



Council of the European Union  
General Secretariat

Brussels, 13 July 2020

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## COMMUNICATION

### WRITTEN PROCEDURE

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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 [2020/0128 (COD)]

Initiation of the written procedure:

- Adoption of the legislative act, and
  - Derogation from the 8-week period provided for in Article 4 of Protocol 1 to the TFEU on the role of national parliaments in the EU
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Following the decision of the Permanent Representatives Committee (Part 2) on 8 July 2020 to use the written procedure, please state:

1. whether you agree to 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.

Please answer YES, NO or ABSTENTION.

2. whether you agree 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, in view of the urgency of the matter as set out in the preamble of the legislative act.

Please answer YES, NO or ABSTENTION.

Any unilateral statements should be made at the same time as answering the question.

Replies by e-mail to [codecision.adoption@consilium.europa.eu](mailto:codecision.adoption@consilium.europa.eu) must reach the General Secretariat of the Council as soon as possible and at the latest by **Tuesday, 14 July 2020 at 17.00 (Brussels time)**. Delegations' attention is drawn to the exceptional short duration of this written procedure.