

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—

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- (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;

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“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;

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“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

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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;

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“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

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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”—

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- (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 [F18regulation 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.

Textual Amendments

- 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\(1\)](#)

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- 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}.

Textual Amendments

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.

Textual Amendments

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

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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.]

Textual Amendments

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)

SCHEDULE 2

Regulations 12(1)(a); 13; 17;19(2)(a);
20(2)(a); 23(7); 24; 25(1);29(1) and (3)

Capital fees for applications for, and variations to, marketing
authorisations, licences, registrations and certificates

PART 1

General: interpretation and categories of applications and variations

Interpretation

1. In this Schedule—

“active ingredient from a new source” means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted;

“EU marketing authorisation” means—

- (a) a marketing authorisation; or
- (b) an authorisation issued by a competent authority of an EEA State other than the United Kingdom for the purposes of Article 6 of the 2001 Directive;

“the MHRA portal” means the internet-based hosted platform which enables persons to carry out business with the Medicines and Healthcare products Regulatory Agency of the Department of Health [F22 and Social Care] electronically, known as the “the MHRA Portal”;

“new active ingredient” means an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;

“new excipient” means—

- (a) except in Part 2, paragraph 35 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—
 - (i) which is intended to be administered by the same route of administration as the product in question; and
 - (ii) in respect of which a marketing authorisation (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted,

except that in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union) as an approved ingredient or additive in food or in a food product;

- (b) in Part 2, paragraph 35 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorisation (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted, except that—
 - (i) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union) as an approved ingredient or additive in food or in a food product; and
 - (ii) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union) as an approved ingredient or additive in a cosmetic product;

“Phase I trial” means a clinical trial to study the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial;

“Phase II or Phase III trial” means a clinical trial, other than a Phase I trial, where the medicinal product being tested—

- (a) does not have an EU marketing authorisation; or
- (b) has an EU marketing authorisation, but—
 - (i) there has been a change—
 - (aa) to the process of manufacture of the product or its active ingredient; or
 - (bb) of manufacturer of that product, or
 - (ii) the product is to be used in the trial other than in accordance with the terms of the summary of product characteristics under that authorisation;

“Phase IV trial” means a clinical trial other than a Phase I trial or a Phase II or Phase III trial;

“TSE risk ingredient from a new source” and “TSE risk excipient from a new source” means an active ingredient or excipient, respectively, which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

- (a) the application names as manufacturer, a manufacturer not previously named as the manufacturer of that ingredient or excipient included in a medicinal product in respect

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of which a marketing authorisation (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted; and

- (b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

“vitamin or mineral from a new source” means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted.

Textual Amendments

F22 Words in Sch. 2 para. 1 inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), Sch. para. 20(ff) (with art. 14)

General: categories of Applications and Variations

2.—(1) In this Schedule, references to a particular type of application, variation or variation application shall be interpreted in accordance with this paragraph and paragraphs 3 to 23.

(2) A reference to a “European reference product application” means an application for a marketing authorisation to which the third sub-paragraph of Article 10(1) of the 2001 Directive applies.

Administrative variation application

3. An administrative variation application is an application by a traditional herbal registration holder to vary a traditional herbal registration where the variation applied for falls within one of the following sub-paragraphs—

- (a) a change of either or both of the name and the address of the holder of the registration;
- (b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the registration where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place; or
- (c) the removal from the registration of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place.

Extension application

4. An extension application is an application—

[^{F23}(a) for an extension of a marketing authorisation—

- (i) in the case of a UKMA(NI) or UKMA(UK), within the meaning of Article 2(4) of Commission Regulation (EC) No 1234/2008; or
- (ii) in the case of a UKMA(GB), within the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations; and]

- (b) which includes the result of pre-clinical tests or clinical trials as specified in Article 8(3) (i) of the 2001 Directive.

Textual Amendments

F23 Sch. 2 para. 4(a) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(2) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, Sch. 2 para. 188(g)(i))

Complex application

5. A complex application is an application, other than a major application, for a marketing authorisation where the application falls within one or more of the following sub-paragraphs—

- (a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as treatment for a new category of disease;
- (b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (c) the application relates to a medicinal product containing a new excipient;
- (d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in relation to any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (e) the application relates to a medicinal product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (f) the application relates to a medicinal product which is a controlled release preparation and is not a simple application;
- (g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (i) unless a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application, the application names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorisation which the applicant holds in respect of that product;

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- (k) the application is for the grant of a marketing authorisation for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorisation which the applicant holds;
- (l) the application is for the grant of a marketing authorisation for a medicinal product which is to be delivered by way of a metered dose inhaler;
- (m) the application is for the grant of a marketing authorisation for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;
- (n) the application relates to a medicinal product—
 - (i) which is administered to the site of action or absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question; and
 - (ii) in respect of that other product, a marketing authorisation (other than a product licence of right) has previously been granted;
- (o) the application is an application for a marketing authorisation to which Article 10(3) of the 2001 Directive applies;
- (p) the application is an application where the sole or primary evidence for the safety and efficacy of the medicinal product consists of published scientific literature;
- (q) the application is an extension application;
- (r) the application—
 - (i) is not an application in accordance with Article 10, 10a or 10c of the 2001 Directive; and
 - (ii) includes the results of pre-clinical tests or clinical trials as specified in Article 8(3) (i) of the 2001 Directive; or
- (s) the application is an application for a marketing authorisation to which the first subparagraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies.

Complex registration application

6. A complex registration application is an application for a traditional herbal registration relating to a medicinal product containing an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted.

Complex variation application

7. A complex variation application is an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

- (a) a change in that product's active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;
- (b) a change in that product's excipients which involves the addition of one or more TSE risk excipients from a new source; or
- (c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application.

Decentralised procedure application

8. A decentralised procedure application is a major application, a complex application, a standard application or a simple application for a marketing authorisation for a medicinal product in respect of which at the time of the application—

- (a) a marketing authorisation has not been granted in any EEA State; and
- (b) an application for a marketing authorisation has been made in more than one EEA State under the procedure in Title III, Chapter 4 of the 2001 Directive.

Extended Type II Complex Variation Application

9. An Extended Type II Complex Variation Application is an application by a marketing authorisation holder to vary a marketing authorisation (not being a parallel import licence) so that the medicinal product is indicated for use—

- (a) in a therapeutic area for which the product was not previously indicated for use; or
- (b) in respect of an organ, or any other part, of the human body for which the product was not previously indicated for use, if the application is supported by data which comprises or includes the results of clinical trials or physico-chemical, microbiological or pharmacological and toxicological tests.

Major application

10. A major application is an application for a marketing authorisation made to the licensing authority on the grounds that a medicinal product contains a new active ingredient.

Mutual recognition procedure incoming application

11. A mutual recognition procedure incoming application is a major application, a complex application or a standard application for a marketing authorisation for a medicinal product in respect of which—

- (a) a marketing authorisation has already been granted in another EEA State; and
- (b) recognition of that marketing authorisation is sought from the licensing authority by way of the grant of a marketing authorisation in the United Kingdom, under the procedure in Title III, Chapter 4 of the 2001 Directive.

New excipient variation application

12. A new excipient variation application is an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient.

New indication variation application

13. A new indication variation application is an application to vary a marketing authorisation for a national homoeopathic product, so that product is indicated for a therapeutic use not previously covered by that authorisation.

Parallel Import Licence application

14.—(1) An application for a simple parallel import licence means an application for a parallel import licence in respect of a proposed importation of a medicinal product (“P”) which is similar to

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a medicinal product (“R”) in respect of which a marketing authorisation has already been granted in the United Kingdom.

(2) For the purposes of sub-paragraph (1) “similar” means—

- (a) the manufacturer of P and the manufacturer of R are either the same company or belong to the same group of companies or, in the case of independent companies, agreements have been concluded with the same licensor; and
- (b) product P and R are manufactured according to the same formulation, using the same active ingredients, have the same pharmaceutical form and have no differences that will result in a difference in the therapeutic effect.

(3) An application for a complex parallel import licence means an application for a parallel import licence which is not a simple parallel import licence and the application is in respect of a medicinal product—

- (a) containing a new excipient;
- (b) containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (c) which is a controlled release preparation;
- (d) which is a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (e) which is a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (f) containing an active ingredient which, unless that active ingredient is covered by a European Pharmacopoeia certificate of suitability, is not manufactured by a manufacturer of the active ingredient which is included in the medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (g) which is an influenza vaccine;
- (h) which is to be delivered by way of a metered dose inhaler;
- (i) which is in powder form and is to be delivered by inhalation;
- (j) which falls within the description of the medicinal product set out in Article 10(3) of the 2001 Directive;
- (k) where the sole or primary evidence for the safety and efficacy of that product consists of published scientific literature;
- (l) in respect of which a marketing authorisation has not been made under Article 10, 10a or 10c of the 2001 Directive by the competent authority in the member State of exportation, and the application includes the results of pre-clinical tests or clinical trials within the meaning of Article 8(3)(i) of the 2001 Directive; or
- (m) in respect of which a marketing authorisation to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applied in the member State of exportation.

(4) An application for a standard parallel import licence means an application for a parallel import licence which is not a complex parallel import licence or a simple parallel import licence.

(5) An application shall not fall within the meaning of sub-paragraph (1), (3) or (4) where the applicant and the holder of the marketing authorisation in the member State of exportation in respect of which the medicinal product in question relates are a parent undertaking and subsidiary undertaking within the meaning of section 1162 (taken together with section 1161 of, and Schedule 7 to) the Companies Act 2006 ^{F24}.

Textual Amendments

F24 2006 c.46.

Reclassification variation application

15. A reclassification variation application is an application for variation of a marketing authorisation which has the effect that a medicinal product to which that authorisation relates—

- (a) is to be available only from a pharmacy or on general sale, where previously it was available only on prescription; or
- (b) is to be available on general sale, where previously it was available only from a pharmacy.

Reduced registration application

16.—(1) A reduced registration application category I is an application other than a complex registration application for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea.

(2) A reference to a reduced registration application category II means an application, other than a complex registration application, or a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows—

- (a) the application relates to a medicinal product which is presented in the form of a herbal tincture;
- (b) the application relates to a medicinal product which is presented in the form of an essential oil;
- (c) the application relates to a medicinal product which is presented in the form of a fatty oil; or
- (d) the application relates to a medicinal product which contains only herbal substances in a capsule.

Simple application

17. A simple application is an application—

- (a) for a marketing authorisation to which Article 10c of the 2001 Directive applies; or
- (b) made no later than three months after the expiry of a marketing authorisation, which is for a marketing authorisation containing identical provisions to those contained in the expired authorisation and which is made by the person who held the expired authorisation.

Standard application

18. A standard application is any application for the grant of a marketing authorisation which is not a major application, a complex application, a simple application, a change of ownership application or an application for a parallel import licence.

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Standard registration application

19. A standard registration application means any application for the grant of a traditional herbal registration which is not a complex registration application, a reduced registration application category I, a reduced registration application category II or a change of ownership application.

Standard variation application

20. A standard variation application is an application by a traditional herbal registration holder to vary a traditional herbal registration which is not a complex variation application, a new excipient variation application or an administrative variation application.

Standard variation application for a homoeopathic medicinal product

21. A standard variation application for a homoeopathic medicinal product is an application for a variation of a marketing authorisation for a national homoeopathic product which requires—

- (a) the replacement of an excipient used in the manufacture of the product;
- (b) the replacement of a reagent indirectly associated with the manufacturing process of the product or which disappears from that process with a comparable reagent;
- (c) a change to the qualitative composition of the container or other form of packaging immediately in contact with the product;
- (d) a change to the method of manufacture of a homoeopathic stock included in the product;
- (e) a change to the specification of any reagent or excipient used in the manufacture of the product;
- (f) a change to the finished product specification of the product;
- (g) a change to the test procedure for any raw material used in the manufacture of the product;
- (h) a change to the test procedure for the product;
- (i) a change to the test procedure for the container or other form of packaging immediately in contact with the product;
- (j) a change to comply with a supplement to the European Pharmacopoeia or any national pharmacopoeia of a member State;
- (k) a change to the shape of the container in which the product may be placed on the market;
- (l) an additional pack size in which the product may be placed on the market;
- (m) a change to the approved storage conditions for the product;
- (n) a change to the shelf life of an unopened container of the product after the container has been opened for the first time;
- (o) a change to the dimensions of an approved dosage form of the product (for example, tablets); or
- (p) a change following modification to the manufacturing authorisation referred to in Article 40 of the 2001 Directive.

Type IB and Type II Applications

22.—(1) A Type IB Application is an application by a marketing authorisation holder to vary a marketing authorisation (not being a parallel import licence) which is a “minor variation of type IB” within the meaning of

- ^{F25}(a) in the case of a UKMA(NI) or UKMA(UK), Article 2(5) of Commission Regulation (EC) No 1234/2008;

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- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations]
- (2) A Type II Application is an application by a marketing authorisation holder to vary a marketing authorisation (not being a parallel import licence) which is not—
- (a) a reclassification variation;
 - (b) a Type IA Application;
 - (c) a Type IB Application;
 - (d) a Type II Complex Variation Application;
 - (e) an Extended Type II Complex Variation Application; or
 - (f) an application for an extension of a marketing authorisation within the meaning of Article 2(4) of Commission Regulation (EC) No 1234/2008.
- [^{F26}(a) in the case of a UKMA(NI) or UKMA(UK), Article 2(4) of Commission Regulation (EC) No 1234/2008;
- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations]
- (3) For the purposes of sub-paragraph (2)(b), a “Type IA Application” means an application by a marketing authorisation holder to vary a marketing authorisation (not being a parallel import licence) which is a “minor variation of type IA” within the meaning of
- [^{F27}(a) in the case of a UKMA(NI) or UKMA(UK), Article 2(2) of Commission Regulation (EC) No 1234/2008;
- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations]

Textual Amendments

- F25** Sch. 2 para. 22(1)(a)(b) substituted for words in Sch. 2 para. 22(1) (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(3)(a) (as amended by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(ii)(aa)**)
- F26** Sch. 2 para. 22(2)(a)(b)(f) substituted for words in Sch. 2 para. 22(2)(f) (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(3)(b) (as amended by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(ii)(bb)**)
- F27** Sch. 2 para. 22(3)(a)(b) substituted for words in Sch. 2 para. 22(3) (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(3)(c) (as amended by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(ii)(cc)**)

Type II Complex Variation Application

23. A Type II Complex Variation Application is an application for a variation of a marketing authorisation, other than an Extended Type II Complex Variation Application, which relates to a change—

- (a) in the formulation of a medicinal product comprising one or more of the following changes, other than a change to which [^{F28}in the case of a UKMA(NI) or UKMA(UK), paragraph 1 (changes to active substances) or paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex I to Commission Regulation (EC) No 1234/2008 applies or, in the case of a UKMA(GB), sub-paragraph (a) (changes to active substances) or sub-paragraph (b) (changes to strength, pharmaceutical form and route of administration) of the definition of “extension of a UK marketing authorisation” in paragraph 1 of Schedule 10A to the Human Medicines Regulations applies] —

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- (i) a change which necessitates in-vivo bioavailability studies to be performed on that product;
 - (ii) a change in that product's preservative system; or
 - (iii) a change in that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or
- (b) which is considered a “major variation of type II” within the meaning of [F29] in the case of a UKMA(NI) or UKMA(UK), Article 2(3) of [Commission Regulation \(EC\) No 1234/2008](#) or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations] and which is—
- (i) supported by data which comprises or includes the results of clinical trials or physicochemical, biological, microbiological or pharmacological and toxicological tests; or
 - (ii) accompanied by evidence relating to post-marketing experience which is information of any type described in paragraph 5.2.6 of Part I of Annex I to the 2001 Directive (clinical documentation); or
- (c) in the composition, manufacture or use of a medicinal product to which—
- (i) sub-paragraph (c), (e), (g), (h), (j) or (n) of the definition of complex application in paragraph 5 of this Schedule would apply where an application for a marketing authorisation is made in respect of a medicinal product; or
 - (ii) sub-paragraph (i) of that definition would so apply and the change is not a minor variation of type IA or a minor variation of type IB within the meaning of [F30] in the case of a UKMA(NI) or UKMA(UK), [Commission Regulation \(EC\) No 1234/2008](#) or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations] .

Textual Amendments

- F28** Words in [Sch. 2 para. 23\(a\)](#) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, [Sch. 1 para. 7\(4\)\(a\)](#) (as amended by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(g\)\(iii\)\(aa\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F29** Words in [Sch. 2 para. 23\(b\)](#) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, [Sch. 1 para. 7\(4\)\(b\)](#) (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\(g\)\(iii\)\(bb\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F30** Words in [Sch. 2 para. 23\(c\)](#) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, [Sch. 1 para. 7\(4\)\(c\)](#) (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\(g\)\(iii\)\(cc\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

PART 2

Capital Fees for Applications for Authorisations, Licences, Registrations and Certificates

Marketing authorisations

24.—(1) Unless sub-paragraphs (2) or (4) or paragraphs 25, 26, 28 or 29 apply, the fee payable under regulation 12(1)(a) in connection with an application for a marketing authorisation of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

(2) This paragraph applies—

- (a) to a complex application for a marketing authorisation of a kind described in item 2 in column 1 of the following table; and
- (b) where the application only concerns a new source or supply of a substance listed in Part 7 of this Schedule.

(3) If sub-paragraph (2) applies the appropriate fee is the amount specified for an application of the same type under item 3 of the following table.

(4) This paragraph applies—

- (a) to a complex application for a parallel import licence of a kind described in item 5(c) in column 1 of the following table; and
- (b) where the application only concerns a new source or supply of a relevant substance listed in Part 7 of this Schedule.

(5) If sub-paragraph (4) applies the appropriate fee is the amount specified for item 5(b) in the following table.

[^{F31}Fees for marketing authorisation applications

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
1. Major Application	
(a) in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex 1 to the 2001 Directive applies	£29,732
(b) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£62,421
(c) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£62,421
(d) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for UKMA(GB)	£62,421
(e) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£18,437

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<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
(f) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	£62,421
(g) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£18,437
(h) in any other case	£92,753
2. Complex application	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£17,330
(b) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£17,330
(c) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£17,330
(d) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£10,443
(e) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	£17,330
(f) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£10,443
(g) in any other case	£25,643
3. Standard application	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£6,350
(b) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£6,350

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<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
(c) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£6,350
(d) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£5,783
(e) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	£6,350
(f) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£5,783
(g) in any other case	£9,402
4. Simple application	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£2,564
(b) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£2,564
(c) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£2,564
(d) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive	£2,564
(e) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£2,564
(f) in any other case	£2,564
5. Parallel import licence applications	
(a) in respect of a simple parallel import licence	£1,792
(b) in respect of a standard parallel import licence	£6,663

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<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
(c) in respect of a complex parallel import licence	£18,180
6. Change of ownership application	£442]

(6) Each reference in paragraphs 25, 27 and 28 to an amount payable under paragraph 24 in respect of an application refers to the amount payable under this paragraph in respect of an application of the kind in question.

Textual Amendments

F31 Sch. 2 para. 24 Table substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(5)** (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(g)(iv)**); 2020 c. 1, Sch. 5 para. 1(1)

[^{F32}Fees where an application for a European Union marketing authorisation had been made before IP completion day

24A.—(1) This paragraph applies where, before IP completion day —

- (a) an application has been made to the EMA for a European Union marketing authorisation;
- (b) day 120 has passed; and
- (c) no final decision has been made by the European Commission in relation to the grant of an European Union marketing authorisation under Article 10 of Regulation (EC) No 726/2004.

(2) Where this paragraph applies and the applicant for the European Union marketing authorisation applies for a UK marketing authorisation in accordance with paragraph 31(2) of Schedule 33A to the Human Medicines Regulations, the fee payable under regulation 12(1) shall be waived.

(3) In this paragraph, “day 120” means the day during the assessment of an application for a European Union marketing authorisation on which the Committee for Medicinal Products for Human Use adopts the list of questions, as well as the overall conclusions and review of the scientific data, to be sent to the applicant.]

Textual Amendments

F32 Sch. 2 para. 24A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(6)** (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(g)(v)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fees where application includes reclassification

25.—(1) Unless paragraph 27 applies, where an application, other than a major application, includes a reclassification element and—

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- (a) the reclassification falls within the category of application described in paragraph 15(a), an amount of £11,992 is payable in addition to the amount payable under paragraph 24 in respect of that application; or
 - (b) the reclassification falls within the category of application described in paragraph 15(b), an amount of £8,162 is payable in addition to the amount payable under paragraph 24 in respect of that application.
- (2) For the purposes of this paragraph, an application includes a reclassification element if—
- (a) in the case of an application falling within the category described in paragraph 15(a), the medicinal product in question is to be available in the United Kingdom only from a pharmacy, unless there is an analogous medicinal product available in the United Kingdom only from a pharmacy or on general sale; or
 - (b) in the case of an application falling within the category described in paragraph 15(b), the medicinal product in question is to be available in the United Kingdom on general sale, unless there is an analogous medicinal product also so available.
- (3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorisation or a European Union marketing authorisation and which—
- (a) has the same active ingredient, route of administration and use,
 - (b) has the same strength or a higher strength,
 - (c) has the same dosage or daily dosage, or a higher dosage or daily dosage, and
 - (d) is for sale or supply at the same quantity or a greater quantity,
- as the medicinal product in relation to which the application is made.

Fees where person holds clinical trial certificate

26. Where a major application is made by a person who holds a clinical trial certificate for a medicinal product which contains the same active ingredient as the medicinal product in respect of which the marketing authorisation is applied for, the fee payable under regulation 12(1)(a) in connection with the application is reduced by the amount of the application fee paid for the clinical trial certificate.

Joint development

27.—(1) In this paragraph—

“joint development” means the development by two or more applicants for marketing authorisations relating to medicinal products—

- (a) each of which contains the same new active ingredient or combination of new active ingredients but with different proprietary names and which does not require separate consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products;
- (b) the development of which has been notified to the licensing authority at or before the time the application is submitted, as being a joint development undertaken by those applicants; and
- (c) in respect of which applications for marketing authorisations have been received by the licensing authority within one month of each other;

“primary applicant” means—

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- (a) that party to a joint development who first makes an application for a marketing authorisation relating to a new active ingredient which was the subject of that joint development; or
 - (b) that party to a joint development who first makes an application for a marketing authorisation relating to a different dosage form or strength of that new active ingredient;
- “secondary applicant” means any party to a joint development, other than the primary applicant, who makes an application for a marketing authorisation relating to the same new active ingredient as that which was the subject of the application made by the primary applicant.

(2) Unless sub-paragraph (3) applies, where a joint development relates to a medicinal product and two or more applications for marketing authorisations are submitted to the licensing authority by parties to the joint development, the fee payable under regulation 12(1)(a) is the amount payable in respect of a major application under paragraph 24 plus—

- [^{F33}(a) in respect of the first or only marketing authorisation applied for by that secondary applicant—
 - (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or
 - (ii) in any other case, the amount payable in respect of a complex application under paragraph 24;
- (b) in respect of each additional marketing authorisation applied for by that secondary applicant which relates to a medicinal product of the same dosage form—
 - (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
 - (ii) in any other case, the amount payable in respect of a standard application under paragraph 24;
- (c) in respect of the first additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—
 - (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or
 - (ii) in any other case, the amount payable in respect of a complex application under paragraph 24;
- (d) in respect of any other additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—
 - (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
 - (ii) in any other case, the amount payable in respect of a standard application under paragraph 24.]

(3) Where a joint development relates to a medicinal product and an application for an additional marketing authorisation is submitted by both the primary applicant and the secondary applicant, both or all of which applications relate to identical dosage forms and strengths of the product—

- [^{F34}(a) where the amount payable by the primary applicant is that in respect of a complex application, the fee payable under regulation 12(1)(a) by the secondary applicant is—

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- (i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
 - (ii) in any other case, the amount payable in respect of a standard application under paragraph 24;]
- (b) where the amount payable by the primary applicant is that in respect of a standard application, the fee payable under regulation 12(1)(a) by the secondary applicant is that in respect of a simple application under paragraph 24.

Textual Amendments

- F33** Sch. 2 para. 27(2)(a)-(d) substituted for Sch. 2 para. 27(2)(a)-(c) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(7)(a)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)
- F34** Sch. 2 para. 27(3)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(7)(b)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Application for multiple authorisations

28.—(1) Unless sub-paragraph (2), (3) or (4) applies, where an application for a marketing authorisation is for more than one such authorisation each relating to a medicinal product containing the same active ingredient or combination of ingredients, the fee payable under regulation 12(1)(a) is an amount equal to the total of the amounts payable under paragraph 24 in respect of a separate application for each such authorisation.

(2) If the application is a major application, the amount payable is the amount payable in respect of a major application under paragraph 24 and—

- [^{F35}(a) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form with a different route of administration—
- (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or
 - (ii) in any other case, the amount payable in respect of a complex application under paragraph 24;
- (b) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form but with the same route of administration—
- (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
 - (ii) in any other case, the amount payable in respect of a standard application under paragraph 24; and
- (c) in respect of each additional marketing authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients—
- (i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

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- (ii) in any other case, the amount payable in respect of a standard application under paragraph 24.]
- (3) If the application is a complex application, the amount payable is the amount payable in respect of a complex application under paragraph 24 plus—
- (a) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 24;
- [^{F36}(b) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form but with the same route of administration—
- (i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
- (ii) in any other case, the amount payable in respect of a standard application under paragraph 24; and
- (c) in respect of each additional marketing authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients—
- (i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or
- (ii) in any other case, the amount payable in respect of a standard application under paragraph 24.]
- (4) If the application includes any applications for marketing authorisations that include a reclassification element, the amount payable is the amount payable in accordance with sub-paragraphs (1) to (3) and—
- (a) in respect of the first marketing authorisation applied for that includes a reclassification element, the additional amount payable in respect of the relevant category of reclassification variation application under paragraph 25(1); and
- (b) in respect of each other marketing authorisation applied for that includes a reclassification element, £734.
- (5) For the purposes of sub-paragraph (4), a “reclassification element” has the meaning given in paragraph 25(2).

Textual Amendments

F35 Sch. 2 para. 28(2)(a)-(c) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, **Sch. 1 para. 7(8)(a)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

F36 Sch. 2 para. 28(3)(b)(c) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, **Sch. 1 para. 7(8)(b)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

[^{F37}Application by pre-assessment of modules

28A.—(1) Where an applicant for a United Kingdom marketing authorisation submits material in accordance with regulation 50(5) of the Human Medicines Regulations for pre-assessment by the licensing authority rather than as part of the submission of a full application for that marketing

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authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

- (a) £23,188.25 in respect of Module 3 (chemical, pharmaceutical and biological information);
- (b) £23,188.25 in respect of Module 4 (non-clinical reports);
- (c) £23,188.25 in respect of Module 5 (clinical study reports).

(2) Where an applicant for a United Kingdom marketing authorisation for a similar biological medicinal product submits material in accordance with regulations 53, 53A or 53B of the Human Medicines Regulations for pre-assessment of a complex abridged application by the licensing authority rather than as part of the submission of a full application for that marketing authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

- (a) £4,332.50 in respect of Module 3 (chemical, pharmaceutical and biological information);
- (b) £4,332.50 in respect of Module 4 (non-clinical reports);
- (c) £4,332.50 in respect of Module 5 (clinical study reports).

(3) The fee payable under sub-paragraphs (1) and (2) must be paid within a period of 14 days, commencing on the date of the written notice issued by the licensing authority requiring payment of the fee.

(4) Where a fee has been paid under this paragraph, any fee payable under regulation 12(1) in connection with an application for the grant of a United Kingdom marketing authorisation in respect of the same product is reduced by the amount paid under this paragraph provided that no further assessment of the Module concerned is required.]

Textual Amendments

F37 Sch. 2 para. 28A inserted by S.I. 2019/775, **Sch. 1 para. 7(8A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(vi)**)

Authorisation for a national homoeopathic product

29.—(1) In this paragraph—

“formulation” does not include the formulation of a homoeopathic stock;

“identical” means—

- (a) in relation to the formulation of the product, identical as regards the requirements in respect of composition, preparation and testing; and
- (b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the test which it is required to undergo;

“product” includes a series of products each of which is prepared from identical homoeopathic stocks.

(2) This paragraph does not apply to an application which is a mutual recognition procedure incoming application or a decentralised procedure application.

(3) In connection with an application for a marketing authorisation for a national homoeopathic product prepared from not more than 5 homoeopathic stocks, the fee payable under regulation 12(1) (a) is the amount set out in column 2 in the table below opposite the description in column 1 appropriate to that application.

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(4) In connection with any other application for a marketing authorisation for a national homeopathic product, the fee payable under regulation 12(1)(a) shall be the amount set out in column 3 in the table below opposite the description in column 1 appropriate to that application.

Fees for homeopathic marketing authorisation applications

<i>Column 1</i> <i>Description of application</i>	<i>Column 2</i> <i>Fee for applications in respect of products prepared from not more than 5 homeopathic stocks</i>	<i>Column 3</i> <i>Fee for other applications</i>
1. An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation	£517	£732
2. An application in respect of a product which is either—	£808	£1,014
(a) prepared solely from repeat stocks; or		
(b) is of a repeat formulation		
3. Any other application	£1,088	£1,312

(5) Each reference in sub-paragraphs (6) to (8) to an amount payable under sub-paragraph (3) or (4) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(6) Where an application relates to a national homeopathic product which is manufactured using a method of sterilisation—

- (a) not used in the manufacture of a medicinal product in respect of which a marketing authorisation (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted; and
- (b) not referred to in the European Pharmacopoeia or any national pharmacopoeia of a member State,

an amount of £2,154 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

(7) Where an application relates to a national homeopathic product which contains one or more new excipients, an amount of £7,185 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

(8) Where an application relates to a national homeopathic product which contains one or more TSE risk ingredients from a new source or TSE risk excipients from a new source, an amount of £635 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

Manufacturer's licences and authorisations

30.—(1) The fee payable under regulation 12(1)(a) in connection with an application for a manufacturer's licence or a manufacturing authorisation is—

- (a) £183 in a case to which sub-paragraph (2) applies;
- (b) £344 in the case of a change of ownership application; and

(c) £3,143 in any other case.

(2) This sub-paragraph applies to the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products which are to be sold or supplied in circumstances to which regulation 169 (mixing of general sale medicinal products) of the Human Medicines Regulations applies.

Wholesale dealer's licences

31.—(1) Unless sub-paragraph (2) or (5) applies, the fee payable under regulation 12(1)(a) in connection with an application for a wholesale dealer's licence is £1,803.

(2) Where this sub-paragraph applies, the fee payable under regulation 12(1)(a) is £902.

(3) Subject to sub-paragraph (4), sub-paragraph (2) applies where an application for a wholesale dealer's licence—

(a) relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the sale of authorised medicinal products carried on at that pharmacy;

(b) does not relate to anything done in a registered pharmacy but where the total turnover of the sale by way of wholesale dealing of authorised medicinal products does not exceed £35,000; or

(c) relates only to medicinal products classified as subject to general sale under regulation 5(1) (classification of medicinal products) or paragraph 3(5) of Schedule 32 (transitional provisions and savings: product licences of right) to the Human Medicines Regulations.

(4) Sub-paragraph (2) does not apply where the applicant has not held a wholesale dealer's licence during the 12 month period preceding the date of the application unless at the time of making the application it is reasonable for the applicant to believe—

(a) in the case of an application for a wholesale dealer's licence which relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and which amounts to wholesale dealing, that such dealing will constitute no more than 15% of the gross amount of the total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence, or

(b) in the case of an application for a wholesale dealer's licence which does not relate to anything done in a registered pharmacy, that the gross amount of total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence will not exceed £35,000,

and that applicant so informs the licensing authority when the application is made.

(5) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

Broker's registrations

32.—(1) The fee payable under regulation 12(1)(a) in connection with an application for a broker's registration is £1,803.

(2) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

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Active substance registrations

33.—(1) The fee payable under regulation 12(1)(a) in connection with an application for an active substance registration is—

- (a) £3,143 where the application includes the manufacture of active substances; or
- (b) £1,803 where the application only concerns the importation or distribution of active substances.

(2) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

Clinical trial authorisations

34. The fee payable under regulation 12(1)(a) in connection with an application for a clinical trial authorisation is—

- (a) £3,060, where the application is for a product that is not marketed; or
- (b) £225, where the application is for a product that is marketed.

Traditional herbal registrations

35.—(1) Subject to sub-paragraphs (3) to (6), the fee payable under regulation 12(1)(a) in connection with an application for a traditional herbal registration of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

Fee for application for traditional herbal registration

<i>Column 1</i> <i>Kind of application</i>	<i>Column 2</i> <i>Fee payable</i>
1. Complex registration application	
(a) in respect of a medicinal product containing a single active ingredient	£4,846
(b) in any other case	£7,269
2. Standard registration application	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£2,423
(b) in any other case	£3,634
3. Reduced registration application category II	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£807
(b) in any other case	£1,212
4. Reduced registration application category I	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£539
(b) in any other case	£807
5. Change of ownership application	£442

(2) Each reference in sub-paragraphs (3) to (6) to an amount payable under sub-paragraph (1) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

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(3) Where an application relates to a medicinal product which contains one or more vitamins or minerals which are vitamins or minerals from a new source, a fee of—

- (a) £1,077, if European Pharmacopoeia certificates of suitability covering all the vitamins or minerals which are a vitamin or mineral from a new source have been submitted with the application; or
- (b) £2,154, in any other case,

is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(4) Where an application relates to a medicinal product which contains one or more new excipients, an amount of £7,186 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(5) Where an application relates to a medicinal product which contains one or more TSE risk excipients from a new source, an amount of £638 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(6) Where an application relates to a medicinal product which is a sterile medicinal product, an amount of £2,154 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

Online sellers of medicines

36. The fee payable under regulation 13 in connection with an application to be included on the list of online sellers of medicines is £100.

PART 3

Capital Fees for Assistance in Obtaining Marketing Authorisations in Other EEA States

Outgoing mutual recognition applications

37.—(1) The fee payable for regulatory assistance under regulation 17 is the fee specified in sub-paragraphs (2) to (5).

(2) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation was granted in the United Kingdom (the application relating to that authorisation is referred to in this paragraph as the “original application”) and the original application had been a major application or would fall within the meaning of a major application, in respect of—

- (a) the first application for regulatory assistance (“the first application”), the fee is £41,573;
- (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,564;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £27,308; and
- (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,564.

(3) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation was granted in the United Kingdom and the original application had been a complex application or would fall within the meaning of a complex application, in respect of—

- (a) the first application for regulatory assistance (“the first application”), the fee is £10,753;

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- (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,564;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £7,133; and
 - (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,564.
- (4) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation was granted in the United Kingdom and the original application had been a standard application or would fall within the meaning of a standard application, in respect of—
- (a) the first application for regulatory assistance (“the first application”), the fee is £4,282;
 - (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,564;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £3,567; and
 - (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,564.
- (5) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation was granted in the United Kingdom and the original application had been a simple application or would fall within the meaning of a simple application, in respect of—
- (a) the first application for regulatory assistance (“the first application”), the fee is £2,564;
 - (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,564;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £2,564; and
 - (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,564.
- (6) The condition referred to in sub-paragraphs (2) to (5) is that all applications fall within the meaning given to a “set of applications” in regulation 16.

PART 4

Capital Fees for Applications for Variations of Authorisations, Licences and Registrations

Marketing authorisations

38.—(1) Unless sub-paragraph (2) or any of paragraphs 39 to 42 and 51 to 53 applies, the fee payable under regulation 19(1) in connection with an application for a variation to the terms of a marketing authorisation of a kind described in column 1 of the appropriate table is the fee specified in the corresponding entry in column 2 of the appropriate table.

- (2) This paragraph applies—
 - (a) to an application for a variation to the terms of a marketing authorisation of a kind described in item 1(c) or 2(c) in Table 1 or item 3 in Table 2; and
 - (b) where the application only concerns a new source or supply of a substance listed in Part 7 of this Schedule.
- (3) If paragraph (2) applies, the appropriate fee for an application of the kind described—

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- (a) in item 1(c) of column 1 to Table 1, is the amount specified for an application of that type in item 1(b) of column 2;
 - (b) in item 2(c) of column 1 to Table 1, is the amount specified for an application of that type in item 2(b) of column 2;
 - (c) in item 3 of column 1 of Table 2, is the amount specified for item 2 in column 2 of Table 2.
- (4) In sub-paragraph (1), the appropriate table is—
- (a) in respect of an application for a variation of a marketing authorisation which is within the scope of Chapter II (variations to marketing authorisations granted in accordance with Directive 87/22/EEC, Chapter 4 of Directive 2001/82/EC or Chapter 4 of Directive 2001/83/EC) of Commission Regulation (EC) No 1234/2008, Table 1;
 - (b) in respect of an application for a variation of a marketing authorisation which is within the scope of Chapter IIa (variations to purely national marketing authorisations) of Commission Regulation (EC) 1234/2008^{F38}[^{F39}and of marketing authorisations in force in Great Britain], Table 2;
 - (c) in respect of a reclassification variation application, Table 3.
- (5) In Table 1, “reference authority” has the meaning given in Article 20(2)(b) of Commission Regulation (EC) No 1234/2008.
- (6) In Table 2 “UK national application” means an application for a variation to the terms of a UK national marketing authorisation within the meaning of Article 2(9) of Commission Regulation (EC) 1234/2008.

[^{F40}Table 1

Fees for applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008

<i>Column 1 Kind of variation</i>	<i>Column 2 Fee payable</i>
1. Application for a single kind variation	
(a) Type IB Application	£277
(b) Type II Application	£277
(c) Type II Complex Variation Application	£2,493
(d) Extended Type II Complex Variation Application	£7,693
2. Applications for a Group	
(a) Minor Variation (Type IB) Group Application	£277
(b) Major Variation (Type II) Group Application	£496
(c) Major Variation (Type II) Complex Group Application	£2,703
(d) Major Variation (Type II) Extended Complex Group Application	£7,883]

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Table 2

Fees for applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008^{F41} and of marketing authorisations in force in Great Britain]

<i>Column 1 Kind of national variation</i>	<i>Column 2 Fee payable</i>
1. National Type 1B Application	£277
2. National Type II Application	£734
3. National Type II Complex Variation Application	£8,309
4. National Type II Extended Complex Variation Application	£25,643
5. National Type IB Minor Variation Group Application	£622
6. National Type II Major Variation Group Application	£1,652
7. National Type II Major Variation Complex Group Application	£9,010
8. National Type II Major Variation Extended Complex Group Application	£26,276
[^{F429} Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related UKMA(NI) for the same product	£nil
10 Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related European Union marketing authorisation for the same product	Apply fees and fee categories in Table 1
11 Variation of a UKMA(UK) or a UKMA(GB) which was granted following an application made under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive, provided a corresponding variation has been approved to the related marketing authorisation or UKMA(NI) for the same product	Apply fees and fee categories in Table 1
12 Variation of a UKMA(GB) which was granted following an application where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), provided a corresponding variation has been approved to the related European Union marketing authorisation or UKMA(NI) for the same product	Apply fees and fee categories in table 1]

Table 3

Fees for reclassification variation applications

<i>Column 1 Kind of reclassification variation</i>	<i>Column 2 Fee payable</i>
Application falling within the category described in—	
(a) paragraph 15(a)	£11,992

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(b) paragraph 15(b)

£8,162

Textual Amendments

- F38** Chapter IIa of the Regulation was inserted by Commission Regulation (EU) No 712/2012 (OJ No L 209, 4.8.2012, p4)
- F39** Words in [Sch. 2 para. 38\(4\)\(b\)](#) inserted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(9)(a) (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(g\)\(vii\)](#))
- F40** [Sch. 2 para. 38\(6\) Table 1](#) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(9)(b)(i) (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(g\)\(vii\)](#))
- F41** Words in [Sch. 2 para. 38\(6\) Table 2 heading](#) inserted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(9)(b)(ii)(aa) (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(g\)\(vii\)](#))
- F42** Words in [Sch. 2 para. 38\(6\) Table 2](#) inserted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 7(9)(b)(ii)(bb) (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(g\)\(vii\)](#))

Variation of marketing authorisations

39.—(1) Subject to sub-paragraph (3) [^{F43}and paragraph 39A] , if an application to vary a marketing authorisation of a kind described in sub-paragraph (2) is—

- (a) the first application to vary a marketing authorisation;
- (b) made within 5 years of the date of grant of the marketing authorisation; and
- (c) an application to authorise use of the medicinal product in a new therapeutic area,

the fee payable for that application is the fee payable under regulation 19(1) together with the difference between that fee and the fee which would have been payable if the application had been a major application.

(2) In this paragraph a marketing authorisation is one which has been granted in accordance with an application to which point 6 of Part II of Annex I to the 2001 Directive applies or which is [^{F44}an orphan marketing authorisation].

(3) Sub-paragraph (1) and (2) shall not apply where the first application for variation of the marketing authorisation relates to a therapeutic area, in respect of which the applicant would be entitled (had the applicant not already held a marketing authorisation) to apply for a marketing authorisation to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of [^{F45}a medicinal product which meets the orphan criteria listed in regulation 50G(2) of the Human Medicines Regulations].

Textual Amendments

- F43** Words in [Sch. 2 para. 39\(1\)](#) inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, [Sch. 1 para. 7\(10\)\(a\)](#) (with Sch. 1 para. 11); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F44** Words in [Sch. 2 para. 39\(2\)](#) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, [Sch. 1 para. 7\(10\)\(b\)](#) (with Sch. 1 para. 11); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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F45 Words in Sch. 2 para. 39(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 1 para. 7(10)(c) (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

[^{F46}Variation of orphan marketing authorisations: small and medium companies

39A.—(1) Subject to sub-paragraph (2), if an application to vary an orphan marketing authorisation is made by, or on behalf of, a small or a medium company within 12 months of the date of grant of the marketing authorisation, the fee payable for that variation application shall be waived.

(2) Sub-paragraph (1) does not apply to an application to authorise use of the medicinal product in a new therapeutic area which does not meet the orphan criteria listed in regulation 50G(2) of the Human Medicines Regulations.]

Textual Amendments

F46 Sch. 2 para. 39A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 1 para. 7(11) (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Reclassification of marketing authorisations

40.—(1) Where an application is a reclassification variation application to which this paragraph applies, the fee payable under regulation 19(1) in connection with the application for variation of a marketing authorisation is £734.

(2) This paragraph applies to a reclassification variation application which would have the effect that a medicinal product to which the marketing authorisation relates—

- (a) is to be available only from a pharmacy (where previously it was available only on prescription), if an analogous medicinal product is available only from a pharmacy or on general sale; or
- (b) is to be available on general sale (where previously it was available only on prescription or only from a pharmacy), if an analogous medicinal product is available on general sale.

(3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorisation or a European Union marketing authorisation and which—

- (a) has the same active ingredient, route of administration and use;
- (b) has the same strength or a higher strength;
- (c) has the same dosage or daily dosage, or a higher dosage or daily dosage; and
- (d) is for sale or supply at the same quantity or a greater quantity,

as the medicinal product in relation to which the variation application is made.

[^{F47}Fees where an application for a variation or an extension of a European Union marketing authorisation had been made before IP completion day

40A.—(1) Paragraph (2) applies where, before IP completion day —

- (a) an application for a variation to which paragraph 11(7) of Schedule 33A to the Human Medicines Regulations applies, has been made to the EMA; and

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- (b) the Committee for Medicinal Products for Human Use has adopted a request for supplementary information to be sent to the applicant, or, in the case of an extension, day 120 has passed.
- (2) Where this paragraph applies and the holder of a converted EU marketing authorisation submits the application to the licensing authority in order to have the variation made to the converted EU marketing authorisation, the fee payable under regulation 19(1) shall be waived.
- (3) In this paragraph—
- “day 120” means the day during the assessment of an extension on which the Committee for Medicinal Products for Human Use adopts the list of questions, as well as the overall conclusions and review of the scientific data, to be sent to the applicant;
- “converted EU marketing authorisation” has the meaning given in paragraph 6(1) and (2) of Schedule 33A to the Human Medicines Regulations; and
- “extension” has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations.]

Textual Amendments

F47 Sch. 2 para. 40A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 1 para. 7(12) (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(g)(viii)(aa)(bb)); 2020 c. 1, Sch. 5 para. 1(1)

Variation of marketing authorisation: national homoeopathic products

41. The fee payable under regulation 19(1) in connection with an application for a variation of a marketing authorisation in respect of a national homoeopathic product is—

- (a) £243 where the application is a standard variation application for a homoeopathic medicinal product;
- (b) £374 where the application is a new indication variation application; and
- (c) £123 for any other application.

Variation of parallel import licence

42.—(1) The fee payable under regulation 19(1) in connection with an application for variation of a parallel import licence is—

- (a) £11,992 if, were the marketing authorisation not a parallel import licence, the application for the variation would be a reclassification variation application falling within paragraph 15(a) and to which paragraph 38 of this Schedule does not apply;
- (b) £8,162 if, were the marketing authorisation not a parallel import licence, the application for the variation would be a reclassification variation application falling within paragraph 15(b) and to which paragraph 38 of this Schedule does not apply; and
- (c) £357 in any other case other than where the variation applied for is an administrative variation.

(2) For the purposes of sub-paragraph (1)(c) an application for an administrative variation is where the variation applied for falls within one of the following paragraphs—

- (a) a change of either or both of the name and the address of the holder of the licence;
- (b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence where the change has been occasioned by the taking

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over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place;

- (c) the removal from the licence of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;
- (d) the removal from the licence of details of any of the activities to which the licence relates;
- (e) the removal from the licence of details of any of the medicinal products which the holder of the licence is authorised to import;
- (f) the addition or deletion of the name and address of the suppliers of the medicinal product to which the licence relates, or a change in the name, the address, or both the name and address, of the suppliers of that product; or
- (g) unless paragraph 9 of Schedule 7 applies, a change consequential upon any or any combination of the following—
 - (i) a change of ownership of the United Kingdom marketing authorisation in respect of which the parallel import licence was granted,
 - (ii) a change to the number of the United Kingdom marketing authorisation in respect of which the parallel import licence was granted,
 - (iii) a change to the name of the holder of the United Kingdom marketing authorisation in respect of which the parallel import licence was granted,
 - (iv) a change to the address of the holder of the United Kingdom marketing authorisation in respect of which the parallel import licence was granted,
 - (v) a change to the number of the marketing authorisation for the product in the country where the product originates,
 - (vi) a change of ownership of the marketing authorisation for the product in the country where the product originates,
 - (vii) a change to the name of the holder of the marketing authorisation for the product in the country where the product originates, or
 - (viii) a change to the address of the holder of the marketing authorisation for the product in the country where the product originates,

where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, if the marketing authorisation was not a parallel import licence, the application for that variation would be a reclassification variation application to which paragraph 40 of this Schedule applies.

Manufacturer's authorisations and licences

43. Unless the fee in paragraph 44 is payable or paragraph 51 applies, the fee payable under regulation 19(1) in connection with an application for variation of a manufacturing authorisation or a manufacturer's licence is—

- (a) £257 in the case of a manufacturer's licence referred to in paragraph 30(2); and
- (b) £514 in any other case.

Variation of manufacturer's authorisations and licences

44. The fee payable under regulation 19(1) in connection with an application for variation of a manufacturing authorisation or a manufacturer's licence is £257 in respect of each variation applied for which constitutes a change to the authorisation or licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Wholesale dealer's licences

45. Unless the fee in paragraph 46 is payable or paragraph 51 applies, the fee payable under regulation 19(1) in connection with an application for a variation of a wholesale dealer's licence is £486.

Variation of wholesale dealer's licence

46. The fee payable under regulation 19(1) in connection with an application for variation of a wholesale dealer's licence is £257 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Variation of a broker's registration

47. The fee payable under regulation 19(1) in connection with an application for variation of a broker's registration is £257 in respect of each variation applied for which consists of a change to the registration not requiring an inspection.

Variation of an active substance registration

48. The fee payable under regulation 19(1) in connection with an application for variation of an active substance registration is £257 in respect of each variation applied for which consists of a change to the registration not requiring an inspection.

Clinical trial authorisations

49.—(1) A fee of £225 is payable under regulation 20(2)(a) in connection with a notice of amendment relating to an amendment to the dossier, or to the protocol, related to a request for authorisation to conduct a clinical trial.

Traditional herbal registrations

50. Unless paragraph 51 applies, the fee payable under regulation 19(1) in connection with an application for variation of a traditional herbal registration is—

- (a) £240 if the application is a standard variation application;
- (b) £635 if the application is a complex variation application;
- (c) £7,186 if the application is a new excipient variation application; and
- (d) £152 if the application is an administrative variation application.

Identical variations

51.—(1) Unless paragraph 52 or 53 applies, where more than one application—

- (a) of a type referred to in sub-paragraph (2) is made at the same time by the same marketing authorisation holder and all of the applications are for identical kinds of variations; or
- (b) by the same applicant is made at the same time for a traditional herbal registration, a manufacturer's licence, or a wholesale dealer's licence and where the applications are for identical variations,

the fee payable under regulation 19(1) is that specified in sub-paragraph (3).

(2) The type of application referred to in sub-paragraph (1) is a—

- (a) Type IB Application;
- (b) Type II Application;

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- (c) Minor Variation (Type IB) Group Application; or
 - (d) Major Variation (Type II) Group Application.
- (3) The fee referred to in sub-paragraph (1)—
- (a) in connection with the first application considered by the licensing authority is the appropriate amount specified in this Part of this Schedule; and
 - (b) in connection with each of the other applications is 50% of that amount.

Complex Variation Applications

52.—(1) Where more than one application of a type referred to in sub-paragraph (2) is made at the same time by the same marketing authorisation holder and all of the applications are for identical kinds of variations, the fee payable under regulation 19(1)—

- (a) in connection with the first application considered by the licensing authority is the appropriate amount specified in this Part of the Schedule; and
 - (b) in connection with each of the other applications in respect of which no further medical, scientific or pharmaceutical assessment is required, is the amount which would be payable if the application was a Type II Application.
- (2) The type of application referred to in sub-paragraph (1) is a—
- (a) Type II Complex Variation Application;
 - (b) Extended Type II Complex Variation Application;
 - (c) Major Variation (Type II) Complex Group Application; or
 - (d) Major Variation (Type II) Extended Complex Group Application.

Multiple reclassification variation applications

53. Where more than one reclassification variation application is made at the same time by the same applicant, each relating to medicinal products which have the same active ingredient or combination of ingredients, the fee payable under regulation 19(1)—

- (a) if one or more of the applications is an application to which paragraph 40 does not apply—
 - (i) in connection with the first application to which paragraph 40 does not apply, is the appropriate amount specified in this Part of the Schedule;
 - (ii) in connection with each other application to which paragraph 40 does not apply, the fee payable is £734; and
 - (iii) in connection with each other application to which paragraph 40 does apply, the fee payable is £367; and
- (b) in any other case—
 - (i) in connection with the first application, is the appropriate amount specified in this Part of the Schedule; and
 - (ii) in connection with each other application, the fee payable is £367.

PART 5

Capital Fees for Assessment of Labels and Leaflets

A set of changes

54.—(1) Unless paragraph 55 applies, the fee payable under regulation 25(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product is—

- (a) £518, in respect of a product which is the subject of a United Kingdom marketing authorisation (other than a parallel import licence); and
- (b) £328, in respect of a product which is the subject of a parallel import licence.

(2) If the proposed changes in respect of a product to which the fee in sub-paragraph (1)(a) applies are submitted in accordance with the National Guidance on labels and leaflets self-certification, the fee payable under regulation 25(1) is £186.

(3) For the purpose of this paragraph—

- (a) changes are submitted in accordance with the National Guidance on labels and leaflets self-certification if they are of a type described in the National Guidance on labelling and patient information leaflets for self-certification and comply with the conditions set out in relation to those changes in that Guidance; and
- (b) the “National Guidance on labelling and patient information leaflets for self-certification” means the documents entitled “Guidance on changes to labelling and patient information for self-certification” and “Guidance on changes to labelling for self certification – compliance with Article 56(a) of the 2001 Directive – inclusion of Braille on the labelling” published by the licensing authority and available on its website ^{F48}.

Textual Amendments

F48 Copies of the documents can be downloaded from the licensing authority's website at www.mhra.gov.uk or obtained by writing to the licensing authority at 151 Buckingham Palace Road, London, SW1W 9SZ or by sending an email to info@mhra.gsi.gov.uk.

More than one set of changes proposed

55.—(1) In this paragraph, “clinical particulars” means the clinical particulars contained in the Summary of Product Characteristics for that product as specified in of Article 11 of the 2001 Directive.

(2) This paragraph applies where more than one set of proposed changes falling within regulation 25(1) is submitted by the same marketing authorisation holder at the same time and where—

- (a) the sets of proposed changes consist of identical changes to the labelling or package leaflets of products with the same active ingredient or combination of ingredients, dosage form and clinical particulars; or
 - (b) the sets of proposed changes consist of identical changes to different versions of the labelling or package leaflet of the same product.
- (3) Where this paragraph applies, the fee payable under regulation 25(1) is—
- (a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 54; and
 - (b) in connection with each of the other sets of proposed changes, 50% of that amount.

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[^{F49} PART 6

Capital Fee for the Renewal of a Marketing Authorisation

Textual Amendments

F49 Sch. 2 Pts. 6-6B, substituted for Sch. 2 Pt. 6 (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(13)** (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(g)(ix)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Renewal of a marketing authorisation

56. Unless paragraph 57 applies, the fee payable under regulation 27A in connection with an application for the renewal of a United Kingdom marketing authorisation is—

- (a) in respect of an application for renewal of a UKMA(GB) granted under the unfettered access route, £747;
- (b) in respect of an application for renewal of a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), £747;
- (c) in all other cases, £9,682.

Renewal of multiple marketing authorisations

57.—(1) This sub-paragraph applies if more than one application falling within regulation 27A is made by the same applicant at the same time, each of which relates to medicinal products which have the same active ingredient or combination of ingredients, dosage form and therapeutic indications, and the marketing authorisations for those products have the same date for renewal.

(2) The fee payable under regulation 27A for applications to which sub-paragraph (1) applies is—

- (a) in respect of applications for renewal of more than one UKMA(GB) granted under the unfettered access route or UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), and provided a corresponding renewal application has been made to the related European Union marketing authorisation or UKMA(NI) for the same product—
 - (i) £747 for the first application considered by the licensing authority; and
 - (ii) £747 for each other application;
- (b) in all other cases—
 - (i) £9,682 for the first application considered by the licensing authority; and
 - (ii) £747 for each other application.

PART 6A

Capital Fee for Conducting a Major Safety Review

57A. The fee payable under regulation 19D(1) in connection with the carrying out of a major safety review is—

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- (a) £51,286, where one or two active ingredients, or combinations of active ingredients, are included in the assessment;
- (b) £59,595, where three active ingredients, or combinations of active ingredients, are included in the assessment;
- (c) £67,904, where four active ingredients, or combinations of active ingredients, are included in the assessment; or
- (d) £76,213, where five or more active ingredients, or combinations of active ingredients, are included in the assessment.

PART 6B

Capital Fee for Testing of Samples by the Appropriate Authority

57B.—(1) Unless sub-paragraph (2) applies, the fee payable under regulation 19F(1) in connection with the submission of a sample of a batch of a medicinal product of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

(2) This sub-paragraph applies where—

- (a) the holder of the marketing authorisation submits, with a sample of a batch of medicinal product, a certificate issued by a laboratory in a designated country for batch testing and certification of biological medicinal products that relates to the sample of the batch submitted; and
- (b) on the basis of the documentation submitted with the sample, the appropriate authority considers that it is only necessary to carry out a paper based assessment of the sample.

(3) Where sub-paragraph (2) applies, the fee payable under regulation 19F(1) in connection with the submission of a sample of a batch of medicinal product of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 3 of that table.

(4) Where a product falls within more than one of the Bands referred to in the following table, the product is to be treated as if it only falls within the Band which attracts the highest fee.

Fees for testing of samples

<i>Column 1 Product Type</i>	<i>Column 2 Fee payable where the licensing authority carries out a full assessment</i>	<i>Column 3 Fee payable where the licensing authority carries out a paper-based assessment</i>
1. Plasma pools which require—		
(a) three or fewer tests	£180	£90
(b) four or five tests	£215	£90
(c) six or more tests	£230	£90
2. Band A	£1,660	£305
3. Band B	£1,910	£305
4. Band C	£2,340	£305
5. Band D	£3,690	£677

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6. Band E	£6,410	£677
7. Band F	£10,350	£677

(5) In this paragraph—

“Band A” means a single component product, other than Botulinum toxin, requiring five or fewer in vitro tests;

“Band B” means Factor VIII, Factor IX or intravenous Immunoglobulin;

“Band C” means a multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests;

“Band D” means a product requiring six to nine in vitro tests;

“Band E” means a product requiring—

- (a) ten or more in vitro tests, or
- (b) one or more in vivo tests;

“Band F” means a product—

- (a) which requires one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under the Control of Substances Hazardous to Health Regulations 2002 ; or
- (b) requires the use of human cells or tissues as part of its testing;

“Multi-component product” means a product containing two or more analytes that require testing; and

“Single component product” means a product containing a single analyte that requires testing.]

PART 7

Relevant Substances

Substances listed for the purposes of paragraph 24(2)(b) and (4)(b) and 38(2)(b)

58.—(1) The substances listed for the purposes of paragraphs 24(2)(b) and (4)(b) and 38(2)(b) (fees payable where the application concerns certain substances) are—

- Acetic Acid
- Aluminium Chloride
- Aluminium Hydroxide
- Aluminium Sulfate
- Ammonia
- Ammonium Bicarbonate
- Ammonium Chloride
- Ascorbic Acid
- Barium Sulfate
- Benzoic Acid
- Benzoyl Peroxide
- Benzyl Alcohol
- Benzyl Benzoate

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- Bismuth Subgallate
- Calamine
- Calcium Acetate
- Calcium Carbonate
- Calcium Chloride
- Calcium Gluconate
- Calcium Glycerophosphate
- Calcium Hydroxide
- Calcium Lactate
- Calcium Phosphate
- Charcoal
- Chlorobutanol
- Chlorocresol
- Citric Acid
- Coal Tar
- Ethanol
- Ethanolamine
- Ferric Chloride
- Ferrous Fumarate
- Ferrous Gluconate
- Ferrous Sulfate
- Formaldehyde Solution
- Glucose
- Glycine
- Hydrogen Peroxide
- Iodine
- Isopropyl Alcohol
- Isopropyl Myristate
- Kaolin
- Lactic Acid
- Lactose
- Lactulose
- Lithium Carbonate
- Lithium Citrate
- Magnesium Acetate
- Magnesium Carbonate
- Magnesium Chloride
- Magnesium Hydroxide
- Magnesium Oxide
- Magnesium Sulfate

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- Magnesium Trisilicate
- Malic Acid
- Manganese Sulfate
- Oleic Acid
- Paraffin
- Phenol
- Phosphoric Acid
- Potassium Acetate
- Potassium Bicarbonate
- Potassium Chloride
- Potassium Citrate
- Potassium Dihydrogen Phosphate
- Potassium Hydrogen Tartrate
- Potassium Hydroxide
- Potassium Iodate
- Potassium Iodide
- Potassium Nitrate
- Silver Nitrate
- Sodium Acetate
- Sodium Ascorbate
- Sodium Bicarbonate
- Sodium Carbonate
- Sodium Chloride
- Sodium Citrate
- Sodium Dihydrogen Phosphate
- Sodium Fluoride
- Sodium Hydroxide
- Sodium Iodide
- Sodium Lactate
- Sodium Sulfate
- Sorbic Acid
- Sucrose
- Sulphur
- Tar
- Tartaric Acid
- Undecenoic Acid
- Urea
- Wool Alcohols
- Wool Fat
- Zinc Acetate

- Zinc Chloride
- Zinc Oxide
- Zinc Sulfate
- Zinc Undecenoate

(2) The list of substances under this Part includes any dried, anhydrous, hydrate, hydrous, activated, strong, light, heavy and coloured forms of substances listed under paragraph (1) that are the subject of a pharmacopoeial monograph of the European Pharmacopoeia or the British Pharmacopoeia.

SCHEDULE 3

Regulations 30(1); 34;35(2) and (3); and
36(1)

Fees for inspections

General provisions relating to fees for inspections

1.—(1) In this Schedule, a reference to 1 day means a period of 7 hours.

(2) For the purposes of paragraphs 3(2)(c), 4(2)(c), 6(2)(c) and 8, in calculating the number of days taken to make an inspection, any part day shall be calculated as a whole day.

(3) Where an inspection is made at a site which is outside the United Kingdom, the fee for the inspection shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs (such as interpreters' fees) reasonably incurred by the inspector in respect of that inspection as a result of its being at a site outside the United Kingdom.

(4) If an inspection is made by more than one inspector, the time taken by the licensing authority to make an inspection is the total amount of time spent by each inspector in making the inspection.

Fees: general

2.—(1) The fee for an inspection made at a site is—

- (a) £2,655, if the time taken to make the inspection is not more than 1 day; and
- (b) thereafter, £1,328 for every additional period of 3 hours and 30 minutes or less taken to make the inspection.

(2) Sub-paragraph (1) does not apply if the inspection is one for which a fee is payable under paragraphs 3 to 7.

Traditional herbal medicinal products

3.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the manufacture, assembly or import from a third country of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect of an inspection of a site in connection with the grant, variation or renewal of a manufacturer's licence or during the currency of such a licence, is—

- (a) £994 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,615 if the time taken to make the inspection is more than 3 hours but not more than 1 day; and

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- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,615.

Sites concerned with starting materials for traditional herbal medicinal products

4.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the manufacture or assembly of starting material for use in the manufacture of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect of an inspection of an API manufacturer under Article 111(1g)(a) of the 2001 Directive, is—

- (a) £994 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,615 if the time taken to make the inspection is more than 3 hours but not more than 1 day; and
- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days to make the inspection by £1,615.

Wholesale dealer's licence: general

5. Except in the case of an inspection falling within paragraphs 6 or 7, the fee for an inspection of a site made in connection with the grant or variation of a wholesale dealer's licence or during the currency of such a licence, is—

- (a) if the time taken to make the inspection is not more than 1 day, £1,936; and
- (b) if the time taken is 1 day or more, £1,936 for the first day and £968 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

Wholesale dealer's licence: traditional herbal medicinal products

6.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the wholesale dealing of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect of an inspection of a site in connection with the grant, variation or renewal of a wholesale dealer's licence or during the currency of such a licence is—

- (a) £744 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,367 if the time taken to make the inspection is more than 3 hours but not more than 1 day; and
- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,367.

Wholesale dealer's licences: inspection of short duration

7.—(1) Sub-paragraph (3) applies if the time taken to make the inspection is not more than 3 hours and 30 minutes, and

- (a) the site is that of a wholesale dealer whose licence is limited to dealing only in medicinal products classified as subject to general sale under regulation 5(1) of the Human Medicines Regulations;
- (b) the site relates to a registered pharmacy as referred to in paragraph 31(3) of Part 2 of Schedule 2; or
- (c) the total turnover in respect of sales by way of wholesale dealing in authorised medicinal products of the wholesale dealer does not exceed £35,000.

(2) If paragraph (c) of sub-paragraph (1) applies because the applicant has not held a wholesale dealer's licence during the 12 month period preceding the date of the application, sub-paragraph (1) does not apply unless at the time of making the application—

- (a) it is reasonable for the applicant to believe that the gross amount of total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence will not exceed £35,000; and
- (b) the applicant so informs the licensing authority.

(3) If this sub-paragraph applies, the fee payable in respect of an inspection of a site made in connection with the grant, variation or renewal of a wholesale dealer's licence is £968.

Broker's registrations

8.—(1) Except in the case of an inspection where sub-paragraph (2) applies, the inspection fee payable in connection with the grant, variation or review of a broker's registration is—

- (a) £1,936 if the time taken to make the inspection is not more than 1 day; and
- (b) if the time taken is 1 day or more, £1,936 for the first day and £968 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

(2) This paragraph applies where an application or variation of a broker's registration is considered under paragraph 10 but it is necessary to carry out a site inspection before the registration is granted or varied.

(3) If sub-paragraph (2) applies, a fee of £582 is payable in addition to any fee under paragraph 10.

Active substance registrations

9.—(1) Except in the case of an inspection where sub-paragraph (2) applies, the fee payable in connection with the grant, variation or review of an active substance registration where the inspection relates to—

- (a) a manufacturer of an active substance, is—
 - (i) £2,655 if the time taken to make the inspection is not more than 1 day; and
 - (ii) if the time taken is 1 day or more, £2,655 for the first day and £1,328 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection;
- (b) an importer or distributor of an active substance, is—
 - (i) £1,936 if the time taken to make the inspection is not more than 1 day; and
 - (ii) if the time taken is 1 day or more, £1,936 for the first day and £968 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

(2) This paragraph applies where an application or variation of an active substance registration is considered under paragraph 10 but it is necessary to carry out a site inspection before the registration is granted or varied.

(3) If sub-paragraph (2) applies—

- (a) a fee of £792 is payable in addition to any fee under paragraph 10 where the inspection relates to a manufacturer of an active substance;
- (b) a fee of £582 is payable in addition to any fee under paragraph 10 where the inspection relates to an importer or distributor of an active substance.

Office-based inspections

10. The fee for an inspection comprising an office-based evaluation and risk assessment of documentation but not involving inspection of a site, in connection with the monitoring of—

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- (a) good manufacturing practice, good clinical practice or good pharmacovigilance practice, is £1,863 per day;
- (b) good distribution practice, is £1,354 per day.

SCHEDULE 4

Regulations 38(1) to (3); and 39(2)

Periodic fees for licences

PART 1

Interpretation

1. In this Schedule—

“anthroposophic product” means a medicinal product prepared in accordance with the methods of anthroposophic medicine which is sold or supplied as an anthroposophic product and is so described by the person who sells or supplies that medicinal product;

“derivative”, in relation to a limited use drug or a new active substance, means a medicinal product—

- (a) which contains the same active ingredient or combination of active ingredients as that drug or substance but which is either—
 - (i) a different dosage form of that drug or substance; or
 - (ii) of the same dosage form as, but of a different strength of active ingredient to, or of a different combination of active ingredients to, that drug or substance; and
- (b) in respect of which an application for a marketing authorisation was made before the determination of the application for the marketing authorisation for that drug or substance;

“general sale list medicine” means a medicinal product (not being an anthroposophic product, a herbal remedy or a homoeopathic medicinal product) classified as subject to general sale within the meaning of regulation 5(1) of the Human Medicines Regulations;

“limited use drug” means a medicinal product in respect of which an application for a marketing authorisation has been submitted, to which point 6 of Part II of Annex I to the 2001 Directive applies or [F50 in respect of which an orphan marketing authorisation has been granted];

“lower fee” means the periodic fee payable—

- (a) where the medicinal product has not been manufactured or imported into the United Kingdom during the period of 12 months preceding the commencement of the relevant fee period; or
- (b) in relation to a medicinal product that has been manufactured or imported into the United Kingdom during the period referred to in (a) above, where the value of the product sold or supplied during that period did not exceed £1,000; and
- (c) in relation to a prescription only product, where the authorisation holder has notified the licensing authority that the medicinal product to which the marketing authorisation relates, is not expected to be manufactured, or imported into the United Kingdom during the relevant fee period; or

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(d) in relation to a pharmacy medicine or a general sale list medicine, the periodic fee payable during the relevant fee period;

“new active substance” means a medicinal product which is not a limited use drug and which contains an active ingredient which has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has been granted in the five years preceding 31st December in the fee period preceding the relevant fee period;

“pharmacy medicine” means a medicinal product (not being an anthroposophic product, a herbal remedy or a homoeopathic medicinal product) classified as a pharmacy medicine within the meaning of regulation 5(5) of the Human Medicines Regulations;

“prescription only medicine” means a medicinal product (not being an anthroposophic product, a herbal remedy, a homoeopathic medicinal product, a new active substance or a derivative of a new active substance) classified as a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations;

“reduced rate fee” means the periodic fee payable in relation to a prescription only medicine where the total value of the product which is sold or supplied in the relevant fee period does not exceed £35,000;

“standard fee” means the periodic fee payable in relation to a prescription only medicine where the total value of the product which is sold or supplied in the relevant fee period exceeds £35,000; and

“total value of the product” means the amount calculated in accordance with Part 2 of this Schedule.

Textual Amendments

F50 Words in Sch. 4 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. 8](#) (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

PART 2

Value of the Product Sold or Supplied

Determining the total value of the product

2. For the purposes of this Schedule, the “total value of the product” means, the gross value at manufacturer's prices of all medicinal products to which the authorisation relates that are sold or supplied in the United Kingdom by the holder of that authorisation during a period of 12 months preceding the commencement of the relevant fee period.

Manufacturer's prices

3. For the purposes of paragraph 2 manufacturer's prices means—

- (a) for products manufactured or obtained, sold or supplied by the authorisation holder to wholesalers or to distributors or assemblers named in the marketing authorisation, which that holder has manufactured or obtained from the manufacturer, the prices charged for the supply;
- (b) for products sold or supplied by the authorisation holder to retailers, which that holder has manufactured or obtained from the manufacturer, the prices which, in the opinion of the

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licensing authority, the authorisation holder would have charged, in accordance with the practice prevailing during the relevant year, to a wholesaler of the product; or

- (c) for products sold or supplied by the authorisation holder which that holder has neither manufactured nor obtained from the manufacturer, the price which the authorisation holder paid for the supply.

Information requirements

4.—(1) The authorisation holder shall determine the total value of product sold or supplied in accordance with paragraphs 2 and 3 and provide such information to the licensing authority if required to do so.

(2) The licensing authority may additionally require an auditor's certificate verifying the authorisation holder's determination of the value of products sold or supplied.

(3) If an auditor's certificate has not been provided to the licensing authority within one month of it being required, or such longer period that the authority may allow, the periodic fee shall be calculated in accordance with sub-paragraph (4).

(4) The periodic fees for the relevant fee period in question shall be equal to the fee provided for in paragraphs 10 and 13 of Part 3 of this Schedule or, such lesser sum as the licensing authority may specify in a written notice served on the authorisation holder.

PART 3

Periodic Fees for Marketing Authorisations and Licences

Marketing authorisations

5. Unless paragraphs 6 to 10 apply, the fee payable under regulation 38(1) in connection with the holding of a marketing authorisation relating to a medicinal product of a kind described in column 1 of the following table is the applicable fee specified in the corresponding entry in column 2 of that table.

Periodic fees for holding a marketing authorisation

<i>Column 1 Type of Medicinal Product</i>	<i>Column 2 Fee payable</i>
1. New Active Substance	£9,710
2. Parallel Import	£307
3. Others	
(a) Any product (not being a derivative of a new active substance) in respect of which a marketing authorisation has been granted in consequence of a complex application submitted on or after 1st April 1989	£9,710
(b) Prescription Only Medicine	
(i) Standard Fee	£2,428
(ii) Reduced Rate Fee	£1,211
(iii) Lower Fee	£307

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(c) Pharmacy	£307
(d) General Sale List	£307
(e) Herbal remedy	£76
(f) Traditional herbal registrations	£76
(g) National homoeopathic product	£76
(h) Homoeopathic or anthroposophic product which is the subject of a licence of right	£76

Marketing authorisation: where Part 2 of the Act applies

6. In the case of an article or substance to which Part 2 of the Act applies by virtue of the Medicines (Surgical Materials) Order 1971^{F51}, the fee payable under regulation 38(1) in connection with the holding of a marketing authorisation or licence is £307.

Textual Amendments

F51 [S.I. 1971/1267](#): Part 2 of the Act is applied by article 3 of the Order which has been amended by [S.I. 1994/3119](#), [2004/1031](#) and [2006/2407](#).

Marketing authorisation: derivatives

7. Unless paragraph 8 applies, where a marketing authorisation is held in respect of a derivative of a new active substance, the fee payable under regulation 38(1) is—

- £9,710 where the medicinal product to which the authorisation relates has a different route of administration from that of the new active substance; or
- £6,554 in any other case.

Number of fee periods

8.—(1) The fee specified in—

- paragraph 5 for a new active substance; and
- in paragraph 7 for a derivative of a new active substance,

is only payable for the five relevant fee periods following that in which the marketing authorisation is granted.

(2) The fee payable in accordance with entry 3(a) of the table set out in paragraph 5 is only payable for the three relevant fee periods following the year beginning 1st April during which the marketing authorisation is granted.

(3) Where a marketing authorisation is surrendered and at the same time another marketing authorisation held by the authorisation holder is varied so as to include in that other authorisation the provisions of the first authorisation, the fee payable—

- for the five relevant fee periods following the fee period during which the marketing authorisation is granted is the fee specified at entry 1 of the table set out in paragraph 5, where the first authorisation relates to a new active substance;
- in all other cases, for each fee period mentioned in sub-paragraph (2), is the fee specified at entry 3(a) of that table.

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(4) In respect of fee periods following those referred to in sub-paragraphs (1) to (3) of this paragraph, the periodic fees are the appropriate fees for the kind of medicinal product in question specified in entries 3(b), (c) or (d) of the table set out in paragraph 5.

(5) In connection with the holding of a marketing authorisation in respect of a limited use drug or a derivative of a limited use drug—

- (a) where the total value of the product sold or supplied exceeds £200,000, until the expiry of the five relevant fee periods following the fee period during which the marketing authorisation was granted, the periodic fee payable is the fee that would be payable if the drug were, respectively, a new active substance or a derivative of a new active substance;
- (b) where the total value of the product sold or supplied does not exceed £200,000 or where a periodic fee has been payable in respect of the limited use drug or derivative of a limited use drug for five relevant fee periods following the fee period during which the marketing authorisation was granted, the periodic fee payable is the fee payable in respect of a prescription only medicine in accordance with entry 3(b)(i) of the table set out in paragraph 5.

Authorisation for two or more kinds of medicinal product

9. Where a marketing authorisation relates to any two or more medicinal products of a kind described in entries 3(b), (c) or (d) of column 1 of the table in paragraph 5, the fee payable under regulation 38(1) shall be the lower of the fee specified as corresponding to those entries in column 2 of that table.

Reduced fees

10. Where a reduced rate fee or a lower fee may be payable in respect of any relevant fee period and an authorisation holder does not submit information about the total value of the product sold or supplied in relation to the relevant calendar year to the satisfaction of the licensing authority, the periodic fee payable shall, where applicable, be the standard fee for each description of medicinal product in respect of which a marketing authorisation is held by the authorisation holder.

Manufacturer's licences or manufacturing authorisations

11.—(1) Unless sub-paragraph (3) applies, the fee payable under regulation 38(1) in connection with the holding of a manufacturer's licence is £468.

(2) The fee payable under regulation 38(1) in connection with the holding of a manufacturing authorisation is £468.

(3) The fee payable under regulation 38(1) in connection with the holding of a manufacturer's licence which relates to the import of special medicinal products from a third country is the fee payable in accordance with sub-paragraph (1) and an additional amount calculated in accordance with paragraph 15.

Wholesale dealer's licences

12.—(1) Subject to sub-paragraph (2) and to paragraphs 13 and 16, the fee payable under regulation 38(1) in connection with the holding of a wholesale dealer's licence is £288.

(2) The fee payable under regulation 38(1) is £172 where the wholesale dealer's licence—

- (a) relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total value of the sale of authorised medicinal products carried on at that pharmacy;

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(b) does not relate to anything done in a registered pharmacy, where the total value of the sale by way of wholesale dealing in authorised medicinal products does not exceed £35,000; or

(c) relates to general sale list medicines only.

(3) For the purposes of sub-paragraph (2), the total value shall be calculated in accordance with Part 2 of this Schedule and the references to “marketing authorisation” and “authorisation holder” in Part 2 shall be interpreted as if they were references to “wholesale dealer's licence” and “licence holder”, respectively.

Wholesale dealer's licences: evidence

13. Where in respect of any relevant fee period, the holder of a wholesale dealer's licence does not submit evidence of turnover in relation to the relevant fee period to the satisfaction of the licensing authority, the periodic fee payable shall be the fee prescribed in paragraph 12(1).

Wholesale dealer's licences: special medicinal products

14. The fee payable under regulation 38(1) in connection with the holding of a wholesale dealer's licence which relates to special medicinal products imported from another EEA member State is the fee payable in accordance with paragraphs 12 and 13 and an additional amount calculated in accordance with paragraph 15.

Additional amount for manufacturer's licences and wholesale dealer's licences which relate to special medicinal products

15.—(1) The additional amount referred to in paragraph 11(3) and 14 in relation to any fee period shall be the fee specified in the entry in column 2 of the following table corresponding to the estimated number of special import notices for that fee period specified in column 1.

Additional periodic fee in connection with imported special medicinal products

<i>Column 1 Number of special import notices</i>	<i>Column 2 Additional amount</i>
1 to 20	£130
21 to 100	£519
101 to 1,000	£2,077
1,001 to 5,000	£10,383
5,001 to 20,000	£25,957
20,001 to 50,000	£51,914
50,001 to 100,000	£103,828
100,001 or more	£155,742

(2) For the purposes of this paragraph, the estimated number of special import notices for any fee period shall be the number notified in writing to the licence holder by the licensing authority before the start of that fee period as the number of such notices which the authority estimate will be given by the holder during the fee period.

Traditional herbal registrations

16. The fee payable under regulation 38(1) in connection with the holding of a traditional herbal registration is £76.

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Online sellers of medicines

17.—(1) Subject to sub-paragraph (2), the fee payable under regulation 39(1) by a person included on the list of online sellers of medicines is £97.

(2) For the fee period beginning with 1st April 2016 and ending with 31st March 2017, the fee payable under regulation 39(1) by a person included on the list of online sellers of medicines is the fee payable in accordance with sub-paragraph (1) and an additional amount of £100.

(3) The fee payable in accordance with sub-paragraph (2) is payable on invoice.

PART 4

Types of Marketing Authorisation for which only One Periodic Fee is Payable

Parallel import licences

18. In a case where a parallel import licence has been granted by the licensing authority the periodic fee relating to that licence is payable once only.

SCHEDULE 5

Regulation 46(1) and (2)

Fees for certificates of registration

<i>Column 1</i> <i>Type of application</i>	<i>Column 2</i> <i>Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks</i>	<i>Column 3</i> <i>Fees for other applications</i>
1 An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation.	£159	£393
2 An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation.	£478	£704
3 A mutual recognition procedure incoming application.	£501	£638
4 A mutual recognition outgoing application (regulatory assistance).	£287	£374
5 A decentralised procedure application where the UK is a concerned member State.	£430	£563
6 A decentralised procedure application where the UK is the reference member State.	£813	£1,063
7 Any other application.	£790	£1,034

SCHEDULE 6

Regulation 51(1)

Time for payment of capital fees: small companies

Interpretation

1. In this Schedule a reference to an application is to an application made by or on behalf of a small company.

Major application

2. In connection with a major application for a marketing authorisation for which the fee payable is that specified in [F52 entry 1(h)] of the table in paragraph 24 of Part 2 of Schedule 2, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 25% at the time of the application and as to 75% within 30 days following written notice from the licensing authority that the application has been determined.

Textual Amendments

F52 Words in [Sch. 6 para. 2](#) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 8A (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 188\(h\)](#))

Complex application

3. In connection with a complex application for a marketing authorisation, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable—

- (a) as to 50% at the time of the application; and
- (b) as to 50% within 30 days following written notice from the licensing authority that the application has been determined.

Multiple application

4. In connection with an application to which paragraph 28 of Part 2 of Schedule 2 applies, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable—

- (a) as to 50% of the total payable in accordance with that paragraph at the time of the application; and
- (b) as to 50% of that total within 30 days following written notice from the licensing authority that the application has been determined.

Outgoing mutual recognition application

5. As regards the fee payable under regulation 17 in connection with an application—

- (a) to which paragraph 36(2) of Part 3 of Schedule 2 applies—
 - (i) 25% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under the second sub-paragraph of Article 28(1) of the 2001 Directive for an assessment report to be prepared or updated; and
 - (ii) 75% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end;

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(b) to which paragraph 36(3), (4) or (5), of Part 3 of Schedule 2 applies—

- (i) 50% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under the second sub-paragraph of Article 28(1) of the 2001 Directive for an assessment report to be prepared or updated, and
- (ii) 50% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end,

if the applicant so requests in writing.

Application for traditional herbal registration

6. In connection with an application for a traditional herbal registration, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Traditional herbal registration: complex variation

7. In connection with a complex variation application or a new excipient variation application to vary a traditional herbal registration, the fee payable under regulation 19(1) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Application for manufacturer's licence, manufacturing authorisation or wholesale dealer's licence

8. In connection with an application for a manufacturer's licence, manufacturing authorisation, or a wholesale dealer's licence, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Inspection fees in connection with applications

9. In connection with an application for a marketing authorisation, traditional herbal registration, manufacturer's licence or manufacturing authorisation, the fee payable in respect of an inspection at any site other than one named as a possible site for manufacture of a medicinal product by three or more applicants shall, if the applicant so requests in writing, be payable as to 50% within the period of 14 days referred to in regulation 50(1)(b) and as to 50% within 12 months after that date.

SCHEDULE 7

Regulation 57(2)

Waiver, reduction or refund of capital fees

Interruptions of manufacture, assembly, sale or supply

1. Where the manufacture, assembly, sale or supply of medicinal products of a particular class or description will be, or is likely to be, interrupted for a period and in consequence thereof the health of the community will be, or is likely to be, put at risk, any capital fees payable under these Regulations in connection with an application for the grant of a marketing authorisation or a manufacturer's licence relating to a medicinal product falling within that class or description and made during that period or, if the period will, or is likely to, exceed 3 months of that period, shall be waived.

Reclassification

2.—(1) Where—

- (a) an application for a marketing authorisation includes a reclassification element within the meaning of paragraph 25 of Part 2 of Schedule 2; and
- (b) the licensing authority is satisfied that the reclassification element does not require consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products,

50% of the additional amount payable under paragraph 25(1)(a) or (b) or 28(4)(a) of Part 2 of that Schedule shall be refunded, or if it has not yet been paid, shall be waived.

(2) Where—

- (a) an application for variation of a marketing authorisation is a reclassification variation application (not being an application falling within paragraph 40 of Part 4 of Schedule 2); and
- (b) the licensing authority is satisfied that the application does not require consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products,

50% of the fee payable under paragraph 38 of Schedule 2 and entry 1(c)(i) of Table 1 referred to in that paragraph or of the fee payable under paragraph 53 (a)(i) of Part 4 of Schedule 2 shall be refunded, or if it has not yet been paid, shall be waived.

(3) Where—

- (a) an application for variation of a parallel import licence falls within paragraph 42 (1)(a) of Part 4 of Schedule 2; and
- (b) the licensing authority is satisfied that the application does not require consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products,

50% of the fee payable under that paragraph shall be refunded, or if it has not yet been paid, shall be waived.

(4) For the purposes of sub-paragraphs (1) to (3), a reclassification element or, as the case may be, a variation application does not require consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products where—

- (a) the licensing authority is satisfied that the application does not require consideration by the Commission, committee or board; and
- (b) the Commission, committee or board are consulted only by virtue of, or in accordance with any Community provision, referred to the Committee for Medicinal Products for Human Use or the Committee on Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the Directive.

(5) In sub-paragraph (4), “Committee for Medicinal Products for Human Use” and “Committee on Herbal Medicinal Products” mean the Committee for Medicinal Products for Human Use and Committee on Herbal Medicinal Products established under Regulation (EC) No 726/2004.

Variation of a traditional herbal registration

3. Where at the specific written request of the licensing authority, or in response to the imposition of an urgent safety restriction under regulation 149 (urgent safety restrictions) of the Human Medicines Regulations, an application is made for the variation of a traditional herbal registration so as to—

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- (a) restrict any one or more of the indications, dosage or target population; or
- (b) add a new contraindication or a warning or both of these,

as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 19(1) shall be refunded or, if it has not yet been paid, shall be waived.

Withdrawal of application in relation to marketing authorisation, traditional herbal registration or clinical trial authorisation

4.—(1) Subject to sub-paragraph (2), where an application for the grant of, or for a variation to, a marketing authorisation or traditional herbal registration, or, an application for a clinical trial authorisation or a notice of amendment to a clinical trial authorisation is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulations 12(1)(a), 19(1) or 20(1) in connection with that application or notice shall be refunded or, if it has not yet been paid, shall be waived—

- (a) if the application or notice has been received but no medical, scientific or pharmaceutical assessment thereof has begun, 90%;
- (b) except in a case to which sub-paragraph (c) applies, if medical, scientific or pharmaceutical assessment has begun but not been completed, 50%;
- (c) if a request for further information in connection with the application has been made by the licensing authority under regulation 30 (provision of information) of the Human Medicines Regulations or in pursuance of a European Union provision which applies to applications for marketing authorisations or traditional herbal registrations, 25%.

(2) If an application for the grant of, or for a variation to, a marketing authorisation or traditional herbal registration, or an application for a clinical trial authorisation or a notice of amendment to a clinical trial authorisation, is withdrawn either after medical, scientific and pharmaceutical assessment has been completed or following consideration of that application by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products, no refund or waiver of the fee payable under regulation 12(1)(a), 19(1) or 20(1) in connection with that application or notice shall be made under this paragraph.

Withdrawal of application in relation to a certificate of registration

5. Where a person withdraws an application for the grant of a certificate of registration before it has been determined by the licensing authority the following percentage of the fee otherwise payable under regulation 46 of these Regulations shall be refunded, or if it has not yet been paid, shall be waived—

- (a) if the application has been received but no medical, scientific or pharmaceutical assessment of the application has begun, 90%;
- (b) if medical, scientific or pharmaceutical assessment of the application has begun but has not been completed, 50%;
- (c) if medical, scientific or pharmaceutical assessment or consideration by the Advisory Board on the Registration of Homoeopathic Products of the application has been completed, no refund or waiver of the fee shall be made.

Withdrawal of application in relation to manufacturing authorisation, wholesale dealer's licence, manufacturer's licence, broker's registration or active substance registration

6.—(1) Where an application for the grant of, or for a variation to, a manufacturing authorisation, a manufacturer's licence, a wholesale dealer's licence, a broker's registration or an active substance

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registration is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 12(1)(a) or 19(1) in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

- (a) if the application is withdrawn before any inspection in connection with that application has been made, 90%; or
- (b) if such an inspection has been made, 50%.

Refusal of application for grant of marketing authorisation, traditional herbal registration or clinical trial authorisation

7. Where an application for the grant of a marketing authorisation or traditional herbal registration, or an application for a clinical trial authorisation is refused by the licensing authority and—

- (a) the information contained in it, or submitted with it, was not sufficient to enable a full medical, scientific or pharmaceutical assessment to be undertaken; and
- (b) if the applicant had withdrawn it before it was refused, part of the fee payable in respect of it would have been refunded or waived under paragraph 3,

there shall be refunded or waived the amount which would have been refunded or waived if the application had been withdrawn before it was refused by the licensing authority.

[^{F53}Orphan marketing authorisation

7A. Where the licensing authority grants an orphan marketing authorisation, the following percentage of the fee otherwise payable under regulation 12(1)(a) in connection with the application for that authorisation shall be refunded or, if it has not yet been paid, shall be waived—

- (a) in the case of an application made by or on behalf of a small or medium company, 100%;
- (b) in the case of a major application that is not made by or on behalf of a small or medium company but to which paragraph 6 of Part II of Annex 1 to the 2001 Directive applies, 50%; or
- (c) in any other case, 10%.]

Textual Amendments

F53 Sch. 7 para. 7A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 1 para. 9 (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Parallel import licence

8. The fee payable for an application to vary a parallel import licence shall be waived if the application is made only—

- (a) because of a change to the number of an authorisation granted under the provisions of the 2001 Directive by another member State for a product to which the licence relates; and
- (b) so that the number of that authorisation shown on the licence can be changed.

Surrender of marketing authorisation at same time as a variation application

9.—(1) Subject to sub-paragraphs (2) and (3), where an applicant applies to vary a marketing authorisation in the circumstances set out in paragraph 8(3) of Part 3 of Schedule 4, the fee payable under regulation 19(1) shall be refunded or waived.

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(2) Subject to sub-paragraph (3), where an applicant on the same occasion submits more than one such application which relates to medicinal products containing the same active ingredients but no other active ingredient, sub-paragraph (1) shall apply only to one of those applications.

(3) Where in respect of any two or more of the applications mentioned in sub-paragraph (2) provision is made for fees of different amounts by paragraphs 51 and 52 of Part 4 of Schedule 2, sub-paragraph (1) shall apply to the application in respect of which of those paragraphs make provision for the higher or highest fee.

Clinical trial authorisation

10.—(1) In relation to an application for a clinical trial authorisation in relation to a Phase I trial or a Phase II or Phase III trial, the fee payable in respect of such an application may be reduced in accordance with the following sub-paragraphs.

(2) Where the licensing authority is satisfied that the investigational medicinal product dossier submitted in accordance with paragraph 11 of Part 2 of Schedule 3 to the Clinical Trials Regulations does not require a full medical, scientific or pharmaceutical assessment, the fee may be reduced by an amount which the authority considers to be the cost of the assessment work which is not required.

(3) The fee payable may not be reduced below £100.

(4) Where the fee has been reduced by the licensing authority but the applicant has paid the full fee, the amount by which the fee has been reduced shall be refunded.

(5) In this paragraph, “Phase I trial” and “Phase II or Phase III trial” have the same meaning as in paragraph 1 of Schedule 2.

Scientific advice: paediatric indications

11.—(1) Where the licensing authority holds a meeting referred to in regulation 4 in order to provide scientific advice with a view to a person making an application other than a major application or an application for a paediatric use marketing authorisation the fee shall be waived if—

- (a) sub-paragraphs (2) or (3) apply to the application; and
- (b) the meeting is held solely for the purpose of providing advice in relation to the application.

(2) This sub-paragraph applies to the application if—

- (a) the application relates to a medicinal product which is intended to be used in accordance with an authorisation for a paediatric indication; and
- (b) no other product which has the same active ingredient and is intended to be used in accordance with the same indication and for the same part of the paediatric population as the product in question has previously been granted a marketing authorisation.

(3) This sub-paragraph applies to the application if—

- (a) the application relates to a medicinal product which is intended to be used in accordance with an authorisation for a paediatric indication;
- (b) as a result of the application the medicinal product will be available in a formulation which the licensing authority considers to be of significant benefit to that population in comparison to other medicinal products on the market in the United Kingdom; and
- (c) no other product which has the same active ingredient and is in the same formulation as proposed for the product in question has previously been granted a marketing authorisation.

(4) In this paragraph—

- (a) a medicinal product is authorised for a paediatric indication if it is authorised for use in part or all of that part of the population aged between birth and 18 years and the details

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of the authorised indication are specified in the summary of characteristics drawn up in accordance with Article 11 of the 2001 Directive ^{F54};

- (b) “paediatric use marketing authorisation” means a marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate or by a patent which qualifies for the granting of such a certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product; and
- (c) “supplementary protection certificate” means a certificate granted under Council Regulation (EC) No 469/2009 concerning the creation of a supplementary protection certificate for medicinal products ^{F55} and a patent qualifies for the granting of such a certificate if the provisions of that Regulation so provide.

Textual Amendments

F54 Article 11 has been amended by Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34) and Directive 2010/84/EU of the European Parliament and of the Council (OJ No L 348, 31.12.2010, p74).

F55 OJ No L 152, 16.6.2009, p1.

Refunds: treated as having been paid on account

12. Any sums payable to the applicant by way of refund of any fees under the provisions of this Schedule may be treated as having been paid on account of any other fee which the applicant is liable to pay (whether by instalments or otherwise) under the provisions of these Regulations.

SCHEDULE 8

Regulation 57(2)

Adjustment [^{F56}, waiver] reduction or refund of periodic fees

Textual Amendments

F56 Word in Sch. 8 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 1 para. 10(2) (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Refund on surrender or revocation of authorisation, registration or licence

1. Where, after payment of a periodic fee payable in accordance with the provisions of these Regulations, the marketing authorisation, traditional herbal registration or licence in respect of which such a fee has been paid is either—

- (a) surrendered at the specific written invitation of the licensing authority; or
- (b) revoked by the licensing authority on a date earlier than the date of expiry stated in the marketing authorisation, traditional herbal registration or licence,

the licensing authority shall refund the whole or any part of the difference between such periodic fee as has been paid and the amount of the periodic fee payable on the basis of the actual duration of

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the marketing authorisation, traditional herbal registration or licence up to the date of such surrender or revocation.

Adjustment and refund: licences relating to imported special medicinal products

2.—(1) This paragraph applies to periodic fees payable in connection with a manufacturer's licence or a wholesale dealer's licence which relates to imported special medicinal products.

(2) If during a fee period the number of special import notices given by a licence holder is greater than the estimated number notified by the licensing authority in accordance with paragraph 15 of Part 3 of Schedule 4, the periodic fee payable in relation to that period shall be increased by the difference, if any, between the amount payable in accordance with that paragraph and the amount which would have been payable if the estimated number notified by the licensing authority for that fee period had been the same as the actual number of notices given during that year.

(3) If during a fee period the number of special import notices given by a licence holder is less than the estimated number notified by the licensing authority in accordance with paragraph 15 of Part 3 of Schedule 4, the licensing authority shall refund the difference, if any, between the amount payable in accordance with that paragraph and the amount which would have been payable if the estimated number notified by the licensing authority for that fee period had been the same as the actual number of notices given during that year.

[^{F57}Waiver or refund: converted EU marketing authorisations

2A.—(1) Where the licensing authority revokes a converted EU marketing authorisation in accordance with paragraph 6(3) of Schedule 33A to the Human Medicines Regulations, the periodic fee payable under regulation 38(1) in relation to that authorisation shall be refunded, or if it has not yet been paid, shall be waived.

(2) In this paragraph, “converted EU marketing authorisation” has the meaning given in paragraph 6(1) and (2) of Schedule 33A to the 2012 Regulations.]

Textual Amendments

F57 Sch. 8 para. 2A inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, **Sch. 1 para. 10(3)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

Refunds: treated as having been paid on account

3. Any sums payable to the applicant by way of refund of any fees under the provisions of this Schedule may be treated as having been paid on account of any other fee which the applicant is liable to pay (whether by instalments or otherwise) under the provisions of these Regulations.

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Changes and effects yet to be applied to :

- Sch. 1 para. 1 words inserted by [S.I. 2023/314 reg. 23](#)
- Sch. 2 para. 38 omitted by [S.I. 2019/775 Sch. 1 para. 7\(9\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by [S.I. 2020/1488, reg. 1, Sch. 2 para. 188\(g\)\(vii\)](#))
- Sch. 2 para. 38(4) substituted by [S.I. 2019/775 Sch. 1 para. 7\(9\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by [S.I. 2020/1488, reg. 1, Sch. 2 para. 188\(g\)\(vii\)](#))
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(vi\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(d\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(f\)](#)
- Sch. 2 para. 25(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(4\)\(a\)](#)
- Sch. 2 para. 25(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(4\)\(b\)](#)
- Sch. 2 para. 28(4)(b) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(c\)](#)
- Sch. 2 para. 30(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(a\)](#)
- Sch. 2 para. 30(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(b\)](#)
- Sch. 2 para. 30(1)(c) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(c\)](#)
- Sch. 2 para. 31(1) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(a\)](#)
- Sch. 2 para. 31(2) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(b\)](#)
- Sch. 2 para. 31(5) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(c\)](#)
- Sch. 2 para. 32(1) sum substituted by [S.I. 2023/314 reg. 24\(10\)\(a\)](#)
- Sch. 2 para. 32(2) sum substituted by [S.I. 2023/314 reg. 24\(10\)\(b\)](#)
- Sch. 2 para. 33(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(a\)\(i\)](#)
- Sch. 2 para. 33(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(a\)\(ii\)](#)
- Sch. 2 para. 33(2) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(b\)](#)
- Sch. 2 para. 34(a) sum substituted by [S.I. 2023/314 reg. 24\(12\)\(a\)](#)
- Sch. 2 para. 34(b) sum substituted by [S.I. 2023/314 reg. 24\(12\)\(b\)](#)
- Sch. 2 para. 35(1) sum substituted by [S.I. 2023/314 reg. 24\(13\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(i\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(ii\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(iii\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(iv\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(v\)](#)

- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vi)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(i)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(ii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iv)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(v)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vi)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(viii)
- Sch. 2 para. 40(1) sum substituted by S.I. 2023/314 reg. 24(16)
- Sch. 2 para. 42(1)(a) sum substituted by S.I. 2023/314 reg. 24(17)(a)
- Sch. 2 para. 42(1)(b) sum substituted by S.I. 2023/314 reg. 24(17)(b)
- Sch. 2 para. 42(1)(c) sum substituted by S.I. 2023/314 reg. 24(17)(c)
- Sch. 2 para. 43(a) sum substituted by S.I. 2023/314 reg. 24(18)(a)
- Sch. 2 para. 43(b) sum substituted by S.I. 2023/314 reg. 24(18)(b)
- Sch. 2 para. 44 sum substituted by S.I. 2023/314 reg. 24(19)
- Sch. 2 para. 45 sum substituted by S.I. 2023/314 reg. 24(20)
- Sch. 2 para. 46 sum substituted by S.I. 2023/314 reg. 24(21)
- Sch. 2 para. 47 sum substituted by S.I. 2023/314 reg. 24(22)
- Sch. 2 para. 48 sum substituted by S.I. 2023/314 reg. 24(23)
- Sch. 2 para. 49(1) sum substituted by S.I. 2023/314 reg. 24(24)
- Sch. 2 para. 53(a)(ii) sum substituted by S.I. 2023/314 reg. 24(25)
- Sch. 2 para. 54(1)(a) sum substituted by S.I. 2023/314 reg. 24(26)(a)(i)
- Sch. 2 para. 54(1)(b) sum substituted by S.I. 2023/314 reg. 24(26)(a)(ii)
- Sch. 2 para. 54(2) sum substituted by S.I. 2023/314 reg. 24(26)(b)
- Sch. 2 para. 56(a) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 56(b) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 57(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(a)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(28)(b)
- Sch. 2 para. 57(2)(b)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(c)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(a)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(b)
- Sch. 2 para. 4(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(2) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (i))
- Sch. 2 para. 22(1) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(aa))
- Sch. 2 para. 22(2)(f) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(b) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(bb))
- Sch. 2 para. 22(3) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(c) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(c) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(cc))
- Sch. 2 para. 23(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(4)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (iii)(aa))
- Sch. 3 para. 2(1)(a) sum substituted by S.I. 2023/314 reg. 25(2)(a)
- Sch. 3 para. 2(1)(b) sum substituted by S.I. 2023/314 reg. 25(2)(b)
- Sch. 3 para. 5(a) sum substituted by S.I. 2023/314 reg. 25(3)(a)
- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(a)

- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(b)
- Sch. 3 para. 6(2)(a) sum substituted by S.I. 2023/314 reg. 25(4)(a)
- Sch. 3 para. 6(2)(b) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 6(2)(c) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 7(3) sum substituted by S.I. 2023/314 reg. 25(5)
- Sch. 3 para. 8(1)(a) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(ii)
- Sch. 3 para. 8(3) sum substituted by S.I. 2023/314 reg. 25(6)(b)
- Sch. 3 para. 9(1)(a)(i) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(ii)
- Sch. 3 para. 9(1)(b)(i) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(ii)
- Sch. 3 para. 9(3)(a) sum substituted by S.I. 2023/314 reg. 25(7)(c)(i)
- Sch. 3 para. 9(3)(b) sum substituted by S.I. 2023/314 reg. 25(7)(c)(ii)
- Sch. 3 para. 10(a) sum substituted by S.I. 2023/314 reg. 25(8)(a)
- Sch. 3 para. 10(b) sum substituted by S.I. 2023/314 reg. 25(8)(b)
- Sch. 4 para. 15(1) substituted by S.I. 2023/314 reg. 26(7)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(a)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(b)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(c)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(d)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(e)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(f)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(g)
- Sch. 4 para. 6 sum substituted by S.I. 2023/314 reg. 26(3)
- Sch. 4 para. 7(a) sum substituted by S.I. 2023/314 reg. 26(4)(a)
- Sch. 4 para. 7(b) sum substituted by S.I. 2023/314 reg. 26(4)(b)
- Sch. 4 para. 11(1) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 11(2) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 12(1) sum substituted by S.I. 2023/314 reg. 26(6)(a)
- Sch. 4 para. 12(2) sum substituted by S.I. 2023/314 reg. 26(6)(b)
- Sch. 4 para. 16 sum substituted by S.I. 2023/314 reg. 26(9)
- reg. 4(a) sum substituted by S.I. 2023/314 reg. 3(a)
- reg. 4(b) sum substituted by S.I. 2023/314 reg. 3(b)
- reg. 4(c) sum substituted by S.I. 2023/314 reg. 3(c)
- reg. 4(d) sum substituted by S.I. 2023/314 reg. 3(d)
- reg. 4(e) sum substituted by S.I. 2023/314 reg. 3(e)
- reg. 5(1)(a) sum substituted by S.I. 2023/314 reg. 4(a)
- reg. 5(1)(b) sum substituted by S.I. 2023/314 reg. 4(b)
- reg. 6 sum substituted by S.I. 2023/314 reg. 5
- reg. 7(1)(a) sum substituted by S.I. 2023/314 reg. 6(a)
- reg. 7(1)(b) sum substituted by S.I. 2023/314 reg. 6(b)
- reg. 8 sum substituted by S.I. 2023/314 reg. 7
- reg. 9 sum substituted by S.I. 2023/314 reg. 8
- reg. 10(1) sum substituted by S.I. 2023/314 reg. 9
- reg. 12(1) words inserted by S.I. 2023/314 reg. 10
- reg. 14 sum substituted by S.I. 2023/314 reg. 11
- reg. 15(1)(a) sum substituted by S.I. 2023/314 reg. 12(a)
- reg. 15(1)(b) sum substituted by S.I. 2023/314 reg. 12(b)
- reg. 15(3) sum substituted by S.I. 2023/314 reg. 12(c)
- reg. 21(1) sum substituted by S.I. 2023/314 reg. 18
- reg. 22(1) sum substituted by S.I. 2023/314 reg. 19
- reg. 23(3)(b)(i) substituted by S.I. 2019/775 Sch. 1 para. 3(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 3(2)-(4) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(d))

- reg. 27(1) sum substituted by S.I. 2023/314 reg. 20(a)
- reg. 27(3) sum substituted by S.I. 2023/314 reg. 20(b)
- reg. 41(1) sum substituted by S.I. 2023/314 reg. 21(a)
- reg. 41(2) sum substituted by S.I. 2023/314 reg. 21(b)
- reg. 42(1) sum substituted by S.I. 2023/314 reg. 22

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