STATUTORY INSTRUMENTS

# 2008 No. 552

# The Medicines (Products for Human Use-Fees) Regulations 2008

## PART 1

### General

**Citation and commencement**

**1.** These Regulations may be cited as the Medicines (Products for Human Use-Fees) Regulations 2008 and shall come into force on 1st April 2008.

**Interpretation**

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

"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(**1**);

"the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994(**2**);

"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;

"API manufacturer" means a person, other than the holder of a manufacturer's licence, engaged in the manufacture or assembly of active substances used as starting materials in the manufacture of medicinal products;

"application", in relation to a clinical trial authorisation, means a request for authorisation to conduct a clinical trial made in accordance with regulation 17 (request for authorisation to conduct a clinical trial) of the Clinical Trials Regulations, and "applicant", in relation to such authorisation, means the person making the request;

"authorised medicinal product" means a medicinal product in respect of which a marketing authorization 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—

(**1**) OJ No. L311, 28.11.2001, P.67; relevant amending instruments are Directive 2002/98/EC of the European Parliament and of the Council, OJ No. L33, 8.2.2003, p.30, Commission Directive 2003/63/EC, OJ No. L159, 27.6.2003, p.46, Directive 2004/24/EC of the European Parliament and of the Council, OJ No. L136, 30.4.2004, p.34, Regulation (EC) No. 1901/2006 of the European Parliament and of the Council, OJ No. L378, 27.12.2006, p.1.

(**2**) S.I. 1994/3144; relevant amending instruments are S.I. 2000/795, 2002/236, 2003/ 2321, 2004/3224 and 2005/50, 1710 and 2759.

(a) for—

(i) a marketing authorization for a medicinal product in respect of which another person holds a marketing authorization,

(ii) a manufacturing authorisation for activities in respect of which another person holds a manufacturing authorisation,

(iii) a traditional herbal registration for a medicinal product in respect of which another person holds a traditional herbal registration,

(iv) a manufacturer's licence for activities in respect of which another person holds a manufacturer's licence, or

(v) a wholesale dealer's licence for activities in respect of which another person holds a wholesale dealer's licence;

(b) which refers to particulars which are in all material respects identical to the particulars of the marketing authorization, manufacturing authorisation, traditional herbal registration, manufacturer's licence, or wholesale dealer's licence which is held by that other person; and

(c) which includes a statement to the effect that that other person intends to cease the activities to which his marketing authorization, manufacturing authorisation, traditional herbal registration or licence relates and has consented in writing to the making of the application,

and in this definition particulars do not include particulars relating to the name and address of the applicant, the labelling of any medicinal product or the content of any leaflet relating to such a product;

"clinical trial" means any investigation in human subjects, other than a non-interventional trial, intended—

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

(b) to identify any adverse reactions to one or more such products; or

(c) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products;

"clinical trial authorisation" means authorisation of the conduct of a clinical trial—

(a) by the licensing authority in accordance with regulation 18 (authorisation procedure for clinical trials involving general medicinal products), 19 (authorisation procedure for clinical trials involving general medicinal products for gene therapy etc.) or 20 (authorisation procedure for clinical trials involving general medicinal products with special characteristics) of the Clinical Trials Regulations; or

(b) which is treated as having been given by the licensing authority by virtue of Schedule 12 to those Regulations;

"Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**3**);

"Commission Regulation (EC) No. 1084/2003" means Commission Regulation (EC) No. 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State(**4**);

(**3**) S.I. 2004/1031; relevant amending instruments are S.I. 2005/2754 and 2759 and 2006/1928 and 2984.
(**4**) OJ No. L 159, 27.6.2003, p.1.

"Community marketing authorization" means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93 or Regulation (EC) No. 726/2004;

"concerned member State" means an EEA State, the competent authorities of which receive an application to obtain recognition, according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive, of a United Kingdom marketing authorization;

"conditions and principles of good clinical practice" means the conditions and principles specified in Schedule 1(conditions and principles of good clinical practice and for the protection of clinical trial subjects) to the Clinical Trials Regulations;

"contract laboratory" means a laboratory carrying out the examinations and tests referred to in—

(a) paragraph 5A(2) of Schedule 2 (standard provisions for manufacturer's licences and manufacturer's licences of right) to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**5**); and

(b) Article 11(1) of Directive 2003/94/EC,

on behalf of the holder of a manufacturing authorisation, manufacturer's licence or wholesale dealer's licence, pursuant to Article 11(2) of that Directive and Article 20(b) of the 2001 Directive;

"Council Regulation (EEC) No. 2309/93" means Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**6**);

"Directive 75/319/EEC" means Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (**7**);

"Directive 2003/94/EC" means Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (**8**);

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

"exempt imported product" means a medicinal product, as defined in Article 1(2) of the 2001 Directive, to which paragraph 1 of Schedule 1 (exemptions and exceptions from the provisions of regulation 3) to the 1994 Regulations applies, which was not manufactured in the United Kingdom and in relation to which no marketing authorization has been granted;

"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;

"Herbal Regulations" means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**9**);

"herbal substances" has the meaning given by Article 1(31) of the 2001 Directive;

"holder", in relation to a clinical trial authorisation, means—

(a) in the case of an authorisation treated as having been given by the licensing authority by virtue of Schedule 12 (transitional provisions) to the Clinical Trials Regulations, the person acting as sponsor of the clinical trial for the purposes of those Regulations; or

(**5**) S.I. 1971/972 to which relevant amendments have been made by S.I. 1992/2846, 1994/2852, 2004/1031 and 2005/2789.
(**6**) OJ No. L 214, 24.8.1993. This Regulation has been replaced by Regulation (EC) No 726/2004.
(**7**) OJ No. L 147, 9.6.1975, p.13. This Directive has been codified and assembled with others into Directive 2001/83/EC.
(**8**) OJ No. L 262, 14.10.2003, p.22.
(**9**) S.I. 2005/2750.

(b) in any other case, the person who made the request for that authorisation;

"homoeopathic medicinal product" means any 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, by any pharmacopoeia used officially in a member State;

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

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

"manufacturing authorisation" means a manufacturing authorisation granted for the purposes of regulation 36 (requirement for authorisation to manufacture or import investigational medicinal products) of the Clinical Trials Regulations;

"marketing authorization" means, except in regulation 3—

(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;

"medicinal product" includes any medicinal product for human use to which the 2001 Directive applies 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(**10**) which directs that Part II of the Act or the Clinical Trials Regulations shall have effect in relation to such substance or article;

"national homoeopathic product" means a homoeopathic medicinal product which –

(a) does not satisfy the conditions set out in article 14(1) of the 2001 Directive; and

(b) is indicated for the relief or treatment of minor symptoms or minor conditions in humans;

"operator", in relation to a contract laboratory, means the person having control of the contract laboratory;

"orphan medicinal product" has the meaning given in article 2(b) of Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products(**11**);

"parallel import licence" means a United Kingdom marketing authorisation granted by the licensing authority under the 1994 Regulations in respect of a relevant 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;

"penalty fee" means a fee payable under regulation 41;

"periodic fee" means the fee payable under regulation 31 or 32 by the holder of a marketing authorization (other than a Community marketing authorization), a traditional herbal registration, a manufacturing authorisation, a manufacturer's licence, a wholesale dealer's licence or a clinical trial authorisation for the holding of the authorization, registration, authorisation or licence;

(**10**) Amendments have been made to these sections by S.I. 2004/1031 and S.I. 2006/2407.
(**11**) OJ No. L18, 22.1.2000, p.1.

"Periodic Safety Update Report" means a report prepared to meet the requirements of the 2001 Directive;

"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 (**12**) which is a licence of right within the meaning of section 25(4) (entitlement to licence of right) of the Act;

"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(**13**);

"relevant fee period" means any fee period during any part of which a marketing authorization, a traditional herbal registration, a clinical trial authorisation, manufacturing authorisation or licence in respect of which a periodic fee is payable is in force;

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply other than–

(a) a traditional herbal medicinal product, or

(b) a homoeopathic medicinal product that fulfils the conditions laid down in Article 14(1) of the 2001 Directive;

"special import notice" means a written notice given to the licensing authority in accordance with paragraph 7(2) of Schedule 2 (standard provisions which may be incorporated in a manufacturer's licence relating to the import of relevant medicinal products from a third country) to, or paragraph 3(2) of Schedule 4 (standard provisions which may be incorporated in a wholesale dealer's licence) to, the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005(**14**);

"traditional herbal medicinal product" has the meaning given by Article 1(29) of the 2001 Directive;

"traditional herbal registration" means a registration granted by the licensing authority under the Herbal Regulations;

"United Kingdom marketing authorization" means a marketing authorization granted by the licensing authority under the 1994 Regulations;

"variation"—

(a) in relation to—

(i) a United Kingdom marketing authorization, or

(ii) 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 3(1) of Commission Regulation (EC) No. 1084/2003;

(b) in relation to a traditional herbal registration, means a variation of the provisions of a traditional herbal registration;

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

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

(**12**) Repeals and amendments to section 7 have been made by S.I.1977/1050, 1983/1724, 1992/604, 1994/276, 2004/1031, 2005/50, 2005/2753, and 2006/2407.
(**13**) OJ No. L136, 30.4.2004, p.1.
(**14**) S.I. 2005/2789.

(2) For the purposes of these Regulations, a clinical trial authorisation is in force unless the licensing authority has—

(a) received notification of the conclusion of the clinical trial to which the authorisation relates, in accordance with regulation 27 (conclusion of clinical trial) of the Clinical Trials Regulations; or

(b) suspended or terminated the trial at all sites at which that clinical trial was conducted, in accordance with regulation 31 (suspension or termination of clinical trial) of those Regulations (**15**).

(3) In these Regulations any reference to an application for the variation of a marketing authorization includes a reference to a notification of such a variation and any reference to an applicant for a variation to a marketing authorization includes a reference to a person who submits such a notification.

(**15**) Revocations and amendments to regulation 31 have been made by S.I. 2005/2754 and 2006/1928.