Council of the European Union

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	9047/17 PHARM 20 SAN 190 MI 398 COMPET 325 + ADD 1
Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use *- Decision no to oppose adoption*

1. On 8 May 2017, the Commission in accordance with the Regulatory Procedure with Scrutiny[1] submitted the draft Directive[2] to the European Parliament and the Council. The legal basis for the draft Directive is the first paragraph of Article 47 of Directive (EC) 2001/83/EC of the European Parliament and of the Council[3].

2. The Working Party on Pharmaceuticals and Medical devices considered through an informal written procedure[4] that there are no grounds for the Council to oppose the adoption of the draft Commission Directive.

[1] Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23), as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
[2] Doc. 9047/17.
[3] OJ L 311, 28.11.2001, p. 67.
[4] WK 5105/2017 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 opposing the adoption of the draft Commission Directive.