SCHEDULE 5

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)(**1**), 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.".

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

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

(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—

"**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

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

(e) if there is a requirement in force under section 1(1)(a) of the Medicines Act 1971(**5**) 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 —

(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

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

(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".

(**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.