Council of the European Union

Brussels, 3 July 2020
(OR. en)

9277/20

Interinstitutional File: 2020/0128(COD)

CODEC 571
PHARM 27
SAN 224
MI 210
COMPET 299
AGRILEG 74
ENV 391

'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Draft Regulation of the European Parliament and of the Council on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease **(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 June 2020 the Commission sent its proposal[1], based on Articles 114 and 168(4)(c) 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 8-10 July 2020.

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5. Given the urgency entailed by the exceptional circumstances justifying the proposed measures, it will only be possible to adopt the Regulation by written procedure, within a very short deadline, as the act will be signed on 15 July 2020 and published shortly after.

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 (EU) 2020/702[2], that the Council uses the written procedure:

   – for the adoption of the draft Regulation of the European Parliament and of the Council on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease, as set out in document PE- CONS 28/20[3]; and

   – 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.

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[2] Council Decision (EU) 2020/702 of 20 May 2020 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decision (EU) 2020/556 in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 165, 27.5.2020, p. 38–39).

[3] PE-CONS 28/20 will be available in due time.