EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.DDG1.D.2/MG/EB(2023)4292284

Subject: **Summary of feedback**

Excellency,

From 13 December 2022 to 7 February 2023, in the framework of the Commission's *Better Regulation* agenda, the Commission collected feedback from stakeholders on the proposal for a Regulation of the European Parliament and of the Council 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 (*COM/2022/721 final*). Please find attached for your information a summary of the feedback received during this period. The same letter is being sent to the European Parliament.

Yours faithfully,

Sandra GALLINA

Enclosure: Summary of the feedback received on the proposal for a Regulation of the European Parliament and of the Council 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.

c.c.: Mr J. Svensson, Chair of the Council Working Party,
Secretary General: SG-STAKEHOLDER-CONSULTATION@ec.europa.eu
DG SANTE: Ms C. Modoran, Mr N. Pradalié, Mr L. Battistini, Mr J. Ryan, Ms R. Ardeleanu, Ms O. Solomon, Ms A. Bolufer de Gea, Ms M. Moya Diaz, Mr S. Giraud, Mr M. Griva, Mr M. Capellino, Ms V. Lyons, Ms E. Zamora Escribano, Mr L. Goranov.

Mr Lars Danielsson
Ambassador and Permanent Representative to the EU, Permanent Representation of Sweden to the EU
agneta.bergendahl@gov.se

Summary report of the feedback received ([1])

The feedback period ran from 13 December 2022 to 7 February 2023 and was intended to gather views from stakeholders on the proposal to update the current framework regulating fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 ([2]) of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 ([3]) and Regulation (EU) 658/2014 ([4]) of the European Parliament and of the Council.

The Commission received ten valid replies, of which, according to respondents' self-identification, six ([5]) came from business associations, two from EU citizens, one from a company/business, and one from an academic/research institution. Among respondents other than individual EU citizens, six were active at EU level, three were active internationally, and the rest were active nationally. Among the business associations, there were associations representing the pharmaceutical industry operating in Europe, representing generic or biosimilar medicines industries, representing manufacturers of non-prescription medicines, representing manufacturers of veterinary medicines and also trade associations operating at national level in two EU Member States.

Feedback received

Almost all responses indicated that **the general cost-based approach of the proposal is well-received.** Respondents commented that the proposed EMA fee system provides a **simplified** and **more streamlined structure**. The **reduction of administrative burden** and through specific provisions (Type IA and IB variations included in annual fees) was welcomed as well as the proposed fee system being **more agile** and, therefore, more **future-proof**.

Regarding other individual proposal measures, the **initial application fee level for generic medicinal products** was deemed appropriate by the industry association active in this field.

Among the critical points was mentioned the amount of fees relating to **pharmacovigilance annual fee**. According to the feedback, the nature of the pharmacovigilance costs should be more detailed. The provision of the pharmacovigilance annual fee, based on "chargeable unit", was deemed to disproportionately impact the

([1]) *'Have Your Say'* webpage where all feedback responses are published: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2091-Human-and-veterinary-medicines-updating-the-rules-on-fees-payable-to-the-European-Medicines-Agency/feedback_en?p_id=31738699

([2]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

([3]) Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products

([4]) Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

([5]) The contribution of the trade association "Medicines for Europe" is included in this category, as the Commission deems that its indication by the submitter as a "trade union" contribution was an unintentional error.

sustainability of some **generic medicinal products** and concerns were voiced that authorisation fee would soon become too high for **biosimilar** medicinal products.

For **orphan medicinal products**, specific additional incentives have been requested for academic/non-profit developers.

A concern has been raised regarding the considerably increased amounts for the fees for **veterinary medicinal products (VMP)** and the **negative impact on the sustainability of the veterinary sector and the availability of VMP** that the proposed fees could have particularly on small product lines, vaccines for less numerous species or for diseases occurring infrequently or in limited geographical areas, and in smaller EU Member States. It was claimed this could reflect on public and animal health, as well as on animal welfare.

Possible negative repercussion on quality and timeline of **Scientific Advice**, was voiced by some respondents, due to the decrease in **remuneration for national competent authorities**, while others considered such reduction to **encourage innovation** if there are **no consequences on the engagement of experts**.

In a broader general context, it has been requested to confirm that the proposal **supports sustainable development and adequate resources for high-quality scientific assessment** within competitive timeframes (1 mention).

The need for an adequate transition period for **implementation was** expressed.

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0417 (COD)

Brussels, 10 May 2023

WK 6218/2023 INIT

LIMITE

PHARM
SAN
MI
COMPET
CODEC
VETER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

INFORMATION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - Summary of the feedback

Delegations will find enclosed a summary report of the feedback received on the EMA fees proposal provided by Commission services.