



Council of the European Union
General Secretariat

Brussels, 22 April 2020

CM 2063/20

CODEC
PHARM
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COMPET
PROCED

COMMUNICATION

WRITTEN PROCEDURE

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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 [2020/0060
(COD)]

Outcome of the written procedure initiated by CM 2043/20:

- Adoption of the legislative act, and
 - Derogation from the 8-week period provided for in Article 4 of Protocol 1
on the role of national Parliaments in the EU
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Delegations are informed that the written procedure, opened by CM 2043/20 of 20 April 2020 was completed on 22 April 2020 and that all delegations voted in favour of:

1. 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 PE-CONS 10/20;
2. the derogation, on the basis of the second subparagraph of Article 3(3) of the Council's Rules of Procedure, from the eight-week period referred to in the first subparagraph of that Article.

The required qualified majority has been reached. Therefore, the above Regulation is adopted.

The Council agreed to derogate, on the basis of the second subparagraph of Article 3(3) of the Council's Rules of Procedure, from the eight-week period referred to in the first subparagraph of that Article.
