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'I' ITEM NOTE

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

Subject: Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions **(first reading)**

- Decision to use the written procedure for the adoption of the legislative act
- Decision to derogate from the 8-week period provided for in Article 4 of Protocol 1 on the role of national parliaments in the EU

1. On 2 April 2020 the Commission sent its proposal¹, based on Articles 114 and 168(4) TFEU, to the Council.
2. The European Economic and Social Committee has been consulted and is set to reply shortly.
3. The Committee of the Regions has been consulted and is set to reply shortly.
4. The European Parliament will adopt its position at first reading on the Commission proposal at its plenary on 16-17 April 2020.

¹ 7179/20.

5. Given the urgency entailed by the exceptional circumstances justifying the proposed measures, it will only be possible to adopt the Regulation via the written procedure.
6. In view of the above, the Permanent Representatives Committee is invited to decide, in accordance with the first subparagraph of Article 12(1) of the Council's Rules of Procedure and Article 1 of Council Decision 2020/430, that the Council uses the written procedure:
 - for the adoption of the draft Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions, as set out in document PE- CONS 10/20²; and
 - for the adoption, on the basis of Article 3(3) of the Council Rules of Procedure, of the derogation from the 8 week period provided for in Article 4 of Protocol 1 on the role of national Parliaments in the European Union.

² PE-CONS 10/20 will be available in due time.