EMA/37378/2026
Executive Director

Decision of the Executive Director

On the access to financial and administrative incentives for micro, small and medium-sized enterprises

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;

Having regard to the Financial Regulation applicable to the budget of the European Medicines Agency from 1 July 2019 (EMA/MB/911312/2019) (hereafter the "Financial Regulation");

Having regard to Regulation (EU) 2024/568 of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (the "Fee Regulation");

Having regard to the Fee Regulation working arrangements on fees and charges payable to the European Medicines Agency applicable from 1 January 2025 (EMA/MB/183645/2024) (the "Working Arrangements");

Having regard to Commission Regulation (EC) No 2049/2005 of 15 December 2005 regarding the payment of fees to, and the receipt of administrative assistance from the European Medicines Agency by micro, small and medium-sized enterprises (the "SME Regulation");

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

Whereas the financial and administrative provisions of the SME Regulation apply to SMEs within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003, which are established in the European Economic Area;

Whereas an SME wishing to benefit from the provisions of the SME Regulation and other legal acts establishing benefits for SMEs shall submit to the Agency the information necessary to demonstrate compliance with the SME criteria within the applicable timelines;

Whereas in accordance with Article 4(2) of the Annex to Commission Recommendation 2003/361/EC, where at the date of closure of the accounts an enterprise finds that, on an annual basis, it has exceeded the SME headcount or financial ceilings, this will not result in the loss of SME status unless those ceilings are exceeded over two consecutive accounting periods; and the enterprise's SME status will, therefore, expire two years after the date of closure of the accounts on which the declaration has been based;

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Whereas the aim of the SME Regulation is to promote innovation and the development of new medicines by SMEs, the European Medicines Agency ("EMA" or the "Agency") will take into account mergers and acquisitions of SMEs and contractual arrangements with non-SMEs when determining the validity of the SME status and the application of SME incentives;

HAS DECIDED:

Article 1 – Access to SME incentives

The access to the financial incentives[1] laid down for SMEs under the SME Regulation, the Fee Regulation and its Working Arrangements and any other legal act ("SME incentives") is subject to the enterprise's SME status being assigned by EMA and remaining valid, within the meaning of Commission Recommendation 2003/361/EC, on the corresponding "Applicable fee level date"[2] set out in the Appendix to the Working Arrangements, unless otherwise provided for in this Decision or in other applicable provisions.

As regards the renewals of the SME status, to access the financial incentives the enterprise must have submitted the request for renewal of the SME status before its expiry and by the "Applicable fee level date" for the concerned service, unless otherwise provided for in this Decision or in other applicable provisions.

For translation assistance, pursuant to Article 10 of the SME Regulation, the enterprise's SME status assigned by EMA must remain valid at, or a request for renewal of the SME status must have been submitted by, the time that the translations are initiated by EMA.

Article 2 – Mergers and acquisitions of SMEs

The SME Office at EMA should be informed immediately of a merger or acquisition of a registered SME with or by another entity.

If a registered SME merges with or is acquired by another entity and the SME criteria are no longer met by the newly formed entity or the group which acquired the SME, with effect from the date of the change in ownership, the SME status will cease to be valid and there will be no further access to the SME incentives for future services. Furthermore, the fees for ongoing services shall no longer be subject to fee deferrals and will become payable, and the entity will not have access to conditional fee exemptions for ongoing marketing authorisation procedures.

Where EMA has not been informed immediately about the merger or acquisition, the Agency will proceed to recover any SME incentive unduly granted from the date of the change in ownership, if any. Any fee reductions granted, and the cost of translations incurred by EMA, from the date of change in ownership, shall become payable.

Article 3 – Contractual arrangements between SME and non-SMEs

The SME incentives shall not be granted to SMEs acting as applicant or marketing authorisation holder for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity, where said non-SME legal entity would benefit from the SME incentives.

[1] Including fee and charge reductions, fee deferrals and conditional fee exemptions.
[2] As defined in the Appendix to the Working Arrangements.

Such contractual arrangements shall be declared to the Agency ahead of any service. This includes agreements for regulatory consultancy services between a non-SME legal entity and a SME regulatory consultancy, and out-licencing agreements by which an SME grants licencing rights for a medicinal product to a non-SME.

With effect from the signature date of the contractual arrangement, there will be no further access to SME incentives for future services and the fees for ongoing services shall no longer be subject to a fee deferral and will become payable. This will apply also in cases where the contractual arrangement envisages a future transfer of the marketing authorisation for the concerned medicinal product to a non-SME. The SME will not have access to a conditional fee exemption for the concerned product(s).

Where the contractual arrangement is declared to the Agency only after a request for service, the Agency will proceed to recover any SME incentive unduly granted after the date of signature of the arrangement, if any.

Article 4 – Effective date

This decision shall take effect from the date of its signature and shall replace the previous decision dated 29 April 2013 (EMA/150401/2013).

Amsterdam,

Emer Cooke Digitally signed by Emer Cooke
Date: 2026.03.18 12:52:59 +01'00'

Emer Cooke

Executive Director