SCHEDULE 5 Regulation 47(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 authorization 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 authorization includes a reclassification element within the meaning of paragraph 25 of Part 2 of Schedule 1; and

(b) the licensing authority is satisfied that the reclassification element does not require consideration by a committee established under section 4 (establishment of committees) of the Act(**1**) or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act(**2**),

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 authorization is a reclassification variation application (not being an application falling within paragraph 37 of Part 4 of Schedule 1); and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act,

50% of the fee payable under paragraph 35 of Schedule 1 and entry 1(c)(i) of Table 1 referred to in that paragraph or of the fee payable under paragraph 48(a)(i) of Part 4 of Schedule 1 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 39(1)(a) of Part 4 of Schedule 1; and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act,

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 a committee established under section 4

(**1**) Amendments and substitutions to section 4 have been made by S.I. 2004/1031, 2005/1094 and 2754 and 2006/2407.
(**2**) Section 2A was inserted by S.I. 2005/1094.

(establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act where—

(a) the licensing authority is satisfied that the application does not require consideration by such a committee or the Commission; and

(b) the committee or the Commission are consulted only by virtue of, or in accordance with, paragraph 5 of Schedule 2 to the Marketing Authorisation Regulations (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations).

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 8 of the Herbal 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 authorization, 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 authorization 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 section 44(1) (provision of information to licensing authority) of the Act(**3**) or in pursuance of a European Union provision which applies to applications for marketing authorizations or traditional herbal registrations, 25%.

(2) If an application for the grant of, or for a variation to, a marketing authorization 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 a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act, 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.

(**3**) Amendments to section 44 have been made by S.I. 2005/1094 and 2006/2407.

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

5. Where an application for the grant of, or for a variation to, a manufacturing authorisation, a manufacturer's licence or a wholesale dealer's licence 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 authorization, traditional herbal registration or clinical trial authorisation

6. Where an application for the grant of a marketing authorization 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

7. 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 authorization granted pursuant to 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 authorization shown on the licence can be changed.

Surrender of marketing authorization at same time as a variation application

8.—(1) Subject to sub-paragraphs (2) and (3), where an applicant applies to vary a marketing authorization in the circumstances set out in paragraph 8(3) of Part 3 of Schedule 3, 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 46 and 47 of Part 4 of Schedule 1, 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

9.—(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 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 to the applicant.

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

Scientific advice: paediatric indications

10.—(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 authorization.

(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 authorization.

(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(**4**);

(b) "paediatric use marketing authorization" means a marketing authorization 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 (EEC) No. 1768/92 concerning the creation of a supplementary protection

(**4**) Article 11 has been amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

certificate for medicinal products(**5**) and a patent qualifies for the granting of such a certificate if the provisions of that Regulation so provide.

(**5**) OJ L 182, 2.7.1992, p.1, which has been amended by Regulation (EC) No. 1901/2006 (OJ L 378, 27.12.2006, p.1).