STATUTORY INSTRUMENTS

1994 No. 105

The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

PART II

CERTIFICATES OF REGISTRATION

Application for certificate

4.—(1) An application for a certificate of registration shall be made in writing to the licensing authority and shall be accompanied by the material and information specified in Schedule 1 to these Regulations.

(2) An application for such a certificate may relate to a series of homoeopathic medicinal products derived from the same homoeopathic stock or stocks.

Determination of application for certificate

5.—(1) In dealing with an application for a certificate of registration, the licensing authority shall, in respect of any product to which the application relates, take due account of any registration granted by any member State other than the United Kingdom in accordance with Article 7 of Council Directive 92/73/EEC and of any authorisation granted by any such member State in accordance with Article 9 of that Directive.

(2) On an application for a certificate of registration, the licensing authority may grant such a certificate, but shall, subject to paragraph (3) below, refuse to grant such a certificate where—

(a) the product is not for oral or external administration;

(b) a specific therapeutic indication appears on the labelling of the product or in any information relating thereto;

(c) the product does not have a sufficient degree of dilution to guarantee its safety;

(d) after verification of the material and information submitted in accordance with regulation 4(1) of these Regulations, the product proves to be harmful in the normal conditions of use, or the qualitative or quantitative composition of the product is not as declared; or

(e) the application does not comply with regulation 4(1) of these Regulations.

(3) Products shall not be considered to have a sufficient degree of dilution to guarantee their safety where they contain more than —

(a) one part per 10,000 of the mother tincture; or

(b) one hundredth of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product would require it to be sold by retail or supplied in circumstances corresponding to retail sale in accordance with a prescription given by a doctor.

(4) The licensing authority shall not refuse to grant a certificate of registration on the ground set out in paragraph (2)(c) or (d) above except after consultation with the Board.

(5) Subject to paragraph (6) below, the licensing authority shall take all appropriate measures to ensure that the procedure for determining an application for a certificate of registration is completed within 120 days of the date of submission of the application by the applicant.

(6) The time limit referred to in paragraph (5) above may be extended for a further 90 days where the applicant is notified that the time is to be so extended, in writing, prior to the expiry of that time limit.

Grant of a certificate

6. Where a certificate of registration is granted—

(a) the appropriate Ministers shall determine which, if any, of their powers under sections 51(1) (general sale lists) and 58(1) (medicinal products on prescription only) of the Act they propose to exercise in respect of that product; and

(b) the licensing authority shall publish the decision to grant the certificate in the Gazette.

Requirements in respect of controls

7. The holder of a certificate of registration shall be responsible for furnishing to the licensing authority, on request, details of controls carried out on the finished product and, where applicable, on the ingredients of that product and of the controls carried out at an intermediate stage of the manufacturing process, in each case in accordance with the methods notified to the licensing authority at the time the certificate was applied for.

Duration and renewal of certificates

8.—(1) A certificate of registration shall, unless previously revoked, expire at the end of the period of five years beginning with the date on which it was granted or the date from which it was last renewed, as the case may be.

(2) A certificate which has not been revoked may, on the application of the holder of the certificate, be renewed by the licensing authority for five years from the date on which it would otherwise expire.

(3) An application for renewal of a certificate shall be made, in writing, no later than three months before the date of expiry of that certificate.

(4) The provisions of regulation 5 of these Regulations shall apply in relation to applications for the renewal of certificates of registration as they apply to applications for such certificates and any reference in that regulation to the grant of or the refusal to grant a certificate shall be construed as a reference to its renewal or to a refusal to renew it, as the case may be.

Suspension and revocation

9.—(1) Subject to paragraph (2) below, the licensing authority shall suspend a certificate of registration for such period as it may determine, or shall revoke a certificate, where —

(a) the product to which the certificate relates proves to be harmful in the normal conditions of use;

(b) the qualitative or quantitative composition of such product is not as declared; or

(c) any of the material or information provided in accordance with regulation 4(1) of these Regulations proves to be incorrect.

(2) Except in the interests of safety, where the licensing authority propose to suspend a certificate of registration with immediate effect, they shall not do so on the ground set out in paragraph (1)(a) or (b) above, except after consultation with the Board.

(3) The licensing authority shall publish any decision to revoke a certificate of registration in the Gazette.

Withdrawal from the market

10.—(1) Subject to paragraph (3) below, the holder of a certificate of registration shall withdraw from the market all products to which that certificate relates within the time and for the period specified in any written notice issued by the licensing authority for the purpose of this regulation.

(2) A notice referred to in paragraph (1) above may be issued on one or more of the following grounds—

(a) that the product to which the certificate relates proves to be harmful in the normal conditions of use;

(b) that the qualitative and quantitative composition of the product is not as declared;

(c) that details of the controls referred to in regulation 7 of these Regulations have not been furnished to the licensing authority pursuant to a request under that regulation; or

(d) that a requirement or obligation upon the holder of a manufacturer's licence or upon the holder of a manufacturing authorisation granted by the competent authority of a member State other than the United Kingdom relating to the product or, where the product has been imported, but was not consigned from a member State, a requirement or obligation on the holder of a wholesale dealer's licence, has not been met.

(3) The licensing authority may order the holder of the certificate of registration to withdraw from the market specified batches only of a product to which a notice under paragraph (1) above applies.

(4) A notice under paragraph (1) above shall be served on the holder of the relevant certificate and shall specify the grounds for the issue of the notice.

Variation of certificates

11. The licensing authority may, on the application of the holder of a certificate of registration, vary the provisions of the certificate in accordance with any proposals contained in the application which relate to a change to the certificate which does not require, in their opinion, medical, scientific or pharmaceutical assessment.