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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:	ANNEXES 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

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ANNEX 6

ANNEXES

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 VI

Performance information

The following information shall relate to each calendar year:

(1) the overall cost and breakdown of staff and non-staff costs relating to the fees and charges referred to in Article 3;

(2) number of Agency staff involved and the overall costs for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(3) number of procedures for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(4) number of fee reductions granted per type of fee reduction as set out in Annex V;

(5) attribution of rapporteurs, co-rapporteurs, or roles considered as equivalent for the purposes of this regulation as referred to in the Annexes to this regulation, per Member State, per type of procedure;

(6) number of working hours spent by the rapporteur and the co-rapporteurs and experts contracted for the procedures of the expert panels on medical devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board based on a proposal by the Agency.