



Council of the  
European Union

Brussels, 16 October 2018  
(OR. en)

13176/18

---

---

**Interinstitutional File:  
2017/0328 (COD)**

---

---

**ECO 86  
AGRILEG 156  
SAN 320  
CODEC 1679  
PREP-BXT 34**

**NOTE**

---

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 2)
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending the Regulation (EC) 726/2004 as regards the location of the seat of the European Medicines Agency (First reading) - Confirmation of the final compromise text with the view to agreement

---

Delegations will find attached the consolidated version of the above-mentioned proposal as outcome of the negotiations between the Council and the European Parliament.<sup>1</sup>

---

<sup>1</sup> NB. The numbering of the recitals reflects the numbers of the accepted EP amendments.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Regulation (EC) No 726/2004 as regards the location of the seat of the European  
Medicines Agency**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114  
and article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the ordinary legislative procedure,

---

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

Whereas:

- (1) In the context of the United Kingdom's notification on 29 March 2017 of its intention to leave the Union, pursuant to Article 50 of the Treaty on European Union, the other 27 Member States, meeting in the margins of the General Affairs Council ('Article 50'), selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency.
- (2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines Agency ("**the Agency**") should take its new seat ~~as from the date on which the Treaties cease to apply to the United Kingdom or~~ from 30 March 2019, ~~whichever is the earlier.~~
- (3) To ensure the proper functioning of the European Medicines Agency in its new location, a headquarters agreement should be concluded before the European Medicines Agency takes up its new seat.
- (3b) It is to be welcomed that the Dutch authorities are making efforts to ensure the operational effectiveness, continuity and uninterrupted functioning of the Agency during and after the relocation. Nevertheless, given the extraordinary situation, the Agency may have to temporarily focus on its core tasks and prioritise other activities according to their impact on public health and the Agency's ability to function.**
- (3c) The Commission should monitor the overall relocation process of the Agency to its new seat and assist that process within the limits of its competences.**
- (4) To give the European Medicines Agency sufficient time to relocate, this Regulation should enter into force as a matter of urgency.
- (5) Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>4</sup> should therefore be amended accordingly,

---

<sup>4</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 European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

HAVE ADOPTED THIS REGULATION:

*Article 1*

In Regulation (EC) No 726/2004, the following Article 71a is inserted:

*“Article 71a*

*The Agency shall have its seat in Amsterdam, the Netherlands.”*

**The competent authorities of the Netherlands shall take all necessary measures to ensure that the Agency can move to its temporary location no later than 1 January 2019 and that it can move to its permanent location no later than 16 November 2019.**

**The competent authorities of the Netherlands shall submit a written report to the European Parliament and the Council on the progress on the adjustments of the temporary premises and on the construction of the permanent building three months after the entry into force of this Regulation, and every three months thereafter, until the Agency has moved into its permanent headquarters.”**

*Article 2*

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall apply from ~~the date on which the Treaties cease to apply to the United Kingdom or from 30 March 2019, whichever is the earlier.~~

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*