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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	6211/18 PHARM 8 SAN 59 MI 90 COMPET 73
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 847/2000 as regards the definition of the concept 'similar medicinal product' - <i>Decision not to oppose adoption</i>

1. On 13 February 2018, the Commission submitted for scrutiny by the European Parliament and by the Council the above draft Regulation, on the basis of Article 8(4) of Regulation (EC) No 141/2000 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 oppose the adoption of the draft Commission Regulation.
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 draft measures.

¹ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

² WK 1882/2018 INIT and WK 2244/2018 INIT.