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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use **(first reading)** - Adoption of the legislative act

1. On 11 September 2014 the Commission sent the above proposal[1], based on Article 114 and Article 168(4)(c) TFEU, to the Council.

2. On 25 October 2018 the European Parliament adopted its position at first reading on the Commission proposal. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council[2].

3. The European Economic and Social Committee delivered its opinion on 21 January 2015[3].

1 13240/14.
2 13327/18.
3 OJ C 242, 23.7.2015, p. 39.

4. The Committee of the Regions was consulted.

5. The Permanent Representatives Committee is therefore asked to confirm its agreement and to suggest that the Council

   - approve the European Parliament's position, as set out in PE-CONS 44/18, as an "A" item at a forthcoming meeting;

   - order that the statement in the addendum to this note be entered in the minutes of that meeting.

   If the Council approves the European Parliament's position, the legislative act will be adopted.

   After being signed by the President of the European Parliament and the President of the Council, the legislative act will be published in the Official Journal of the European Union.