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## STATUTORY INSTRUMENTS

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# 2005 No. 2789

## MEDICINES

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

<i>Made</i>	- - - -	<i>10th October 2005</i>
<i>Laid before Parliament</i>		<i>10th October 2005</i>
<i>Coming into force</i>	- -	<i>30th October 2005</i>

The Secretary of State, being a Minister designated <sup>M1</sup> for the purposes of section 2(2) of the European Communities Act 1972 <sup>M2</sup> in relation to medicinal products, in exercise of the powers conferred on her by the said section 2(2), and the Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, in exercise of the powers conferred on them by sections 18(1), 47(1) and 129(1) and (5) of the Medicines Act 1968 <sup>M3</sup> or, as the case may be, the powers conferred by those provisions and now vested in them <sup>M4</sup>, make the following Regulations.

In accordance with section 129(6) of the Medicines Act 1968, they have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

#### Marginal Citations

**M1** [S.I. 1972/181](#).

**M2** [1972 c. 68](#).

**M3** [1968 c. 67](#); the expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations, is defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, [S.I. 1969/388](#), by articles 2(1) and 5 of, and the Schedule to, [S.I. 1999/3142](#), and by article 5(1) of, and paragraph 15 of Schedule 1 to, [S.I. 2002/794](#).

**M4** In the case of the Secretary of State, by virtue of article 2(2) of, and Schedule 1 to, [S.I. 1969/388](#), [article 2\(1\)](#) of, and paragraph 1 of the Schedule to, [S.I. 1999/3142](#), and article 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, [S.I. 2002/794](#); in the case of the Northern Ireland Departments, the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the [Northern Ireland Act 1998 \(c. 47\)](#) may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the [Northern Ireland Act 2000 \(c. 1\)](#); the Departments were renamed by virtue of article 3(4) and (6) of [S.I. 1999/283 \(N.I.1\)](#).

## 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 <sup>M5</sup>;

“the 1994 Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 <sup>M6</sup>;

“the Applications Regulations” means the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 <sup>M7</sup>;

“the Standard Provisions Regulations” means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 <sup>M8</sup>;

“BCG” means the bacillus of Calmette and Guérin;

“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 Guérin;

“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<sup>M9</sup> 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;

“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 <sup>M10</sup>, 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 <sup>M11</sup>,
- (b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use <sup>M12</sup>,
- (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 <sup>M13</sup> 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 <sup>M14</sup>;

“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 <sup>M15</sup>;

“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<sup>M16</sup> or Regulation (EC) No. 726/2004<sup>M17</sup>;
- (d) a traditional herbal registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 <sup>M18</sup>; or
- (e) a certificate of registration granted by the licensing authority under the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994 <sup>M19</sup>;

“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<sup>M20</sup>;

“qualified person” means—

- (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,

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- (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.

#### Marginal Citations

- M5** 1968 c. 67.
- M6** 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.
- M7** S.I. 1971/974 as amended by S.I.1977/1052, 1978/1140, 1983/1725, 1993/832 and 2002/236.
- M8** 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.
- M9** OJ No. L262, 14.10.2003, p.22.
- M10** OJ No. L311, 28.11.2001, p67
- M11** OJ No. L33, 8.2.2003, p30.
- M12** OJ No L159, 27.6.2003, p 46.
- M13** OJ No L 136, 30.4. 2004, p.85.
- M14** OJ No. L136, 30.4.2004, p.85.
- M15** OJ No. C63 1.3.1994.
- M16** OJ No. L214, 24.8.1993, p.1.
- M17** OJ No L136, 30.4.2004, p.1.
- M18** S.I. 2005/2750.
- M19** 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.
- M20** OJ No. L 262 14.10.2003, p 22.

#### 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—

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- (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

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(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 <sup>M21</sup>.

(2) Regulations 7, 8, 9 and 10 shall have effect as they were made under section 8(3D) of the Act <sup>M22</sup>.

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**Marginal Citations**

- M21** Subsection 8(2D) is inserted by paragraph 1 of Schedule 5 to these Regulations, and will come into force on 30th October 2005.
- M22** 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<sup>M23</sup> 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.

**Marginal Citations**

- M23** [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](#).

**Transitional provisions**

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

Signed by authority of the Secretary of State for Health

5th October 2005

*Warner*  
Minister of State, Department of Health

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

L.S.

10th October 2005

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

Sealed with the Official Seal of the Department of Agriculture and Rural Development

L.S.

7th October 2005

*Pat Toal*  
Permanent Secretary, Department of Agriculture  
and Rural Development

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## SCHEDULE 1

Regulation 6

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A  
MANUFACTURER'S LICENCE RELATING TO THE MANUFACTURE  
AND ASSEMBLY OF RELEVANT MEDICINAL PRODUCTS

1. The manufacturer's licence holder shall place the quality control system referred to in Article 11(1) of Commission Directive [2003/94/EC](#) under the authority of the person notified to the licensing authority in accordance with paragraph 7(2) of Schedule 1 to the Applications Regulations as being responsible for quality control.

2. The manufacturer's licence holder may use a contract laboratory pursuant to Article 11(2) of Commission Directive [2003/94/EC](#) if operated by a person approved by the licensing authority.

3. The manufacturer's licence holder shall provide such information as may be requested by the licensing authority—

- (a) about the products currently being manufactured or assembled under his authorisation; and
- (b) about the operations being carried out in relation to such manufacture or assembly.

4. The manufacturer's licence holder shall inform the licensing authority of any change that he proposes to make to any personnel named in his licence as respectively—

- (a) responsible for supervising the production operations;
- (b) in charge of the animals from which are derived any substances used in the production of the medicinal products being manufactured or assembled; or
- (c) responsible for the culture of any living tissues used in the manufacture of the medicinal products being manufactured or assembled.

5. The manufacturer's licence holder shall—

- (a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive [2003/94/EC](#); and
- (b) permit the person authorised to take copies or make extracts from such documentation.

6. The manufacturer's licence holder shall keep readily available for examination by a person authorised by the licensing authority, the samples of each batch of finished relevant medicinal product referred to in Article 11(4) of Commission Directive [2003/94/EC](#).

7. Where the manufacturer's licence holder has been informed by the licensing authority that any batch of any relevant medicinal product to which his licence relates has been found not to conform as regards strength, quality or purity with—

- (a) the specification of the relevant product; or
- (b) the provisions of these Regulations, the Act or any other regulations under the Act that are applicable to the relevant medicinal product,

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

8. The manufacturer's licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture of a relevant medicinal product shall, 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 in the manufacture as may be approved by the licensing authority.

9. Where the manufacturer's licence relates to the assembly of any relevant medicinal product or class of product, and the licence holder supplies that relevant medicinal product at such a stage of

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assembly that does not fully comply with the provisions of the product specification that relate to labelling, the licence holder shall communicate the particulars of those provisions to the person to whom that product has been so supplied.

**10.** Where—

- (a) the manufacturer's licence relates to the assembly of a relevant medicinal product;
- (b) that medicinal product is not manufactured by the licence holder; and
- (c) particulars as to the name and address of the manufacturer of, or of the person who imports, that relevant medicinal product have been given by the licence holder to the licensing authority,

the licence holder shall forthwith notify the licensing authority in writing of any changes in such particulars.

**11.** The licence holder shall keep readily available for examination by a person authorised by the licensing authority durable records of the details of manufacture of any intermediate products held by him which are for use in the manufacture of biological medicinal products for human use, and these records shall—

- (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 any finished biological medicinal product for human use which he manufactures 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 any finished medicinal products which were or may be manufactured using those intermediate products may be destroyed in accordance with the requirements of these Regulations.

**12.** Where—

- (a) animals are used in the production of any medicinal products; and
- (b) relevant marketing authorizations contain provisions relating to them,

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

**13.** The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of—

- (a) any medicinal product for human use which he manufactures or assembles; or
- (b) any starting materials or intermediate products that he holds which are for use in the manufacture of relevant medicinal products,

is not false or misleading in any material particular.

## SCHEDULE 2

Regulation 6

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE RELATING TO THE IMPORT OF RELEVANT MEDICINAL PRODUCTS FROM A THIRD COUNTRY

**1.** The manufacturer's licence holder shall place the quality control system referred to in Article 11(1) of Commission Directive [2003/94/EC](#) under the authority of the person notified to the licensing

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authority in accordance with paragraph 7(2) of Schedule 1 to the Applications Regulations as being responsible for quality control.

2. The manufacturer's licence holder may use a contract laboratory pursuant to Article 11(2) of Commission Directive [2003/94/EC](#) if operated by a person approved by the licensing authority.

3. The manufacturer's licence holder shall provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal products which he imports.

4. The manufacturer's licence holder shall—

- (a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive [2003/94/EC](#); and
- (b) permit the person authorised to take copies or make extracts from such documentation.

5. Where the manufacturer's licence holder has been informed by the licensing authority that any batch of any medicinal product to which his licence relates has been found not to conform as regards strength, quality or purity with—

- (a) the specification of the relevant product; or
- (b) the provisions of these Regulations, the Act or any regulations under the Act that are applicable to the investigational medicinal product,

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

6. The manufacturer's licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture of a relevant medicinal product shall, 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 in the manufacture as may be approved by the licensing authority.

7.—(1) Where and insofar as the licence relates to relevant medicinal products to which paragraph 1 of Schedule 1 to the 1994 regulations applies, the licence holder shall only import such products from a third country—

- (a) in response to an order which satisfies the requirements of paragraph 1 of Schedule 1 to the 1994 Regulations; and
- (b) where the conditions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days prior to each importation of an exempt imported product, the licence holder shall give written notice to the licensing authority stating his intention to import that medicinal product and stating the following particulars—

- (a) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the medicinal product is to be sold or supplied in the United Kingdom,
- (b) any trademark or the name of the manufacturer of the medicinal product;
- (c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name or, where that constituent does not have an international non-proprietary name, a British approved name or a monograph name, the accepted scientific name or any other name descriptive of the true nature of that constituent;
- (d) the quantity of medicinal product which is to be imported which shall not exceed the quantity specified in sub-paragraph (6); and



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

(3) Subject to sub-paragraph (4), the licence holder shall not import the exempt imported product if, before the end of 28 days from the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that they have received the notice referred to in sub-paragraph (2) above, the licensing authority have notified him in writing that the product should not be imported.

(4) The licence holder may import the exempt imported product referred to in the notice where he 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 exempt imported product may be imported.

(5) Where the licence holder sells or supplies exempt imported products, he shall, in addition to any other records which he is required by the provisions of his licence to make, 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 so sold or supplied of which he becomes aware.

(6) The licence holder shall import no more on any one occasion 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 on any such occasion shall not import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder shall inform the licensing authority forthwith of any matter coming to his attention which might reasonably cause the licensing authority to believe that the medicinal product can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(8) The licence holder shall not issue any advertisement, catalogue, price list or circular relating to the exempt relevant medicinal product or make any representations in respect of that product.

(9) The licence holder shall cease importing or supplying an exempt imported product if he has received a notice in writing from the licensing authority directing that, as from a date specified in that notice, a particular product or class of products shall 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 appropriate body in accordance with section 100 of the Act and published by the Ministers on the recommendation of the Commission and “current” in this definition means current at the time the notice is sent to the licensing authority;

“common name” means the international non-proprietary name or, if one does not exist, the usual common name;

“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 British Pharmaceutical Codex, 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.

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8. The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of any medicinal product for human use which he imports from a third country, handles, stores or distributes is not false or misleading in a material particular.

## SCHEDULE 3

Regulation 7

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

#### PART 1

##### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES

1.—(1) The licence holder shall provide separate premises or separate parts of premises referred to in this Part as “the designated premises”, for the activities specified in the following subparagraphs, namely—

- (a) the production and the testing involved in the production of cell cultures for use in the production of vaccine;
- (b) the production and the testing involved in the production of vaccine prepared from viruses; and
- (c) the production and the testing involved in the production of vaccine prepared from micro-organisms or detoxified microbial toxins,

and shall ensure that only persons necessary to each of the above mentioned activities shall have access to the designated premises provided for that activity.

2. The licence holder shall ensure that any procedure which, in the course of any of the activities specified in the preceding paragraph involves or might involve—

- (a) the presence of transmissible agents; or
- (b) the use of cell cultures, animal tissues or micro-organisms,

other than those from which the vaccine is produced, shall not be carried out in the designated premises referred to in paragraph 1.

3. The licence holder shall ensure that no person who has been in contact with transmissible agents or experimental animals (other than those connected with the vaccine being produced in the designated premises referred to in paragraph 1) shall enter the designated premises on the same day that such contact has occurred.

4. Before an animal is used in the production of a vaccine, the licence holder shall take all reasonable steps to ensure that it is free from disease, and to that end shall keep the animal in quarantine and under observation for such period as the licensing authority may specify.

5. The licence holder shall ensure—

- (a) that animals used in the production of vaccine are isolated and shall provide separate premises (not being the designated premises referred to in paragraph 1) for this purpose; and

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- (b) that only persons engaged in the production and testing of vaccines or in the maintenance of animals or premises shall have access to the separate premises in which the animals are isolated.
6. The licence holder shall provide a separate room in the premises referred to in paragraph 5 which is capable of being washed and disinfected and which is to be used for the purpose of—
- (a) the inoculation of animals; and
  - (b) the collection of material to be used in the preparation of vaccine.
7. Without prejudice to any other requirements to keep records, where vaccines contain or might contain micro-organisms or microbial toxins, the licence holder shall keep a durable record, readily available for inspection by a person authorised by the licensing authority, of the origin, properties and characteristics of the cell cultures used in the production of those vaccines and shall ensure that that record is not destroyed for a period of five years from the date when the relevant production occurred.
8. Nothing in this Schedule shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.

## PART 2

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SMALLPOX VACCINES

1. The licence holder shall ensure that animals used in the production of smallpox vaccine—
- (a) shall only be inoculated on a part of the skin that has been depilated and cleansed and which cannot be soiled by urine or faeces, and
  - (b) are kept under observation for 28 days after the collection of the vaccinal material.
2. Should any animal during the 28 day period referred to in paragraph 1 be found to be suffering from any infection other than vaccinia or show serious or persistent signs of ill health, vaccinal material obtained from that animal shall not be used in the production of smallpox vaccine.
3. Where it is necessary for an animal which has been inoculated for use in the production of smallpox vaccine to be killed, the licence holder shall ensure that—
- (a) the vaccinal material is collected immediately after the animal has been killed;
  - (b) if the licensing authority so directs, a post-mortem examination of the carcass of the animal is made by a person with experience of the diseases of the particular animal which has been killed;
  - (c) a durable record of the examination is made and retained for a period of five years from the date when the animal was killed, and kept readily available for inspection by a person authorised by the licensing authority; and
  - (d) where the examination indicates that the animal was suffering from diseases other than vaccinia, no vaccinal material obtained from that animal is used in the production of smallpox vaccine.

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## PART 3

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO BCG VACCINES

1. The licence holder shall provide separate premises or separate parts of premises for the production of BCG vaccine, and shall ensure that only persons necessary to the production and testing of that vaccine shall have access to those separate premises or separate parts of premises.

2. The licence holder shall ensure that any procedure which involves or might involve—

- (a) the presence of transmissible agents other than BCG, or
- (b) the use of microbial cultures other than BCG,

shall not be carried out in the separate premises or separate parts of premises referred to in paragraph 1 of this Schedule.

3. The licence holder shall ensure that all media, glassware and other apparatus issued in the production of BCG vaccine shall be kept and prepared for use in the separate premises or separate parts of premises referred to in paragraph 1 of this Part of this Schedule.

4. The licence holder shall not permit animals to be in the separate premises or separate parts of premises referred to in paragraph 1 of this Part of this Schedule and where it is necessary to use animals for testing BCG vaccine, the tests shall not be carried out in those separate premises or separate parts of premises.

5.—(1) The licence holder shall arrange for all persons engaged in the production of BCG vaccine to be examined clinically by a doctor and where appropriate, radiologically and bacteriologically, at least every twelve months and whenever such a person shows signs of ill health.

(2) The licence holder shall ensure (as far as paragraph (c) below is concerned, in so far as is reasonably practicable), that persons falling within the following descriptions shall not engage in the production of BCG vaccine, that is to say—

- (a) persons examined as aforesaid who are found to be suffering from active or potentially active tuberculosis lesions,
- (b) persons who show a negative reaction when tested with tuberculin, or
- (c) persons who are in close contact with a person who is suffering from any active form of tuberculosis.

(3) If on examination in accordance with subparagraph (1), a person engaged in the production of BCG vaccine is found to be suffering from active or potentially active tuberculosis lesions, then, after that person has been removed from the separate premises or separate parts of premises referred to in paragraph (1), the licence holder shall—

- (a) make arrangements for those separate premises or separate parts of premises and all equipment used in the production of BCG vaccine to be treated in such a manner as to remove the risk of contamination of the vaccine; and
- (b) cease to use any unsealed cultures of BCG and all current preparations of BCG vaccine which may have become contaminated with other Mycobacterium tuberculosis organisms.

6. The licence holder shall ensure that no person who has been in contact with transmissible agents other than BCG vaccine shall enter the separate premises or separate parts of premises referred to in paragraph 1 on the same day that such contact has been made.

## PART 4

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO TOXINS

1. The licence holder shall provide separate premises or separate parts of premises for the production and the testing involved in the production of toxins and shall ensure that only persons necessary to the production and testing of toxins (or related toxoids) shall have access to the separate premises or separate parts of those premises.

2. Nothing in paragraph 1 shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.

3. The licence holder shall ensure that any procedure which in the course of the production and testing referred to in the previous paragraph involves or might involve the presence of micro-organisms, plants or animals other than those from which the toxins are to be produced, shall not be carried out in the separate premises or separate parts of premises referred to in paragraph 1.

## PART 5

### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SERA

1. The licence holder shall ensure that blood used in the production of any serum shall only be collected from living animals in separate premises which—

- (a) are used for no other purpose,
- (b) have impervious walls and floors, and
- (c) are capable of being washed and chemically disinfected.

2. The licence holder shall ensure that an adequate system of manure removal is in operation in the separate premises referred to in paragraph 1.

3. Before an animal is used in the production of any serum, the licence holder shall take all reasonable steps to ensure that it is free from disease and to this end shall keep the animal in quarantine and under observation for such period as the licensing authority may direct.

4. The licence holder shall notify the licensing authority if any animal which has been used in the production of any serum is found to be suffering from an infection other than an infection produced by living organisms against which it is being immunised or shows serious or persistent signs of ill-health not attributable to the process of immunisation and shall withhold any serum obtained from that animal from sale, supply or exportation until he has obtained the consent of the licensing authority in writing to its release.

5. The licence holder shall notify the licensing authority if any post-mortem examination on any animal indicates that any other animals used in the production of any serum are or are likely to be unhealthy, and the licence holder shall not use those animals for the production of any serum until either he has obtained the consent of the licensing authority in writing or has complied with any requirements the licensing authority may consider necessary in the interest of safety.

6. The licence holder shall ensure that laboratories in which any serum is processed are separate from premises in which animals are housed.

7. The licence holder shall provide such number of sterilizers as are necessary for the sterilization of all glassware and other apparatus used in the production of sera.

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**8.** Without prejudice to any other requirements to keep records, the licence holder shall keep the following durable records relating to the production of sera readily available for inspection by a person authorised by the licensing authority, and shall ensure that those records are not destroyed for a period of five years from the date when the relevant production occurred—

- (a) as to the cultures used—
  - (i) the source from which the culture was obtained,
  - (ii) the nature of the material from which the culture was isolated,
  - (iii) the date of the isolation, and
  - (iv) evidence of the identity and specificity of the culture;
- (b) as to the procedure used in the immunizing of animals—
  - (i) the method of preparing the culture or antigen used for immunization,
  - (ii) the dosage and methods employed in administering the culture or antigen, and
  - (iii) the time in the course of immunization at which blood is withdrawn for preparation of the serum; and
- (c) the results of any tests which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

**9.** Nothing in this Part shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.

#### SCHEDULE 4

Regulation 11

##### STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A WHOLESALE DEALER'S LICENCE

**1.** The licence holder shall not use any premises for the purpose of the handling, storage or distribution of relevant medicinal products other than those specified in his licence or notified to the licensing authority by him from time to time and approved by the licensing authority.

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

**3.—(1)** Where and insofar as the licence relates to relevant medicinal products to which paragraph 1 of Schedule 1 to the 1994 Regulations apply, the licence holder shall only import such products from another EEA State—

- (a) in response to an order which satisfies the requirements of paragraph 1 of Schedule 1 to the 1994 Regulations; and
- (b) where the conditions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days prior to each importation of an exempt imported product, the licence holder shall give written notice to the licensing authority stating his intention to import that medicinal product and stating the following particulars—

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

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- (c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name or, where that constituent does not have an international non-proprietary name, a British approved name or a monograph name, the accepted scientific name or any other name descriptive of the true nature of that constituent;
- (d) the quantity of medicinal product which is to be imported which shall not exceed the quantity specified in sub-paragraph (6); and
- (e) the name and address of the manufacturer or assembler of that medicinal product in the form in which it is to be imported and, if the person who will supply that medicinal product for importation is not the manufacturer or assembler, the name and address of such supplier.

(3) Subject to sub-paragraph (4), the licence holder shall not import the exempt imported product if, before the end of 28 days from the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that they have received the notice referred to in sub-paragraph (2) above, the licensing authority have notified him in writing that the product should not be imported.

(4) The licence holder may import the exempt imported product referred to in the notice where he 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 exempt imported product may be imported.

(5) Where the licence holder sells or supplies exempt imported products, he shall, in addition to any other records which he is required by the provisions of his licence to make, 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 so sold or supplied of which he becomes aware.

(6) The licence holder shall import no more on any one occasion 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 on any such occasion shall not import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder shall inform the licensing authority forthwith of any matter coming to his attention which might reasonably cause the licensing authority to believe that the medicinal product can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(8) The licence holder shall not issue any advertisement, catalogue, price list or circular relating to the exempt relevant medicinal product or make any representations in respect of that product.

(9) The licence holder shall cease importing or supplying an exempt imported product if he has received a notice in writing from the licensing authority directing that, as from a date specified in that notice, a particular product or class of products shall 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 appropriate body in accordance with section 100 of the Act and published by the Ministers on the recommendation of the Commission and “current” in this definition means current at the time the notice is sent to the licensing authority;

“common name” means the international non-proprietary name or, if one does not exist, the usual common name;

“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

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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 British Pharmaceutical Codex, 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.

4. The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of any medicinal product for human use which he handles, stores or distributes is not false or misleading in a material particular.

## SCHEDULE 5

Regulation 13

### CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

## PART 1

### AMENDMENTS TO THE ACT

1.—(1) Section 8 of the Act (provisions as to manufacture and wholesale dealing)<sup>M24</sup>, is amended as follows.

(2) In subsection (2)—

- (a) for “subsection (2A)” substitute “ subsections (2A) and (2C) ”;
- (b) for “manufacture or assemble”, substitute “ manufacture, assemble or import from a third country ”.

(3) After subsection (2B), insert—

“(2C) The prohibition in subsection (2) does not apply to a person who, in connection with the importation of a medicinal product from a third country—

- (a) provides facilities solely for transporting the product, or
- (b) in the course of a business carried on by him as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(2D) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—

- (a) with which the holder of a manufacturer's licence must comply, and
- (b) which are to have effect as if they were provisions of the licence.”.

(4) After subsection (3D), insert—

“(3E) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—

- (a) with which the holder of a wholesale dealer's licence must comply, and
- (b) which are to have effect as if they were provisions of the licence.”.



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#### Marginal Citations

**M24** [Section 8](#) was amended by [S.I. 1977/1050](#), 1992/604/ 1993/834, 2002/236 and 2004/1031.

2. In section 14 of the Act (exemption for re-exports)<sup>M25</sup>, in subsection (2), for “a member State.”, substitute “ an EEA State. ”.

#### Marginal Citations

**M25** [Section 14](#) was amended by [S.I. 1993/834](#) and 2002/236.

3. Section 20 of the Act (grant or refusal of licence)<sup>M26</sup> is amended as follows—
- (a) in subsection (1), for “the last preceding section,”, substitute “ sections 8(2E) and (3E) and 19, ”; and
  - (b) after subsection (1), insert—
    - “(1A) The licensing authority must either grant or refuse any application for a licence under this Part, before the end of a period of 90 days from the date upon which they receive the application.
    - (2B) If there are requirements in force under section 18 that apply to the application, subsection (1A) applies only if the requirements have been met
    - (2C) If a notice under section 44 requires the applicant to provide the licensing authority with information, the period specified in subsection (1) stops running when the notice is given, and does not start running again until—
      - (a) the licensing authority receives the information; or
      - (b) the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it.”.

#### Marginal Citations

**M26** [Section 20](#) was amended by [S.I. 1977/1050](#) and 2005/1094.

- 4.—(1) Section 24 of the Act (duration and renewal of licence)<sup>M27</sup> is amended as follows.
- (2) For subsection (1), substitute—
    - “(1) A licence granted under this Part expires—
      - (a) in accordance with the provisions of the licence, or
      - (b) if there is no such provision, at the end of the period of five years beginning with the date on which the licence was granted, or if it has been renewed the date on which it was last renewed.
    - (1AA) But so far as the licence relates to a medicinal product to which the 2001 Directive applies, it remains in force until—
      - (a) revoked by the licensing authority; or
      - (b) surrendered by the holder.”.
  - (3) After subsection (2), insert—
    - “(2A) Subsection (2) does not apply to a licence insofar as it relates to a medicinal product to which the 2001 Directive applies.”.

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(4) After subsection (3) insert—

“(3A) References to a licence in subsection (3) are to be read as references to a licence only insofar as that licence relates to a medicinal product to which the 2001 Directive does not apply.”.

(5) After subsection (5), insert—

“(5A) Subsection (5) does not apply to a licence insofar as it relates to a medicinal product to which the 2001 Directive applies.”.

#### Marginal Citations

**M27** Section 24 was amended by S.I. 1977/1050, 1994/276, 2002/236 and 2005/1094.

5. For section 30 of the Act (variation of licence on application of holder), substitute—

#### “30 Variation of licence on application of holder

(1) This section applies if the holder of a licence under this Part applies to the licensing authority for the licence to be varied.

(2) The application must—

- (a) be in writing,
- (b) specify the required variation,
- (c) be signed by or on behalf of the applicant,
- (d) be accompanied by such information as is reasonably required to enable the licensing authority to consider the application, and
- (e) if there is a requirement in force under section 1(1)(a) of the Medicines Act 1971<sup>M28</sup> to pay a fee in respect of the application, be accompanied by the required fee.

(3) The licensing authority must consider any application properly made under this section.

(4) If subsection (5) applies, they must either vary the licence or refuse to vary it before the end of the period allowed for considering the application.

(5) This subsection applies to a variation which would have the effect of altering—

- (a) the types of medicinal product,
- (b) any operation carried out under the licence,
- (c) any premises, or
- (d) any equipment or facilities,

in respect of which the licence was granted.

(6) If the licensing authority considers that it is necessary for them to conduct an inspection of any premises to which the application relates, the period allowed is 90 days beginning with the date on which they receive the application.

(7) Otherwise, the period allowed is 90 days beginning with that date.

(8) The licensing authority may give the applicant written notice requiring him to give them such further information in connection with the application as they consider reasonable.

(9) The period allowed for consideration stops running when a notice is given under paragraph (8) and does not start running again until—

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- (a) the licensing authority receives the information; or
  - (b) the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it
- (10) Nothing in this section affects the powers conferred by section 28.”.

#### Marginal Citations

**M28** Section 24 was amended by [S.I. 1977/1050](#), 1994/276, 2002/236 and 2005/1094.

6. Section 49A of the Act is repealed.
7. After section 49 of the Act (postponement of restrictions in relation to export)—

#### “49B Special provisions in respect of exporting certain products to EEA States

**49B.** Nothing in section 48 of this Act affects the operation of section 8(3A) of this Act in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if —

- (a) it is a product to which the 2001 Directive applies; and
- (b) the exportation is, or is to be, to an EEA State.”.

8. In section 67 of the Act (offences under Part III)—
- (a) after subsection (3) insert the following subsection—

“(3A) A person who has in his possession a medicinal product to which paragraph (a) of section 58(2) applies, with the intention of supplying it otherwise than in accordance with the requirements of that paragraph, is guilty of an offence.”; and
  - (b) in subsection (4)(b) <sup>M29</sup>, for “subsection (1A), (1B), subsection (2) or subsection (3)”, substitute “subsection (1A), (1B), (2), (3) or (3A) ”.

#### Marginal Citations

**M29** Subsections (1A) and (1B) and the references to those subsections in subsection (3) were inserted by section 63 of the Health and Social Care Act 2001.

9. In section 111 of the Act (rights of entry)—
- (a) in subsection (1)(a), at the end, “or” is repealed; and
  - (b) after paragraph (1)(a), insert the following paragraph—

“(aa) for the purpose specified in the third sub-paragraph of Article 111(1) of the 2001 Directive, or”.
10. In section 132 (general interpretation provisions)—
- (a) In the definition of “the 2001 Directive” after “as amended” insert—

“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,
    - (b) Commission Directive [2003/63/EC](#) amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use,

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- (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; 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;”;
- (b) insert, in the appropriate places, the following definitions—
- ““EEA State” means a Member State, Norway, Iceland or Liechtenstein; and
  - “import from a third country” means import from any country other than an EEA State; and”.

## PART 2

### AMENDMENTS TO ORDERS AND REGULATIONS

#### Amendments to the Standard Provisions Regulations

- 1.—(1) The Standard Provisions Regulations are amended as follows—
- (2) In regulation 2 (interpretation)—
  - (a) In the definition of “the 2001 Directive” after “as amended” insert—
    - “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,
    - (b) Commission Directive [2003/63/EC](#) amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use,
    - (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, 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;”;
  - (b) omit the definition of “exempt imported product”; and
  - (c) in the definition of “imported proprietary product” for “other than from a member State” substitute “ from a third country ”.
- (3) In regulation 3 (standard provisions for licences and certificates)—
  - (a) in paragraph (4), after “manufacturer's licences of right,” insert “ insofar as those licences relate to the manufacture or assembly of medicinal products, ”; and
  - (b) after paragraph (4), insert the following paragraph—
    - “(4A) For manufacturer's licences including manufacturer's licences of right insofar as those licences relate to the import from a third country of medicinal products, those provisions set out in Schedule 2A to these Regulations.”.
- (4) In Schedule 2 (standard provisions for manufacturer's licences and manufacturer's licences of right), omit paragraphs 5, 16(7) and 17(5)(b) and 17(7).
- (5) After Schedule 2, insert the following Schedule—

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## “SCHEDULE 2A

### STANDARD PROVISIONS FOR MANUFACTURER'S LICENCES AND MANUFACTURER'S LICENCES OF RIGHT IN RELATION TO THE IMPORT OF MEDICINAL PRODUCTS FROM A THIRD COUNTRY

1. The licence holder shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products which he handles, stores or distributes under his licence, as are necessary to maintain the quality of those products.

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

3. The licence holder shall provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal product which he currently handles, stores or distributes.

4. The licence holder shall inform the licensing authority of any proposed structural alterations 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.

5. The licence holder shall keep such documents relating to his transactions as will facilitate the withdrawal or recall from sale or exportation of such products.

6. Where the licence holder has been informed by the licensing authority or by the holder of the product licence that any batch of any medicinal product to which his licence relates has been found not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale or exportation, so far as may be reasonably practicable, for such period not exceeding six weeks as may be specified by the licensing authority.

7.—(1) Subject to the provisions of sub-paragraph (2) of this paragraph, no medicinal product to which the licence relates shall be imported from a third country unless there has been granted in respect of that medicinal product a product licence which is for the time being in force and any sale or offer for sale shall be in conformity with the provisions of such product licence.

(2) The provisions of the preceding sub-paragraph of this paragraph shall not apply where—

- (a) by virtue of any provisions of the Act or of any order made under Part II of the Act, the sale (other than sale by way of wholesale dealing) or supply of the medicinal product to which the licence relates is not subject to the restrictions imposed by section 7(2) of the Act, or
- (b) the sale or offer for sale or supply by way of wholesale dealing is of a medicinal product the dealings in which, at the time of its acquisition by the licence holder, were not subject to the said restrictions imposed by section 7(2) of the Act, or
- (c) at the time of such sale or offer for sale, the licence holder does not know, or could not by reasonable diligence and care have known, that such sale or offer for sale is of a medicinal product, or believes, on reasonable grounds, that the provisions of sub-paragraphs (a) or (b) of this paragraph apply in relation to such sale or offer for sale.

8. The licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds for suspending, revoking or varying any licence or certificate granted or issued under 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

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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 licence holder, 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 or certificate.

9.—(1) Subject to sub-paragraph (7) below, the licence holder shall at all times have at his disposal the services of a person who as respects qualifications and experience satisfies the provisions of Articles 49 and 50 of the 2001 Directive to carry out the functions specified in sub-paragraph (3) below (“qualified person”). For the purposes of this paragraph, but without prejudice to sub-paragraph (6) below, the licence holder may regard a person as satisfying the provisions of Article 50 as respects formal qualifications if he produces evidence that he is a member of the Pharmaceutical Society or of the Royal Institute of Chemistry or of such other body as may appear to the licensing authority to be an appropriate body for the purpose, and that he is regarded by the body of which he is a member as so satisfying those provisions

(2) 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 to carry out the said functions.

(3) The functions to be carried out by the qualified person shall be as follows—

- (a) to ensure that each production batch of any imported proprietary product to which the licence relates has undergone a full qualitative analysis, a quantitative analysis of at least all the active ingredients and all other tests or checks necessary to ensure that the quality of the product imported satisfies the requirements of the product licence which relates to the product; or
- (b) where there is in relation to the imported proprietary product, a certificate of registration, to ensure that each batch of product has been tested in accordance with the manufacturing and control file submitted with the application for that certificate;
- (c) to certify in a register, or other record appropriate for the purpose, whether each batch of the imported proprietary product to which the licence relates satisfies the requirements set out in (a) or (as the case may be) (b) above and to ensure that such register or other record is regularly maintained:

Provided that the above functions shall be deemed to be carried out in respect of a batch which had entered the territory of another Member State prior to its importation if there is available evidence in writing, signed by a person carrying out the functions of a qualified person in that member State, that the batch in question satisfies the requirements set out in (a) above.

(4) The licence holder shall keep the said register or other record readily available for inspection by a person authorised by the licensing authority and such register or other record shall not be destroyed for a period of five years from the date of the certification referred to in sub-paragraph (3)(b) above.

(5) The licence holder 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 a qualified person and shall notify the licensing authority of any change as to the qualified person and shall not permit any person to act as a qualified person except the person named in his licence as the qualified person for the purposes of this paragraph or, subject to the provisions of paragraph (6) below, any such person whose name is notified to the licensing authority.

(6) 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 are of the opinion that the person so acting does not satisfy the provisions of Articles 49 and 50 of the 2001 Directive as respects qualifications and experience, or that he is failing to carrying out the functions specified in sub-paragraph (3) above, and have notified the licence holder

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accordingly in writing, the licence holder shall not permit that person to act as a qualified person so long as the said notification has not been withdrawn by the licensing authority.

(7) The provisions of this paragraph shall not apply where the imported proprietary product that is to be sold or offered for sale or in any other way distributed has been in the possession of a person in the course of his business who is the holder of a wholesale dealer's licence which relates to imported proprietary products of the same description in circumstances by virtue of which that licence holder is required to comply with the provisions of this paragraph.

**10.** The licence holder shall—

- (a) ensure that all manufacture and assembly operations have been carried out by a duly authorised manufacturer or assembler and that the products have been manufactured and assembled in accordance with the principles and guidelines of good manufacturing practice;
- (b) keep readily available for examination by a person authorised by the licensing authority samples of each batch of finished products for at least one year after their expiry date except where the licence holder is authorised by the licensing authority to destroy such samples earlier;
- (c) implement a system for recording and reviewing complaints relating to the medicinal products to which his licence relates, together with an effective system for recalling promptly and at any time any such medicinal product in the distribution network; and
- (d) record and investigate all such complaints and immediately inform the licensing authority of any defect which could result in a recall from sale, supply or exportation or in an abnormal restriction on such sale, supply or exportation.”.

(6) In Schedule 3 (standard provisions for wholesale dealer's licences including wholesale dealer's licences of right), omit paragraphs 4A, 4B, 7A, 7B, 7C, 8, 8A, 8B and 9.

## **Amendments to the Applications Regulations**

**2.—**(1) The Applications Regulations are amended as follows—

(2) In regulation 2 (interpretation)—

(a) in the definition of “the 2001 directive”, at the end insert —

“as amended by—

- (i) 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,
  - (ii) Commission Directive [2003/63/EC](#) amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use,
  - (iii) 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; and
  - (iv) 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;”;
- (b) in the definition of “imported proprietary product” for “imported other than from a member State of the European Communities;” substitute “ imported from a third country; ”;
- (c) for the definition of “proprietary medicinal product and ready made veterinary drug” substitute the following definition— “ “proprietary medicinal product” has the same meaning as in section 7(7) of the Act; ”;

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- (d) in the definition of “standard provisions for licences” after “1971”, add “, or the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005”;
  - (e) insert, in the appropriate alphabetical places, the following definitions—
    - ““qualified person” means—
      - (a) a person whose qualifications and experience satisfy the requirements of Article 49 or 50 of the 2001 Directive, or
      - (b) where—
        - (i) an application for a licence is made before 30th April 2013; and
        - (ii) insofar as the activities of in respect of which the application is made are limited to traditional herbal medicinal products, a person who, without satisfying the requirements referred to in paragraph (a), has been engaged in activities equivalent to those to be performed in accordance with Article 51 of the 2001 Directive in respect of traditional herbal medicinal products on or before 30th April 2011;
    - “responsible person” means the person who will be responsible for ensuring in relation to any wholesale distribution activity carried out pursuant to a licence that—
      - (a) any 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;
    - “traditional herbal medicinal product” has the meaning given by Article 1(29) of the 2001 Directive;”.
- (3) In regulation 3 (form of application for a manufacturer's licence and for a wholesale dealer's licence)—
    - (a) in paragraph (1), after “manufacturer's licence“ insert “, where that licence relates to the manufacture or assembly of medicinal products, ”; and
    - (b) after paragraph (1), insert the following paragraph—
      - “(1A) Every application for the grant of a manufacturer's licence where that licence relates to import from a third country of medicinal products shall contain or be accompanied by the particulars specified in Schedule 1A to these Regulations;”.
  - (4) In Schedule 1 (particulars required on application for grant of a manufacturer's licence)—
    - (a) for paragraph 2, substitute
      - “2. Whether the application relates to any medicinal products which are not medicinal products to which the 2001 Directive applies, and if so, in respect of those products, the period for which the licence is desired, where it is for less than five years.”;
    - (b) in paragraph (4)—
      - (i) omit sub-paragraphs (b) and (d), and
      - (ii) in sub-paragraph (c), omit “or animals”; and
    - (c) in paragraph 7, for sub-paragraph (5), substitute—
      - “(5) The name and address and degrees, diplomas or other qualifications of the qualified person.”.
  - (5) After Schedule 1, insert the following Schedule—



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## “SCHEDULE 1A

### PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A MANUFACTURER'S LICENCE WHERE THAT LICENCE RELATES TO THE IMPORT OF MEDICINAL PRODUCTS FROM A THIRD COUNTRY

1. The name and address of the applicant, and where the applicant is not to be the licence holder, the name and address of the proposed licence holder.
  2. Whether the application relates to any medicinal products which are not medicinal products to which the 2001 Directive applies, and if so, in respect of those products, the period for which the licence is desired, where it is for less than five years.
  3. A statement of the importation operations to which the licence is to relate.
  4. The name, pharmaceutical form, country of origin and Marketing authorization number of each imported proprietary product.
  5. The address of each site where the importation operation is to take place.
  6. The address of each site where any testing associated with the importation is to take place.
  7. The address of each site where it is proposed to store or distribute proprietary medicinal products.
  8. A statement indicating the facilities and equipment available at each site for storing the proprietary medicinal products, and distributing them.
  9. A statement of any manufacturing operations, other than those to which the licence relates, that are carried on by the applicant at each of the sites referred to above, and of the substances or articles which are the subject of any such operation.
  10. The name and address and degrees, diplomas or other qualifications of the qualified person.
  11. The name and degrees, diplomas or other qualifications and experience of the person in charge of quality control.
  12. A description of the arrangements for storage of the medicinal products after importation.
  13. A description of the arrangement at each site for ensuring a satisfactory turn-over of stock of proprietary medicinal products.
  14. A description of the arrangements for—
    - (a) maintaining records of importation;
    - (b) maintaining records of analytical and other testing procedures applied in the course of importation for ensuring compliance; and
    - (c) keeping reference samples of the medicinal products.”.
- (6) In Schedule 2 (particulars required on an application for the grant of a wholesale dealer's licences)—
- (a) for paragraph 2, substitute—
    - “2. Whether the application relates to any medicinal products which are not a medicinal products to which the 2001 Directive applies, and if so, in respect of those products, the period for which the licence is desired, where it is for less than five years.”;
  - (b) in paragraph 3, omit sub-paragraph (e);

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- (c) in paragraph 4—
  - (i) omit sub-paragraphs (b) and (d), and
  - (ii) in sub-paragraph (c), omit “or animals”;
- (d) in paragraph 6, omit “Where the licence relates to imported proprietary products or imported ready made veterinary drugs, the statement shall indicate the description of the medicinal products”;
- (e) for paragraph 8A, substitute

“**8A.** The name and address and the degrees, diplomas and qualifications of the responsible person”; and
- (f) in paragraph 8B for “paragraph 4A of Schedule 3 to the Standard Provisions Regulations”, substitute “ regulation 8(4) of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 ”.

### **Amendments to the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974**

**3.**—(1) The Medicines (Renewal Applications for Licences and Certificates) Regulations 1974 are amended as follows.

- (2) In Part II of the Schedule (renewal application particulars)—
  - (a) in paragraph 8, after “a manufacturer's licence“ insert “ where that licence relates to the manufacture or assembly of medicinal products, ”; and
  - (b) after paragraph 8, insert the following paragraph—

“**8A.** In the case of renewal of a manufacturer's licence, where that licence relates to the importation from a third country of medicinal products, the following particulars—

    - (a) the names and qualifications of the persons under whose supervision the importation operations to be carried out pursuant to the licence will be carried out;
    - (b) particulars of the arrangement made or to be made for securing the safekeeping, and the maintenance of adequate records in respect of medicinal products to be imported from a third county in pursuance of the licence as renewed;
    - (c) particulars of the premises on which will be stored medicinal products of the description to which the licence as renewed is intended to relate;
    - (d) particulars of the equipment which is or will be available for storing medicinal products on those premises;
    - (e) particulars of the equipment and facilities which are or will be available for distributing medicinal products from those premises; and
    - (f) particulars of arrangements made or to be made for securing the safekeeping and maintenance of adequate records in respect of medicinal products to be stored or distributed from those premises.”.

### **Amendments to the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977**

**4.** In The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 <sup>M30</sup>, in regulation 3 (exemption for certain herbal remedies), in paragraph (2)(c)(ii), after “in respect of” insert “ the manufacture or assembly of ”.

**Marginal Citations**

**M30** [S.I. 1977/2130](#).

SCHEDULE 6

Regulation 15

TRANSITIONAL PROVISIONS

**Wholesale dealer's licences granted before 30th October 2005 relating to the import of medicinal products from third countries**

- 1.—(1) This sub-paragraph applies—
- (a) where a wholesale dealer's licence has been granted by the licensing authority pursuant to section 20 of the Act before 30th October 2005 and remains in force as at that date; and
  - (b) insofar as such licence relates to the import from a third country of medicinal products.
- (2) Where sub-paragraph (1) applies—
- (a) the licence shall have effect as though it were a manufacturer's licence granted by the licensing authority in respect of the import from a third country of those medicinal products;
  - (b) insofar as the licence relates to relevant medicinal products, the provisions of paragraph 3 of this Schedule shall accordingly apply to the licence as though it were a manufacturer's licence; and
  - (c) insofar as the licence relates to medicinal products which are not relevant medicinal products—
    - (i) the standard provisions as respects manufacturer's licences set out in Schedule 2 to the Standard Provisions Regulations shall, notwithstanding the provisions of section 47(4) of the Act, be deemed to be incorporated into those licences with effect from 30th October 2005; and
    - (ii) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
      - (aa) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
      - (bb) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (cc) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
      - (cc) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into

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the licence with such exceptions or modifications as may be specified in the application; and

(dd) references to applications to the licensing authority to so direct, and shall be construed in accordance with paragraphs (bb) and (cc),

and subsection 47(7) shall be construed accordingly,

(iii) subsection 47(8) of the Act shall not apply as respect those standard provisions; and

(iv) any standard provisions set out in Schedule 3 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.

### **Applications for wholesale dealer's licences made before 30<sup>th</sup> October 2005**

2.—(1) This paragraph applies where—

- (a) an application has been made to the licensing authority before 30th October 2005 for the grant or variation of a wholesale dealer's licence;
- (b) as at 30th October 2005 the licensing authority has not granted or refused the application; and
- (c) that application relates to the import from a third country of medicinal products.

(2) The application, insofar as it relates to import from a third country, shall be treated by the licensing authority as though it were an application for grant or variation of a manufacturer's licence in respect of the import from a third country of medicinal products.

### **Manufacturer's and wholesale dealer's licences granted before 30<sup>th</sup> October 2005**

3.—(1) This sub-paragraph applies where a manufacturer's or wholesale dealer's licence has been granted by the licensing authority pursuant to section 20 of the Act before 30th October 2005 and remains in force as at that date.

(2) Where sub-paragraph (1) applies and insofar as that licence relates to relevant medicinal products—

- (a) the standard provisions as respects such licences set out in Schedules 1, 2 3 and 4 to these Regulations insofar as they are applicable in each case to the licence shall, notwithstanding the provisions of section 47(4) of the Act, be incorporated into those licences with effect from 30th October 2005; and
- (b) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
  - (i) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
  - (ii) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (iii) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
  - (iii) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read

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- as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into the licence with such exceptions or modifications as may be specified in the application; and
- (iv) references to applications to the licensing authority to direct shall be construed in accordance with paragraphs (ii) and (iii),
- and subsection 47(7) shall be construed accordingly;
- (c) subsection 47(8) of the Act shall not apply as respect those standard provisions, and
- (d) any standard provisions set out in Schedule 2, 3 or 4 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.
- (3) Where sub-paragraph (1) applies and insofar as that licence relates to medicinal products which are not relevant medicinal products—
- (a) the standard provisions as respects such licences set out in Schedules 2, 3 and 4 of the Standard Provisions Regulations as amended by Part 2 of Schedule 5 to these Regulations shall, notwithstanding the provisions of section 47(4) of the Act, apply to such licences with effect from 30<sup>th</sup> October 2005.
- (b) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
- (i) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
- (ii) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (iii) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
- (iii) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into the licence with such exceptions or modifications as may be specified in the application; and
- (iv) references to applications to the licensing authority to direct shall be construed in accordance with paragraphs (ii) and (iii),
- and subsection 47(7) shall be construed accordingly; and
- (c) subsection 47(8) of the Act shall not apply as respect those standard provisions; and
- (d) any standard provisions set out in Schedule 2, 3 or 4 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement certain provisions of Directive [2004/27/EC](#) of the European Parliament and of the Council (“the 2004 Directive”) amending Directive [2001/83/EC](#) on the Community code for medicinal products for human use (“the 2001 Directive”), make changes to certain existing provisions which implement Directive [2001/83/EC](#) and make consequential amendments to various enactments.

These Regulations implement the requirements of the 2004 Directive insofar as they relate to the manufacture, assembly, importation and wholesale distribution of medicinal products to which those Directives apply (“relevant medicinal products”), and, as respects relevant medicinal products, replace the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, as amended, which implemented the requirements of the 2001 Directive as respects those matters.

Regulation 1 concerns citation, commencement and interpretation.

Regulation 2 imposes certain requirements on the holder of a manufacturer's licence granted pursuant to section 20 of the Medicines Act 1968 (“the Act”) in connection with the manufacture and assembly of relevant medicinal products.

Regulation 3 imposes certain requirements on the holder of such a licence in connection with the import of relevant medicinal products from outside the European Economic Area.

Regulation 4 makes provision as to qualified persons who are responsible under the terms of the Directives for carrying out certain functions in relation to the manufacture, assembly and import from outside the European Economic Area of relevant medicinal products.

Regulation 5 provides that it is an offence to supply starting materials for use in the manufacture of a relevant medicinal product (other than a relevant medicinal product to which section 1 of the Medicines for Human Use (Marketing Authorisations Etc. Regulations 1994 applies) where the starting materials have not been manufactured in accordance with the principles of good manufacturing practice.

Regulation 6 and Schedules 1 and 2 set out certain additional obligations which the licensing authority may impose on manufacturer's licence holders as “standard provisions” of their licences. Section 47 of the Act provides, save where the exceptions set out in that section of the Act apply, that “standard provisions” shall have effect as provisions of the licences granted pursuant to section 20 of the Act.

Regulation 7 and Schedule 3 provide that the licensing authority may impose additional standard provisions on the holders of manufacturer's licences which relate to vaccines, toxins and sera.

Regulations 8 – 10 impose certain requirements on the holder of a wholesale dealer's licence granted pursuant to section 20 of the Act.

Regulation 11 and Schedule 4 set out certain further obligations which the licensing authority may impose on wholesale dealer's licence holders as “standard provisions” of their licences.

Regulation 12 provides that certain parts of these Regulations shall have effect as though they were made in exercise of the new regulation making powers which are inserted into section 8 of the Act by regulation 14 and Schedule 5.

Regulations 13 and 14 and Schedule 5 make provision for revocations, and for consequential amendments to the Act and other enactments.

Regulation 15 and Schedule 6 make certain transitional provisions.

Regulatory Impact Assessments in relation to these Regulations, and a Transposition Note in relation to the implementation of the 2004 Directive, have been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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**Changes and effects yet to be applied to :**

- Sch. 2 para. 7(8) words revoked by [S.I. 2010/1882 reg. 10\(b\)\(i\)](#)
- Sch. 4 para. 3(8) words revoked by [S.I. 2010/1882 reg. 10\(b\)\(ii\)](#)
- Regulations revoked by [S.I. 2012/1916 Sch. 35](#)
- reg. 1(2) words substituted by [S.I. 2010/1882 reg. 10\(a\)](#)
- reg. 8(3) substituted by [S.I. 2009/1164 reg. 4](#)