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

G.N. No. S 145/1977

REVISED EDITION 2000

(31st January 2000)

[24th June 1977]

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

compliance with the specifications relating to the product.

Further information

8. The holder of a product licence or provisional product licence shall forthwith inform the licensing authority of any information received by him that casts doubt on the continued validity of the data submitted in connection with the application for the product licence or provisional product licence for the purpose of being taken into account in assessing the safety, quality or efficacy of the veterinary medicinal product to which the licence relates.

Information on adverse effects of product

9.—(1) The holder of a product licence or provisional product licence shall inform the licensing authority of any reports of which he is aware of adverse effects on human beings or animals, or both, associated with the use of any veterinary medicinal or any of the constituents of the veterinary medicinal product to which the licence relates.

(2) The licensing authority may require the holder of a product licence or provisional product licence to furnish him with a copy of any such reports.

Notification of withdrawal from sale

10. The holder of a product licence or provisional product licence shall notify the licensing authority forthwith of any decision to withdraw from sale, supply or exportation any veterinary medicinal product to which the licence relates, and shall state the reason for that decision.

Records

11.—(1) An importer shall keep readily available for inspection by the licensing authority records of his imports and distribution of veterinary medicinal products and shall when directed by him submit such records to him.

(2) The records shall not be destroyed for a period of 5 years from the date of the importation of the veterinary medicinal products and the importer shall keep such records as will facilitate the withholding from sale, supply or exportation of any veterinary medicinal products.

Substandard veterinary medicinal product

12. Where any veterinary medicinal product is suspected or 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 any regulations made thereunder, the licensing authority may direct the importer or any person in possession of any veterinary medicinal product

to withhold such product from sale, supply or exportation for such period as may be specified by him.

Fees

13. The fees for licences granted by the licensing authority shall be as follows:

(*a*)	an import licence	$3 per consignment;
(*b*)	a product licence	$50 per product; and
(*c*)	a provisional product licence	$25 per product.

Penalty

14. Any person who contravenes or fails to comply with regulation 7, 8, 9, 10 or 11, or who fails to comply with any direction of the licensing authority under regulation 12, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $2,000.

[G.N. No. S 145/77]

LEGISLATIVE HISTORY

MEDICINES (VETERINARY MEDICINAL PRODUCTS) (IMPORT AND PRODUCT LICENCES) REGULATIONS (CHAPTER 176, RG 1)

This Legislative History is provided for the convenience of users of the Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations. It is not part of these Regulations.

1. G. N. No. S 145/1977—Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations 1977

Date of commencement : 24 June 1977

2. 1990 Revised Edition—Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations

Date of operation : 25 March 1992

3. 2000 Revised Edition—Medicines (Veterinary Medicinal Products) (Import and Product Licences) Regulations

Date of operation : 31 January 2000