



Council of the
European Union

168952/EU XXVII. GP
Eingelangt am 12/01/24

Brussels, 12 January 2024
(OR. en)

5183/24

Interinstitutional File:
2022/0417(COD)

CODEC 32
PHARM 4
SAN 14
MI 14
COMPET 26

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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 (first reading) - Adoption of the legislative act

1. On 13 December 2022 the Commission submitted its proposal¹, based on Article 114 and Article 168(4), points (b) and (c), of the TFEU, to the Council.
2. The European Economic and Social Committee delivered its opinion on 24 January 2023².
3. The Committee of the Regions was consulted and decided not to issue an opinion.

¹ 16070/22 + ADD1 to ADD7.

² OJ C 140, 21.4.2023, p. 85.

4. On 12 December 2023 the European Parliament adopted its position at first reading on the Commission proposal. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council³.
5. The Permanent Representatives Committee is therefore asked to confirm its agreement and to suggest that the Council approve the European Parliament's position as set out in PE-CONS 59/23 as an 'A' item at a forthcoming meeting.
6. If the Council approves the European Parliament's position, the legislative act will be adopted.

After being signed by the Presidents of the European Parliament and of the Council, the legislative act will be published in the *Official Journal of the European Union*.

³ 16617/23.