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) [M1], 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.".

Marginal Citations

M1 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) [M2], in subsection (2), for "a member State.", substitute " an EEA State. ".

Marginal Citations

M2 Section 14 was amended by S.I. 1993/834 and 2002/236.

3. Section 20 of the Act (grant or refusal of licence) [M3] 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

M3 Section 20 was amended by S.I. 1977/1050 and 2005/1094.

4.—(1) Section 24 of the Act (duration and renewal of licence) [M4] 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.".

Marginal Citations

M4 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 [M5] 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.".

Marginal Citations

M5 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) [M6], for "subsection (1A), (1B), subsection (2) or subsection (3)", substitute " subsection (1A), (1B), (2), (3) or (3A) ".

Marginal Citations

M6 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,

(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—

"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.

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

(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.

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 [M7], 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

M7 S.I. 1977/2130.

Status:
Point in time view as at 30/10/2005.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.