STATUTORY INSTRUMENTS

2004 No. 666

The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004 and shall come into force on 1st April 2004.

(2) In these Regulations—

"the Devices Regulations" means the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**1**);

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**2**); and

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**3**).

Amendment of the Homoeopathic Products Regulations

2.—(1) The Homoeopathic Products Regulations are amended as follows.

(2) In regulation 14(**4**) (fees for variations of certificates)—

(a) in paragraph (2)(a), for "£216" substitute "£218";

(b) in paragraph (2)(b)(i), for "£216" substitute "£218";

(c) in paragraph (2)(b)(ii), for "£216" substitute "£218";

(d) in paragraph (2)(b)(iii), for "£108" substitute "£110"; and

(e) in paragraph (2)(b)(iv), for "£54" substitute "£55".

(3) In regulation 15(1)(**5**) (fees payable by holders of certificates), for "£14" substitute "£15".

(4) In the Table in Schedule 2(**6**) (fees for applications for the grant of certificates of registration)—

(a) in column (2) (fees for applications in respect of products prepared from not more than 5 homoeopathic stocks)—

(i) for "£132" substitute "£134",

(ii) for "£397" substitute "£402", and

(iii) for "£656" substitute "£664"; and

(**1**) S.I.1995/449; as amended by S.I. 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625.
(**2**) S.I. 1995/1116; as amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795, 2002/236 and 542, and 2003/625 and 2321.
(**3**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625 and 2321.
(**4**) As amended by regulation 2(2) of S.I. 2003/625.
(**5**) As amended by regulation 2(3) of S.I. 2003/625.
(**6**) As amended by regulation 2(4) of S.I. 2003/625.

(b) in column (3) (fees for other applications)—

(i) for "£326" substitute "£330",

(ii) for "£585" substitute "£592", and

(iii) for "£859" substitute "£869".

Amendment of regulation 3 of the Devices Regulations

3. In regulation 3 of the Devices Regulations(**7**) (fees)—

(a) in paragraph (1)(a), for "£3,533" substitute "£3,575";

(b) in paragraph (1)(b), for "£8,234" substitute "£8,333";

(c) in paragraph (2)(a), for "£699" substitute "£707";

(d) in paragraph (2)(b), for "£1,955" substitute "£1,978";

(e) in paragraph (3)(a), for "£3,533" substitute "£3,575";

(f) in paragraph (3)(b), for "£8,234" substitute "£8,333";

(g) in paragraph (4)(a), for "£699" substitute "£707";

(h) in paragraph (4)(b), for "£1,955" substitute "£1,978";

(i) in paragraph (5)(a), for "£36,126" substitute "£36,560"; and

(j) in paragraph (5)(b), for "£8,969" substitute "£9,077".

Amendment of regulation 2 of the General Fees Regulations

4. In regulation 2 of the General Fees Regulations (interpretation), in paragraph (1)—

(a) after the definition of "concerned member State"(**8**) insert the following definition—

""contract laboratory" means a laboratory carrying out the tests specified in paragraph 5A(2) of Schedule 2 or paragraph 8(3)(a) of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**9**) on behalf of a holder of a manufacturer's licence or a wholesale dealer's licence, pursuant to Article 20(b) of the 2001 Directive;";

(b) after the definition of "medicinal product" insert the following definition—

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

(c) after the definition of "parallel import licence"(**10**) insert the following definition—

""penalty fee" means a fee payable under regulation 18A;".

Amendment of Part IA of the General Fees Regulations

5.—(1) Part IA of the General Fees Regulations(**11**) (capital fees for pre-application meetings) is amended as follows.

(2) In regulation 3A—

(a) after the definition of "EC marketing authorization" insert the following definitions—

(**7**) As amended by regulation 3 of S.I. 2003/625.
(**8**) The definition of "concerned member State" was inserted by regulation 2 of S.I. 2000/3031.
(**9**) S.I. 1971/972; relevant amending instruments are S.I. 1977/1053 and 1992/2846.
(**10**) The definition of "parallel import licence" was inserted by regulation 5(1)(c) of S.I. 2001/795.
(**11**) Part 1A was inserted by regulation 4(3) of S.I. 2003/625 and amended by regulation 9 of S.I. 2003/2321.

""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 EC marketing authorization, or is given with a view to a person making such an application, and relates to—

(i) the obligations that would relate to the holder of such an authorization by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or

(ii) a post-authorization safety study protocol,

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

(i) compliance with the obligations that relate to him by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or

(ii) a post-authorization safety study protocol;

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

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

(b) after the definition of "quality development" insert the following definition—

""regulatory advice" means advice, other than scientific advice, in relation to the requirements of the 2001 Directive or Council Regulation (EEC) No. 2309/93 and which falls within one or more of the descriptions specified in paragraphs (a) to (c)—

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

(b) the advice is in connection with—

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

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

in relation to a product range, or

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

(i) an application for the variation or renewal of one or more EC marketing authorizations, or

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

in relation to a product range.".

(3) After regulation 3B, insert the following regulations—

"**3BA.** Subject to regulation 19, where the licensing authority holds a meeting with the holder of a marketing authorization for the purpose of providing advice to him before the publication of advertising of a medicinal product by his undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, there shall be payable by the holder of that authorization a fee of £1,346.

3BB.—(1) Subject to regulation 19, where the licensing authority holds a meeting with a person for the purpose of providing pharmacovigilance advice to that person, there shall be payable by that person—

(a) in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours, a fee of £1,690,

(b) in any other case, a fee of £1,346.

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

3BC. Subject to regulation 19, where the licensing authority holds a meeting with the holder of one or more marketing authorizations for the purpose of providing advice to that person on proposed changes to the labelling or the package leaflets of the medicinal products to which those authorizations relate, there shall be payable by that person a fee of £1,012.

3BD. Subject to regulation 19, where the licensing authority holds a meeting with the holder of a marketing authorization for the purpose of providing regulatory advice to that person, there shall be payable by that person a fee of £1,346.".

Amendment of regulation 4 of the General Fees Regulations

6. In regulation 4 of the General Fees Regulations (applications for authorizations, licences or certificates), after "paragraphs 2 to 6 of that Schedule", insert—

",

except that where such an inspection is made of a contract laboratory the fee in respect of that inspection shall be payable by the operator of that laboratory".

Amendment of regulation 5 of the General Fees Regulations

7. In regulation 5 of the General Fees Regulations (inspections in connection with multiple applications for authorizations or licences) after "an inspection mentioned in regulation 4(b)", insert ", except for an inspection of a contract laboratory,".

Amendment of regulation 7 of the General Fees Regulations

8. In regulation 7 of the General Fees Regulations (variations of authorizations, licences or certificates),—

(a) in paragraph (1) after "Subject to" insert "paragraph (3) and"; and

(b) after paragraph (2) insert the following paragraph—

"(3) Where an inspection referred to in paragraph (2)(a) is an inspection of a contract laboratory, the fee in respect of that inspection shall be payable by the operator of that laboratory.".

Amendment of regulation 8 of the General Fees Regulations

9. In regulation 8 of the General Fees Regulations (inspections in connection with multiple applications for variations of authorizations and licences) after "an inspection", insert ", except for an inspection of a contract laboratory,".

Amendment of regulation 13 of the General Fees Regulations

10. In regulation 13 of the General Fees Regulations (fees for inspections), in paragraph (2), after "holder of that licence", insert ", except that where an inspection is made of a contract laboratory the fee shall be payable by the operator of that laboratory".

Amendment of Part VII of the General Fees Regulations

11. After regulation 18 (time for payment of periodic fees), insert the following regulations—

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

18A.—(1) Subject to paragraph (2), if a person has failed to pay a periodic fee, at the time it should have been paid by virtue of regulation 18, a penalty fee shall be payable by that person.

(2) A penalty fee is payable only if after 60 days following written notice from the licensing authority requiring payment of that fee, the fee remains unpaid.

(3) Subject to regulation 18B, the penalty fee shall be—

(a) £100 where the total periodic fee unpaid by a person after 60 days following the notice referred to in paragraph (2) exceeds £200, or

(b) £50 where the total periodic fee unpaid by a person after such period does not exceed £200.

(4) In paragraph (3), the "total periodic fee" means the aggregate of all the periodic fees payable by a person in connection with all the authorizations or licences held by that person.

18B. If the periodic fee and penalty fee under regulation 18A ("the outstanding amount") have not been paid within 90 days following the written notice from the licensing authority, the amount of penalty fee payable shall be the amount specified in regulation 18A(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.

18C. 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 authorization or licence was not responsible for the failure to pay the periodic fee within the period specified in regulation 18A(2) or 18B."

Amendment of Part I of Schedule 1 to the General Fees Regulations

12. In Part I of Schedule 1 to the General Fees Regulations (interpretation), in paragraph (1)—

(a) in the definition of "complex application", after sub-paragraph (b) insert the following sub-paragraph—

"(bb) the application is an application for a marketing authorization to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies;"; and

(b) in the definition of "simple application", in sub-paragraph (a), after "other than" insert "an application to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies or".

Amendment of Schedule 2 to the General Fees Regulations

13.—(1) Schedule 2 to the General Fees Regulations (fees for inspections) is amended as follows.

(2) In sub-paragraph (1) of paragraph 1—

(a) after the definition of "non-routine inspection" insert the following definition—

""principles of good laboratory practice" means—

(a) the principles of good laboratory practice set out in Schedule 1 to the Good Laboratory Practice Regulations 1999(**12**), read with

(b) the revised guidance for the conduct of test facility inspections and study audits set out in Schedule 2 to those Regulations;"; and

(b) in the definition of "principle or guideline of good manufacturing practice"(**13**), for "Chapter II of Commission Directive 91/356/EEC(**14**) laying down the principles and guidelines of good manufacturing practice for medicinal products for human use" substitute "Commission Directive 2003/94/EC(**15**) laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use".

(3) After paragraph 4, insert the following paragraph—

"**4A.**—(1) Subject to sub-paragraph (2), the fee payable in respect of an inspection of a contract laboratory pursuant to Article 20(b) and Article 111 of the 2001 Directive shall be—

(a) if the laboratory carries out only one type of analytical work, £2,000,

(b) if the laboratory carries out two types of analytical work, £3,000, and

(c) if the laboratory carries out three or more types of analytical work, £4,000.

(2) Where an inspection referred to in sub-paragraph (1) takes place at the same time as an inspection, by a person appointed by the Good Laboratory Practice Monitoring Authority under regulation 3(4) of the Good Laboratory Practice Regulations 1999, for the purposes of ascertaining whether a contract laboratory complies with the principles of good laboratory practice, the fee payable shall be—

(a) if the laboratory carries out only one type of analytical work, £500,

(b) if the laboratory carries out two types of analytical work, £1,250, and

(c) if the laboratory carries out three or more types of analytical work, £2,000.

(3) The types of analytical work referred to in sub-paragraphs (1) and (2) are—

(a) physico-chemical analysis,

(b) microbiological analysis including sterility testing,

(c) LAL endotoxin analysis, and

(d) rabbit pyrogen testing.".

Amendment of Schedule 5 to the General Fees Regulations

14. In Schedule 5 to the General Fees Regulations (waiver, reduction or refund of capital fees), in paragraph 1A(**16**), after sub-paragraph (1) insert the following sub-paragraph—

(**12**) S.I. 1999/3106.
(**13**) The definition of "principle or guideline of good manufacturing practice" was inserted by regulation 4(1) and (7)(a)(ii) of S.I. 2003/625.
(**14**) OJ No. L 193, 17.7.1991, p. 30.
(**15**) OJ No. L 262, 14.10.1993, p. 22.
(**16**) Paragraph 1A was inserted by regulation 13(1) and (2) of S.I. 2003/2321.

"(1A) Where the licensing authority holds a meeting referred to in regulations 3BA to 3BD and that meeting was held at the request of the authority, any fee payable under those regulations in respect of that meeting may be waived.".

Amendment of the General Fees Regulations

15. In each provision of the General Fees Regulations specified in the entries in column (1) of the Schedule to these Regulations (the content of which is described in column (2) of that Schedule), for the amount specified opposite that provision in column (3) of that Schedule substitute the amount specified opposite that provision in column (4) of that Schedule.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
9th March 2004 Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

Gowdy D. C.
Permanent Secretary,
Department of Health, Social Services and
8th March 2004 Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary,
Department of Agriculture and Rural
9th March 2004 Development

We consent,

Derek Twigg
Nick Ainger
Two of the Lords Commissioners of Her
10th March 2004 Majesty's Treasury