STATUTORY INSTRUMENTS

1997 No. 322

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

PART I

GENERAL

Title and commencement

1. These Regulations may be cited as the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 and shall come into force on 31st March 1997.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**1**);

"Article 24 authorisation" means an authorisation of the type specified in Article 24.1 of Directive 81/851;

"Article 8 documents" means the particulars and documents specified in Article 8 of the Homoeopathics Directive;

"Article 8 dossier" means the Article 8 documents on which a registration relating to a product is based, and—

(a) where the registration relating to a product has been renewed in accordance with regulation 7, the expression shall mean the Article 8 documents as updated by the Article 15 dossier provided in connection with the renewal application, and

(b) where the documents have been altered in accordance with regulation 8, the expression shall mean the Article 8 documents as so altered;

"Article 15 dossier" means a dossier of the type specified in Article 15.1 of Directive 81/851;

"Article 11 ground" means a ground specified in—

(a) sub-paragraph 1 or 3 of the first paragraph, or

(b) the second paragraph,

of Article 11 of Directive 81/851;

"Article 25 particulars" means particulars which meet the requirements of sub-paragraphs (a) to (c) of Article 25 of Directive 81/851, and—

(a) where an Article 24 authorisation has been issued, it shall mean the Article 25 particulars on which such authorisation is based, and

(**1**) 1968 c. 67.

(b) where, following the issue of an Article 24 authorisation, an Article 25 particular is changed in accordance with regulation 15, it shall mean the Article 25 particulars as so changed;

"the Board" means the Advisory Board on the Registration of Homoeopathic Products established by the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995(**2**);

"the Commission" means the Medicines Commission established by the Act;

"Directive 91/851" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**3**) as amended by Council Directives 90/676/EEC(**4**) and 93/40/EEC(**5**) as widened by the Homoeopathics Directive(**6**) and as adapted by the EEA Agreement;

"Directive 91/412" means Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**7**);

"EEA Agreement" means the Agreement on the European Economic Area(**8**) signed at Oporto on 2nd May 1993 as adjusted by the Protocol(**9**) signed at Brussels on 17th March 1993 and as amended by the Decision of the EEA Joint Committee No 7/94(**10**);

"EEA State" means a State which is a contracting party to the EEA Agreement other than the United Kingdom;

"the Homoeopathics Directive" means Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products(**11**) as adapted by the EEA Agreement;

"homoeopathic veterinary medicinal product" has the meaning given by Article 1 of the Homoeopathics Directive;

"manufacture" includes the activities specified in the first paragraph of Article 24.2 of Directive 81/851 but does not include the activities specified in the second paragraph of that provision;

"the Ministers" means the Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England and the Secretaries of State for Wales and Scotland, the Department of Agriculture for Northern Ireland and the Department of Health and Social Services for Northern Ireland;

"notice" means notice in writing;

"product" means a product to which these Regulations apply by virtue of regulation 3(1);

"qualified person" means a person, other than a person in respect of whom a suspension notice served under regulation 27(4) is in force, who—

(a) fulfils the conditions laid down in Article 31 of Directive 81/851, or

(b) is eligible to act as a qualified person by virtue of Article 32 of that Directive;

(**2**) S.I.1995/309.
(**3**) OJNo. L317, 6.11.81, p. 1.
(**4**) OJ No. L373, 31.12.90, p. 15.
(**5**) OJ No. L214, 24.8.93, p. 31.
(**6**) OJ No. L297, 13.10.92, p. 12.
(**7**) OJ No. L228, 17.8.91, p. 70.
(**8**) OJ No. L1, 3.1.94, p. 3.
(**9**) OJ No. L1, 3.1.94, p. 572.
(**10**) OJ No. L160, 28.6.94, p. 1.
(**11**) OJ No. L297, 13.10.92, p. 12.

"registered" means registered by the Ministers under these Regulations; and

"the relevant enforcement authority" means—

(a) in relation to England, the Minister of Agriculture, Fisheries and Food,

(b) in relation to Scotland and Wales, the Secretary of State, and

(c) in relation to Northern Ireland, the Department of Health and Social Services for Northern Ireland.

(2) The expressions listed in Part I of Schedule 1 have the same meaning as in the Homoepathics Directive, and any other expression which is used in these Regulations and the Homoeopathics Directive, other than an expression which is listed in Part II of Schedule 1, shall have, insofar as the context admits, the same meaning as in that Directive.

(3) The expressions listed in Part II of Schedule 1 have the same meaning as in Directive 81/851.

(4) Any reference in these Regulations to a provision of Directive 81/851 shall mean the specified provision of that Directive as such provision applies to a product by virtue of Article 3, 4 or 7.3 of the Homoeopathics Directive.

(5) Any function conferred on the Ministers under these Regulations may be performed by any one of those Ministers acting alone or by any two or more of them acting jointly.

(6) In these Regulations, unless the context otherwise requires—

(a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation of or the Schedule to these Regulations so numbered in these Regulations,

(b) any reference in a regulation or a Schedule to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which the reference occurs, and

(c) any reference in a paragraph to a numbered or lettered sub-paragraph is a reference to the sub-paragraph so numbered or lettered in the paragraph in which the reference occurs.

Homoeopathic veterinary medicinal products to which these Regulations apply

3.—(1) Subject to paragraph (2), these Regulations apply to homoeopathic veterinary medicinal products to which the provisions of the Homoeopathics Directive apply and which satisfy all of the conditions specified in Article 7.1 of that Directive.

(2) These Regulations do not apply to homoeopathic veterinary medicinal products that were marketed in the United Kingdom for the first time before 31st March 1997.