STATUTORY INSTRUMENTS

2001 No. 795

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2001

Amendment of the Marketing Authorisations Regulations

2.—(1) In regulation 1(2) of the Marketing Authorisations Regulations (interpretation)—

(a) after the definition of "Community marketing authorisation" there shall be inserted the following definition—

> ""EEA State" means a contracting party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**1**) as adjusted by the Protocol signed at Brussels on 17th March 1993(**2**);";

(b) after the definition of "the EMEA" there shall be inserted the following definition—

> ""parallel import licence" means a United Kingdom marketing authorisation granted by the licensing authority under these Regulations in respect of a relevant medicinal product which is imported into the United Kingdom from another EEA state in accordance with the rules of Community law relating to parallel imports";

(c) the definition of "parallel import" shall be omitted; and

(d) for the definition of "United Kingdom marketing authorisation" there shall be substituted the following definition—

> ""United Kingdom marketing authorisation" means a marketing authorisation granted by the licensing authority under these Regulations and includes a parallel import licence.".

(2) In regulation 4(1) of the Marketing Authorisations Regulations (applications for the grant, renewal or variation of a United Kingdom marketing authorisation), for the words "any provision of Community law affecting" there shall be substituted the words "the rules of Community law relating to".

(3) In regulation 5 of the Marketing Authorisations Regulations (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorisation)—

(a) in paragraph (1), after the word "provisions" at each place where it occurs, there shall be inserted the words "and (where applicable) the rules of Community law relating to parallel imports";

(b) in paragraph (2), after the words "every authorisation" there shall be inserted the words ", other than a parallel import licence,"; and

(c) in paragraph (4), after the words "the 1965 Directive" there shall be inserted the words "or in relation to a parallel import licence".

(**1**) OJNo. L1, 3.1.1994, p.3.
(**2**) OJ No. L1, 3.1.1994, p.572.