Council of the European Union

Brussels, 1 July 2020
(OR. en)

9131/20

Interinstitutional File:
2020/0128(COD)

PHARM 25
SAN 214
MI 200
COMPET 291
AGRILEG 72
ENV 376
CODEC 553

'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	8944/20 PHARM 21 SAN 207 MI 181 COMPET 280 AGRILEG 69 ENV 365 CODEC 521
Subject:	Proposal for a 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 *- Mandate for negotiations with the European Parliament*

Introduction

1. On 17 June 2020, the Commission submitted its proposal[1] for a Regulation 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 to the Council and to the European Parliament.

2. The aim of the proposal is to speed up the start of clinical trials with medicinal products for human use that contain or consist of GMOs and are intended to treat or prevent COVID-19 and to clarify that such medicinal products can be administered swiftly in the exceptional situations foreseen in Article 5(1) and (2) of Directive 2001/83/EC ("special needs" and "unauthorised products to fight spread of pathogens"), and Article 83 of Regulation (EC) No 726/2004 ("compassionate use").

[1] Document 8944/20.

3. The proposal therefore allows such clinical trials to be started and clarifies that such medicinal products can be administered without a prior environmental risk assessment and/or consent under Directive 2001/18/EC[2] or Directive 2009/41/EC[3].

4 The proposed Regulation will apply as long as there is a valid declaration of pandemic by the World Health Organisation, or if COVID-19 is declared an emergency situation in accordance with Decision No 1082/2013/EU[4] and remains so. The proposed Regulation is limited to clinical trials and those specific situations for administration of medicinal products and an environmental risk assessment for the medicinal products in question will be performed as part of the marketing authorisation procedure.

Preparation of the negotiation mandate

5. The Commission presented the proposal to the members of the Working Party on Pharmaceuticals and Medical devices in an informal videoconference on 25 June. The Working Party continued and completed its examination at its meeting on 1 July. At that meeting all delegations agreed that in view of the urgency to fight the public health emergency created by the COVID-19 pandemic the Permanent Representatives Committee should be invited to recommend to the Council that the Regulation be adopted as proposed by the Commission.

Future steps

6. At its meeting on 3 July, the Permanent Representatives Committee is invited to agree to inform the European Parliament that the Council is ready to adopt the Regulation as proposed by the Commission, but subject to finalisation by the lawyer-linguists of the two Institutions, as its position at first reading. This information will be transmitted to the European Parliament in a letter in which the Chair of the Committee also informs the Parliament about the Council intention to reach an agreement at first reading.

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2 OJ L 106, 17.4.2001, p. 1.
3 OJ L 125, 21.5.2009, p. 75.
4 OJ L 293, 5.11.2013, p. 1.

7. The European Parliament is expected to vote its position at first reading already at its plenary on 8 July.

8. If the European Parliament in that vote adopts the Regulation as proposed by the Commission as its position at first reading, then the Permanent Representatives Committee will be invited to agree to use a written procedure in order for the Council:
   - to approve the draft Regulation as prosed by the Commission, and
   - to agree to derogate from the eight-week period foreseen for scrutiny by the national parliaments[5].

9. It is noted that consultation of the European Economic and Social Committee and the Committee of the Regions is compulsory, as this proposal concerns public health. Both consultations must be finished before the proposed Regulation is adopted. Both Committees have been contacted with the aim of speeding up the consultation.

CONCLUSION

10. The Permanent Representatives Committee is invited to:
   - agree on the text of the proposal for a Regulation 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 proposed by the Commission;
   - authorise the Presidency to send a letter to the Chair of the ENVI Committee confirming that, should the European Parliament, in accordance with Article 294 paragraph 3 of the Treaty, adopt the Regulation as proposed by the Commission (subject to revision by the lawyer-linguists of the Council and the European Parliament) as its position at first reading, the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act would be adopted in a wording which corresponds to the European Parliament's position;
   - authorise the Presidency to request to the European Parliament the use of the urgent procedure.

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[5] The eight week period is provided for in Article 4 of Protocol 1 on the role of national Parliaments in the EU.