STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

Consideration of application

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130.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration before the end of the period of 210 days beginning immediately after the day on which an application for the registration is submitted in accordance with regulation 128.

(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) If the licensing authority requests the applicant to give an oral or written explanation of the application, 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 explanation is provided.

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

(a) the product complies with conditions A to E of regulation 125 (conditions for a product to be a traditional herbal medicinal product);

(b) the product to which the application relates is not harmful under normal conditions of use;

(c) the application and the accompanying material complies with the requirements of this Part;

(d) the product's qualitative and quantitative composition is as described in the application and the accompanying material; and

(e) the product's pharmaceutical quality has been satisfactorily demonstrated.

(5) The licensing authority need not take into account any updated information supplied in connection with the application under regulation 129 (obligation to update information supplied in connection with application), unless it thinks that the information is unfavourable in respect of the safety, quality or efficacy of the product concerned

(6) The licensing authority may refuse the application on the ground that it is more appropriate to consider whether to authorise the placing of the product on the market in response to an application for a marketing authorisation or certificate of registration for the product.

(7) Paragraph (4)(a) is subject to Article 16c(4) of the 2001 Directive (procedure where product has been used in the European Union for less than 15 years).

(8) If the application relates to a herbal medicinal product that is contained in the list referred to Article 16f(1) of the 2001 Directive—

(a) paragraph (4)(a) applies as if it referred to conditions A to D of regulation 125; and

(b) paragraph (4)(b) does not apply.

(9) Where Article 16d(1) of the 2001 Directive (products to which the mutual recognition procedure and decentralised procedure apply) does not apply to the product, the licensing authority must, in considering the application, take into account any registrations granted by other member States in accordance with Chapter 2a of Title III of the 2001 Directive.

(10) The licensing authority must take into account—

(a) any herbal monograph of the kind referred to in Article 16h(3) of the 2001 Directive that the authority thinks relevant to the application; or

(b) if no relevant monograph within sub-paragraph (a) has been established, such other monographs, publications or data as the authority thinks relevant.

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

(12) This regulation does not apply where Article 16d(1) applies to the product and the application—

(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 Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(13) An application to which paragraph (12) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.