EMA/CAT/317778/2023
Executive Director

Decision of the Executive Director

on fee incentives for scientific advice, marketing authorisation applications and pre-authorisation inspections in the ATMP support pilot for academia

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 use and establishing a European Medicines Agency (hereafter the 'Agency' or 'EMA'), and in particular letters (a), (i) and (n) of Article 57(1) 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, paragraph 1, thereof,

Having regard to the pilot on advanced therapy medicinal product (hereafter 'ATMP') support for applicants from the academic sector,[1] approved by the Agency's Executive Board on 10 March 2022, whereby EMA provides regulatory support for up to five selected ATMPs that address unmet clinical needs and are solely developed by academic developers in Europe (hereafter 'ATMP support pilot for academia'),

Whereas while applicants from the academic sector largely contribute to the research for innovative advanced therapies, experience shows that they face important financial entry hurdles in various (pre-) marketing authorisation procedures, which may hinder the authorisation of medicinal products that address unmet clinical needs and, therefore, have a significant negative impact on public health,

Whereas in view of the above, it is considered that, as part of the above-mentioned pilot, the Agency should also provide financial support to applicants from the academic sector for the activities concerning the five selected ATMPs, as they aim to address unmet clinical needs, in particular by granting, for those activities, the same incentives as the Agency grants for micro-, small- and medium-sized enterprises,

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, in accordance with Article 9, paragraph 1, of Council Regulation (EC) No 297/95,

Whereas following consultation of the Committee on Advanced Therapies at its meeting on 14th July 2023, said Committee acknowledged that there are exceptional circumstances and imperative reasons

[1] As defined in the 'Framework of collaboration between the European Medicines Agency and academia' (EMA/125511/2017).

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of public health that justify the granting of fee incentives as captured in the present Decision for scientific advice, pre-authorisation inspections, and initial marketing authorisation applications for the five applicants selected for the ATMP support pilot,

Whereas in view of the number of requests expected, it is not deemed efficient to require separate decisions on these fee reductions,

HAS DECIDED:

Article 1 - Scope of the decision

The Agency shall grant fee incentives to applicants from the academic sector (hereinafter 'applicants') that comply with the requirements laid down in this Decision, in relation to medicinal products included in the ATMP support pilot (which will amount to a maximum of 5 products in total, by the end of 2024[2]), in accordance with the terms laid down in this Decision.

Article 2 – Requirements

To qualify for the fee incentives laid down in Article 3 of this Decision, an applicant:

1. must be one of the applicants selected by the Agency for the ATMP support pilot after having submitted an application and successfully overcome all the selection steps[2],
2. must continue to fulfil all the selection criteria[2] for participating in the pilot at the time of an application for a procedure or service for which a fee incentive is to be granted:
    a. the product is an ATMP of sufficient maturity and with the potential to address an unmet medical need,
    b. the applicant is from the academic sector as defined in the framework of collaboration between the European Medicines Agency and academia (EMA/125511/2017),
    c. the applicant has freedom to operate and must be free from operating agreements with any pharmaceutical company,
    d. the applicant is able and willing to collaborate with the Agency.
3. shall be established in the EEA, which may be evidenced by the founding document or any other suitable document proving that the entity is established in the EU, Iceland, Liechtenstein or Norway.

The applicant shall submit to the Agency a declaration on their establishment in the EEA and supporting documents to demonstrate that it continues to fulfil the requirements listed in this Article, as applicable.

The applicant shall notify the Agency of any changes to the information declared by the applicant, without delay and in writing.

Article 3 - Fee incentives

For the selected products in the pilot, applicants complying with the requirements set out in Article 2 shall benefit from the following incentives to the corresponding fees laid down in Council Regulation (EC) No 297/95 and its Implementing Rules:

[2] As described in the 'Q&A on EMA pilot offering enhanced support to academic and non-profit developers of Advanced Therapy Medicinal Products (ATMPs)' (EMA/797476/2022).

(a) 90% fee reduction for initial scientific advice and follow-up,

(b) 90% fee reduction for pre-authorisation inspections,

(c) 100% fee reduction for marketing authorisation applications for designated orphan medicinal products for human use and

(d) for marketing authorisation applications not covered under (c) above, deferral of the payment of the fee until the notification of the final decision on the marketing authorisation for the concerned ATMP is issued.

Article 4 – Remuneration of national competent authorities

Notwithstanding Article 3, the remuneration of national competent authorities for those activities shall not be reduced.

Article 5 - Processing of fee reductions

The Agency shall verify the declaration and supporting documents submitted by the applicant and shall notify the applicant about the outcome of said verification.

If the Agency confirms that the applicant qualifies for the fee reduction(s) and deferral laid down in Article 3, to benefit from said fee reduction and deferral the applicant shall submit its request for scientific advice and/or marketing authorisation within six months from the date of said confirmation.

The Agency reserves its right to conduct ex–post controls and request evidence confirming that the criteria for the fee reduction(s) and deferral 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 as of the date of its signature. It shall be valid for applications validated from 01.09.2023 until 31.12.2025.

Amsterdam,

Emer Cooke Digitally signed by Emer Cooke
Date: 2023.07.27 12:17:45 +02'00'

Emer Cooke
Executive Director