Council of the European Union

Brussels, 14 December 2022
(OR. en)

16070/22
ADD 3

Interinstitutional File:
2022/0417(COD)

PHARM 191
SAN 663
MI 949
COMPET 1040
CODEC 2028

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 December 2022
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2022) 721 final
Subject:	ANNEX to the 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

Delegations will find attached document COM(2022) 721 final.

Encl.: COM(2022) 721 final

EUROPEAN
COMMISSION

Brussels, 13.12.2022
COM(2022) 721 final

ANNEX 3

ANNEX

to the

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

{SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final} -
{SWD(2022) 415 final}

ANNEX III
Annual fees and remuneration

1. Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004

1.1. An annual fee of EUR 48 900 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(1) and (3) and Article 10c of Directive 2001/83/EC. The remuneration shall be EUR 6 400 for the rapporteur and EUR 5 600 for the co-rapporteur.

1.2. An annual fee of EUR 95 600 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(4) of Directive 2001/83/EC. The remuneration shall be EUR 12 900 for the rapporteur and EUR 11 400 for the co-rapporteur.

1.3. An annual fee of EUR 188 000 shall apply to each marketing authorisation of a medicinal product for human use not covered by point 1.1 or 1.2. The remuneration shall be EUR 25 700 for the rapporteur and EUR 22 700 for the co-rapporteur.

2. Annual fee for veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6

2.1. An annual fee of EUR 21 500 for shall apply for each marketing authorisation of a veterinary medicinal product authorised pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 5 000 for the rapporteur and EUR 4 600 for the co-rapporteur.

2.2. An annual fee of EUR 87 500 shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 20 400 for the rapporteur and EUR 18 800 for the co-rapporteur.

3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

3.2. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

3.3. The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.

3.4. The annual fees referred to in points 3.1 and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.