Council of the
European Union

Brussels, 15 July 2020
(OR. en)

9668/20

Interinstitutional File:
2020/0128 (COD)

VOTE 44
INF 141
PUBLIC 55
CODEC 638

NOTE

Subject:	– Voting result – 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 = Adoption of the legislative act = Derogation from the 8-week period provided for in Article 4 of Protocol 1 on the role of national Parliaments in the EU = Outcome of the written procedure completed on 14 July 2020

The outcome of voting on the above mentioned legislative act can be found in Annex 1 to this note.

Reference document:

PE-CONS 28/20

date of adoption by Coreper of the decision to use the Written Procedure

08.07.2020

The statements and/or explanations of vote are in Annex 2 to this note.

General Secretariat of the Council

Institution: **Council of the European Union**
Session:
Configuration:
Item: **2020/0128 (COD)** (Document: **28/20**)
Voting Rule: **qualified majority**
Subject: 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 (COVID-19)

Vote	Members		Population (%)
Yes	25		93,75%
No	0		0%
Abstain	2		6,25%
Not participating	0		
Total	27		

Sitting date: **14/07/2020**
Final result

Member State	Weighting	Vote
BELGIQUE/BELGIË	2,56	✓
БЪЛГАРИЯ	1,56	✓
CESKÁ REPUBLIKA	2,35	○
DANMARK	1,30	✓
DEUTSCHLAND	18,54	✓
EESTI	0,30	✓
ÉIRE/IRELAND	1,10	✓
ΕΛΛΑΔΑ	2,40	✓
ESPAÑA	10,49	✓
FRANCE	14,98	✓
HRVATSKA	0,91	✓
ITALIA	13,65	✓
ΚΥΠΡΟΣ	0,20	✓
LATVIJA	0,43	✓
LIETUVA	0,62	✓
LUXEMBOURG	0,14	✓
MAGYARORSZÁG	2,18	✓
MALTA	0,11	✓
NEDERLAND	3,89	○
ÖSTERREICH	1,98	✓
POLSKA	8,49	✓
PORTUGAL	2,30	✓
ROMÂNIA	4,34	✓
SLOVENIJA	0,47	✓
SLOVENSKO	1,22	✓
SUOMI/FINLAND	1,23	✓
SVERIGE	2,29	✓

** When acting on a proposal from the Commission or the High Representative, qualified majority is reached if at least 55 % of members vote in favour (15 MS) accounting for at least 65% of the population*
For information: http://www.consilium.europa.eu/public-vote

ANNEX 2

Statement by the Netherlands

The Netherlands feels a strong sense of urgency to speed up the development of a vaccine or treatment against COVID-19. Facilitating this process as much as possible is a key priority for the Netherlands. This is exactly why Germany, France, Italy and the Netherlands established the Inclusive Vaccine Alliance and welcomed the EU Vaccine Strategy. The Netherlands appreciates the Commission proposal[1] for accelerating existing procedures for clinical trials with GMOs to facilitate quicker development of a vaccine or a cure for COVID-19.

However, the Netherlands' Commission on Genetic Modification[2] points out serious concerns with the proposal as it allows a derogation of the requirements for an environmental risk assessment (ERA) for clinical trials with GMOs, including clinical trials with unknown GMOs and unknown risks. In addition, the lack of an ERA brings forth questions on liability and responsibility, if an incident with negative effects would occur.

Although the Netherlands supports faster, more harmonised procedures in the EU regarding clinical trials involving GMOs, the Netherlands shares the concerns of its Commission on Genetic Modification with regard to ensuring safety for human health and the environment. An approach that simplifies and shortens the procedures for an ERA would be preferred above a generic derogation. However, amending this proposal in such a manner would significantly delay its adoption. In light of the current, unprecedented pandemic and the urgent need for a vaccine or medicine, such a delay can currently not be afforded.

The Netherlands urges sponsors of clinical trials, Member States and the European Commission to take full responsibility to seriously consider and prevent all possible negative impacts of GMOs for human health or the environment, when performing clinical trials with GMOs or administering medicinal products before a market authorisation is granted.

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[1] COM(2020) 261

[2] The Netherlands Commission on Genetic Modification (COGEM) is an independent scientific advisory body that provides advice to the government on the risks to human health and the environment of the production and use of GMOs, and informs the government of ethical and societal issues linked to genetic modification.

If unforeseen negative impacts occur, the Netherlands urges all those involved to take all appropriate measures to prevent further escalation and immediately notify national authorities and the European Commission, so that coordinated efforts can be made to minimize newly identified risks.

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