SCHEDULE 5

WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

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(**1**);

(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 certificate for medicinal products(**2**) and a patent qualifies for the granting of such a certificate if the provisions of that Regulation so provide.

(**1**) Article 11 has been amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).
(**2**) 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).