



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 May 2016
EMA/63484/2016
Executive Director

Decision of the Executive Director

on fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector

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 (hereafter 'the Agency') ("Founding Regulation") and in particular Article 57(1)(n) thereof,

Having regard to 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 and in particular the preamble thereof,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, and in particular Article 9(1) thereof ("Fee Regulation"),

Having regard to the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Agency for the evaluation of medicinal products, and in particular Annex I, thereof ("Implementing Rules"),

Having regard to the Financial Regulation of the European Medicines Agency and its implementing rules and in particular Article 29(1) and (2) 2nd sentence of the Financial Regulation,

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)" and repealing Regulation (EC) No 1906/2006 and the MSCA Standard Eligibility Conditions of 10 December 2013: Extract from the MSCA part of the main Work Programme" of 10 December 2013, 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 Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises,



Having regard to the entry into force of the PRIME scheme, aimed enhancing early dialogue to facilitate accelerated assessment of priority medicines (EMA/CHMP/57760/2015, 25 February 2016),

Having regard to the analysis conducted by EMA of the impact on resources and fees of PRIME (EMA/709943/2015, 26 October 2015),

Having regard to the consultation with the competent scientific committee (CHMP, 26 May 2016) regarding the exceptional circumstances and the imperative reason of public health for scientific advice requests on PRIME products for SMEs and applicants from the academic sector,

Whereas the Executive Director may, without prejudice to more specific provisions of Union law, in exceptional circumstances and for imperative reasons of public or animal health, grant fee reductions case by case after consultation of the competent scientific committee,

Whereas it is imperative for the health of European citizens that the development of new medicines that address unmet medical need is not refrained by financial constraints,

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

Whereas experience shows that the main financial and administrative entry hurdles for SMEs, and even more so for applicants from the academic sector are the various steps involved in pre-marketing authorisation procedures, such as the seeking of scientific advice.

Whereas the increase in the overall fee reductions and waivers the agency grants on a yearly basis can be absorbed in the overall budget of Agency without impacting on the level of contribution from the EU budget,

Whereas appropriations shall be used in accordance with the principles of sound financial management whilst respecting the principle of efficiency aiming for the best relationship between resources employed and results achieved,

Whereas in view of number of requests expected, it is not deemed efficient to require case-by-case decisions on these fee reductions.

HAS DECIDED

Article 1 – Scope

Fee waivers for scientific advice requests on medicinal products falling under the scheme for priority medicines ("PRIME") shall be introduced for SMEs and applicants from academia / academic sector.

Article 2 - Definitions

1. **'SME'** -the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003
2. **'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;

3. **'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;
4. **'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;
5. **'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

Applicants shall be established in the EEA and shall be

1. registered as an SME with the Agency or,
2. academia or academic sector, as defined in article 2(2), which is not financed or managed by private profit organisations in the pharmaceutical sector ("PPO"), nor has concluded any operating agreements with any PPO concerning their sponsorship or participation to the specific research project for which a fee exemption is sought for scientific advice under the PRIME scheme. 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.

Upon receipt of a scientific advice request, the EMA will check the applicant's declaration of eligibility to PRIME, and the registration as SME, or in case of academia or academic sector the acceptability of the declaration (based on defined template) and supporting documents.

The Agency reserves its right to conduct *ex -post* control and request evidence confirming that the criteria for the fee exemption are fulfilled at any time until the adoption of the final advice letter.

Article 4 - Fee reductions

A total exemption from the payment of the fees laid down in the Fee Regulation and the Implementing Rules is granted for scientific advice requests and follow-up requests submitted on products eligible to the PRIME scheme for applicants established in the EEA and comply with the definitions in Article 2 and requirements in article 3.

Article 5 - Processing of fee reductions

Request received and fulfilling the requirements as described in article 3 will be checked by the Agency in order to be granted a total fee reduction. No separate request for fee reductions by the applicant will be required.

Article 6 - Entry into force

This decision shall enter into force on 1 June 2016.

[signature on file]

Guido Rasi
Executive Director