Council of the European Union

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PHARM 28
SAN 245
MI 483
COMPET 482
DELACT 98

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	10015/17 PHARM 27 SAN 241 MI 482 COMPET 479 DELACT 92
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 23.5.2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections - *Intention not to raise objections to a delegated act*

1. On 23 May 2017, the Commission notified the European Parliament and the Council of the adoption of the Delegated Regulation[1]. The legal basis for the Delegated Regulation is Article 63(1) of regulation (EU) No 536/2014 of the European Parliament and of the Council[2].

2. The Working Party on Pharmaceuticals and Medical devices considered through an informal written procedure[3] that there are no grounds for the Council to object to the Commission Delegated Regulation.

1 Doc. 10015/17.
2 OJ L 158, 27.5.2014, p. 1.
3 WK 6309/2017 INIT.

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 to the Commission Delegated Regulation.

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