STATUTORY INSTRUMENTS

# 2012 No. 1916

# The Human Medicines Regulations 2012

## PART 6

## Certification of homoeopathic medicinal products

*Application for certificate of registration and consideration of application*

**Application for certificate of registration**

**103.**—(1) The licensing authority may, subject to regulation 104, grant an application for a certificate of registration for a registrable homoeopathic medicinal product in response to an application made in accordance with this Part.

(2) A certificate granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The application may relate to two or more homoeopathic medicinal products derived from the same homoeopathic stock or the same combination of homoeopathic stocks.

(4) The applicant must be established in the European Union.

(5) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(6) An application is treated as signed for the purposes of paragraph (5)(b) if it is signed with an electronic signature.

(7) The application and any accompanying material must be in English.

(8) The applicant must provide each of the following for each product to which the application relates—

(a) a statement of the scientific name, or other name given in a pharmacopoeia, of the homoeopathic stock or stocks from which the product is derived;

(b) a statement of the routes of administration, pharmaceutical forms and degree of dilution of the product;

(c) a dossier describing how the homoeopathic stock or stocks are obtained and controlled and justifying their homoeopathic use on the basis of an adequate bibliography;

(d) a manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation of the product;

(e) evidence that each manufacturer of the medicinal product is authorised to manufacture it (which, in the case of a product manufactured in the United Kingdom or another EEA

State, means the manufacturer's licence or (as the case may be) its equivalent in that EEA State);

(f) where an authorisation to place the product on the market has been granted by another member State, a copy of the authorisation;

(g) a mock-up of the outer and immediate packaging of the product; and

(h) data concerning the stability of the product.

(9) This material, taken as a whole, must be such as to demonstrate the pharmaceutical quality and batch to batch homogeneity of each product to which the application relates.

(10) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

**Consideration of application**

**104.**—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration before the end of the period of 210 days beginning immediately after the day on which an application for the certificate is submitted in accordance with regulation 103.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the information or material is provided.

(3) The licensing authority may grant a certificate only if, having considered the application and the accompanying material, the authority thinks that—

(a) the risks to the health of patients or of the public associated with the product do not outweigh any beneficial effects of the homoeopathic medicinal product in question;

(b) the application and the accompanying material complies with regulation 103; and

(c) the product's qualitative or quantitative composition is as described in the application and the accompanying material.

(4) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a certificate of registration.

(5) This regulation does not apply to an application that—

(a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or

(b) has been referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(6) An application to which paragraph (5) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

**Conditions of certificate of registration**

**105.**—(1) The licensing authority may—

(a) grant a certificate of registration subject to conditions; or

(b) vary or remove a condition to which the certificate of registration is subject.

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the certificate or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—

(a) in exceptional circumstances; and

(b) when the applicant can show that the applicant is unable to provide comprehensive data on the safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the certificate relates.

(6) The conditions may, in particular, require that, where there is an incident relating to the use of the product—

(a) the incident must be reported to the licensing authority; and

(b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

(a) the conditions to which a certificate of registration is subject; and

(b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

(a) at the end of the period of one year beginning with the date on which the certificate was granted; and

(b) at the end of each subsequent period of one year.

(9) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a certificate of registration is subject.

**Classification of certificate of registration**

**106.**—(1) A certificate of registration must include a term that the product to which the certificate relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

(2) A certificate of registration may include a term that the product to which the certificate relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

**Validity of certificate of registration**

**107.**—(1) Subject to the following paragraphs, a certificate of registration remains in force—

(a) for an initial period of five years beginning with the date on which it is granted; and

(b) if the authorisation is renewed under regulation 108 for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of a certificate, determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the certificate remains in force—

(a) for a further period of five years beginning with the date on which it is first renewed; and

(b) if the authorisation is further renewed under regulation 108 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a certificate is made in accordance with regulation 108 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

(a) regulation 109 (failure to place on the market etc); and

(b) regulation 110 (revocation etc of certificate of registration).

### Application for renewal of certificate

**108.**—(1) An application for the renewal of a certificate of registration must be made to the licensing authority.

(2) The applicant must be established in the European Union.

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (as the case may be) (3)(a) of regulation 107 (initial and further period of validity).

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy (including all amendments made since the authorisation was granted).

(7) The licensing authority may renew a certificate only if, having considered the application and the material accompanying it, the authority thinks that the risks to the health of patients or of the public associated with the homoeopathic medicinal product to which the certificate relates do not outweigh any beneficial effects of the product.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a certificate of registration.

### Failure to place on the market etc

**109.**—(1) A certificate of registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom during the period of three years beginning immediately after the day on which it was granted.

(2) A certificate of registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

(a) in response to an application in writing by the holder of the certificate of registration; or

(b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

(a) in exceptional circumstances; and

(b) on public health grounds.

(6) An exemption—

(a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and

(b) may be renewed or further renewed.