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

(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.