SCHEDULES

SCHEDULE 4

Standard provisions of licences under Part 3

PART 4

Wholesale dealer's licence

All wholesale dealer's licences

28. The provisions of this Part are standard provisions of a wholesale dealer's licence.

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

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

31. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided by the licence holder to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product which the licence holder handles, stores or distributes is not false or misleading.

Wholesale dealer's licence relating to special medicinal products

32. The provisions of paragraphs 33 to 42 are incorporated as additional standard provisions of a wholesale dealer's licence relating to special medicinal products.

33. Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from another EEA State—

(a) in response to an order which satisfies the requirements of regulation 167, and

(b) where the conditions set out in paragraphs 34 to 41 are complied with.

34. No later than 28 days prior to each importation of a special medicinal product, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name 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 any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in paragraph 38; and

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

35. The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in paragraph 34, the licensing authority has notified the licence holder in writing that the product should not be imported.

36. The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in paragraph 35, that the product may be imported.

37. Where the licence holder sells or supplies special medicinal products, the licence holder must, in addition to any other records which are required by the provisions of the licence, 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 sold or supplied of which the licence holder becomes aware.

38. The licence holder must not, on any one occasion, import more 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 must not, on any one occasion, import more than the quantity notified to the licensing authority under paragraph 34(d).

39. The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

40. The licence holder must not publish any advertisement, catalogue, or circular relating to a special medicinal product or make any representations in respect of that product.

41. The licence holder must cease importing or supplying a special medicinal product if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

42. In this Part—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia- lists of names);

"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 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.

Wholesale dealer's licence relating to exempt advanced therapy medicinal products

43. The provisions of paragraph 44 are incorporated as additional standard provisions of a wholesale dealer's licence relating to exempt advanced therapy medicinal products.

44. The licence holder shall keep the data referred to in paragraph 16 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.