STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

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).