SCHEDULE 7 Regulation 2

INTERPRETATION

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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 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**);

"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(**2**);

"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 (**3**);

"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(**4**);

"EC Regulation No. 1234/2008" means Commission Regulation (EC) No. 1234/2008 concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use and veterinary medicinal products(**5**);

"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(**6**);

"active ingredient" has the meaning given in paragraph 1 of Schedule 1;

"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;

(**1**) OJ No. L 311, 28.11.2001, p.67; relevant amending instruments are Directive 2002/98/EC of the European Parliament and of the Council (OJ No. L 33, 8.2.2003, p.30), Commission Directive 2003/63/EC (OJ No. L 159, 27.6.2003, p.46), Directive 2004/24/EC of the European Parliament and of the Council (OJ No. L 136, 30.4.2004, p.85), Directive 2004/27/EC of the European Parliament and of Council (OJ No. L 136, 30.4.2004, p.34), Regulation (EC) No. 1901/2006 of the European Parliament and of the Council (OJ No. L 378, 27.12.2006, p.1), Regulation (EC) No. 1394/2007 of the European Parliament and of the Council (OJ No. L 324, 10.12.2007, p.121), Directive 2008/29/EC of the European Parliament and of Council (OJ No. L 81, 20.3.2008, p.51), Directive 2009/53/EC of the European Parliament and of Council (OJ No. L 168, 30.6.2009, p.33) and Commission Directive 2009/120/EC (OJ No. L 242, 15.9.2009, p.3).

(**2**) OJ No. L 262, 14.10.2003, p.22.

(**3**) OJ No. L 147, 9.6.1975, p.13. This Directive has been codified and assembled with others into Directive 2001/83/EC.

(**4**) OJ No. L 214, 24.8.1993. This Regulation has been replaced by Regulation (EC) No 726/2004.

(**5**) OJ No. L 334, 12.12.2008, p.7.

(**6**) OJ No. L 136, 30.4.2004, p.1; relevant amending instruments are Regulation (EC) No. 1901/2006 of the European Parliament and of the Council (OJ No. L 378, 27.12.2006, p.1), Regulation (EC) No. 1394/2007 of the European Parliament and of the Council (OJ No. L 324, 10.12.2007, p.121), Regulation (EC) No. 219/2009 of the European Parliament and of the Council (OJ No. L 87, 31.3.2009, p.109) and Regulation (EC) No. 470/2009 of the European Parliament and of the Council (OJ No. L 168, 16.6.2009, p.11).

"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—

(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 the other person intends to cease the activities to which the 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 development" means the conduct of studies of a medicinal product in human subjects in order to—

(a) discover or verify the effects of such a product;

(b) identify any adverse reaction to such a product; or

(c) study absorption, distribution, metabolism and excretion of such a product,

with the object of ascertaining the safety or efficacy of that product, in accordance with section 5 of Part 1 of Annex I to the 2001 Directive;

"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(**7**);

"complex application" has the meaning given in paragraph 5 of Schedule 1;

"concerned Member State" means for the purpose of—

(a) regulation 12 and Part 2 of Schedule 1 (capital fees for Applications for Authorizations, Licences, Registrations and Certificates), 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;

(b) regulation 18 and Part 4 of Schedule 1 (capital fees for applications for variations of authorizations, Licences and Registrations), an EEA State, the competent authority of which has received an application for a variation to the terms of a marketing authorization under the procedure laid down in EC Regulation No. 1234/2008 for a medicinal product in respect of which an authorization was granted by that competent authority, other than the reference Member State;

"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(**8**); 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;

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

"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 Marketing Authorisation 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;

"good clinical practice" means the conditions and principles of good clinical practice specified in Schedule 1 to the Clinical Trials Regulations;

(**7**) S.I. 2004/1031; relevant amending instruments are S.I. 2004/3224, 2005/2754 and 2759, 2006/562, 1928 and 2984, 2007/289 and 3101, 2008/941 and 2009/1164.
(**8**) S.I. 1971/972; relevant amending instruments are S.I. 1992/2846, 1994/2852, 2004/1031 and 2005/2789.

"good distribution practice" means the Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C63/03) published by the European Commission pursuant to Article 84 of the 2001 Directive;

"good manufacturing practice" means the principles and guidelines of good manufacturing practice set out in Directive 2003/94/EC;

"good pharmacovigilance practice" means the Guidelines on Pharmacovigilance for Medicinal Products for Human Use published by the European Commission pursuant to Article 106 of the 2001 Directive;

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

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

"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

(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;

"Homoeopathic Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**10**);

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

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

"major application" has the meaning given in paragraph 10 of Schedule 1;

"manufacturer's licence" means a manufacturer's licence falling within the meaning of section 8(2) of the Act 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 Marketing Authorisation Regulations;

(b) a European Union 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 Marketing Authorisation Regulations,

which relates to a medicinal product for human use;

"Marketing Authorisation Regulations" means the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994(**11**);

(**9**) S.I. 2005/2750, as amended by S.I. 2006/914.

(**10**) S.I. 1994/105; relevant amending instruments are S.I. 1994/899, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 254, 2003/625 and 2321, 2005/2753, 2006/2125 and 2407, 2007/803 and 2009/389.

(**11**) S.I. 1994/3144; relevant amending instruments are S.I. 1996/1499, 1998/3105, 2000/292, 2001/795, 2002/236 and 542, 2003/1618, 2317 and 2321, 2004/856 (as regards England), 1016 (as regards Wales), 1031, 2290 and 3224, 2005/50, 768,

"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(**12**) 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(**13**);

"parallel import licence" means a United Kingdom marketing authorisation granted by the licensing authority under the Marketing Authorisation 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 European Union law relating to parallel imports;

"penalty fee" means a fee payable under regulation 44;

"periodic fee" means the fee payable under regulation 33 or 34 by the holder of—

(a) a marketing authorization (other than a European Union marketing authorization), a traditional herbal registration, a manufacturing authorisation, a manufacturer's licence, a wholesale dealer's licence; or

(b) a clinical trial authorisation in respect of the holding of the authorization, registration, authorisation or licence;

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

"pharmacovigilance advice" means advice, other than scientific advice, which falls within one or more of the descriptions specified in paragraphs (a) and (b)—

(a) the advice is in connection with an application for an EU marketing authorization, or is given with a view to a person making such an application, and relates to—

  (i) the obligations that would relate to the holder of such an authorization by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004;

  (ii) the pharmacovigilance and risk-management systems that the applicant would be required to introduce in accordance with Article 8(3)(ia) of the 2001 Directive; or

  (iii) a post-authorization safety study protocol;

(b) the advice is given to the holder of a United Kingdom marketing authorization or a European Union marketing authorization and relates to—

  (i) compliance with the obligations that relate to him by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004;

1094, 1520, 1710, 2754 and 2759, 2006/562 (as regards England), 914, 1952 and 2407, 2007/289, 2008/3097 and 2009/1164, 2820, 3063 and 3222.

(**12**) Amendments have been made to these sections by S.I. 2004/1031 and 2006/2407.

(**13**) OJ No. L 18, 22.1.2000, p.1, as amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L 188, 18.7.2009, p.14).

(ii) the pharmacovigilance and risk-management systems that he has introduced in accordance with Article 8(3)(ia) of the 2001 Directive; or

(iii) a post-authorization safety study protocol;

"post-authorization safety study protocol" means a document that describes the objectives, design, methodology, statistical considerations and organisation of a post-authorization safety study;

"product licence" means a product licence falling within the meaning of section 7 of the Act;

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

"product range" means one or more medicinal products containing the same active substance in relation to which the same person holds more than one EU marketing authorization;

"quality development" means the chemical, pharmaceutical and biological testing necessary to demonstrate the quality of a relevant medicinal product, in accordance with section 3 of Part 1 of Annex I to the 2001 Directive;

"regulatory advice" means advice, other than scientific advice, in relation to the requirements of the 2001 Directive or Regulation (EC) No. 726/2004 and which falls within one or more of the descriptions specified in sub-paragraphs (a) to (c)—

(a) the advice is in connection with a change to the dates for renewal of one or more EU marketing authorizations relating to a product range pursuant to Article 24 of the 2001 Directive;

(b) the advice is in connection with—

(i) a referral pursuant to Article 30, 31 or 36 of the 2001 Directive; or

(ii) the procedure referred to in Article 35(2) of the 2001 Directive,

in relation to a product range; or

(c) the advice is given to a person with a view to that person making—

(i) an application for the variation or renewal of one or more EU marketing authorizations; or

(ii) an application to amend the time periods for submitting Periodic Safety Update Reports under Article 104(6) of the 2001 Directive,

in relation to a product range;

"relevant fee period" means any fee period during any part of which a marketing authorization, traditional herbal registration, 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;

"safety development" means the toxicological and pharmacological testing necessary to demonstrate the safety of a relevant medicinal product, in accordance with section 4 of Part 1 of Annex 1 to the 2001 Directive;

(**14**) Repeals and amendments to section 7 have been made by S.I. 1977/1050, 1983/1724, 1992/604, 1994/276, 2004/1031, 2005/50 and 2753 and 2006/2407.

"scientific advice" means advice in connection with the quality, safety or clinical development for a relevant medicinal product;

"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(**15**);

"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 Marketing Authorisation 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 the Marketing Authorisation Regulations,

means "variation to the terms of a marketing authorization" as defined in Article 2(1) of EC Regulation No. 1234/2008;

(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 falling within the meaning of section 8(3) of the Act which relates wholly or partly to medicinal products for human use.

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(**16**).

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**) S.I. 2005/2789.
(**16**) Revocations and amendments to regulation 31 have been made by S.I. 2005/2754 and 2006/1928.