Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations

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MEDICINES ACT
(CHAPTER 176, SECTION 74)

MEDICINES (VETERINARY MEDICINAL PRODUCTS) (IMPORT AND PRODUCT LICENCES) REGULATIONS

Rg 1

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Citation

1. These Regulations may be cited as the Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations.

Definition

2. In these Regulations, unless the context otherwise requires, "importer" means an importer of veterinary medicinal products.

Period of validity of product licences

3.—(1) A product licence (other than a provisional product licence) shall be granted for a period of 5 years or any shorter period as the licensing authority may determine.

(2) A provisional product licence shall be granted for a period of 2 years or any shorter period as the licensing authority may determine.

Period of validity of import licence

4.—(1) Every import licence shall be valid only in respect of one consignment of veterinary medicinal products for which the application for a licence to import has been made.

(2) Such licence shall be in force for a period of one month from the date of issue thereof.

Application for licence

5.—(1) Any application for the grant of a product licence or provisional product licence shall be made to the licensing authority in such form and manner and be

accompanied by such information, documents, samples and other material as may be required by the licensing authority.

(2) A person applying for a product licence or provisional product licence shall furnish to the licensing authority a separate application in respect of each veterinary medicinal product.

(3) A single application for a product licence or provisional product licence may be made in respect of 2 or more veterinary medicinal products which have the same pharmaceutical form and consist of —

(*a*) a single active constituent in different strengths; or

(*b*) a mixture of 2 or more active constituents of different strengths but in the same proportion.

Submission of other particulars

6. A person applying for a product licence or provisional product licence shall submit such particulars of the veterinary medicinal product as the licensing authority may require including particulars relating to —

(*a*) chemical, pharmaceutical, experimental and biological studies carried out in respect of the veterinary medicinal product;

(*b*) animal tests and studies carried out on the veterinary medicinal product;

(*c*) possible hazards of the veterinary medicinal product to man, livestock and wild life; and

(*d*) precautions or contra-indications in the use of the veterinary medicinal product.

Changes in particulars

7. The holder of a product licence or provisional product licence shall forthwith inform the licensing authority of any material change that has been made or that he proposes to make in the particulars contained in his application, in relation to any veterinary medicinal product to which the licence relates, that is to say —

(*a*) in the specification of the veterinary medicinal product;

(*b*) in the specification of any of the constituents of the veterinary medicinal product;

(*c*) in the composition of the veterinary medicinal product, or of any of the constituents of the veterinary medicinal product; and

(*d*) in the methods and procedures described in the application for ensuring