STATUTORY INSTRUMENTS

1995 No. 1116

The Medicines (Products for Human Use — Fees) Regulations 1995

PART I

GENERAL

Interpretation

2.—(1) In these Regulations, unless the context requires otherwise—

"the Act" means the Medicines Act 1968 and, except as provided below, expressions used in these Regulations have the same meaning as in the Act;

"the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**1**);

"authorised medicinal product" means a medicinal product in respect of which either a marketing authorization or marketing authorization (parallel import) has been granted;

"blood product" means any medicinal product derived from human blood or human plasma and includes albumin, coagulating factor and immunoglobulin of human origin;

"capital fee" means any fee, other than a periodic fee, payable under the provisions of these Regulations;

"change of ownership application" means an application for a marketing authorization for a medicinal product in respect of which a person other than the applicant is the holder of a marketing authorization and which—

(a) includes a statement to the effect that that other person intends to cease selling or supplying that product pursuant to that authorization;

(b) is signed by or on behalf of that other person, as well as by or on behalf of the applicant; and

(c) except for the name and address of the applicant and particulars in relation to the labelling of the product and any leaflet relating to it, contains, or is accompanied by, particulars which are in all material respects identical to the particulars referred to in the marketing authorization already held by that other person;

"Community marketing authorization" means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93(**2**);

"fee period" means the period beginning with the first day of April in any year and ending with the last day of March in the following year;

"immunological product" means any medicinal product which is a vaccine, toxin, serum or allergen product;

(**1**) S.I.1994/3144.
(**2**) OJ No. L214, 24.8.93. p.1.

"manufacturer's licence" means a manufacturer's licence which relates wholly or partly to medicinal products for human use;

"marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations;

(b) a Community marketing authorization; or

(c) a product licence, including one which is a licence of right or one which has effect as a marketing authorization by virtue of paragraph 1 of Schedule 6 (transitional provisions) to the 1994 Regulations;

which relates to a medicinal product for human use;

"marketing authorization (parallel import)" means a marketing authorization granted by the licensing authority in respect of a medicinal product which is imported into the United Kingdom from another member State of the European Community, in respect of which there has been granted a marketing authorization by another member State of the Community and which has no differences having therapeutic effect from a medicinal product in respect of which a marketing authorization has previously been granted in the United Kingdom;

"medicinal product" includes any medicinal product for human use to which Chapters II to V of Council Directive 65/65/EEC(**3**) apply and any substance or article specified in any order for the time being in force made under section 104 (application of the Act to certain articles and substances) or 105(1)(a) (application of the Act to certain other substances which are not medicinal products) of the Act which directs that Part II of the Act shall have effect in relation to such substance or article;

"periodic fee" means a fee payable under regulation 14;

"product licence of right" means a product licence within the meaning of section 7 (general provisions as to dealing with medicinal products) of the Act which is a licence of right within the meaning of section 25(4) (entitlement to licence of right) of the Act;

"relevant fee period" means any fee period during any part of which a marketing authorization or licence in respect of which a periodic fee is payable is in force;

"variation" in relation to—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations; or

(b) a product licence which has effect as such a marketing authorization by virtue of paragraph 1 of Schedule 6 (transitional provisions) to those Regulations;

means "variation to the terms of a marketing authorization" as defined in Article 2.1 of Commission Regulation (EC) No. 541/95(**4**);

"wholesale dealer's licence" means a wholesale dealer's licence which relates wholly or partly to medicinal products for human use;

and Part I of Schedule 1 shall have effect for the purpose of interpreting that Schedule.

(2) In these Regulations any reference to a regulation or a Schedule shall be construed as a reference to a regulation contained in these Regulations or, as the case may be, to a Schedule thereto; any reference in a regulation or a Schedule to a paragraph shall be construed as a reference to a paragraph of that regulation or, as the case may be, Schedule, and any reference in a paragraph to a sub-paragraph shall be construed as a reference to a sub-paragraph of that paragraph.

(**3**) 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); 89/341/EEC (OJ No. L142, 25.5.89, p.11); 89/343/EEC (OJ No. L142, 25.5.89, p. 16) and 93/39/EEC (OJ No. L214, 24.8.93, p. 22).

(**4**) OJ No. L55, 11.3.95, p. 7.