STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

Application for grant of UK marketing authorisation

49.—(1) The licensing authority may, subject to regulation 58, grant a UK marketing authorisation for a relevant medicinal product in response to an application made in accordance with this Part.

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

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

(4) 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.

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

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

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the authorisation are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

Accompanying material

50.—(1) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide the material specified in Schedule 8 in relation to the product.

(2) An applicant for the grant of a UK marketing authorisation for a radionuclide generator must, in addition, provide—

(a) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nucleid preparation; and

(b) qualitative and quantitative particulars of the eluate or the sublimate.

(3) 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 dealing with the application.

(4) If any of the medicinal products to which the application relates is liable to be imported from a country other than an EEA State, the material or information referred to in paragraph (3) may include an undertaking from the manufacturer of the product to comply with the matters set out in Schedule 9.

(5) Material that is submitted under this regulation must be submitted in accordance with the applicable provisions of Annex I to the 2001 Directive.

(6) This regulation is subject to—

(a) regulation 51 (applications relating to generic medicinal products);

(b) regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc);

(c) regulation 53 (applications relating to certain biological medicinal products);

(d) regulation 54 (applications relating to products in well-established medicinal use);

(e) regulation 55 (applications relating to new combinations of active substances);

(f) regulation 56 (applications containing information supplied in relation to another medicinal product with consent); and

(g) Schedule 10 (applications relating to national homoeopathic products).

Applications relating to generic medicinal products

51.—(1) An applicant for a UK marketing authorisation for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UK marketing authorisation for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in the United Kingdom before the time at which it may be placed on the market in accordance with—

(a) Article 10(1) of the 2001 Directive; or

(b) in a case where the application for the marketing authorisation for the reference medicinal product referred to in the application was submitted on or before 30th October 2005, Article 10(1) of the 2001 Directive as it stood before it was amended by Article 1(8) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending the 2001 Directive(**1**) ("Directive 2004/27/EC"), in accordance with Article 2 of Directive 2004/27/EC .

Applications relating to certain medicinal products that do not qualify as generic etc

52.—(1) This regulation applies where—

(**1**) OJ No L 136, 30.4.2004, p. 34.

(a) an application is made for a UK marketing authorisation in respect of a product by reference to another medicinal product as reference medicinal product; and

(b) one or more of the circumstances listed in Article 10(3) of the 2001 Directive applies in respect of the application.

(2) The applicant must provide information in accordance with Article 10(3) and (6) of the 2001 Directive.

(3) Regulation 51(2) shall apply to the application as it applies in relation to an application made in accordance with regulation 51(1).

Applications relating to similar biological medicinal products

53.—(1) This regulation applies if an applicant for a UK marketing authorisation for a biological medicinal product is not able to show that it meets a condition for its being a generic version of a similar medicinal product because of any of the reasons described in Article 10(4) of the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10(4) and (6) of the 2001 Directive.

(3) Regulation 51(2) shall apply to the application as it applies in relation to an application made in accordance with regulation 51(1).

Applications relating to products in well-established medicinal use

54.—(1) This regulation applies if an applicant for a UK marketing authorisation for a relevant medicinal product is able to demonstrate that the active substances of the product have been in well-established medicinal use within the European Union for at least 10 years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I to the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10a of the 2001 Directive.

Applications relating to new combinations of active substances

55.—(1) This paragraph applies to an application for a UK marketing authorisation for a relevant medicinal product that contains active substances that—

(a) have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004; but

(b) have not been used in that combination for therapeutic purposes.

(2) The applicant must provide information in accordance with Article 10b of the 2001 Directive.

Applications containing information supplied in relation to another product with consent

56.—(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product where—

(a) the product that is the subject of the application ("product A") has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as a product ("product B");

(b) product B is the subject of a UK marketing authorisation; and

(c) the holder of the marketing authorisation for product B has allowed use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on product B with a view to examining subsequent applications relating to other medicinal products

possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

(2) The documentation referred to in paragraph (1)(c) in relation to product B may be used in relation to the application in relation to product A, in accordance with Article 10c of the 2001 Directive.

Obligation to update information supplied in connection with application

57.—(1) The applicant for a UK marketing authorisation must update information supplied in accordance with paragraphs 18 to 21 of Schedule 8 (material to accompany an application for a UK marketing authorisation) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.