STATUTORY INSTRUMENTS

2005 No. 2750

The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**1**);

"appropriate committee", for the purposes of any provision of these Regulations under which a function falls to be performed, means—

(a) in a case where—

(i) a committee has been established under section 4 of the Act for purposes which consist of or include any of those specified in subsection (3) of that section, and

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission;

"the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**2**) as amended by—

(c) 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**),

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

(e) 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

(f) 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**);

"EEA State" means a Member State, Norway, Iceland or Liechtenstein;

"EC traditional herbal registration" means a traditional herbal registration granted by a competent authority of an EEA State in accordance with the simplified registration procedure for traditional herbal medicinal products set out in Chapter 2a of the 2001 Directive;

"licensing authority" shall be construed in accordance with section 6 of the Act;

(**1**) 1968 c. 67.
(**2**) OJNo. L311, 28.11.2001, p.67.
(**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.

"parallel import licence" means a traditional herbal registration granted by the licensing authority under these Regulations in respect of a traditional herbal 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;

"the relevant Community provisions" means the provisions of the 2001 Directive which apply to traditional herbal medicinal products and to traditional herbal registrations;

"traditional herbal registration" means a registration granted by the licensing authority under these Regulations and includes a parallel import licence.

(2) Expressions used in these Regulations which are also used in the 2001 Directive shall have the same meaning as they have there and related expressions shall be construed accordingly.

(3) Subject to paragraph (2), section 11 of the Interpretation Act 1978(**7**) shall apply for the interpretation of these Regulations as if they were made in the exercise of a power conferred by the Act.

(4) Any reference in these Regulations to an application that is signed includes a reference to an application that is signed with an electronic signature.

(**7**) 1978 c. 30.