STATUTORY INSTRUMENTS

2004 No. 3224

The Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations 2004

Amendment of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

3.—(1) The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**1**) ("the 1994 Regulations") are amended as follows.

(2) In regulation 1 (citation, commencement and interpretation)—

(a) in paragraph (2)—

(i) in the definition of "the 2001 Directive", after "as amended" insert "by Commission Directive 2003/63/EC(**2**) and Article 1(21), (44), (45) and (54) of Directive 2004/27/EC",

(ii) after the definition of the "the 2001 Directive" insert the following definition—

""Directive 2004/27/EC" means Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**3**);",

(iii) for the definition of "the EMEA" substitute—

""the EMEA" means the European Medicines Agency established by Regulation (EC) No. 726/2004;",

(iv) after the definition of "parallel import licence", insert the following definition—

""Regulation (EC) No. 726/2004" means Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**4**);", and

(v) in the definition of "the relevant Community provisions"—

(aa) omit "and" in both places that word appears, and

(bb) after the entry for "Regulation (EC) No. 1085/2003" insert the following entry—

"and

Title IV of Regulation (EC) No. 726/2004;"; and

(b) after paragraph (5), insert the following paragraph—

"(5A) For the purposes of these Regulations—

(**1**) S.I. 1994/3144; relevant amending instruments are S.I. 2001/795, 2002/236 and 2003/2321.
(**2**) OJ No. L159, 27.6.2003, p.46.
(**3**) OJ No. L136, 30.4.2004, p.34.
(**4**) OJ No. L136, 30.4.2004, p.1.

(a) references to "the Agency" in the 2001 Directive and in Titles I and II of Regulation (EEC) No. 2309/93(**5**) shall be taken to refer to the European Medicines Agency established by Article 55 of Regulation (EC) No. 726/2004; and

(b) references to "the Committee" in the 2001 Directive and in Title II of Regulation (EEC) No. 2309/93 shall be taken to refer to the Committee for Medicinal Products for Human Use specified in Article 56(1)(a) of Regulation (EC) No. 726/2004.".

(3) In Schedule 2 (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorization), in paragraph 3, for "the Committee for Proprietary Medicinal Products" substitute "the Committee for Medicinal Products for Human Use".

(4) In Schedule 3 (offences, penalties etc.)—

(a) in paragraph (6), after sub-paragraph (c), insert the following sub-paragraph—

"(cc) provide information to the licensing authority as required by the third or fourth paragraphs of Article 23 of the 2001 Directive; or",

(b) after paragraph (6) insert the following paragraph—

"**6A.** Any holder of a United Kingdom marketing authorization who fails to forward to the licensing authority any data requested by the authority pursuant to the final paragraph of Article 23 of the 2001 Directive—

(a) where the licensing authority have served a written notice on the holder under regulation 7(5) in relation to the request, within the time specified in that notice; or

(b) where there is no such notice, promptly,

shall be guilty of an offence.".

(5) In Schedule 6 (transitional provisions), after paragraph 4, insert the following paragraph—

"**4A.** Until 1st July 2008, these Regulations shall apply, in so far as they relate to the package leaflets of medicinal products in respect of which—

(a) a marketing authorization is in force on 1st January 2005,

(b) a United Kingdom marketing authorization is granted, or an application for the grant of such an authorization is made, in the period from 1st January 2005 to 30th June 2005, or

(c) a Community marketing authorization is granted in the period from 1st January 2005 to 29th October 2005,

as if the 2001 Directive had not been amended by Article 1(44) and (45) of Directive 2004/27/EC.".

(**5**) OJ No. L214, 24.08.93, p.1.