European Parliament
2019-2024

Committee on Budgets
The Chair

23.5.2023

Mr Pascal Canfin
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the Commission proposal on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council (2022/0417(COD))

Dear Mr Chair,

Under the procedure referred to above, the Committee on Budgets' Coordinators decided at their meeting of 31 January 2023 to adopt an opinion in the form of a letter. The committee adopted the opinion at its meeting[1] on 23/05/2023 and mandated me to convey the position set out below.

Background to the proposal

Article 67(3) of the founding Regulation[2] of the European Medicines Agency (EMA, the Agency) stipulates that fees and charges are part of the revenues of the Agency and Article 86a

[1] The following were present for the final vote: Olivier Chastel (2nd Vice-Chair), Margarida Marques (3rd Vice-Chair), Niclas Herbst (4th Vice-Chair), Anna-Michelle Asimakopoulou, José Manuel Fernandes, Jan Olbrycht, Karlo Ressler, Rainer Wieland, (for EPP) and Asim Ademov (for EPP pursuant to Rule 209(7)), Pietro Bartolo, Pascal Durand, Eider Gardiazabal Rubial, Camilla Laureti (for S&D), Vlad Gheorghe, Moritz Körner, Nils Torvalds (for Renew), Rasmus Andresen, David Cormand, Alexandra Geese, Francisco Guerreiro (for Verts/ALE), Valentino Grant, Joachim Kuhs (for ID), Zbigniew Kuźmiuk, Bogdan Rzońca (for ECR) and Andor Deli (for NI)

[2] 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 (OJ L 136, 30.4.2004, p. 1).

of that regulation, as amended by Regulation (EU) 2019/5[3], provides that the Commission is to put forward, as appropriate, legislative proposals with a view to update the regulatory framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products (VMP).

EMA fees are currently laid down in two separate regulations: Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 and both regulations convey the will of the co-legislators that revisions of fees levied by the Agency should be based on an evaluation of the costs of the Agency and the costs of the tasks carried out by competent authorities in Member States[4].

Position of the Committee on Budgets

The Committee on Budgets agrees with the Commission analysis that over the years, the legal framework governing EMA fees has become rather complex and welcomes therefore the proposed legislative simplification. In particular, it agrees that following changes introduced to the EMA Founding Regulation (EC) No 726/2004, to Regulation (EU) 2019/6[5] and to Regulation (EU) 2022/123[6], the provisions applicable to the fee system need to be adapted. By addressing these specific problems, the general objective of this proposal is to contribute to providing a sound financial basis to support the EMA's operations, including remuneration for services to the EMA rendered by national competent authorities, in line with the applicable legislation.

The Committee on Budgets notes that following a thorough evaluation of the costs of the Agency and its various statutory tasks and the cost of the contributions of competent authorities of the Member States to its work, the Commission proposal is to provide for fee and remuneration amounts that are cost-based. It counts therefore on the Commissions analysis that the proposal does not have implications on the EU budget and its contribution to the EMA budget and that the proposal will not result in the need for additional resources to effectively manage the fee system.

[3] Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24).
[4] Council Regulation (EC) No 297/95, Article 12.
[5] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43)
[6] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1)

In the event of new evidence or changes to this approach introduced by the co-legislators during the negotiations, the Committee on Budgets stands ready to assess the potential budgetary consequences.

Yours sincerely,

Johan Van Overtveldt