

**2013 No. 532**

**MEDICINES**

**FEES AND CHARGES**

**The Medicines (Products for  
Human Use) (Fees) Regulations  
2013**

*Made* - - - -

*7th March 2013*

*Laid before Parliament*

*11th March 2013*

*Coming into force in accordance with regulation 1*



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The Secretary of State for Health and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in exercise of the powers conferred on them by

section 1(1) and (2) of the Medicines Act 1971(a) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(b).

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(c) and section 56(1) and (2) of the Finance Act 1973(d). The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products(e).

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

In accordance with section 129(6) of the Medicines Act 1968(f), the Secretary of State for Health and the Minister for Health, Social Services and Public Safety have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

## PART 1

### General

#### Citation and commencement

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use) (Fees) Regulations 2013.

(2) Unless paragraph (3) applies these Regulations shall come into force on 1st April 2013.

(3) The following regulations shall come into force on the coming into force of Regulations made under section 2(2) of the European Communities Act 1972 to implement provisions related to importers, manufacturer's and distributors of active substances as provided for by Article 52a and persons brokering medicinal products as provided for by Article 85b of Directive 2001/83/EC(g)—

- (a) 12(1), insofar as it relates to a broker's registration or an active substance registration;
- (b) 18(1)(c);
- (c) 20;
- (d) 21;
- (e) 29(1)(a), insofar as it relates to a broker's registration or an active substance registration;
- (f) 36;

- 
- (a) 1971 c.69; as amended by regulation 45(2) of S.I. 2008/2297 and section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the Medicines Act 1971 ("the 1971 Act"), expressions used in that section have the same meaning as in the Medicines Act 1968 (c.67) ("the 1968 Act"). See therefore section 1 of the 1968 Act, as substituted by paragraph 2 of Schedule 34 to the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the 2012 Regulations") which provides the meaning of the expression "the Ministers", which is relevant to the powers being exercised in the making of these Regulations. By virtue of regulation 348 of, and paragraph 36 of Schedule 34 to, the 2012 Regulations, references in section 1(1) and (2)(b) of the 1971 Act to an application for a licence, or for the variation or renewal of such a licence under Part 2 of the 1968 Act, shall have effect as a reference to any application under Parts 3 to 8 of the 2012 Regulations.
  - (b) In the case of the Secretary of State, by virtue of article 2(1) of S.I. 1999/3142. In the case of the Minister for Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister is responsible was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).
  - (c) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act (2006 c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7).
  - (d) 1973 c.51.
  - (e) See article 2(1) of and Schedule 1 to the European Communities (Designation) Order 1972 (S.I. 1972/1811).
  - (f) Section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.
  - (g) OJ No L 311, 28.11.2001, p67. Articles 52a and 85b were inserted into Directive 2001/83/EC by Article 1(10) and (19) of Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74) and are expected to be implemented shortly after the commencement of these Regulations.

- (g) 37(7), insofar as it relates to a broker’s registration or an active substance registration;
- (h) 40(1), insofar as it relates to a broker’s registration or an active substance registration and (2)(c);
- (i) 48(2)(e);
- (j) Schedule 2, paragraphs 32, 33, 46 and 47;
- (k) Schedule 3, paragraphs 8 and 9;
- (l) Schedule 7, paragraph 6 insofar as it relates to a broker’s registration or an active substance registration.

### **Interpretation**

2. These Regulations shall be interpreted in accordance with Schedule 1.

## **PART 2**

### **Capital Fees for Pre-Application Meetings**

#### **Interpretation of Part 2**

3. In this Part—

“EU marketing authorisation” means—

- (a) a United Kingdom marketing authorisation granted by the licensing authority under Part 5 (marketing authorisations) of the Human Medicines Regulations;
- (b) a marketing authorisation granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive; or
- (c) a European Union marketing authorisation; and

“relevant medicinal product” means a medicinal product for human use to which the provisions of the 2001 Directive apply.

#### **Fee for scientific advice: application for, or variation to, EU marketing authorisation**

4. Unless regulation 5 applies, the fee payable by a person with whom the licensing authority holds a meeting in order to provide scientific advice with a view to that person making an application for an EU marketing authorisation or an application for the variation of an EU marketing authorisation, is—

- (a) £2,445, if the advice provided at that meeting consists of advice in connection with—
  - (i) quality development only; or
  - (ii) safety development only;
- (b) £3,070, if the advice provided at that meeting consists only of advice in connection with clinical development;
- (c) £3,401, if the advice provided at that meeting consists only of advice in connection with quality and safety development;
- (d) £4,027, if the advice provided at that meeting consists of advice in connection with—
  - (i) quality and clinical development; or
  - (ii) safety and clinical development;
- (e) £4,985, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

### **Fee for scientific advice: classification of a medicinal product**

5.—(1) The fee payable by a person with whom the licensing authority holds a meeting to provide scientific advice in connection with the classification of a relevant medicinal product, is—

- (a) £3,070, if the advice relates to a product which, if reclassified, will be available on general sale; and
- (b) £4,027, if the advice relates to a product which, if reclassified, will be available without a prescription from a pharmacy.

(2) For the purposes of this regulation, a product is on general sale if it is a medicinal product subject to general sale within the meaning of regulation 5(1) of the Human Medicines Regulations (classification of medicinal products for general sale).

### **Fee for advertising advice**

6. The fee payable by the holder of a marketing authorisation with whom the licensing authority holds a meeting in order to provide advice before the publication of advertising of a medicinal product by that holder's undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, is £2,445.

### **Fee for pharmacovigilance advice**

7.—(1) The fee payable by a person with whom the licensing authority holds a meeting in order to provide pharmacovigilance advice is—

- (a) £4,027, in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours;
- (b) £3,401, in any other case.

(2) The time taken by the licensing authority for the purposes of paragraph (1) shall be the total time spent by each individual engaged in preparing for or attending the meeting on behalf of the licensing authority.

### **Fee for advice on labelling or leaflets**

8. The fee payable by the holder of one or more marketing authorisations with whom the licensing authority holds a meeting in order to provide advice on proposed changes to the labelling or the package leaflets of the medicinal products to which those authorisations relate, is £2,445.

### **Fee for regulatory advice**

9. The fee payable by the holder of a marketing authorisation with whom the licensing authority holds a meeting in order to provide regulatory advice to that person, is £3,070.

### **Fee for advice for other purposes**

10.—(1) Unless paragraph (4) applies, the fee payable by a person specified in paragraph (2) with whom the licensing authority holds a meeting for a purpose specified in paragraph (3) is £4,945.

(2) A person who—

- (a) is, or is to be, a sponsor of a clinical trial;
- (b) manufactures medicinal products;
- (c) is, or is to be, responsible for placing medicinal products on the market; or
- (d) acts on behalf of, or provides advice or assistance to, a person referred to in subparagraphs (a) to (c),

is a specified person for the purpose of paragraph (1).



(3) A meeting referred to in paragraph (1) is for a specified purpose if it is held to provide advice in relation to—

- (a) scientific or regulatory issues relating to the development of a medicinal product or a type of medicinal product;
- (b) the design of pharmaceutical or pre-clinical tests, or clinical trials, for a medicinal product or a type of medicinal product;
- (c) the management of risk in relation to a medicinal product or a type of medicinal product which is under development, or is being marketed in the European Union; or
- (d) other scientific or regulatory issues relating to a medicinal product or a type of medicinal product after an EU marketing authorisation has been granted for that product or a product of that type.

(4) Paragraph (1) does not apply in the case of a meeting where the purpose of such a meeting is to provide only advice specified in regulations 4 to 9.

(5) In this regulation—

“Directive 93/42/EEC” means Council Directive 93/42/EEC concerning medical devices<sup>(a)</sup>;

“medical device” has the same meaning as in Article 1(2)(a) of Directive 93/42/EEC;

“medicinal product” includes a substance incorporated in a medical device which, if used separately, may be considered to be a medicinal product as defined in Article 1(2) of the 2001 Directive;

“regulatory issues” means issues relating to the application of any EU instrument relating to EU marketing authorisations or to medical devices, or any enactment which implements such an instrument;

“risks” means any risk relating to the quality, safety or efficacy of a medicinal product as regards patients’ health or public health, or any risk of undesirable effects on the environment;

“sponsor” shall be interpreted in accordance with regulation 3 (sponsor of a clinical trial) of the Clinical Trials Regulations<sup>(b)</sup>;

and a reference to the development of a medicinal product or a type of medicinal product is a reference to development for the purposes of—

- (a) obtaining an EU marketing authorisation, or making a variation to an EU marketing authorisation, for that product or a product of that type; or
- (b) obtaining a design-examination certificate of the type mentioned in paragraph 4.3 of Annex II to Directive 93/42/EEC or a type-examination certificate of the type mentioned in paragraph 5 of Annex III to that Directive, for a medical device incorporating that product or a product of that type.

### **Time for payment of fees under regulations 4 to 10**

**11.** All sums payable by way of fees under regulations 4 to 10 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 those fees.

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(a) OJ No L 169, 12.7.1993, p1. This Directive has been amended by Directive 98/79/EC of the European Parliament and of the Council (OJ No L 331, 7.12.1998, p1), Directive 2000/70/EC of the European Parliament and of the Council (OJ No L 313, 13.12.2000, p22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No L 6, 10.1.2002, p50), Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ No L 284, 31.10.2003, p1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No L 247, 21.9.2007, p21).

(b) Regulation 3 has been amended by S.I. 2006/1928.

## PART 3

### Capital Fees for Applications for Authorisations, Registrations, Licences or Certificates and for Associated Inspections

#### **Fees for applications for authorisations, registrations, licences or certificates etc.**

**12.**—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorisation (other than a European Union marketing authorisation), a parallel import licence, a traditional herbal registration, a manufacturer’s licence, a manufacturing authorisation, a wholesale dealer’s licence, a clinical trial authorisation, a broker’s registration or an active substance registration is—

- (a) the fee prescribed for that application in Part 2 of Schedule 2; and
- (b) in respect of an inspection of a site made in connection with that application, the fee payable in accordance with regulations 29 and 31 to 36.

(2) Unless regulation 31 applies, the fee in paragraph (1) is payable by the applicant.

#### **Fee for applications for additional copy certificates**

**13.** The fee payable by an applicant for a certified copy of a certificate issued under Article 111(5) of the 2001 Directive is £68.

#### **Fees for applications for certificates and copy certificates by exporters of medicinal products**

**14.**—(1) The fee payable by an applicant for a certificate issued under regulation 31 (certification of manufacturer’s licence) of the Human Medicines Regulations, is—

- (a) £152, if the applicant requests the certificate to be issued within 24 hours of receipt of the application; and
- (b) £68 in any other case.

(2) The fee in paragraph (1)(a) and (b) is for three identical signed certificates.

(3) The fee payable by the applicant for a certified copy of the certificate referred to in paragraph (1) is £34.

## PART 4

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

#### **Meaning of “set of applications”**

**15.** For the purposes of this Part, a “set of applications” means—

- (a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorisation in other EEA States, but only if all the applications relate to applications for marketing authorisations in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or
- (b) a number of applications to competent authorities of other EEA States for marketing authorisations relating to a single United Kingdom marketing authorisation, but only if all the applications have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive.

### **Fees for applications for regulatory assistance under the mutual recognition procedure**

16. The fee payable by an applicant to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorisation in another EEA State or in other EEA States, is the fee prescribed in Part 3 of Schedule 2 in connection with the application or set of applications.

### **Time for payment of fees under regulation 16**

17. Unless regulation 49 (applications made by small companies) applies, all sums payable by way of fees under regulation 16 must have been paid 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.

## **PART 5**

### **Capital Fees for Applications for Variations of Authorisations, Registrations and Licences and for Associated Compliance Activities**

#### **Fees for variations of authorisations, registrations and licences**

18.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the fee mentioned in paragraph (2) applies for an application—

- (a) under the Human Medicines Regulations, under regulation—
  - (i) 29 (variation of licence on application of holder);
  - (ii) 68 (revocation, variation and suspension of UK marketing authorisation);
  - (iii) 135 (revocation, variation and suspension of a traditional herbal registration) but only in relation to a variation of such a registration;
- (b) to vary a parallel import licence;
- (c) to vary a broker's registration or an active substance registration;
- (d) under regulation 44 (variation of manufacturing authorisation) of the Clinical Trials Regulations<sup>(a)</sup> for the variation of a manufacturing authorisation.

(2) The fee referred to in paragraph (1) is—

- (a) the fee prescribed in Part 4 of Schedule 2 in connection with the application; and
- (b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 29, 31, 32, 34 and 36.

(3) Unless regulation 31 applies, the fee referred to in paragraph (1) is payable by the applicant.

#### **Fees for amendments to clinical trial authorisations**

19.—(1) A person who sends a valid notice of amendment under regulation 24 (amendments by the sponsor) of the Clinical Trial Regulations<sup>(b)</sup> relating to amendment of the protocol or the dossier related to a request for authorisation in accordance with paragraphs 10 or 11 of Part 2 of Schedule 3 (request for authorisation) to those Regulations must pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

- (a) the fee prescribed in paragraph 48 of Schedule 2 in connection with that amendment; and

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(a) Regulation 44 has been amended by S.I. 2006/1928.

(b) Regulation 24 has been amended by S.I. 2006/1928.

- (b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 29, 31, 32, 34 and 36.

#### **Fees for notification of changes and reports for broker's registrations**

**20.**—(1) A fee of £257 is payable by the holder of a broker's registration who provides, in accordance with any Regulations in connection with that registration—

- (a) any report that must be submitted relating to that registration, or
- (b) any notification that must be submitted about changes relating to that registration.

(2) The fee in paragraph (1) is payable for each report or notification of change made in connection with that broker's registration.

#### **Fees for notification of changes and compliance Reports for active substance registrations**

**21.**—(1) A fee of £257 is payable by the holder of an active substance registration who provides, in accordance with any Regulations in connection with that registration—

- (a) any report that must be submitted relating to that registration, or
- (b) any notification that must be submitted about changes relating to that registration.

(2) The fee in paragraph (1) is payable for each report or notification of change made in connection with that active substance registration.

#### **Applications for multiple variations**

**22.**—(1) Unless paragraph (3) or (5) applies, a separate fee is payable in respect of each application to vary each term of a marketing authorisation.

(2) Unless paragraph (5) applies, a separate fee is payable in respect of each variation of each provision of a traditional herbal registration, manufacturing authorisation or licence applied for in any one application.

(3) A separate fee is not payable for each application to vary a term of a marketing authorisation which—

- (a) falls within the same type of group application; or
- (b) the licensing authority—
  - (i) in consultation with other member States concerned, have agreed, in accordance with Article 7(2)(c) of Commission Regulation (EC) No 1234/2008, should be subject to the procedure for grouping of variations within the meaning of that Article; and
  - (ii) have agreed fall, or should be treated as falling, within the same type of group application.

(4) For the purposes of paragraph (3) the reference to a group application means an application which is a—

- (a) Minor Variation (Type IB) Group Application;
- (b) Major Variation (Type II) Group Application;
- (c) Major Variation (Type II) Complex Group Application; or
- (d) Major Variation (Type II) Extended Complex Group Application.

(5) A separate fee is not payable for a variation which is wholly consequential upon another variation of a provision of a marketing authorisation, traditional herbal registration, manufacturing authorisation or licence which is applied for in the same application.

(6) In a case where a recommendation on the classification of a variation is made in accordance with Article 5 of Commission Regulation (EC) No 1234/2008, the fee payable for the application made in respect of that variation shall be the appropriate fee for the classification given to the variation or, as the case may be, the appropriate fee which arises as a consequence of the classification given to the variation.

(7) Unless paragraph (8) applies, in this regulation and Part 4 of Schedule 2—

“Major Variation (Type II) Group Application” means an application for several variations to one marketing authorisation and—

- (a) at least one of the variations is a major variation of type II;
- (b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) and (c) of Commission Regulation (EC) No 1234/2008;
- (c) the variations do not include a variation—
  - (i) of a kind referred to in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to Commission Regulation (EC) No 1234/2008;
  - (ii) which relates to a change which is referred to in paragraph 23 of Schedule 2 (Type II Complex Variation Application); or
  - (iii) of a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2 (Extended Type II Complex Variation Application); and
- (d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB;

“Major Variation (Type II) Complex Group Application” means an application for several variations to one marketing authorisation and—

- (a) at least one of the variations relates to one or more of the changes referred to in paragraph 23 of Schedule 2;
- (b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) and (c) of Commission Regulation (EC) No 1234/2008;
- (c) the variations do not include a variation of—
  - (i) a kind referred to in paragraph 1 or paragraph 3 of Annex III to Commission Regulation (EC) No 1234/2008; or
  - (ii) a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2; and
- (d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB or one or more major variations of type II;

“Major Variation (Type II) Extended Complex Group Application” means an application for several variations to one marketing authorisation and—

- (a) at least one of the variations is a variation to a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2;
- (b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) and (c) of Commission Regulation (EC) No 1234/2008;
- (c) the variations do not include a variation of a kind referred to in paragraph 1 of Annex III to Commission Regulation (EC) No 1234/2008; and
- (d) the variations may include minor variations of type IA, minor variations of type IB or other major variations of type II or a variation relating to a change referred to in paragraph 23(a), (b) or (c) of Schedule 2;

“major variation of type II” has the meaning given in Article 2(3) of Commission Regulation (EC) No 1234/2008;

“Minor Variation (Type IB) Group Application” means an application for several variations to one marketing authorisation and—

- (a) at least one of the variations is a minor variation of type IB;
- (b) subject to sub-paragraph (c), the variations fall within the scope of Article 7(2)(b) and (c) of Commission Regulation (EC) No 1234/2008;
- (c) the variations do not include—

- (i) a variation of a kind referred to in paragraph 1 or paragraph 2 of Annex III of Commission Regulation (EC) No 1234/2008; or
  - (ii) a major variation of type II; and
- (d) the variations may include one or more minor variations of type IA;
- “minor variation of type IA” has the meaning given in Article 2(2) of Commission Regulation (EC) No 1234/2008;
- “minor variation of type IB” has the meaning given in Article 2(5) of Commission Regulation (EC) No 1234/2008; and
- “work sharing” means the work sharing procedure within the meaning of Article 20 of Commission Regulation (EC) No 1234/2008.
- (8) From 4th August 2013, in this regulation and Part 4 of Schedule 2—
- “Major Variation (Type II) Group Application” means an application for several variations to one marketing authorisation and—
- (a) at least one of the variations is a major variation of type II;
  - (b) subject to sub-paragraph (c), the variations fall within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008 (as amended);
  - (c) the variations do not include a variation—
    - (i) of a kind referred to in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to Commission Regulation (EC) No 1234/2008;
    - (ii) which relates to a change which is referred to in paragraph 23 of Schedule 2 (Type II Complex Variation Application); or
    - (iii) of a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2 (Extended Type II Complex Variation Application); and
  - (d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB;
- “Major Variation (Type II) Complex Group Application” means an application for several variations to one marketing authorisation and—
- (a) at least one of the variations relates to one or more of the changes referred to in paragraph 23 of Schedule 2;
  - (b) subject to sub-paragraph (c), the variations fall within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008 (as amended);
  - (c) the variations do not include a variation of—
    - (i) a kind referred to in paragraph 1 or paragraph 3 of Annex III to Commission Regulation (EC) No 1234/2008; or
    - (ii) a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2; and
  - (d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB or one or more major variations of type II;
- “Major Variation (Type II) Extended Complex Group Application” means an application for several variations to one marketing authorisation and—
- (a) at least one of the variations is a variation to a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2;
  - (b) subject to sub-paragraph (c), the variations fall within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008 (as amended);

(c) the variations do not include a variation of a kind referred to in paragraph 1 of Annex III to Commission Regulation (EC) No 1234/2008; and

(d) the variations may include minor variations of type IA, minor variations of type IB or other major variations of type II or a variation relating to a change referred to in paragraph 23(a), (b) or (c) of Schedule 2;

“major variation of type II” has the meaning given in Article 2(3) of Commission Regulation (EC) No 1234/2008;

“Minor Variation (Type IB) Group Application” means an application for several variations to one marketing authorisation and—

(a) at least one of the variations is a minor variation of type IB;

(b) subject to sub-paragraph (c), the variations fall within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008 (as amended);

(c) the variations do not include—

(i) a variation of a kind referred to in paragraph 1 or paragraph 2 of Annex III of Commission Regulation (EC) No 1234/2008; or

(ii) a major variation of type II; and

(d) the variations may include one or more minor variations of type IA;

“minor variation of type IA” has the meaning given in Article 2(2) of Commission Regulation (EC) No 1234/2008;

“minor variation of type IB” has the meaning given in Article 2(5) of Commission Regulation (EC) No 1234/2008; and

“work sharing” means the work sharing procedure within the meaning of Article 20 of Commission Regulation (EC) No 1234/2008.

(9) In this regulation—

“Commission Regulation (EC) No 1234/2008” means Commission Regulation (EC) No 1234/2008 as in force on the 1st April 2013;

“Commission Regulation (EC) No 1234/2008 (as amended)” means Commission Regulation (EC) No 1234/2008 as amended by Commission Regulation (EU) No 712/2012(a) from 4th August 2013.

## PART 6

### Capital Fees for Assessment of Labels and Leaflets

#### Meaning of “set of proposed changes”

**23.** For the purposes of this Part and Part 5 of Schedule 2, a “set of proposed changes” means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

(a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and

(b) those changes are submitted to the licensing authority at the same time.

#### Fees for assessment of a set of proposed changes to labels and leaflets

**24.**—(1) Unless paragraph (2) applies, where—

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(a) OJ No L 209, 4.8.2012, p4.

- (a) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a United Kingdom marketing authorisation (other than a parallel import licence) is submitted to the licensing authority in accordance with Article 61(3) of the 2001 Directive; or
- (b) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a parallel import licence is submitted to the licensing authority,

the fee payable by the holder of that authorisation or licence is the fee prescribed in Part 5 of Schedule 2 in connection with that change.

(2) Paragraph (1) does not apply where a change to the labelling or package leaflet of a medicinal product is proposed in connection with an application for the variation of the marketing authorisation for that product.

#### **Time for payment of fees under regulation 24**

25. All sums payable by way of fees under regulation 24(1) must be paid by the time that the proposed changes are submitted to the licensing authority.

## **PART 7**

### **Capital Fees for Applications for Renewals of Certain Licences, Authorisations and Registrations and for Associated Inspections**

#### **Fees for renewals of certain manufacturer's licences**

26.—(1) The fee payable by the applicant for an application to renew a manufacturer's licence which falls within the description in paragraph (2) is £178.

(2) The licence referred to in paragraph (1) is one—

- (a) which is solely for the manufacture of medicinal products the sale or supply of which does not require a marketing authorisation or a product licence; and
- (b) to which regulation 169 (mixing of general sale medicinal products) of the Human Medicines Regulations applies.

(3) Where an inspection of a site is made in connection with the application referred to in paragraph (1) an inspection fee of £295 is also payable by the applicant.

#### **Fees for renewals in terms which are not identical to the existing authorisation, licence or registration**

27. Where an applicant applies for renewal of a—

- (a) marketing authorisation (other than a European Union marketing authorisation);
- (b) traditional herbal registration, or
- (c) manufacturer's licence,

so as to contain provisions which are not identical to those in the authorisation, registration or licence as in force at the date of the application, the fee payable under this Part is increased by an amount equal to the fee which would have been payable under Part 5 of these Regulations had the applicant made a separate application for variation of that authorisation, registration or licence in respect of each provision which is not identical.



## PART 8

### Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorisations

#### Fees for regulatory assistance for certain marketing authorisations

28.—(1) Where—

- (a) an application is made to the licensing authority for the renewal of a United Kingdom marketing authorisation for a medicinal product which has been subject to the procedures specified in paragraph (2); and
- (b) the United Kingdom is to provide regulatory assistance acting as reference member State in relation to that application,

the fee payable by the applicant is the fee prescribed in Part 6 of Schedule 2 in connection with that regulatory assistance.

(2) The procedures referred to in paragraph (1) are—

- (a) the procedures laid down in Articles 7 and 7a of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products<sup>(a)</sup> and in Articles 17 and 18 of the 2001 Directive;
- (b) the procedures laid down in Article 9(4) of Directive 75/319/EEC and in Article 28 of the 2001 Directive;
- (c) the procedures laid down in Articles 10 to 14 of Directive 75/319/EEC and in Articles 29 to 34 of the 2001 Directive;
- (d) referral to the Committee for Proprietary Medicinal Products in accordance with Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology<sup>(b)</sup>, if the opinion of the Committee in accordance with Article 4(1) of that Directive was given before 1st January 1995.

(3) For the purposes of this regulation and Part 6 of Schedule 2, the United Kingdom provides regulatory assistance acting as reference member State if—

- (a) the licensing authority prepares or updates an assessment report in respect of the medicinal product to which the renewal application relates in order to make it available to the competent authorities of another EEA State; and
- (b) an application to renew the marketing authorisation relating to that product has been made in that other EEA State.

## PART 9

### Capital Fees for Inspections

#### Fees for inspections

29.—(1) Unless regulation 30 or Part 16 of these Regulations applies, a fee is payable in accordance with—

- (a) paragraphs 1 to 9 of Schedule 3 for inspection of any site made in connection with an application for, or during the currency of, a marketing authorisation, a traditional herbal

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(a) OJ No L 22, 9.2.1965, P 369/65. This Directive has been codified and assembled with others into Directive 2001/83/EC.

(b) OJ No L 15, 17.1.1987, p38. This Directive has been repealed by Council Directive 93/41/EEC, OJ No L 214, 24.8.1993, p40.

registration, a clinical trial authorisation, a manufacturing authorisation, a manufacturer's licence, a wholesale dealer's licence, a broker's registration or an active substance registration except for an inspection for which a fee is payable under regulation 26 or 33;

- (b) paragraph 10 of Schedule 3 for any inspection comprising an office-based evaluation and risk assessment of documentation but not involving inspection of a site, in connection with the monitoring of—
- (i) good manufacturing practice;
  - (ii) good clinical practice;
  - (iii) good pharmacovigilance practice; or
  - (iv) good distribution practice.

(2) Unless regulation 31 or 32 applies, the fee in paragraph (1) is payable by the holder of, or as the case may be, applicant for, the authorisation, registration or licence in relation to which the inspection is made.

### **Fees for inspections of pharmacovigilance service providers**

**30.**—(1) Where an inspection is made of a pharmacovigilance service provider and that inspection is not related to anything done under regulation 29(1)(a), a fee is payable in accordance with paragraphs 1 and 2 of Schedule 3.

(2) The fee in paragraph (1) is payable by the pharmacovigilance service provider who is the subject of an inspection.

(3) In this regulation a “pharmacovigilance service provider” means a provider of pharmacovigilance services to a marketing authorisation holder.

### **Payer of inspection fee (contract laboratories and API manufacturing sites)**

**31.** Where an inspection is made of a contract laboratory or a site used by an API manufacturer the fee is payable by the operator of that laboratory, or as the case may be, that API manufacturer.

### **Inspections in connection with multiple applications**

**32.**—(1) Unless paragraph (4) applies, where an inspection is made outside the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

- (a) in more than one marketing authorisation, clinical trial authorisation, traditional herbal registration; or
- (b) by more than one applicant for such an authorisation, registration or licence,

the fee for the inspection referred to in regulation 29(1) is payable in equal proportions by the holders of, or as the case may be, applicants for, the authorisation, registration or licence.

(2) In paragraph (1), the reference to an applicant for a clinical trial authorisation is a reference to a person who sends a valid notice of amendment as mentioned in regulation 19(1).

(3) Where an inspection is made in the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

- (a) in more than one manufacturer's licence or manufacturing authorisation; or
- (b) by more than one applicant for such a licence or authorisation,

the fee for the inspection referred to in regulation 29(1) is payable in equal proportions by each applicant.

(4) This regulation does not apply if the inspection is made of a contract laboratory or a site used by an API manufacturer.

### **Fees for inspections relating to good clinical practice in clinical trials**

**33.** A fee in accordance with paragraph 2 of Schedule 3 is payable by a person in respect of an inspection of one or more sites for the purpose of ascertaining whether that person—

- (a) is—
  - (i) conducting, or has conducted, a clinical trial, or
  - (ii) performing, or has performed, the functions of a sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),  
in accordance with good clinical practice, under regulation 28(1) (good clinical practice and protection of clinical trial subjects) of the Clinical Trials Regulations; or
- (b) has put and kept in place arrangements for the purpose of ensuring that with regard to a clinical trial the requirements of good clinical practice are satisfied or adhered to, under regulation 28(2) of those Regulations.

### **Amount, and time for payment, of inspection fees in respect of an application for a wholesale dealer's licence**

**34.**—(1) All sums payable by way of fees in respect of any inspection of a site in connection with an application for a wholesale dealer's licence under regulation 29(1) must be paid—

- (a) in advance of an application; or
- (b) at the time that application is made.

(2) Except where paragraph (3) applies, the inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 5(a) of Schedule 3.

(3) The inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 7(3) of Schedule 3 where—

- (a) the site to be inspected falls within the description specified in paragraph 7(1)(a) or (b) of Schedule 3; or
- (b) 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 (within the meaning given in paragraph 7(2) of that Schedule).

### **Adjustment and refund of inspection fees in respect of a wholesale dealer's licence**

**35.**—(1) If the inspection in respect of an application for a wholesale dealer's licence takes longer than the standard period, a further fee of the amount specified in paragraph 5(b) of Schedule 3 is payable by the applicant for each subsequent period of 3 hours and 30 minutes or less.

(2) The fee payable under paragraph (1) 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 those fees.

(3) The licensing authority shall refund the whole of the inspection fee paid where, after an inspection fee is paid as a consequence of regulation 34, the application for a wholesale dealer's licence is withdrawn—

- (a) before a date on which the inspection is due to take place is arranged with or notified to the applicant; or
- (b) in the case where a date on which the inspection is due to take place is fixed, 15 or more days before the date on which that inspection is due to take place.

(4) In this regulation “standard period” means—

- (a) in the case where regulation 34(2) applies, a period of more than 7 hours; or
- (b) in the case where regulation 34(3) applies, a period of more than 3 hours and 30 minutes.

**Amount, and time for payment, of inspection fees in respect of an application for a broker's registration or an active substance registration**

36.—(1) All sums payable by way of fees in respect of any assessment or inspection of a site in connection with an application for a broker's registration or an active substance registration under regulation 29(1) must be paid in advance of an application or at the time the application is made.

(2) The inspection fee payable as a consequence of paragraph (1) shall be—

- (a) in relation to broker's registrations, the amount specified in paragraph 8(1) of Schedule 3;
- (b) in relation to active substance registrations, the amount specified in paragraph 9(1) of Schedule 3.

## PART 10

### Periodic Fees for Authorisations, Registrations and Licences

#### Periodic fees

37.—(1) Unless paragraph (4), (5), (6) or (7) or Part 16 of, or Part 4 of Schedule 4 to, these Regulations applies, the periodic fee must be paid for each fee period during which the authorisation, registration or licence is in force, even if it is in force for only part of that fee period.

(2) For the purposes of paragraph (1), marketing authorisations of a type referred to in Part 3 of Schedule 4 shall be treated as if they were one marketing authorisation and only one periodic fee in respect of each relevant fee period is payable in connection with the holding of such authorisations.

(3) The periodic fee is the appropriate fee prescribed in Part 3 of Schedule 4 and, for the purposes of that Part, Parts 1 and 2 of that Schedule have effect.

(4) No periodic fee is payable in respect of the fee period during which a marketing authorisation or a traditional herbal registration is first granted unless the authorisation or registration is granted because of—

- (a) a change of ownership application; or
- (b) an application for a marketing authorisation or traditional herbal registration which—
  - (i) is for a product for which an authorisation or registration has expired;
  - (ii) will contain identical provisions to those contained in the expired authorisation or registration;
  - (iii) is made by the person who held the expired authorisation or registration; and
  - (iv) is made no later than three months after the expiry of the authorisation or registration referred to in paragraph (i),

and, in each case, a periodic fee has not been paid in respect of that fee period in connection with the expired marketing authorisation or a traditional herbal registration.

(5) An authorisation, registration or licence which is in force is treated for the purposes of this regulation as not being in force during any part of a fee period if—

- (a) at least three months before the commencement of that fee period, the holder of that authorisation, registration or licence has given written notice to the licensing authority indicating that he wishes it to cease to have effect before the commencement of that period; and
- (b) no products are sold, supplied or manufactured under that authorisation, registration or licence within that fee period.

(6) No periodic fee is payable in respect of the fee period during which a manufacturing authorisation, a manufacturer's licence or wholesale dealer's licence is first granted unless—

- (a) that authorisation or licence is granted because of a change of ownership application; and

- (b) a periodic fee has not been paid in respect of that fee period in connection with the manufacturing authorisation or manufacturer's licence or wholesale dealer's licence which is mentioned in that application in the statement of intention to cease activities.

(7) No periodic fee is payable in respect of a clinical trial authorisation, broker's registration or active substance registration.

## PART 11

### Capital Fees for Application for Membership of Good Clinical Practice Accreditation Scheme and for Certificate of Membership

#### Meaning of "good clinical practice accreditation scheme"

38. In this Part—

"good clinical practice accreditation scheme" means the non-statutory voluntary scheme of accreditation operated by the licensing authority in relation to Phase 1 trials which participants may join following satisfactory completion of a good clinical practice inspection; and

"Phase 1 trials" are clinical trials 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.

#### Fees for applications for membership and certificates

39.—(1) The fee payable by an applicant for membership of the good clinical practice accreditation scheme is £130.

(2) The fee payable by an applicant for a certificate of membership of the good clinical practice accreditation scheme is £69.

## PART 12

### Capital Fee for a Review Upon Oral Representations or a Person Appointed Hearing

#### Fee for a review upon oral representations or a person appointed hearing

40.—(1) A fee of £10,000 is payable by an applicant or holder of an authorisation, licence, certificate of registration, broker's registration, active substance registration or sponsor or investigator who gives notice, under any of the provisions specified in paragraph (2), of their wish to—

- (a) make further representations to the licensing authority or appear before or be heard by a person appointed, or
- (b) propose that there should be a review upon oral representations.

(2) The specified provisions are—

- (a) in the Human Medicines Regulations—
  - (i) regulation 27(3)(b) (procedure where licensing authority propose to suspend, revoke or vary licence);
  - (ii) paragraphs 11(1), 13(1)(a), 23(2) and 30(2) of Schedule 11 (advice and representations);
  - (iii) paragraph 3(8) of Schedule 32 (transitional provisions and savings in relation to product licences of right);
- (b) in the Clinical Trials Regulations—

- (i) paragraph 3(1)(a) of Schedule 5(a) (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials);
  - (ii) paragraph 4(1)(a) of Schedule 8(b) (procedural provisions relating proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations);
  - (c) provisions in Regulations allowing a representation, appearance, hearing or review in connection with a broker's registration or active substance registration.
- (3) The licensing authority will refund to that person—
- (a) 60% of that fee if the person withdraws the notice two weeks before the commencement of the hearing before the person appointed or the review upon oral representations;
  - (b) 100% of that fee if, in respect of the hearing before the person appointed or the review upon oral representations, the decision notified by the licensing authority is—
    - (i) not to revoke, vary, suspend or terminate, as the case may be, the authorisation, licence or certificate of registration; or
    - (ii) to grant or renew, as the case may be, the authorisation, licence or certificate of registration.

#### **Time for payment under regulation 40**

41. The fee prescribed in regulation 40 is payable at the time the notice is given.

## **PART 13**

### **Fees in relation to the Part 6 of the Human Medicines Regulations (certification of homoeopathic medicinal products)**

#### **Interpretation**

42.—(1) In this Part—

“administrative variation” means a variation of the provisions of a certificate of registration which does not require, in the opinion of the licensing authority, medical, scientific or pharmaceutical assessment;

“application” means an application for the grant of a certificate of registration;

“application to the licensing authority for regulatory assistance” in relation to a single certificate of registration means—

- (a) a single application of that type, or
- (b) a set of applications of that type;

“application for an EC registration in a concerned member State” in relation to a single certificate of registration means—

- (a) a single application of that type, or
- (b) a set of applications of that type in a number of concerned member States;

“decentralised procedure application” means an application relating to a homoeopathic medicinal product in respect of which at the time of the application—

- (a) an EC registration has been granted in an EEA State; and

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(a) Schedule 5 was substituted by regulation 4 of, and paragraph 5 of Schedule 3 to, S.I. 2005/2754.

(b) Paragraph 4 of Schedule 8 was substituted by regulation 4 of, and paragraph 6 of Schedule 3 to, S.I. 2005/2754.

(b) an application for an EC registration has been made in more than one EEA State under Article 28(1) and (3)(a) of the 2001 Directive;

“EC registration” means a registration granted by a competent authority of an EEA State in accordance with the procedure set out in Article 14 of the 2001 Directive;

“formulation” does not include the formulation of 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;

“mutual recognition procedure incoming application” means an application relating to a homoeopathic medicinal product in respect of which—

(a) an EC registration has already been granted in another EEA State; and

(b) recognition of that certificate is sought from the licensing authority by way of the grant of a certificate of registration in the United Kingdom, under the procedure in Articles 28 and 29(1) to (3)(b) of the 2001 Directive;

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

“set of applications” means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in other EEA States, where those applications to the licensing authority all relate to applications for EC certificates of registration in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or

(b) a number of applications to competent authorities of other EEA States for EC certificates of registration relating to a single certificate of registration, where those applications all have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; and

“standard variation” means a variation of the provisions of a certificate of registration which, in the opinion of the licensing authority, requires medical, scientific or pharmaceutical assessment and which requires in respect of any homoeopathic medicinal products to which that certificate relates—

(a) the replacement of an excipient used in the manufacture of the product with a comparable excipient;

(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 minor 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;

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(a) Article 28 has been substituted by Article 1(26) of Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34).

(b) Article 29 has been substituted by article 1(26) of Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34).

- (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 of 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 or to the shelf life 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) which does not entail a change to the quantitative composition or the mean mass of the product; or
  - (p) a change following modification to the manufacturing authorisation.
- (2) In this Part—
- (a) any expression used in this Part which is defined in the Human Medicines Regulations shall have the same meaning which it has in those Regulations;
  - (b) any expressions which are also used in the 2001 Directive shall have the same meaning as they have in the 2001 Directive and related expressions shall be interpreted accordingly;
  - (c) any reference to doing anything in accordance with a certificate of registration shall be interpreted in accordance with regulation 8(1) of the Human Medicines Regulations (general interpretation); and
  - (d) any reference to the holder of a certificate of registration shall be interpreted as a reference to the holder of such a certificate which is for the time being in force.

#### **Fees for applications made at the invitation of the licensing authority**

43. No fee shall be payable under this Part in connection with an application for the grant or variation of a certificate of registration under Part 6 (certification of homoeopathic medicinal products) of the Human Medicines Regulations where the application is made at the specific request of the licensing authority.

#### **Fees for applications for certificates**

44.—(1) The fee payable by a person who makes an application for the grant of a certificate of registration under regulation 103 (application for certificate of registration) of the Human Medicines Regulations shall be the fee specified in the Table in Schedule 5 to these Regulations according to the type of application.

(2) The fee payable by a person who makes an application or set of applications to the licensing authority for regulatory assistance in connection with obtaining recognition in accordance with the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in another EEA State, shall be the fee specified in item 4 of the Table in Schedule 5 to these Regulations.

#### **Fees for variations of certificates**

45.—(1) The fee payable by an applicant in connection with an application for an administrative variation of a certificate of registration shall be—

- (a) where more than one application for an administrative variation is made at the same time by the same applicant and the applications are for identical variations—



- (i) in respect of the first application considered by the licensing authority, a fee of £137, and
- (ii) in respect of each other application so considered, a fee of £69;
- (b) in any other case, a fee of £137.

(2) The fee payable by an applicant in connection with an application for a standard variation of a certificate of registration shall be—

- (a) where more than one application for a standard variation is made at the same time by the same applicant and the applications are for identical variations—
  - (i) in respect of the first application considered by the licensing authority, a fee of £270;
  - (ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £270;
  - (iii) in respect of the second to thirtieth applications so considered, where no further medical, technical or scientific assessment is required, a fee of £137;
  - (iv) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £69;
- (b) in any other case, a fee of £270.

#### **Time for payment of fees**

**46.**—(1) Any fee payable under regulation 44(1) or 45 shall be payable to the licensing authority—

- (a) in advance of the application; or
- (b) at the time the application for grant or variation of the certificate of registration is made.

(2) Any fee payable under regulation 44(2) shall be payable to the licensing authority—

- (a) in advance of any request; or
- (b) at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under Article 28(2) of the 2001 Directive for an assessment report to be prepared or updated.

## PART 14

### Administration

#### **Payment of fees to Ministers**

**47.** Any sum payable under these Regulations must be paid to one of the Ministers.

#### **Time for payment of capital fees in connection with applications or inspections**

**48.**—(1) All capital fees under these Regulations shall be payable in accordance with—

- (a) the specified provisions in paragraph (2) where appropriate, and
- (b) paragraph (3).

(2) The specified provisions are—

- (a) regulation 11 (time for payment of fees under regulations 4 to 10);
- (b) regulation 16 (regulatory assistance);
- (c) regulation 24 (change to labels and leaflets);
- (d) regulation 34 (inspections in respect of wholesale dealer's licence);
- (e) regulation 36 (inspections in respect of brokers and active substance registrations);

- (f) regulation 40 (fee for a review upon oral representations or a person appointed hearing); and
  - (g) regulation 49 (small companies).
- (3) All fees payable under this regulation—
- (a) in respect of inspections made either in connection with an application for, or during the currency of, an authorisation, licence or certificate 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 those fees;
  - (b) in respect of any other application, must have been paid at the time of the application or before.

#### **Time for payment of capital fees – applications made by small companies**

**49.**—(1) Schedule 6 shall have effect with respect to the capital fee payable in connection with an application made by or on behalf of a small company.

(2) For the purpose of these Regulations, a company is a small company if, for the financial year before that in which the application is made, the total value of products it has sold or supplied for the financial year is not more than the amount for the time being specified in item 1 in section 382(3) (qualification of company as small) of the Companies Act 2006<sup>(a)</sup> and the conditions in paragraph (3) are met.

- (3) The conditions for the purposes of paragraph (2) are—
- (a) the company’s balance sheet total as defined in section 382(5) of the Companies Act 2006 is not more than the amount for the time being specified in item 2 in section 382(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 382(3) of that Act.

#### **Payment of fees in respect of a traditional herbal registration**

**50.**—(1) The fee payable under regulation 12 shall be refunded or, if it has not been paid, shall be waived where an application is made for the grant of a traditional herbal registration—

- (a) in accordance with regulation 127 (application for the grant of a traditional herbal registration) of the Human Medicines Regulations;
- (b) on the grounds specified in paragraph (2); and
- (c) in respect of a medicinal product which falls within the description in paragraph (3).

(2) For the purposes of paragraph (1), the specified grounds are—

- (a) that the marketing authorisation in respect of the medicinal product in question; or
- (b) in the case of a corresponding product the marketing authorisation relating to product Y (as defined in paragraph (4)),

is to be revoked.

(3) A medicinal product falls within this paragraph if—

- (a) a marketing authorisation held by the applicant was granted under Part 5 of the Human Medicines Regulations in respect of that medicinal product; or
- (b) that medicinal product is a corresponding product.

(4) For the purposes of paragraph (3), a corresponding product is a product which is characterised by having—

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(a) 2006 c.46. A relevant amendment was made by S.I. 2008/393.

- (a) the same active ingredients, irrespective of the excipients used or reduction in the number or quantity of active ingredients;
- (b) the same or similar intended purpose, equivalent strength and posology; and
- (c) the same or similar route of administration,

as a medicinal product (“product Y”) in respect of which a marketing authorisation held by the applicant was granted under Part 5 of the Human Medicines Regulations.

(5) Where the licensing authority determines that the marketing authorisations in respect of the medicinal product in question or the marketing authorisation in respect of product Y should not be revoked, the fee payable under regulation 12 which has been refunded or waived shall become payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

#### **Time for payment of periodic fees**

**51.** All periodic fees must be paid by the first day of the fee period to which they relate.

#### **Penalty fees for late payment of periodic fees**

**52.**—(1) Subject to paragraph (2), if a person has failed to pay a periodic fee by the time it has become payable under regulation 51, a penalty fee is payable by that person.

(2) A penalty fee is payable only if, after a period of 60 days commencing on the date of the written notice (“the notice”) issued by the licensing authority requiring payment of that fee, the fee remains unpaid.

(3) Unless regulation 53 applies, where a periodic fee remains unpaid after 60 days commencing on the date of the notice, the penalty fee is—

- (a) £100 where the total unpaid fee exceeds £200; or
- (b) £50 where the total unpaid fee does not exceed £200.

(4) In paragraph (3), the “total periodic fee” means the total of all the periodic fees payable by a person in connection with all the authorisations, registrations or licences held by that person.

#### **Daily penalty fees for late payment of periodic fees**

**53.** If the periodic fee and penalty fee under regulation 52 (“the outstanding amount”) have not been paid within a period of 90 days commencing on the date of the written notice issued by the licensing authority, the amount of penalty fee payable shall be the amount specified in regulation 52(3) plus £5 for each day of the period which—

- (a) begins with the day 90 days from the date of the written notice; and
- (b) ends with the day before that on which payment of the outstanding amount is actually made.

#### **Refund or waiver of fees under regulation 52 or 53**

**54.** The licensing authority may refund or waive payment of the penalty fee, or reduce the amount payable, where it is satisfied that the holder of the authorisation, registration or licence was not responsible for the failure to pay the periodic fee within the period specified in regulation 52(2) or 53.

#### **Adjustment, waiver, reduction or refund of fees**

**55.**—(1) If after a capital or periodic fee is paid it becomes apparent that—

- (a) a lesser fee should have been paid, the excess shall be refunded to the applicant or, as the case may be, the holder of the authorisation, registration or licence concerned; or

- (b) a higher fee should have been paid, the balance due shall be payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority to the applicant or, as the case may be, the holder of the authorisation, registration or licence concerned requiring payment of that balance.

(2) The licensing authority shall, to the extent provided in Schedule 7 in relation to capital fees or in Schedule 8 in relation to periodic fees—

- (a) adjust, waive payment of or reduce any fee or part of a fee otherwise payable under these Regulations; or
- (b) refund the whole or part of any fee already paid.

### **Suspension of licences and authorisations**

**56.**—(1) Where any sum due by way of, or on account of, any fee or any part of a fee payable under these Regulations remains unpaid by the holder of a—

- (a) product licence or a product licence of right;
- (b) manufacturer’s licence;
- (c) manufacturer’s authorisation; or
- (d) wholesale dealer’s licence,

the licensing authority may serve a written notice on the holder requiring payment of the sum unpaid.

(2) If after a period of one month commencing on the date of service of the notice referred to in paragraph (1), or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence or, as the case may be, the authorisation until such sum has been paid.

### **Civil proceedings to recover unpaid fees**

**57.** All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.

## **PART 15**

### **Consequential Amendments**

#### **Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004**

**58.**—(1) The Medicines for Human Use (Clinical Trials) Regulations 2004<sup>(a)</sup> are amended as follows.

(2) In regulation—

- (a) 17(2)(b)(ii) (request for authorisation to conduct a clinical trial),
- (b) 24(10) (amendments by the sponsor),
- (c) 38(3)(b) (application for manufacturing authorisation),
- (d) 44(8) (variation of manufacturing authorisation),

for “Medicines (Products for Human Use) (Fees) Regulations 2012” substitute “Medicines (Products for Human Use) (Fees) Regulations 2013”.

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(a) S.I. 2004/1031; relevant amendments are made by S.I. 2006/1928, 2012/504.

## PART 16

### Revocations and Savings

#### **The Medicines (Products for Human Use) (Fees) Regulations 2012**

**59.**—(1) Subject to paragraphs (2) to (4), the Medicines (Products for Human Use) (Fees) Regulations 2012(a) (“the 2012 Regulations”) are revoked.

(2) The savings introduced by regulation 57(2) to (4) and 58(4) and (5) of the 2012 Regulations shall continue to apply as if those paragraphs of those regulations had not been revoked.

(3) The 2012 Regulations shall continue to apply as if they had not been revoked in relation to—

- (a) capital fees payable under the 2012 Regulations in respect of any application or inspection made before the date on which these Regulations come into force; and
- (b) any periodic fee payable under the 2012 Regulations in relation to a fee period ending before the date on which these Regulations come into force.

(4) The revocation of the 2012 Regulations shall not affect any proceedings under those Regulations for the recovery of any fees due as debts to the Crown and for the purposes of those proceedings, the 2012 Regulations shall continue to apply as if they had not been revoked.

#### **The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012**

**60.**—(1) Subject to paragraphs (2) and (3), the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012(b) (“the 2012 Amendment Regulations”) are revoked.

(2) The 2012 Amendment Regulations shall continue to apply as if they had not been revoked in relation to—

- (a) fees payable under the 2012 Amendment Regulations in respect of any application or inspection made before the date on which these Regulations come into force; and
- (b) any periodic fee payable, or not payable as the case may be, under the 2012 Amendment Regulations in relation to a fee period ending before the date on which these Regulations come into force.

(3) The revocation of the 2012 Amendment Regulations shall not affect any proceedings commenced under those Regulations for the recovery of any fees due as debts to the Crown and for the purposes of those proceedings, the 2012 Amendment Regulations shall continue to apply as if they had not been revoked.

#### **Other Revocations**

**61.** The instruments mentioned in Schedule 9 are revoked to the extent specified.

Signed by authority of the Secretary of State for Health.

1st March 2013

*Earl Howe*  
Parliamentary Under-Secretary of State,  
Department of Health

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(a) S.I. 2012/504.  
(b) S.I. 2012/2546.

7th March 2013

*Edwin Poots*  
Minister for Health, Social Services and Public Safety

7th March 2013

*Robert Goodwill*  
*Desmond Swayne*  
Two of the Lords Commissioners of Her Majesty's Treasury

## SCHEDULES

### SCHEDULE 1

Regulation 2

#### General interpretation provisions

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

“the 2001 Directive” means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(a);

“the Act” means the Medicines Act 1968(b) 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(c);

“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;

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(a) 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).

(b) 1968 c.67.

(c) Article 52a was inserted into Directive 2001/83/EC by Article 1(10) of Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

“authorised medicinal product” means a medicinal product in respect of which a marketing authorisation has been granted;

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

“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;

“broker’s registration” means the registration required by a broker of medicinal products under article 85b of the 2001 Directive<sup>(a)</sup>;

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

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

“change of ownership application” means an application—

(a) for—

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

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

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

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

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

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

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

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

“clinical development” means the conduct of studies of a medicinal product in human subjects in order to—

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

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

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

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

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

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(a) Article 85b was inserted into Directive 2001/83/EC by Article 1(19) of Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

- (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
- (b) to identify any adverse reactions to one or more such products; or
- (c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products;

“clinical trial authorisation” means authorisation of the conduct of a clinical trial—

- (a) by the licensing authority in accordance with regulation 18 (authorisation procedure for clinical trials involving general medicinal products), 19 (authorisation procedure for clinical trials involving general medicinal products for gene therapy etc.) or 20 (authorisation procedure for clinical trials involving general medicinal products with special characteristics) of the Clinical Trials Regulations; or
- (b) which is treated as having been given by the licensing authority by virtue of Schedule 12 to those Regulations;

“Clinical Trials Regulations” means the Medicines for Human Use (Clinical Trials) Regulations 2004(a);

“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(b);

“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(c); 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(d);

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(a) 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.  
 (b) OJ No L 334, 12.12.2008, p7. Commission Regulation (EC) No 1234/2008 has been amended by Commission Regulation (EC) No 712/2012 (OJ No L 209, 4.8.2012, p4).  
 (c) S.I. 1971/972; relevant amending instruments are S.I. 1992/2846, 1994/2852, 2004/1031 and 2005/2789.  
 (d) OJ No L 262, 14.10.2003, p22.



“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 **(a)**;

“EEA State” means a member State, Norway, Iceland or Liechtenstein;

“European Union marketing authorisation” means a marketing authorisation granted by the European Commission under Council Regulation (EEC) No 2309/93**(b)** or Regulation (EC) No 726/2004;

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

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

“good distribution practice” means the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive;

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

“good pharmacovigilance practice” means the Guidelines on Pharmacovigilance for Medicinal Products for Human Use published by the European Commission under Article 108a of the 2001 Directive;

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

“holder”, in relation to a clinical trial authorisation, means—

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

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

“homoeopathic medicinal product” means any medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or by any pharmacopoeia used officially in a member State;

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

“Human Medicines Regulations” means the Human Medicines Regulations 2012**(c)**.

“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;

“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—

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

(b) 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).

(c) S.I. 2012/1916.

- (a) a United Kingdom marketing authorisation granted by the licensing authority under Part 5 (marketing authorisations) of the Human Medicines 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” includes any medicinal product for human use to which the 2001 Directive applies and any substance or article specified in any order for the time being in force made under section 104(a) (application of the 2012 Regulations to certain articles and substances) or 105(1)(a)(b) (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;

“orphan medicinal product” has the meaning given in Article 2(b) of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products(c);

“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 52;

“periodic fee” means the fee payable under regulation 37 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;

“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—

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

(b) Relevant amending instrument is S.I. 2012/1916.

(c) OJ No L 18, 22.1.2000, p1, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No L 188, 18.7.2009, p14).

- (i) compliance with the obligations that relate to him by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No 726/2004;
- (ii) the pharmacovigilance and risk-management systems that he has introduced in accordance with Article 8(3)(ia) of the 2001 Directive; or
- (iii) a post-authorisation safety study protocol;

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

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

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

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

“quality development” means the chemical, pharmaceutical and biological testing necessary to demonstrate the quality of a relevant medicinal product, in accordance with Module 3 of Part I 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(a);

“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—

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(a) 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).

- (a) the formulation of a product which is identical to the formulation of another product—
  - (i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorisation; or
  - (ii) to which the applicant has, by the holder of the certificate of registration or the homoeopathic marketing authorisation which relates to it, been authorised in writing to make reference for the purposes of this application; or
- (b) where more than one application is made by the same applicant on the same occasion in respect of products of identical formulations, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the formulation of the product to which the first of those applications which is considered by the licensing authority relates;

“repeat stock” means—

- (a) a homoeopathic stock which is identical to another homoeopathic stock which is used in the preparation of a product—
  - (i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorisation; or
  - (ii) in respect of which another person holds a certificate of registration or a homoeopathic marketing authorisation to which, for the purposes of his application, the applicant has been authorised in writing to make reference by the person (or if more than one, each of the persons) who supplied information to the licensing authority in connection with the application for the certificate of registration or a homoeopathic marketing authorisation which relates to that product; or
- (b) where more than one application is made by the applicant on the same occasion in respect of products prepared from identical homoeopathic stocks, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the homoeopathic stock used in the preparation of the product to which the first of those applications which is considered by the licensing authority relates;

“safety development” means the toxicological and pharmacological testing necessary to demonstrate the safety of a relevant medicinal product, in accordance with Module 4 of Part I of Annex I 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;

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

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

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

“variation”—

(a) in relation to—

(i) a United Kingdom marketing authorisation; or

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

means “variation to the terms of a marketing authorisation” as defined in Article 2(1) of Commission Regulation (EC) No 1234/2008;

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

“wholesale dealer’s licence” means a wholesale dealer’s licence within the meaning of regulation 18(1) (wholesale dealing in medicinal products) of the Human Medicines Regulations.

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(a).

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.

## SCHEDULE 2

Regulations 12(1)(a); 16;  
18(2)(a); 19(2)(a); 22(7); 23; 24(1);  
28(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;

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

“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 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 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.

### **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—

- (a) for an extension of a marketing authorisation within the meaning of Article 2(4) of Commission Regulation (EC) No 1234/2008; and
- (b) which includes the result of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive.

### **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;
- (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 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(a).

#### **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.

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(a) 2006 c.46.

(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.

### **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 Article 2(5) of Commission Regulation (EC) No 1234/2008.

(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.

(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 Article 2(2) of Commission Regulation (EC) No 1234/2008.

### **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 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—
  - (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 Article 2(3) of Commission Regulation (EC) No 1234/2008 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 Commission Regulation (EC) No 1234/2008.

## 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.

#### Fees for marketing authorisation applications

<i>Column 1</i> <i>Kind of application</i>	<i>Column 2</i> <i>Fee payable</i>
<b>1. Major application</b>	
(a) in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex I to the 2001 Directive applies	£33,035
(b) which is a mutual recognition procedure incoming application	£69,357
(c) which is a European reference product application	£69,357

(d)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£99,507
(e)	which is a decentralised procedure application where the United Kingdom is a reference member State	£143,134
(f)	in any other case	£103,059
<b>2. Complex application</b>		
(a)	which is a mutual recognition procedure incoming application	£19,256
(b)	which is a European reference product application	£19,256
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£27,511
(d)	which is a decentralised procedure application where the United Kingdom is a reference member State	£41,922
(e)	in any other case	£28,492
<b>3. Standard application</b>		
(a)	which is a mutual recognition procedure incoming application	£7,056
(b)	which is a European reference product application	£7,056
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£10,087
(d)	which is a decentralised procedure application where the United Kingdom is a reference member State	£18,422
(e)	in any other case	£10,447
<b>4. Simple application</b>		
(a)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£2,849
(b)	which is a decentralised procedure application where the United Kingdom is a reference member State	£9,535
(c)	in any other case	£2,849
<b>5. Parallel import licence applications</b>		
(a)	in respect of a simple parallel import licence	£1,991
(b)	in respect of a standard parallel import licence	£7,403
(c)	in respect of a complex parallel import licence	£20,200
<b>6. Change of ownership application</b>		£491

(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.

#### **Fees where application includes reclassification**

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

- (a) the reclassification falls within the category of application described in paragraph 15(a), an amount of £13,324 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 £9,069 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—

- (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—

- (a) in respect of the first or only marketing authorisation applied for by that secondary applicant, 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, 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, the amount payable in respect of a complex application under paragraph 24 and in respect of any other such application by that secondary applicant, 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—

- (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 that 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.

### **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—

- (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;
- (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, 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, 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;

- (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, 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, 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, £816.

(5) For the purposes of sub-paragraph (4), a “reclassification element” has the meaning given in paragraph 25(2).

### **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.

(4) In connection with any other application for a marketing authorisation for a national homoeopathic 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 homoeopathic 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 homoeopathic stocks</i>	<i>Column 3</i> <i>Fee for other applications</i>
<b>1.</b> An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation	£574	£813
<b>2.</b> An application in respect of a product which is either—	£898	£1,127

(a) prepared solely from repeat stocks; or		
(b) is of a repeat formulation		
<b>3. Any other application</b>	£1,209	£1,458

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(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 homoeopathic 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 £2,393 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 homoeopathic product which contains one or more new excipients, an amount of £7,983 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 homoeopathic product which contains one or more TSE risk ingredients from a new source or TSE risk excipients from a new source, an amount of £705 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.

#### **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) £3,400 where the application is for a product that is not marketed; or
- (b) £250 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>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
<b>1. Complex registration application</b>	

(a) in respect of a medicinal product containing a single active ingredient	£5,384
(b) in any other case	£8,077
<b>2. Standard registration application</b>	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£2,692
(b) in any other case	£4,038
<b>3. Reduced registration application category II</b>	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£897
(b) in any other case	£1,347
<b>4. Reduced registration application category I</b>	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£599
(b) in any other case	£897
<b>5. Change of ownership application</b>	£491

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(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.

(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) £1,197, 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) £2,393, 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 £7,984 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 £709 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 £2,393 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

## PART 3

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

#### **Outgoing mutual recognition applications**

**36.**—(1) The fee payable for regulatory assistance under regulation 16 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 £46,192;

- (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 £2,849;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £30,342; 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 £2,849.

(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 £11,948;
- (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 £2,849;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £7,925; 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 £2,849.

(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 £4,758;
- (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 £2,849;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £3,963; 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 £2,849.

(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 £2,849;
- (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 £2,849;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £2,849; 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 £2,849.

(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 15.

## PART 4

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

#### **Marketing authorisations**

37.—(1) Unless sub-paragraph (2) or any of paragraphs 38 to 41 and 50 to 52 applies, the fee payable under regulation 18(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—

- (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) Unless paragraph (5) applies, 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 Chapter II of Commission Regulation (EC) No 1234/2008(a), Table 1;
- (b) in respect of a UK national variation application, Table 2;
- (c) in respect of a reclassification variation application, Table 3.

(5) From 4th August 2013, 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 Title III of Directive 2001/82/EC or Chapter 4 of Title III of Directive 2001/83/EC) of Commission Regulation (EC) No 1234/2008 (as amended), 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(b) (as amended), Table 2;
- (c) in respect of a reclassification variation application, Table 3.

(6) In Table 1, “reference authority” has the meaning given in Article 20(2)(b) of Commission Regulation (EC) No 1234/2008.

(7) Unless paragraph (8) applies, in Table 2, “UK national variation application” means a variation to a notification of, or an application for, a variation to the terms of a marketing authorisation which is not within the scope of Commission Regulation (EC) No 1234/2008 and which—

- (a) is a change set out in the document entitled “UK National MA Variations Guidance” published by the licensing authority and available on its website on 30th November 2009(c); and
- (b) complies with the procedures and conditions to be fulfilled as set out in that document,

and the expressions “National Type IB Application”, “National Type II Application”, “National Type II Complex Variation Application”, “National Type II Extended Complex Variation Application”, “National Type IB Minor Variation Group Application”, “National Type II Major Variation Group Application” and “National Type II Major Variation Complex Group Application” shall be interpreted accordingly.

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(a) See Article 1 of the Regulation as amended by Commission Regulation (EU) No 712/2012 (OJ No L 209, 4.8.2012, p4).

(b) Chapter IIa of the Regulation was inserted by Commission Regulation (EU) No 712/2012 (OJ No L 209, 4.8.2012, p4).

(c) A copy of the guidance can be downloaded from the licensing authority’s website at [www.mhra.gov.uk](http://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](mailto:info@mhra.gsi.gov.uk).

(8) From 4th August 2013, 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(a) (as amended).

(9) In this paragraph—

“Commission Regulation (EC) No 1234/2008” means Commission Regulation (EC) No 1234/2008 as in force on 1st April 2013;

“Commission Regulation (EC) No 1234/2008 (as amended)” means Commission Regulation (EC) No 1234/2008 as amended by Commission Regulation (EU) No 712/2012(b) from 4th August 2013.

**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</i> <i>Kind of variation</i>	<i>Column 2</i> <i>Fee payable</i>
<b>1. Application for a single kind variation</b>	
(a) Type IB Application where—	
(i) the UK is a concerned member State	£308
(ii) the UK is the reference member State or the licensing authority is the reference authority for work sharing	£611
(b) Type II Application where—	
(i) the UK is a concerned member State	£816
(ii) the UK is the reference member State or the licensing authority is the reference authority for work sharing	£989
(c) Type II Complex Variation Application where—	
(i) the UK is a concerned member State	£9,232
(ii) the UK is the reference member State or the licensing authority is the reference authority for work sharing	£16,007
(d) Extended Type II Complex Variation Application where—	
(i) the UK is a concerned member State	£28,492
(ii) the UK is the reference member State or the licensing authority is the reference authority for work sharing	£39,829
<b>2. Applications for a Group</b>	
(a) Minor Variation (Type IB) Group Application where—	

(a) Paragraph 9 of the Regulation was inserted by Commission Regulation (EU) No 712/2012 (OJ No L 209, 4.8.2012, p4).

(b) OJ No L 209, 4.8.2012, p4.



(i)	the UK is a concerned member State	£691
(ii)	the UK is the reference member State or the licensing authority is the reference authority for work sharing	£1,361
(b)	Major Variation (Type II) Group Application where—	
(i)	the UK is a concerned member State	£1,836
(ii)	the UK is the reference member State or the licensing authority is the reference authority for work sharing	£2,218
(c)	Major Variation (Type II) Complex Group Application where—	
(i)	the UK is a concerned member State	£10,011
(ii)	the UK is the reference member State or the licensing authority is the reference authority for work sharing	£16,926
(d)	Major Variation (Type II) Extended Complex Group Application where—	
(i)	the UK is a concerned member State	£29,196
(ii)	the UK is the reference member State or the licensing authority is the reference authority for work sharing	£40,804

**Table 2**  
**Fees for UK national variation applications**

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of national variation</i>	<i>Fee payable</i>
1. National Type IB Application	£308
2. National Type II Application	£816
3. National Type II Complex Variation Application	£9,232
4. National Type II Extended Complex Variation Application	£28,492
5. National Type IB Minor Variation Group Application	£691
6. National Type II Major Variation Group Application	£1,836
7. National Type II Major Variation Complex Group Application	£10,011
8. National Type II Major Variation Extended Complex Group Application	£29,196

**Table 3**  
**Fees for reclassification variation applications**

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of reclassification variation</i>	<i>Fee payable</i>
Application falling within the category described in—	

(a) paragraph 15(a)	£13,324
(b) paragraph 15(b)	£9,069

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### **Variation of marketing authorisations**

**38.**—(1) Subject to sub-paragraph (3), 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 18(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 in respect of an orphan medicinal product.

(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 an orphan medicinal product.

### **Reclassification of marketing authorisations**

**39.**—(1) Where an application is a reclassification variation application to which this paragraph applies, the fee payable under regulation 18(1) in connection with the application for variation of a marketing authorisation is £816.

(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.

### **Variation of marketing authorisation: national homoeopathic products**

**40.** The fee payable under regulation 18(1) in connection with an application for a variation of a marketing authorisation in respect of a national homoeopathic product is—

- (a) £270 where the application is a standard variation application for a homoeopathic medicinal product;
- (b) £416 where the application is a new indication variation application; and

- (c) £137 for any other application.

### **Variation of parallel import licence**

**41.**—(1) The fee payable under regulation 18(1) in connection with an application for variation of a parallel import licence is—

- (a) £13,324 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 37 of this Schedule does not apply;
- (b) £9,069 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 37 of this Schedule does not apply; and
- (c) £397 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 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 39 of this Schedule applies.

#### **Manufacturer's authorisations and licences**

42. Unless the fee in paragraph 43 is payable or paragraph 50 applies, the fee payable under regulation 18(1)(a)(i) or (b) 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**

43. The fee payable under regulation 18(1)(a)(i) or (1)(b) 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**

44. Unless the fee in paragraph 45 is payable or paragraph 50 applies, the fee payable under regulation 18(1)(a)(i) in connection with an application for a variation of a wholesale dealer's licence is £486.

#### **Variation of wholesale dealer's licence**

45. The fee payable under regulation 18(1)(a) (but only in relation to applications under regulation 29 of the Human Medicines Regulations) 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**

46. The fee payable under regulation 18(1)(a)(ii) 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**

47. The fee payable under regulation 18(1)(a)(iii) 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**

48.—(1) A fee of £250 is payable under regulation 19(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**

49. Unless paragraph 50 applies, the fee payable under regulation 18(1)(a)(v) in connection with an application for variation of a traditional herbal registration is—

- (a) £267 if the application is a standard variation application;
- (b) £706 if the application is a complex variation application;
- (c) £7,984 if the application is a new excipient variation application; and

- (d) £169 if the application is an administrative variation application.

### **Identical variations**

**50.**—(1) Unless paragraph 51 or 52 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 18(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;
- (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**

**51.**—(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 18(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**

**52.** 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 18(1)—

- (a) if one or more of the applications is an application to which paragraph 39 does not apply—
  - (i) in connection with the first application to which paragraph 39 does not apply, is the appropriate amount specified in this Part of the Schedule;
  - (ii) in connection with each other application to which paragraph 39 does not apply, the fee payable is £816; and
  - (iii) in connection with each other application to which paragraph 39 does apply, the fee payable is £408; 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 £408.

## PART 5

### Capital Fees for Assessment of Labels and Leaflets

#### A set of changes

**53.**—(1) Unless paragraph 54 applies, the fee payable under regulation 24(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product is—

- (a) £575, in respect of a product which is the subject of a United Kingdom marketing authorisation (other than a parallel import licence); and
- (b) £364, 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 24(1) is £207.

(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<sup>(a)</sup>.

#### More than one set of changes proposed

**54.**—(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 24(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 24(1) is—

- (a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 53; and
- (b) in connection with each of the other sets of proposed changes, 50% of that amount.

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<sup>(a)</sup> Copies of the documents can be downloaded from the licensing authority’s website at [www.mhra.gov.uk](http://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](mailto:info@mhra.gsi.gov.uk).

## PART 6

### Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorisations

#### **Regulatory assistance**

55. Unless paragraph 56 applies, the fee payable under regulation 28(1) in connection with regulatory assistance provided by the United Kingdom acting as reference member State where an application is made to the licensing authority for the renewal of a United Kingdom marketing authorisation in relation to a medicinal product which has been subject to the procedures specified in regulation 28(2), is—

- (a) £10,758 if the application for renewal relates to a medicinal product which, at the time the United Kingdom marketing authorisation was granted, contained a new active ingredient and that renewal is the first renewal in relation to which the United Kingdom is to provide regulatory assistance acting as reference member State; or
- (b) £830 in any other case.

#### **Regulatory assistance – same manufacturer**

56.—(1) This paragraph applies if more than one application falling within regulation 28(1) 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 United Kingdom marketing authorisations for those products have the same date for renewal.

(2) The fee payable under regulation 28(1) for applications to which sub-paragraph (1) applies is—

- (a) if the applications fall within paragraph 55(a)—
  - (i) £10,758 for the first application considered by the licensing authority; and
  - (ii) £830 for each other application;
- (b) if the applications fall within paragraph 55(b)—
  - (i) £830 for the first application considered by the licensing authority; and
  - (ii) £415 for each other application.

## PART 7

### Relevant Substances

#### **Substances listed for the purposes of paragraph 24(2)(b) and (4)(b) and 37(2)(b)**

57.—(1) The substances listed for the purposes of paragraphs 24(2)(b) and (4)(b) and 37(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  
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  
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 29(1); 33;  
34(2) and (3); and 35(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
- (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 £941.

### **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—

- (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.

## 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 which is in respect of an orphan medicinal product;

“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
- (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.

## 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 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 37(3) 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</i>	<i>Column 2</i>
<i>Type of Medicinal Product</i>	<i>Fee payable</i>
1. New Active Substance	£24,821
2. Parallel Import	£323
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	£10,221
(b) Prescription Only Medicine	
(i) Standard Fee	£2,556
(ii) Reduced Rate Fee	£1,275
(iii) Lower Fee	£323
(c) Pharmacy	£323
(d) General Sale List	£323
(e) Herbal remedy	£80
(f) Traditional herbal registrations	£80
(g) National homoeopathic product	£80
(h) Homoeopathic or anthroposophic product which is the subject of a licence of right	£80

#### 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(a), the fee payable under regulation 37(3) in connection with the holding of a marketing authorisation or licence is £323.

#### 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 37(3) is—

- (a) £10,221 where the medicinal product to which the authorisation relates has a different route of administration from that of the new active substance; or
- (b) £6,899 in any other case.

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(a) 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. Provisions of Part 2 of the Act that were repealed under Schedule 35 (repeals and revocations) to the Human Medicines Regulations 2012 are applied to the extent provided for under paragraph 1 of Schedule 32 (transitional provisions and savings) to those Regulations.

### **Number of fee periods**

**8.**—(1) The fee specified in—

- (a) paragraph 5 for a new active substance; and
- (b) 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—

- (a) 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;
- (b) in all other cases, for each fee period mentioned in sub-paragraph (2), is the fee specified at entry 3(a) of that table.

(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 37(3) 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 37(3) in connection with the holding of a manufacturer's licence is £493.



(2) The fee payable under regulation 37(3) in connection with the holding of a manufacturing authorisation is £493.

(3) The fee payable under regulation 37(3) 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 37(3) in connection with the holding of a wholesale dealer's licence is £303.

(2) The fee payable under regulation 37(3) is £181 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;
- (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 37(3) 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</i>	<i>Column 2</i>
<i>Number of special import notices</i>	<i>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 37(3) in connection with the holding of a traditional herbal registration is £80.

## PART 4

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

#### Parallel import licences

17. 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 44(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.	£177	£437
2 An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation.	£531	£782
3 A mutual recognition procedure incoming application.	£557	£709
4 A mutual recognition outgoing application (regulatory assistance).	£319	£416
5 A decentralised procedure application where the UK is a concerned member State.	£478	£625
6 A decentralised procedure application where the UK is the reference member State.	£956	£1,251
7 Any other application.	£878	£1,149

## 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 entry 1(f) 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.

### 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 16 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;
- (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 18(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 48(1)(b) and as to 50% within 12 months after that date.

## **SCHEDULE 7**

Regulation 55(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 39 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 37 of Schedule 2 and entry 1(c)(i) of Table 1 referred to in that paragraph or of the fee payable under paragraph 52(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 41(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—

- (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 18(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), 18(1) or 19(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), 18(1) or 19(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 44 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 registration is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 12(1)(a) or 18(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.

#### **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 18(1) shall be refunded or waived.

(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 50 and 51 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 of the authorised indication are specified in the summary of characteristics drawn up in accordance with Article 11 of the 2001 Directive<sup>(a)</sup>;
  - (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<sup>(b)</sup> and a patent qualifies for the granting of such a certificate if the provisions of that Regulation so provide.

#### **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 55(2)

### Adjustment, reduction or refund of periodic fees

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

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(a) 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).  
(b) OJ No L 152, 16.6.2009, p1.



### **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.

### **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.

## SCHEDULE 9

Regulation 61

### Further revocations

<i>Instrument</i>	<i>Extent of repeal or revocation</i>
Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998 (S.I. 1998/574)	The whole of the Regulations
Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999 (S.I. 1999/566)	The whole of the Regulations
Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999 (S.I. 2000/592)	The whole of the Regulations
Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2003 (S.I. 2003/625)	The whole of the Regulations
Medicines for Human Use (Fees Amendments) Regulations 2006 (S.I. 2006/2125)	The whole of the Regulations
Medicines (Products for Human Use) (Amendments Relating to Fees for Variations) Regulations 2009 (S.I. 2009/3222)	The whole of the Regulations

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations revoke and re-enact in consolidated form, with some amendments, the Medicines (Products for Human Use) (Fees) Regulations 2012 (“the 2012 Regulations”) and the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012. They make amendments to the Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”).

These Regulations make provision for the fees payable under the Medicines Act 1971 and other fees payable in respect of EU obligations relating to marketing authorisations, licences and certificates and registrations in respect of medicinal products for human use.

The fees prescribed in the Regulations are revised on an annual basis and based on an assessment of the costs associated with a range of licensing requirements and functions. The fee amounts specified in these Regulations are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency (“MHRA”) on 19th October 2012. A summary of the consultation responses is published on the MHRA’s website ([www.mhra.gov.uk](http://www.mhra.gov.uk)).

In general these Regulations provide for an increase in all medicines fees to reflect the higher costs for the MHRA in carrying out related regulatory activities. They also include consequential amendments arising out of the making of the Human Medicines Regulations 2012, some simplification measures, provisions to implement the fees necessary to carry out regulatory activities in relation to brokers of medicinal products, the import, manufacture or wholesale active substances and pharmacovigilance service providers.

Parts 2 to 9 and 11 and 12 and Schedules 2 and 3 provide for capital fees to be payable in connection with pre-application meetings; applications for, or variations to, authorisations, manufacturer’s licences, wholesale dealer’s licences, clinical trial authorisations, broker’s registrations, active substance registrations, traditional herbal registrations and certificates permitting the export of medicinal products; assistance in obtaining or renewing marketing authorisations in other EEA States; the assessment of labels and leaflets; renewals of certain manufacturer’s licences; and inspections. Most of the fees were previously provided for by the 2012 Regulations (as amended).

However, these Regulations also—

- (a) provide new fees in relation to brokers of medicinal products and persons who import, manufacture or distribute an active substance;
- (b) provide new fees in relation to persons who provide a pharmacovigilance service;
- (c) simplify the fees payable for clinical trial authorisations;
- (d) reduce the fees payable by new manufacturers of simple substances that also serve as active pharmaceutical ingredients;
- (e) make minor technical changes to variations of marketing authorisations implementing Commission Regulation (EC) No 1234/2008 as amended by Commission Regulation (EC) No 712/2012.

Part 10 and Schedule 4 provide for periodic fees in connection with authorisations, registrations and licences.

Part 13 and Schedule 5 provides for fees in relation to homoeopathic medicinal products.

Part 14 and Schedules 6, 7 and 8 deal with the time for payment and waiver or refund of both capital and periodic fees in specified circumstances. Schedules 6 and 7 now also apply to applications for a broker’s registration or an active substance registration.

Part 15 makes consequential amendments to the Clinical Trials Regulations to update cross-references to these Regulations.

Part 16 of these Regulations revokes and makes savings provisions in relation to earlier Regulations relating to fees for medicinal products for human use and medical devices for human use.

An impact assessment has not been prepared for this instrument as no impact on the private or voluntary sector is foreseen.

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