STATUTORY INSTRUMENTS

2005 No. 2787

The Medicines (Advertising Amendments) Regulations 2005

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation)—

(a) in the appropriate alphabetical place, insert the following definitions—

""certificate of registration" means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**1**);

"homoeopathic medicinal product" means a medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, any pharmacopoeia used officially in a Member State; and

"traditional herbal registration" means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**2**);";

(b) in the definition of "the 2001 Directive", after "as amended" insert—

"by—

(a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**3**),

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**4**),

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**5**), and

(d) 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(**6**)

(c) for the definition of "marketing authorization" substitute—

""marketing authorization" means—

(**1**) S.I.1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.
(**2**) S.I. 2005/2750.
(**3**) OJ No. L33, 8.2.2003, p.30.
(**4**) OJ No. L159, 27.6.2003, p.46.
(**5**) OJ No. L136, 30.4.2004, p.85.
(**6**) OJ No. L136, 30.4.2004, p.34.

(a) a marketing authorization granted by the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**7**),

(b) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93(**8**) or under 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(**9**),

(c) an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive, or

(d) a product licence granted by the licensing authority under Part II of the Act;";

(d) in the definition of "relevant medicinal product"—

(i) for paragraph (a) substitute—

"(a) a medicinal product for human use to which the 2001 Directive applies and accordingly includes products to which Title II of Regulation (EC) No. 726/2004 applies, or",

(ii) in paragraph (b), in sub-paragraph (ii), omit "or", and

(iii) omit paragraph (c); and

(e) in the definition of "summary of product characteristics", for "product licence" substitute "marketing authorization or traditional herbal registration".

(**7**) S.I. 1994/3144; relevant amending instruments S.I. 1998/3105, 2000/292, 2001/795, 2002/236, 2002/542, 2003/2321, 2004/3224 and 2005/2759.
(**8**) OJ No. L214, 24.8.1993, p.1.
(**9**) OJ No. L136, 30.4.2004, p.1.