



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/135645/2020
Executive Director

Decision of the Executive Director

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 Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("Founding Regulation"), 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 for the Evaluation of Medicinal Products, and in particular Article 9 thereof ("Fee Regulation"),

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 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 the preamble and 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 Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", in particular definitions of 'applicant from the academic sector', 'non-profit organisation', 'non-profit legal entity', 'legal entity' and 'International European interest organisation' thereof,

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

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Having regard to the advice of the Committee for Orphan Medicinal Products on 18 June 2020 regarding the fee reduction levels for different sponsors,

Having regard to the consultation of the European Commission on incentives for academia on 29 May 2020,

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 SMEs and applicants from the academic sector represent an important source of innovation and enrich the product pipelines of larger companies, but lack experience with the Agency and require enhanced regulatory support,

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 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 – Scope

Fee reductions for procedures or services in relation to designated orphan medicinal products shall be granted by the Agency as laid down in this Executive Decision.

Article 2 - Definitions

1. **'Sponsor'** [of a designated orphan medicinal product] should be understood as the applicant or marketing authorisation holder applying to the Agency for a procedure or service in relation to that designated orphan medicinal product;
2. **'SME'** should be understood as a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003;
3. **'Academia' or 'Academic sector'** should be understood as consisting of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations;
4. **'Non-profit organisation' or 'non-profit legal entity'** should be understood as a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members;
5. **'Legal entity'** should be understood as any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations;

6. **'International European interest organisation'** should be understood as an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

Article 3 – Requirements

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 for that sponsor to be eligible for the total or partial fee reduction.
3. The transfer of sponsorship of a designated orphan medicinal product shall be completed prior to submission of an application for a procedure or service by the new sponsor.
4. 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 decision of the European Commission.
5. Applicants shall be established in the EEA.
6. An applicant 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 long as the SME status remains valid at the time the fee falls due for the relevant procedure or service.
7. An applicant from academia or the academic sector, as defined in article 2(3) above, must not be financed or managed by private profit organisations in the pharmaceutical sector ("PPO"), nor have concluded any operating agreements with any PPO concerning their sponsorship of or participation to the specific research project for which a fee reduction is sought. This should be evidenced by:
 - (a) the Legal Entity Form (LEF) and the "founding document" (or any other suitable document provided during the application process).
 - (b) Evidence should be provided of the place of legal establishment, which may be evidenced by the founding document or any other suitable document proving that the entity's seat is located in the EU, Iceland, Liechtenstein or Norway.
 - (c) The applicant should not be under their direct or indirect control of any PPO in the pharmaceutical sector. Control may, in particular, take either of the following forms:
 - i. the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the applicant, or of a majority of the voting rights of the shareholders or associates of that applicant, or
 - ii. the direct or indirect holding, in fact or in law, of decision- making powers in the applicant.

Article 4 - Fee reductions

The partial or total fee reductions, specified in the table below, shall apply. It shall not preclude other reductions provided for in European Union legislation, in respect of the same fee, to 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.

Procedure or service	Fee reduction applicable to	Percentage fee reduction
Protocol assistance, initial and follow-up requests	SME sponsors for all assistance	100%
	Academia for all assistance	100%
	Sponsors for paediatric-related assistance, other than SME sponsors or academia ¹	100%
	Sponsors for non-paediatric-related assistance, other than SME sponsors or academia	75%
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, in the first year from granting of a marketing authorisation	SME sponsors	100%
Pharmacovigilance fees, specified in Regulation (EU) 658/2014	All sponsors	n/a

Article 5 - Processing of fee reductions

Upon receipt of an application for a procedure or service in relation to a designated orphan medicinal product, the Agency will check whether the requirements described in article 3 are fulfilled, in order to grant a fee reduction. No separate request for fee reductions by the applicant will be required.

The Agency reserves its right to conduct ex -post controls and request evidence confirming that the criteria for the fee reduction are fulfilled at any time until the finalisation of the procedure for which the applicant had applied for.

Article 6 - Effective date

This decision shall be effective on 19 June 2020 and replaces the previous decision dated 9 September 2014 (EMA/317270/2014), which is hereby revoked.

Done at Amsterdam,

Guido Rasi
Executive Director

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.