

## 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

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of 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

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.

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.

## 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.



**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

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>(1)</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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<sup>(1)</sup> Section 8 was amended by S.I.1977/1050, 1992/604/ 1993/834, 2002/236 and 2004/1031.

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2. In section 14 of the Act (exemption for re-exports)(2), in subsection (2), for “a member State.”, substitute “an EEA State.”.
3. Section 20 of the Act (grant or refusal of licence)(3) 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.”.
- 4.—(1) Section 24 of the Act (duration and renewal of licence)(4) 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.”.
  - (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.”.
5. For section 30 of the Act (variation of licence on application of holder), substitute—

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

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

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

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

**30.**—(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>(5)</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—

- (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.”.

**6.** Section 49A of the Act is repealed.

**7.** After section 49 of the Act (postponement of restrictions in relation to export)—

### **“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 —

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(5) Section 24 was amended by S.I. 1977/1050, 1994/276, 2002/236 and 2005/1094.

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- (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)(6), for “subsection (1A), (1B), subsection (2) or subsection (3)”, substitute “subsection (1A), (1B), (2), (3) or (3A)”.
- 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,
    - (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;”; and
  - (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—

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(6) 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.

- “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—

#### “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.

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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 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 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

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(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;”;

(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—

"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.

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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);
  - (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(7), in regulation 3 (exemption for certain herbal remedies), in paragraph (2)(c)(ii), after “in respect of” insert “the manufacture or assembly of”.

## 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—

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(7) S.I. [1977/2130](#).

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- (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 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 30<sup>th</sup> 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 30<sup>th</sup> 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 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.

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- (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.