

**Amendment 4****Bas Eickhout**

on behalf of the Verts/ALE Group

**Kateřina Koneřn**

on behalf of the GUE/NGL Group

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–**C9-0185/2020**

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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

**Proposal for a regulation****Recital 26 a (new)***Text proposed by the Commission**Amendment*

***(26a) Given the importance of ensuring the quality, safety and efficacy of any medicinal product for human use intended to treat or prevent COVID-19 containing or consisting of GMOs, the clinical study report that accompanies the application for marketing authorisation should be made publicly available as soon as an application for authorisation has been submitted,***

Or. en

*Justification*

*Member States in cooperation with the Commission should draw the lessons from the Tamiflu fiasco and ensure the highest standards of transparency prior to COVID-19 vaccines and medicines being put on the market, in order to ensure Member States invest in safe and efficient products. Therefore, Member States should register all clinical trials on COVID-19 vaccines in an official public register prior to being started and the clinical trial data should be made public shortly after trial conclusion, including for phase I trials.*

**Amendment 5****Bas Eickhout**

on behalf of the Verts/ALE Group

**Kate ina Kone ná**

on behalf of the GUE/NGL Group

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—**C9-0185/2020**

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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

**Proposal for a regulation****Article 4 a (new)**

Directive 2001/20/EC

Article 11

*Text proposed by the Commission**Amendment***Article 4 a**

**Article 11 of Directive 2001/20/EC is amended as follows:**

**(1) in paragraph 1, the following point is added:**

**‘(fa) clinical study report as defined in point (35) of Article 2 of Regulation (EU) No 536/2014.’;**

**(2) the following paragraph is added:**

**‘4a. By way of derogation from paragraph 1, the Agency shall make public the clinical study report of a medicinal product for human use intended to treat or prevent COVID-19 containing or consisting of GMOs on the day following the reception of the application for authorisation under Regulation (EU) 726/2004<sup>1a</sup>.**

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<sup>1a</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a

*Justification*

*Member States in cooperation with the Commission should draw the lessons from the Tamiflu fiasco and ensure the highest standards of transparency prior to COVID-19 vaccines and medicines being put on the market, in order to ensure Member States invest in safe and efficient products. Therefore, Member States should register all clinical trials on COVID-19 vaccines in an official public register prior to being started and the clinical trial data should be made public shortly after trial conclusion, including for phase I trials.*

**Amendment 6****Bas Eickhout**

on behalf of the Verts/ALE Group

**Kate ina Kone ná**

on behalf of the GUE/NGL Group

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—**C9-0185/2020**

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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

**Proposal for a regulation****Article 4 b (new)**

Regulation (EU) No 536/2014

Articles 37 and 81

*Text proposed by the Commission**Amendment***Article 4 b**

***Regulation (EU) No 536/2014 is amended as follows:***

***(1) in Article 37(4), the following subparagraph is added:***

***‘In addition to the summary of the results, where the clinical trial was intended to be used for obtaining a marketing authorisation for a medicinal product for human use intended to treat or prevent COVID-19 containing or consisting of GMOs, the applicant for marketing authorisation shall submit to the EU database the clinical study report at the same time as submitting the application for authorisation.’;***

***(2) in Article 81, the following paragraph is inserted:***

***‘5a. Without prejudice to paragraph 4, the clinical study report contained in the application dossier for a marketing authorisation for a medicinal product for human use intended to treat or prevent COVID-19 containing or consisting of GMOs shall be publicly accessible on the day following the reception of the***

*application.*'.

Or. enJustification

*Member States in cooperation with the Commission should draw the lessons from the Tamiflu fiasco and ensure the highest standards of transparency prior to COVID-19 vaccines and medicines being put on the market, in order to ensure Member States invest in safe and efficient products. Therefore, Member States should register all clinical trials on COVID-19 vaccines in an official public register prior to being started and the clinical trial data should be made public shortly after trial conclusion, including for phase I trials.*