



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 September 2014
EMA/317270/2014
Executive Director

Executive Director's decision

on fee reductions for designated orphan medicinal products

THE EXECUTIVE DIRECTOR,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and in particular Articles 67(3) and 70 thereof,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, and in particular Articles 4(2) and 7(2) thereof,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Medicines Agency, and in particular Article 3 thereof,

Having regard to the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures, in particular Annex VII(1) thereof,

Having regard to Regulation (EU) No 658/2014 of the European Parliament and the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use,

Having regard to Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises, in particular Article 7 thereof,

Having regard to Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, hereinafter "SME",

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use,

Having regard to the Financial Regulation of the European Medicines Agency,

Having regard to the rules for the implementation of the Financial Regulation applicable to the budget of the European Medicines Agency,

Having regard to the advice of the Committee for Orphan Medicinal Products,

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Whereas a special contribution from the European Union, distinct from that provided for in Article 67(3) of Regulation (EC) No 726/2004, is allocated every year to the European Medicines Agency, hereinafter "the Agency", for the exclusive use of the Agency to waive, in part or in total, all the fees payable under European Union rules adopted pursuant to Regulation (EC) No 726/2004 in respect of designated orphan medicinal products,

Whereas a task of the Committee for Orphan Medicinal Products is to advise on the policy on orphan medicinal products for the European Union,

Whereas the total or partial reduction from the payment of fees for applications for designated orphan medicinal products shall be granted by the Agency as laid down in a decision of the Executive Director that reflects the advice of the Committee for Orphan Medicinal Products,

Whereas no specific reductions are foreseen for pharmacovigilance fees for designated orphan medicines,

Whereas total or partial fee reductions for orphan medicinal products granted by the Agency are subject to the availability of funds from the European Union special contribution,

HAS DECIDED:

Article 1 - Definition of sponsor

For the purposes of this Executive Decision, the sponsor of a designated orphan medicinal product shall mean the applicant or marketing authorisation holder applying to the Agency for a procedure or service in relation to that designated orphan medicinal product.

Article 2 - Eligibility to total or partial fee reductions

1. A sponsor of an orphan medicinal product shall be eligible to a total or partial fee reduction once the decision on orphan medicinal product designation has been granted to that sponsor by the European Commission.
2. An application for a procedure or service must be made to the Agency by the sponsor of the designated medicinal product in order for that sponsor to be eligible for the total or partial fee reduction.
3. An application made by a sponsor to the Agency for a procedure or service shall fall within the scope of the orphan condition specified in the European Commission's decision on orphan designation.

Article 3 - Micro, small and medium-sized enterprises (SMEs)

A sponsor that meets the SME criteria as defined in Commission Recommendation 2003/361/EC of 6 May 2003 and has SME status assigned by the Agency shall be eligible for the fee reductions that are applicable to SMEs, as laid down in this Executive Decision, as long as the SME status remains valid at the time the fee falls due for the relevant procedure or service.

Article 4 - Applicability of fee reductions

The partial or total fee reductions laid down in this Executive Decision do not preclude other reductions provided for in European Union legislation, in respect of the same fee, from which the sponsor of the designated medicinal product may also benefit.

The provisions which are the most favourable to the sponsor in respect of a given fee shall apply. Cumulative fee reductions for a given fee and a given sponsor shall not be allowed.

Article 5 - Fee reductions

The total or partial fee reductions specified in the Annex to this Executive Decision shall apply.

Article 6 - Effective date

This decision shall take effect on 9 September 2014 and supersedes the previous decision dated 19 November 2013, which is hereby revoked.

Done at London, 9 September 2014

[signature on file]

Guido Rasi
Executive Director

Annex

Fee Reductions for centrally (EU) authorised designated orphan medicinal products

Procedure or service	Fee reduction applicable to	Percentage fee reduction
Protocol assistance, initial and follow-up requests	SME sponsors for all assistance	100%
	Non-SME sponsors for non-paediatric-related assistance	75%
	Non-SME sponsors for paediatric-related assistance ¹	100%
Pre-authorisation inspection	All sponsors	100%
Initial marketing authorisation application	SME sponsors	100%
	Non-SME sponsors	10%
Post-authorisation applications and annual fee, specified in Council Regulation (EC) No 297/95, <u>in the first year</u> from granting of a marketing authorisation	SME sponsors	100%
Pharmacovigilance fees, specified in Regulation (EU) 658/2014 ²	All sponsors	n/a

¹ Paediatric-related protocol assistance is restricted to development of an orphan medicinal product for the paediatric population, where the advice requested does not include the adult population.

² Pharmacovigilance fees, specified in Regulation (EU) 658/2014, apply to centrally authorised products (CAP) and non-centrally authorised products (non-CAP) whereas Regulation (EC) No 141/2000 on orphan medicinal products applies to CAPs only.