



Council of the
European Union

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13505/17

PHARM 44
SAN 366
MI 735
COMPET 693
DELECT 199

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

No. Cion doc.: 13457/17 PHARM 42 SAN 364 MI 729 COMPET 690 DELECT 192

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 18.10.2017 amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use
- Intention not to raise objections to a delegated act

1. On 18 October 2017, the Commission notified the European Parliament and the Council of the adoption of the above Delegated Regulation in accordance with Article 18(4) of Regulation (EU) No 658/2014 of the European Parliament and of the Council¹.
2. The Working Party on Pharmaceuticals and Medical devices considered, through an informal written procedure², that there are no grounds for the Council to object to this delegated act.

¹ 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 (OJ L 189, 27.6.2014, p. 112).

² WK 11702/2017.

3. The Permanent Representatives Committee is therefore invited to:

- confirm the agreement reached by the Working Party, and
 - recommend to the Council to confirm, as an "A" item on its agenda, that there are no grounds for objecting the above Commission Delegated Regulation.³
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³ Unless the European Parliament objects to it, the Delegated Regulation will be published and enter into force in accordance with Article 18(5) of Regulation (EU) No 658/2014.