STATUTORY INSTRUMENTS

1994 No. 3144

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

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and shall come into force on 1st January 1995—

(a) in the case of all of these Regulations, immediately after the coming into force of Council Regulation (EEC) No. 2309/93(**1**) and Council Directive 93/39/EEC(**2**); and also

(b) in the case of paragraphs 4, 5 and 6 of Schedule 7, immediately after the coming into force of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**3**).

(2) In these Regulations:

"the Act" means the Medicines Act 1968(**4**); "the Community" means the European Community;

"Community marketing authorization" means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93(**5**);

"the EMEA" means the European Agency for the Evaluation of Medicinal Products established by Council Regulation (EEC) No. 2309/93;

"parallel import" means the import into the United Kingdom from another Member State of the Community of a medicinal product for human use in respect of which there has been granted a Community marketing authorization or a marketing authorization by another Member State of the Community and which has no difference having therapeutic effect from a medicinal product in respect of which a marketing authorization has previously been granted in the United Kingdom;

"the relevant Community provisions" means the provisions of—

Council Directive 65/65/EEC(**6**);

Council Directive 75/318/EEC(**7**);

Chapters I to II and V to VI of Council Directive 75/319/EEC(**8**) and any Regulation adopted by the Commission under Article 15 of that Directive;

(**1**) OJ No. L214, 24.8.93, p.1.
(**2**) OJ No. L214, 24.8.93, p.22.
(**3**) S.I. 1994/ .
(**4**) 1968 c. 67. Relevant amendments were made by the Prescription by Nurses Act 1992 (c. 28), section 1 and S.I. 1977/1050, 1983/1724, 1992/604, 605 and 3271 and 1993/834.
(**5**) OJ No. L214, 24.8.93, p.1.
(**6**) OJ No. L22, 9.2.65, p.369/65. The Directive was amended by Directives 75/319/EEC (OJ No. L147, 9.6.75, p.13); 83/570/EEC (OJ No. L332, 28.11.83, p.1); 87/21/EEC, (OJ No. L15, 17.1.87, p.36), 89/343/EEC (OJ No. L142, 25.5.89, p.16) and 93/39/EEC (OJ No. L214, 24.8.93, p.22.).
(**7**) OJ No. L147, 9.6.75, p.1. The Directive was amended by Directives 89/341/EEC (OJ No. L142, 25.5.89, p.11), 91/507/EEC (OJ No. L270, 26.9.91, p.32) and 93/39/EEC (OJ No. L214, 24.8.93, p.22.).
(**8**) OJ No. L147, 9.6.75, p.13. The Directive was amended by Directives 83/570/EEC (OJ No. L332, 28.11.83, p.1), 89/341/EEC (OJ No. L142, 25.5.89, p.11) and 93/39/EEC (OJ No. L214, 24.8.1993, p.22); see also Directives 89/342/EEC (OJ No. L142, 25.5.89, p.14), 89/343/EEC (OJ No. L142, 25.5.89, p.16) and 89/381/EEC (OJ No. L181, 28.6.89, p.44), which extend the

Council Directive 89/342/EEC(**9**);

Council Directive 89/343/EEC(**10**);

Council Directive 89/381/EEC(**11**);

Council Directive 92/26/EEC(**12**);

Council Directive 92/27/EEC(**13**);

Council Directive 92/73/EEC(**14**);

Regulation (EEC) No. 2309/93(**15**) and any Regulations adopted by the Commission under Article 15.4 or 22.1 of that Regulation,

as they have effect on the day these Regulations come into force;

"relevant medicinal product" means a medicinal product for human use to which Chapters II to V of Council Directive 65/65/EEC apply, and accordingly includes the industrially produced medicinal products mentioned in Article 2.2 of that Directive; and

"United Kingdom marketing authorization" means a marketing authorization granted by the licensing authority under these Regulations.

(3) For the purposes of the definition of "relevant medicinal product" in paragraph (2) a medicinal product which is a herbal remedy is not industrially produced if—

(a) it is, or is to be, sold or supplied in circumstances to which either section 12(1) of the Act or Article 2 of the Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971(**16**) relate and has been manufactured or assembled only for sale or supply in those circumstances; or

(b) the process to which the plant or plants are subjected in producing the product consists only of drying, crushing or comminuting, and the product is, or is to be, sold or supplied only as provided by section 12(2) of the Act.

(4) Except where the contrary intention appears—

(a) any reference in these Regulations to a marketing authorization includes a reference both to a United Kingdom marketing authorization (including a product licence having effect as such an authorization) and to a Community marketing authorization;

(b) any reference in these Regulations to the variation of a marketing authorization includes a reference to a change in the requirements for labels or package leaflets; and

(c) any reference in these Regulations to an application for the grant or renewal of a marketing authorization is a reference to an application made after the coming into force of these Regulations.

(5) Expressions used in these Regulations which are also used in any of the relevant Community provisions shall, except where the contrary intention appears, and except in the case of 'clinical trial', have the same meaning as they have there, and related expressions shall be construed accordingly.

provisions of Directives 65/65/EEC and 75/319/EEC to vaccines, toxins or serums and allergens, radiopharmaceuticals and products derived from human blood or human plasma.

(**9**) OJ No. L142, 25.5.89, p.14.
(**10**) OJ No. L142, 25.5.89, p.16.
(**11**) OJ No. L181, 28.6.89, p.44.
(**12**) OJ No. L113, 30.4.92, p.5.
(**13**) OJ No. L113, 30.4.92, p.8.
(**14**) OJ No. L297, 13.10.92, p.8.
(**15**) OJ No. L214, 24.8.93, p.1.
(**16**) S.I. 1971/1450. The relevant amending instruments are S.I. 1972/1200 and 1989/1184 and 2323.

(6) Subject to paragraph (5), section 11 of the Interpretation Act 1978(**17**) shall apply for the interpretation of these Regulations as if they were made in the exercise of a power conferred by the Act.

(7) In these Regulations—

(a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation of or Schedule to these Regulations bearing that number; and

(b) any reference in a regulation or Schedule to a numbered paragraph is a reference to the paragraph of that regulation or Schedule bearing that number.

(**17**) 1978, c. 30.