SCHEDULES

SCHEDULE 1

Regulation 2

General interpretation provisions

1. In these Regulations—

"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 [F1];

"the Act" means the Medicines Act 1968 [F2] and, except as provided below, expressions used in these Regulations have the same meaning as in the Act;

"active ingredient" means an ingredient of a medicinal product in respect of which efficacy is claimed (whether therapeutic, diagnostic or otherwise);

"active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;

"active substance registration" means the registration required by importers, manufacturers and distributors of active substances under article 52a of the 2001 Directive;

[[F3]"Annex I to the 2001 Directive" has the meaning given by regulation 8(1) of the Human Medicines Regulations;**]**

"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 authorisation has been granted;

[[F3]"biological medicinal product" has the meaning given in paragraph 3.2.1.1.(b) of Part I of Annex I to the 2001 Directive;**]**

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

"British Pharmacopoeia Commission" means the committee called the British Pharmacopoeia Commission carrying out functions under regulation 11 (British Pharmacopoeia Commission) of the Human Medicines Regulations;

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

"certificate of registration" means a certificate for the purposes of Part 6 of the Human Medicines Regulations;

"change of ownership application" means an application—

(a) for—

(i) a marketing authorisation for a medicinal product in respect of which another person holds a marketing authorisation;

(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 authorisation, 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 authorisation, 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 Module 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 [F4];

"Commission on Human Medicines" means the Commission on Human Medicines established under regulation 9 of the Human Medicines Regulations;

"Commission Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [F5];

[[F3]"the Committee for Medicinal Products for Human Use" means the committee established under Article 5(1) of Regulation (EC) No 726/2004;**]**

"complex application" has the meaning given in paragraph 5 of Schedule 2;

"concerned member State" means for the purpose of—

(a) regulation 12 and Part 2 of Schedule 2 (capital fees for applications for authorisations, licences, registrations and certificates), an EEA State, the competent authority of which receives 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 authorisation;

(b) regulation 18 and Part 4 of Schedule 2 (capital fees for applications for variations of authorisations, licences and registrations), an EEA State, the competent authority of which has received an application for a variation to the terms of a marketing authorisation under the procedure laid down in Commission Regulation (EC) No 1234/2008 for a medicinal product in respect of which an authorisation 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 [F6]; 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, under Article 11(2) of that Directive and Article 20(b) of the 2001 Directive;

"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 [F7];

"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 [F8];

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

[[F3]"the EMA" means the European Medicines Agency established by Regulation (EC) No 726/2004;**]**

"European Union marketing authorisation" means a marketing authorisation granted by the European Commission under Council Regulation (EEC) No. 2309/93[F9] or Regulation (EC) No 726/2004;

"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;

"good distribution practice" means the guidelines on good distribution practice published by the European Commission in accordance with 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 under Article 108a of the 2001 Directive;

"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

(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 by any pharmacopoeia used officially in a member State;

"homoeopathic marketing authorisation" means a marketing authorisation granted by the licensing authority in respect of a national homoeopathic medicinal product;

"Human Medicines Regulations" means the Human Medicines Regulations 2012 [F10].

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

"licensing authority" shall be interpreted in accordance with regulation 6 (the licensing authority and the Ministers) of the Human Medicines Regulations;

"the list of online sellers of medicines" has the same meaning as that given to "the list" by regulation 256A [F11] of the Human Medicines Regulations;

"major application" has the meaning given in paragraph 10 of Schedule 2;

"manufacturer's licence" is to be construed in accordance with regulation 17 (manufacturing of medicinal products) of the Human Medicines Regulations;

"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 authorisation" means, except in regulation 3, an authorisation relating to a medicinal product for human use that is—

(a) a United Kingdom marketing authorisation granted by the licensing authority under Part 5 (marketing authorisations) of the Human Medicines Regulations **[**[F12](and a reference to a UKMA(GB), UKMA(NI) or UKMA(UK) should be construed in accordance with those Regulations)**]**;

(b) a European Union marketing authorisation; or

(c) a product licence, including one which is a product licence of right or a product licence which has effect as a marketing authorisation by virtue of paragraphs 1 and 2 of Schedule 32 (transitional provisions and savings) to the Human Medicines Regulations;

"medicinal product" **[**[F13]has the meaning given by regulation 2 of the Human Medicines Regulations and includes**]** any substance or article specified in any order for the time being in force made under section 104 [F14] (application of the 2012 Regulations to certain articles and

substances) or 105(1)(a) [F15] (application of the 2012 Regulations to certain other substances which are not medicinal products) of the Act which directs that the Human Medicines Regulations 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;

[[F16]" orphan marketing authorisation " has the meaning given by regulation 8(1) of the Human Medicines Regulations;**]**

"parallel import licence" means a licence that—

(a) is granted by the licensing authority in compliance with the rules of European Union law relating to parallel imports; and

(b) authorises the holder to place on the market a medicinal product imported into the United Kingdom from another EEA State;

"penalty fee" means a fee payable under regulation 54;

"periodic fee" means the fee payable under—

(a) regulation 38 by the holder of a marketing authorisation (other than a European Union marketing authorisation), a traditional herbal registration, a manufacturing authorisation, a manufacturer's licence or a wholesale dealer's licence; or

(b) regulation 39 by a person included on the list of online sellers of medicines;

"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 authorisation, 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 authorisation 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-authorisation safety study protocol;

(b) the advice is given to the holder of a United Kingdom marketing authorisation or a European Union marketing authorisation 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;

  (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-authorisation safety study protocol;

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

"product licence" means a product licence within the meaning of paragraph 2(1) (product licences) of Schedule 32 to the Human Medicines Regulations;

"product licence of right" means a product licence within the meaning of paragraph 3(2) (product licences of right) of Schedule 32 to the Human Medicines Regulations;

"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 authorisation;

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

"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 [F17];

"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 authorisations relating to a product range under Article 24 of the 2001 Directive;

(b) the advice is in connection with—

  (i) a referral under Article 30 or 31 or in connection with the procedure laid down under Articles 32 to 34 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 an application for the variation or renewal of one or more EU marketing authorisations in relation to a product range;

"relevant fee period" means any fee period during any part of which a marketing authorisation, 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;

"repeat formulation" means—

(a) the formulation of a product which is identical to the formulation of another product—

  (i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorisation; or

  (ii) to which the applicant has, by the holder of the certificate of registration or the homoeopathic marketing authorisation which relates to it, been authorised in writing to make reference for the purposes of this application; or

(b) where more than one application is made by the same applicant on the same occasion in respect of products of identical formulations, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the formulation

of the product to which the first of those applications which is considered by the licensing authority relates;

"repeat stock" means—

(a) a homoeopathic stock which is identical to another homoeopathic stock which is used in the preparation of a product—

(i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorisation; or

(ii) in respect of which another person holds a certificate of registration or a homoeopathic marketing authorisation to which, for the purposes of his application, the applicant has been authorised in writing to make reference by the person (or if more than one, each of the persons) who supplied information to the licensing authority in connection with the application for the certificate of registration or a homoeopathic marketing authorisation which relates to that product; or

(b) where more than one application is made by the applicant on the same occasion in respect of products prepared from identical homoeopathic stocks, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the homoeopathic stock used in the preparation of the product to which the first of those applications which is considered by the licensing authority relates;

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

"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 22(2) (manufacturer's licence relating to the import of medicinal products from a state other than an EEA State) of or, paragraph 34 (wholesale dealer's licence relating to special medical imports) of Schedule 4 to the Human Medicines Regulations.

"special medicinal product" means a product within the meaning of regulation 167 of the Human Medicines Regulations or any equivalent legislation in an EEA State other than the United Kingdom;

"total value" means the gross amount of the total sales made during the period of 12 months preceding the date of the application;

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

"traditional herbal registration" means a traditional herbal registration granted by the licensing authority under Part 7 of the Human Medicines Regulations;

"turnover" in relation to wholesale dealing means the gross amount of the total sales made during the period of 12 months preceding the date of the application;

[[F3]"under the unfettered access route" has the meaning given by regulation 8(1) of the Human Medicines Regulations;**]**

"United Kingdom marketing authorisation" means a marketing authorisation granted by the licensing authority under—

(a) Part 5 of the Human Medicines Regulations; or

(b) Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure);

"variation"—

(a) in relation to—

(i) a United Kingdom marketing authorisation; or

(ii) a product licence which has effect as such a marketing authorisation by virtue of paragraphs 1 and 2 of Schedule 32 (transitional provisions and savings) to the Human Medicines Regulations,

means "variation to the terms of a marketing authorisation" as defined in **[**[F18]regulation 8(1) of the Human Medicines Regulations**]** ;

(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 within the meaning of regulation 18(1) (wholesale dealing in medicinal products) of the Human Medicines Regulations.

F1 OJ No L 311, 28.11.2001, p67; relevant amending instruments are Directive 2002/98/EC of the European Parliament and of the Council (OJ No L 33, 8.2.2003, p30), Commission Directive 2003/63/EC (OJ No L 159, 27.6.2003, p46), Directive 2004/24/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p85), Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34), Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No L 378, 27.12.2006, p1), Regulation (EC) No 1394/2007 of the European Parliament and of the Council (OJ No L 324, 10.12.2007, p121), Directive 2008/29/EC of the European Parliament and of the Council (OJ No L 81, 20.3.2008, p51), Directive 2009/53/EC of the European Parliament and of the Council (OJ No L 168, 30.6.2009, p33), Commission Directive 2009/120/EC (OJ No L 242, 15.9.2009, p3), Directive 2010/84/EU of the European Parliament and of the Council (OJ No L 348, 31.12.2010, p74), Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74) and Directive 2012/26/EU of the European Parliament and of the Council (OJ No L 299, 27.10.2012, p1).

F2 1968 c.67.

F3 Words in Sch. 1 para. 1 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 6(a)(iv)** (with Sch. 1 para. 11) (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(f)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 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**,** 2009/1164, 2010/1882 and 2012/1916.

F5 OJ No L 334, 12.12.2008, p7. This regulation has been amended by Commission Regulation (EC) No 712/2012 (OJ No L 209, 4.8.2012, p4).

F6 S.I. 1971/972; relevant amending instruments are S.I. 1992/2846, 1994/2852, 2004/1031 and 2005/2789.

F7 OJ No L 262, 14.10.2003, p22.

F8 OJ No L 147, 9.6.1975, p13. This Directive has been codified and assembled with others into Directive 2001/83/EC.

F9 OJ No L 214, 24.8.1993, p1. This Regulation has been amended by Commission Regulation (EC) No 649/98 (OJ No L 88, 24.3.1998, p7), Council Regulation (EC) No 807/2003 (OJ No L 122, 16.5.2003, p36) and Council Regulation (EC) No 1647/2003 (OJ No L 245, 29.9.2003, p19).

F10 S.I. 2012/1916.

F11 Regulation 256A was inserted by S.I. 2013/1855.

F12 Words in Sch. 1 para. 1 inserted (31.12.2020) by S.I. 2019/775, **Sch. 1 para. 6(a)(ai)** (with Sch. 1 para. 11) (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(f)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in Sch. 1 para. 1 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 6(a)(i)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

F14 Section 104 has been amended by S.I. 2004/1031, 2006/2407, 2012/1916.

F15 Relevant amending instrument is S.I. 2012/1916.

F16 Words in Sch. 1 para. 1 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 6(a)(ii)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

F17 OJ No L 136, 30.4.2004, p1; relevant amending instruments are Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No L 378, 27.12.2006, p1), Regulation (EC) No 1394/2007 of the European Parliament and of the Council (OJ No L 324, 10.12.2007, p121), Regulation (EC) No 219/2009 of the European Parliament and of the Council (OJ No L 87, 31.3.2009, p109), Regulation (EC) No. 470/2009 of the European Parliament and of the Council (OJ No L 152, 16.6.2009, p11), Regulation (EU) No 1235/2010 of the European Parliament and of the Council (OJ No L 348, 31.12.2010, p1) and Corrigendum (OJ L 201, 27.7.2012, p.138).

F18 Words in Sch. 1 para. 1 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 6(a)(iii)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

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 [F19].

F19 Revocations and amendments to regulation 31 have been made by S.I. 2005/2754 and 2006/1928.

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

4. In these Regulations any reference to an application to be included on the list of online sellers of medicines is a reference to a notification under regulation 256C [F20] of the Human Medicines Regulations (notification requirements for sellers of medicinal products at a distance) and any reference to an applicant to be included on the list of online sellers of medicines is a reference to a person who submits such a notification.

F20 Regulation 256C was inserted by S.I. 2013/1855.

[F21 5.—(1) For the purpose of these Regulations, a company is a medium company if, for the financial year before that in which the application is made, the total value of products it has sold or supplied for the financial year is not more than the amount for the time being specified in item 1 in section 465(3) of the Companies Act 2006 (qualification of company as medium) and the conditions in sub-paragraph (2) are met.

(2) The conditions for the purposes of sub-paragraph (1) are—

(a) the company's balance sheet total as defined in section 465(5) of the Companies Act 2006 is not more than the amount for the time being specified in item 2 in section 465(3) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the number for the time being specified in item 3 in section 465(3) of that Act.

(3) In this paragraph "financial year" is to be construed in accordance with section 390 of the Companies Act 2006.**]**

F21 Sch. 1 para. 5 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 6(b)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Products for Human Use) (Fees) Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 1 para. 1 words inserted by S.I. 2023/314 reg. 23

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 2 para. 35A inserted by S.I. 2023/314 reg. 24(14)
- Sch. 2 para. 27(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(i)
- Sch. 2 para. 27(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(ii)
- Sch. 2 para. 27(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iii)
- Sch. 2 para. 27(2)(d)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iv)
- Sch. 2 para. 27(3)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(b)
- Sch. 2 para. 28(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(i)
- Sch. 2 para. 28(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(3)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28(3)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28A(1)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(a)
- Sch. 2 para. 28A(2)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(b)
- Sch. 2 para. 56(c) sum substituted by S.I. 2023/314 reg. 24(27)(b)
- Sch. 2 para. 57A(a) sum substituted by S.I. 2023/314 reg. 24(29)(a)
- Sch. 2 para. 57A(b) sum substituted by S.I. 2023/314 reg. 24(29)(b)
- Sch. 2 para. 57A(c) sum substituted by S.I. 2023/314 reg. 24(29)(c)
- Sch. 2 para. 57A(d) sum substituted by S.I. 2023/314 reg. 24(29)(d)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(v)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(vii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(viii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ix)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(v)
- Sch. 4 para. 15(3) inserted by S.I. 2023/314 reg. 26(8)
- reg. 19A(1) sum substituted by S.I. 2023/314 reg. 13(a)
- reg. 19A(2)(a) sum substituted by S.I. 2023/314 reg. 13(b)
- reg. 19A(2)(b) sum substituted by S.I. 2023/314 reg. 13(c)
- reg. 19B sum substituted by S.I. 2023/314 reg. 14
- reg. 19C(2)(a) sum substituted by S.I. 2023/314 reg. 15(a)(i)
- reg. 19C(2)(b) sum substituted by S.I. 2023/314 reg. 15(a)(ii)
- reg. 19C(2)(c) sum substituted by S.I. 2023/314 reg. 15(a)(iii)
- reg. 19C(3)(a) sum substituted by S.I. 2023/314 reg. 15(b)(i)
- reg. 19C(3)(b) sum substituted by S.I. 2023/314 reg. 15(b)(ii)
- reg. 19C(3)(c) sum substituted by S.I. 2023/314 reg. 15(b)(iii)

- reg. 19E(2)(a) sum substituted by S.I. 2023/314 reg. 16(a)
- reg. 19E(2)(b) sum substituted by S.I. 2023/314 reg. 16(b)
- reg. 19EA inserted by S.I. 2023/314 reg. 17