STATUTORY INSTRUMENTS

1997 No. 322

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

PART III

ARTICLE 24 AUTHORISATIONS

Applications for Article 24 authorisations

13.—(1) A person who—

(a) manufactures or intends to manufacture a registered product, or

(b) imports or intends to import such a product from a third country,

may apply to the Ministers for an Article 24 authorisation relating to the manufacture or import, as the case may be.

(2) An application made under paragraph (1) shall be 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 Article 25 particulars.

Issue of Article 24 authorisations

14.—(1) Subject to regulation 17, following inquiry in accordance with Article 26.1 of Directive 81/851, the Ministers shall issue an applicant with an Article 24 authorisation in accordance with the provisions of Article 26.2 and 3 and Article 28.1 and 3 of that Directive unless they are not satisfied that the accuracy of the Article 25 particulars provided by the applicant has been established.

(2) Where the Ministers refuse to issue an Article 24 authorisation, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Change of Article 25 particulars

15.—(1) A request to change an Article 25 particular on which an Article 24 authorisation is based may be made to the Ministers by the holder of the authorisation.

(2) Where a request is made under paragraph (1), the Ministers shall authorise the change in the Article 25 particulars in accordance with the provisions of Article 28.2 and 3 of Directive 81/851 unless they are not satisfied that the authorisation holder will continue to meet the relevant requirements of Article 25 of Directive 81/851 if the change in the Article 25 particulars is made.

(3) Where, pursuant to paragraph (2), the Ministers authorise a change in the Article 25 particulars, they shall make any necessary amendments to the Article 24 authorisation in question.

Suspension and revocation of Article 24 authorisations

16.—(1) Subject to paragraph (3) and regulation 17, the Ministers shall suspend or revoke an Article 24 authorisation if they are not satisfied that the authorisation holder is complying with the Article 25 particulars on which the authorisation is based.

(2) Subject to paragraph (3), the Ministers may suspend or revoke an Article 24 authorisation—

(a) in relation to all registered products to which the authorisation relates, or

(b) in relation to one or some of such products,

if they are not satisfied that the holder of such authorisation has complied with the duties imposed on him by regulation 25.

(3) Where, pursuant to paragraph (1) or (2), the Ministers suspend or revoke an Article 24 authorisation they shall notify the authorisation holder in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Procedure where the Ministers propose to refuse Article 24 authorisations or to suspend or revoke such authorisations

17. If the Ministers propose to refuse to issue or to suspend or revoke an Article 24 authorisation the provisions of Schedule 4 shall have effect.