STATUTORY INSTRUMENTS

1997 No. 322

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

PART II

REGISTRATION OF PRODUCTS

Applications for registration

4.—(1) A person responsible for marketing, or intending to market a product, may apply to the Ministers to register the product.

(2) An application made under paragraph (1) shall be made in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by the Article 8 documents relating to the product.

(3) The application may relate to a series of products derived from the same homoeopathic stock or stocks.

Examination of registration applications

5. Where an application is made under regulation 4, the Ministers shall examine it—

(a) in accordance with the criteria and rules of procedure relating to such applications specified in Articles 8 to 12 of Directive 81/851, with the exception, in the case of Article 11, of the proof of therapeutic effect, and

(b) taking account of the matters specified in Article 6.1 of the Homoeopathics Directive.

Registration of products

6.—(1) Subject to regulations 11 and 12, following the examination of an application to register a product pursuant to regulation 5, the Ministers shall register it in accordance with the provisions of Article 15 of Directive 81/851 unless, in their opinion, an Article 11 ground has been established in connection with that product or application.

(2) On registering a product the Ministers shall—

(a) give it a registration number,

(b) determine whether there is a need to exercise or further exercise the powers conferred by section 51, 57 or 58 of the Act concerning the conditions as to the sale or supply of the product, and

(c) publish details of the registration in accordance with the provisions in the second paragraph of Article 40 of Directive 81/851.

(3) Where the Ministers refuse to register a product, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Renewal of registrations

7.—(1) The registration of a product may be renewed on the application of the person responsible for marketing it.

(2) An application under paragraph (1) shall be made to the Ministers at least three months before the expiry of the registration relating to the product and shall be accompanied by an Article 15 dossier relating to it.

(3) Subject to regulations 11 and 12, following the examination of the application, the Ministers shall renew the registration unless, in their opinion, an Article 11 ground has been established in connection with the product.

(4) Where the Ministers refuse to renew a registration, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Alteration of Article 8 dossiers relating to registered products

8.—(1) An application for authorisation to make an alteration to an Article 8 dossier relating to a registered product may be made to the Ministers by the person responsible for marketing the product and shall be accompanied by full details of the proposed alteration.

(2) Where an application is made under paragraph (1), the Ministers shall authorise the proposed alteration unless, in their opinion, the making of the alteration would result in an Article 11 ground being established in connection with that product.

(3) Where the Ministers authorise a proposed alteration of an Article 8 dossier, they shall make any necessary amendments to the registration.

Suspension and revocation of registrations

9.—(1) Subject to paragraph (3) and regulations 11 and 12, the Ministers shall suspend or revoke the registration of a registered product if in their opinion a ground specified in sub-paragraph 1 or 3 of the first paragraph of Article 36 of Directive 81/851 has been established in connection with the product.

(2) Subject to paragraph (3), the Ministers may suspend or revoke the registration of a registered product if in their opinion a ground specified in the last paragraph of Article 36 of Directive 81/851 has been established in connection with the product.

(3) Where the Ministers suspend or revoke the registration of a registered product under paragraph (1) or (2), they shall notify the person responsible for marketing the product in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851 and shall comply with the publication requirements of the second paragraph thereof.

Prohibition and withdrawal notices

10.—(1) Subject to the paragraph (2) and to regulations 11 and 12, if in the opinion of the Ministers a ground specified in paragraph (a), (c) or (e) of Article 37.1 of Directive 81/851 has been established in connection with a product they shall serve a notice on the person responsible for marketing the product requiring that person to stop supplying the product and to withdraw it from the market.

(2) A notice served under paragraph (1) may relate to the registered product in general or to a specific batch of the product as specified in the notice.

Procedure where the Ministers propose to take certain action on grounds relating to safety or quality

11.—(1) Subject to paragraph (2), if the Ministers propose—

(a) to refuse a registration;

(b) to refuse to renew a registration;

(c) to suspend or revoke a registration; or

(d) to serve a notice under regulation 10(1) in respect of a product;

on a ground that concerns the safety or quality of the product in question, the provisions of Schedule 2 shall have effect.

(2) The provisions of paragraph (1) shall not apply where the Ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in sub-paragraph 3 of the first paragraph of Article 11 of Directive 81/851.

Procedure where the Ministers propose to take certain action on grounds other than grounds relating to safety or quality

12.—(1) Subject to paragraph (2), if the Ministers propose to act in a manner specified in sub-paragraphs (a), (b), (c) or (d) of regulation 11(1) on a ground that does not concern the safety or quality of the product, the provisions of Schedule 3 shall have effect.

(2) The provisions of paragraph (1) shall not apply where the Ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in sub-paragraph 3 of the first paragraph of Article 11 of Directive 81/851.