STATUTORY INSTRUMENTS

1994 No. 3144

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

Applications for the grant, renewal or variation of a United Kingdom marketing authorization

4.—(1) Every application for the grant, renewal or variation of a United Kingdom marketing authorization for a relevant medicinal product shall be made in accordance with the relevant Community provisions, subject to any provision of Community law affecting parallel imports, and the applicant shall comply with so much of the relevant Community provisions as impose obligations on applicants as are applicable to the application or the consideration of it.

(2) Every application shall be made in writing, shall be signed by or on behalf of the applicant and shall, unless the licensing authority otherwise direct, be accompanied by any fee which may be payable in connection with that application.

(3) In the case of an application for the grant of a marketing authorization, twenty-six copies, or such lesser number as the licensing authority may direct, of each application and of any accompanying material shall be supplied to the licensing authority in the English language, and where the application or any accompanying material has been translated from another language, also one copy of the application or the accompanying material, as the case may be, in the original language.

(4) In the case of an application for the renewal of a marketing authorization, three copies of each application and of any accompanying material shall be supplied to the licensing authority, but in all other respects the applicant shall comply with the provisions of paragraph (3).

(5) An application for the grant of a marketing authorization shall include a statement indicating—

(a) whether the relevant medicinal product is one that should be available—

(i) only on prescription;

(ii) only from a pharmacy; or

(iii) on general sale; and

(b) what, if any, provisions of the authorization are proposed concerning 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).

(6) For the purposes of point 8(a)(iii) of the second paragraph of Article 4 of the 1965 Directive, the period of 10 years there mentioned (period during which essentially similar products must have been on the market) shall apply to all relevant medicinal products.

(7) An applicant shall not be entitled by virtue of point 8(a) of the second paragraph of Article 4 of the 1965 Directive to omit to provide any particulars or results if proper consideration of the application without them could not be carried out without prejudicing any rights which arise under any law relating to the protection of industrial and commercial property and which are enforceable in the United Kingdom.

(8) The applicant for the grant or renewal of a United Kingdom marketing authorization must be established in the Community.

(9) An application for the renewal of a marketing authorization shall be made not later than 3 months before the date on which the existing authorization expires.