EUROPEAN COMMUNITIES (VETERINARY MEDICINAL PRODUCTS) REGULATIONS 1986

The Minister for Health, in exercise of the powers conferred on him by section 3 of the European Communities Act, 1972 (No. 27 of 1972), hereby makes the following Regulations:

REG 1

1. These Regulations may be cited as the European communities (Veterinary Medicinal Products) Regulations, 1986.

REG 2

2. (1) In these Regulations—
"the Council Directive" means Council Directive 81/851/EEC1.
"a product authorisation" means an authorisation to market a veterinary medicinal product.
(2) In these Regulations words and phrases shall have the same meanings as in the Council Directive.

REG 3

3. The competent authority in the State for the purpose of the Council Directive shall be the National Drugs Advisory Board.

REG 4

4. The competent authority may, where it considers it appropriate, exempt from the provisions of the Regulations veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents in pursuance of article 3 of the Council Directive, provided that the conditions for so doing, as set out in the said article 3 are satisfied.

REG 5

5. (1) A person shall not place on the market a veterinary medicinal product, coming on the market for the first time on or after the 1st day of January, 1987, save in accordance with the provisions of the Council Directive and with a product authorisation granted or renewed by the competent authority.
1Official Journal of the European Communities, No. L317 6/11/81 (Pages 1-15).
(2) On and after the date specified in the second column of the Schedule to these Regulations opposite the mention of a class of veterinary medicinal products in the first column of the Schedule a person shall not place on the market a veterinary medicinal product of that class save in accordance with the provisions of the Council Directive and with a product authorisation granted or renewed by the competent authority.
(3) An application for a product authorisation for a veterinary medicinal product of a class of veterinary medicinal products in the first column of the Schedule to these Regulations shall be made to

the competent authority at least twelve months before the date specified in the second column of the Schedule opposite the mention of the class.

REG 6

6. (1) The competent authority may grant or renew a product authorisation to any person who applies for such authorisation in accordance with article 7.
(2) Unless sooner withdrawn by the competent authority, a product authorisation shall remain in force for a period of five years and may be renewed on application by the holder.

REG 7

7. (1) An application for a product authorisation shall be made to the competent authority and the application shall—
(a) be in such form as the competent authority may require and be accompanied by the appropriate fee required under article 14 of these Regulations and by the particulars and documents specified in article 5 of the Council Directive, and
(b) where the documents and particulars relate to matters referred to in points 8, 9 or 10 of article 5 of the Council Directive, be drafted and signed by experts with the requisite technical or professional qualifications.
(2) Prior to an application for a product authorisation the requirements of Council Directive 81/852/EEC2 relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of the veterinary medicinal product shall have been complied with.
2 Official Journal of the European Communities, No. L317 6/11/81 (pages 16-28).

REG 8

8. In the examination and determination of an application for a product authorisation the competent authority shall take into consideration such criteria as appear to it to be relevant to the provisions of the Council Directive and, in particular, the information supplied by the applicant in relation to—
(a) the quality, safety and efficacy of the veterinary medicinal product to which the application relates,
(b) the proposed sales presentation, labelling and, where appropriate, package inserts of the veterinary medicinal product.

REG 9

9. (1) with effect from the 1st day of January, 1987, a person shall not manufacture any veterinary medicinal product in the State or import a veterinary medicinal product from a country other than a Member State of the European Economic Community except in accordance with the provisions of the Council Directive and with an authorisation, referred to in these Regulations as a "manufacturer's licence", granted or renewed by the competent authority.
(2) An applicant for a manufacturer's licence shall apply to the

competent authority in the form and manner prescribed by the competent authority and shall satisfy the competent authority that the requirements of the Council Directive as regards the manufacture of veterinary medicinal products are complied with.
(3) Unless sooner withdrawn by the competent authority, a manufacturer's licence shall remain in force for a period of three years and may be renewed on application by the holder.

REG 10

10. The competent authority may refuse an application for a product authorisation or an application for a manufacturer's licence where it considers that the requirements of the Council Directive have not been complied with in relation to that application.

REG 11

11. (1) The competent authority may suspend or withdraw a product authorisation or a manufacturer's licence where it considers that the requirements of the Council Directive have not been complied with in relation to that authorisation or licence.
(2) Where the competent authority suspends a product authorisation or a manufacturer's licence the authorisation or the licence shall be regarded as being withdrawn for the period of such suspension.

REG 12

12. As respects a veterinary medicinal product for which a product authorisation has been granted or renewed under these Regulations—
(a) the provisions of section 5 (1) of the Animal Remedies Act, 1956 (No. 41 of 1965) shall not apply and
(b) the reference in section 5 (2) of the Animal Remedies Act, 1956 to the particulars specified in section 5(1) thereof shall be construed as a reference to the labelling requirements of Chapter VII of the Council Directive.

REG 13

13. (1) Where a product authorisation is required under these Regulations for a veterinary medicinal product, such product shall not be administered to an animal unless a product authorisation has been issued in respect of that product.
(2) The provisions of sub-article (1) of this article shall not apply in respect of tests of veterinary medicinal products referred to in point 10 of article 5 of the Council Directive.

REG 14

14. A fee shall be paid to the competent authority in respect of an application for a product authorisation or a manufacturer's licence made pursuant to these Regulations in accordance with such scales as the Minister for Health, with the consent of the Minister for Finance, may from time to time determine.

REG 15

15. A person who contravenes article 5, article 9 or article 13 of these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1.000 and, in the case of a continuing offence, to a further fine not exceeding £100 for each day on which the offence is continued.

REG 16

16. These Regulations may be enforced and executed by the competent authority, by officers of the Minister for Health and by such other persons or class of persons as the Minister for Health may by order authorise in that behalf.

SCHEDULE.

Class of Veterinary Medicinal ProductSpecified DateProducts of the following classes on the market before 1 January, 1987(a) Oestrogenic, androgenic and gestagenic hormones; anabolic agents; Penicillins(a) 1 October, 1987(b) Cephalosporins and other antiinfectives(b) 1 October, 1988(c) Corticosteroids and other hormones; Autocoids; Anthelmintics: Antifungals; Anti-parasitics; Metabolic and haematinic drugs(c) 1 October, 1989(d) Substances affecting the central nervous system, including anaesthetics, tranquillisers, stimulants, and analgesics; Anti-inflammatory agents; Diuretics and substances acting on the cardiovascular system(d) 1 October, 1990(e) Substances acting locally i.e. on skin, eye, ear, nasopharynx, gastrointestinal tract, etc. Diagnostic agents(e) 1 October, 1991(f) Miscellaneous not included above(f) 1 October, 1991

GIVEN under the Official Seal of the Minister for Health this 28th day of January, 1986.

BARRY DESMOND,
Minister for Health.

EXPLANATORY NOTE.

The purpose of these Regulations is to give statutory effect in this country to the requirements of the two EEC Directives relating to veterinary medicinal products referred to in the Regulations.
The principal effects of these Regulations are:
(i) to require that a person shall not place a new veterinary medicinal product on the market on or after 1 January, 1987 save in accordance with the provisions of EEC Council Directive 81/851/EEC and with a product authorisation granted or renewed by the National Drugs Advisory Board which has been designated the competent authority for the purpose of these Regulations;
(ii) to require that a person shall not manufacture a veterinary medicinal product or import such a product from a country other than a Member State of the EEC save in accordance with EEC Council Directive 81/851/EEC and with a manufacturer's licence granted or renewed by the National Drugs Advisory Board; and
(iii) to require the progressive application of the Directives to

veterinary medicinal products which were on the market prior to 1 January, 1987.