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.