wholesale dealer's licence relates to relevant medicinal products, the wholesale dealer's licence holder shall at all times have at his disposal the services of a person (referred to in this regulation as "a responsible person") who, in the opinion of the licensing authority—

(a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate for performing the functions of responsible person; and

(b) has experience in those procedures and activities which is adequate for those purposes.

(2) The functions of the responsible person shall be to ensure, in relation to relevant medicinal products, that—

(a) the conditions under which the licence has been granted have been, and are being, complied with; and

(b) the quality of relevant medicinal products which are being handled by the wholesale dealer's licence holder are being maintained in accordance with the requirements of the marketing authorizations applicable to those products.

(3) The licence holder shall—

(a) notify the licensing authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of responsible person;

(b) notify the licensing authority of any change to the responsible person; and

(c) not permit any person to act as responsible person other than the person named in his licence as responsible person or, subject to paragraph (4) any other such person whose name is notified to the licensing authority.

(4) Where, after giving the licence holder and the person acting as a responsible person the opportunity of making representations to them (orally or in writing), the licensing authority are of the opinion that—

(a) the person so acting does not satisfy the provisions of paragraph (1) as respects qualifications and experience, or

(b) he is failing to carry out the duties referred to in paragraph (2) adequately or at all,

and have notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a responsible person.

Standard provisions for wholesale dealer's licences

11. The standard provisions, for the purposes of Part II of the Act, for wholesale dealer's licences, insofar as those licences relate to relevant medicinal products, shall be those provisions set out in Schedule 4 to these Regulations.

Application of these Regulations to manufacturer's and wholesale dealer's licences

12.—(1) Regulations 2, 3 and 4 shall have effect as though they were made under section 8(2D) of the Act(**17**).

(2) Regulations 7, 8, 9 and 10 shall have effect as they were made under section 8(3D) of the Act(**18**).

(**17**) Subsection 8(2D) is inserted by paragraph 1 of Schedule 5 to these Regulations, and will come into force on 30th October 2005.
(**18**) Subsection 8(3E) is inserted by paragraph 1 of Schedule 5 to these Regulations, and will come into force on 30th October 2005.

Consequential and other amendments to enactments

13. The provisions of the enactments specified in Schedule 5 are amended as there specified.

Revocations

14.—(1) The Standard Provisions Regulations are revoked insofar as they relate to—

(a) manufacturer's licences, and

(b) wholesale dealer's licences,

insofar as such licences relate to relevant medicinal products.

(2) The Medicines (Renewal Applications for Licences and Certificates) Regulations 1974(**19**) are revoked insofar as they relate to—

(a) manufacturer's licences, and

(b) wholesale dealer's licences,

insofar as such licences relate to relevant medicinal products.

Transitional provisions

15. The transitional provisions set out in Schedule 6 shall have effect.

Signed by authority of the Secretary of State for Health

Warner
Minister of State,
Department of Health

5th October 2005

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

L.S.

A.McCormick
Permanent Secretary,
Department of Health, Social Services and
Public Safety

10th October 2005

(**19**) S.I. 1974/832 revoked in relation to veterinary drugs by S.I. 1993/1227 and in relation to clinical trials certificates by S.I. 2004/1031.

Sealed with the OfficialSealof the Department of Agriculture and Rural Development

L.S.

Pat Toal
Permanent Secretary,
Department of Agriculture and Rural Development

7th October 2005