



Council of the
European Union

015613/EU XXVI. GP
Eingelangt am 21/03/18

Brussels, 21 March 2018
(OR. en)

7098/18

Interinstitutional File:
2017/0328 (COD)

CODEC 377
ECO 26
AGRILEG 41
SAN 84
PE 36

INFORMATION NOTE

| | |
|----------|---|
| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee/Council |
| Subject: | 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. - Outcome of the European Parliament's proceedings (Strasbourg, 12 to 15 March 2018) |

I. INTRODUCTION

The rapporteur, Mr Giovanni LA VIA (EPP, IT), presented a report consisting of 8 amendments (amendments 1-8) to the proposal for a Regulation, on behalf of the Committee on the Environment, Public Health and Food Safety.

In addition, three amendments (amendments 9-11) were tabled by more than 38 MEPs and three amendments (amendments 12-14) by the EFDD group. One amendment (amendment 15) was tabled jointly by the EPP, S&D, ALDE, GUE/NGL, Greens/EFA and EFDD.

II. DEBATE

Before the vote, rapporteur Giovanni LA VIA (EPP , IT) said that the Parliament could not be called to just rubberstamp decisions taken on the sidelines of ministerial meetings without any binding legal basis. He invited MEPs from all political groups to recall Parliament's prerogatives and called for a meeting with the Council in connection with the "failure to respect the Ordinary Legislative Procedure".

III. VOTE

When it voted on 15 March 2018 , the Parliament adopted the following amendments: 1-8 and 15.

The amendments adopted are set out in the annex.

At the end of the vote, the proposal was referred back to the Committee, pursuant to Rule 59(4)(4) of the European Parliament's Rules of Procedure, thereby not bringing the Parliament's first reading to a close and opening the negotiations with the Council.

Location of the seat of the European Medicines Agency ***I

Amendments adopted by the European Parliament on 15 March 2018 on the 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 (COM(2017)0735 – C8-0421/2017 – 2017/0328(COD))¹

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines 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.*

Amendment

(2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines Agency ("*the Agency*") should take its new seat from 30 March 2019.

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

(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.*

Amendment

(3) To ensure the proper functioning of the Agency in its new location, a headquarters agreement should be concluded *as soon as possible. The headquarters agreement should include the most appropriate terms and conditions for the successful relocation of the*

¹ The matter was referred back for interinstitutional negotiations to the committee responsible pursuant to Rule 59(4), fourth subparagraph (A8-0063/2018).

Agency and its staff members to Amsterdam.

Amendment 3

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) In order to ensure the Agency's full business continuity, the temporary location in Amsterdam should be provided as of 1 January 2019 and the permanent headquarters of the Agency should be completed by 15 November 2019.

Amendment 4

Proposal for a regulation Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) It is to be welcomed that the new location of the Agency is in line with the preferences of its current staff members and that the Dutch authorities are making efforts to ensure that the double transfer will not jeopardise the operational effectiveness, continuity and uninterrupted functioning of the Agency. However, the double relocation of the Agency to Amsterdam means that the Agency will have to temporarily de-prioritise certain activities, such as its work on paediatric medicines and public health issues including its work on anti-

microbial resistance and flu pandemics, while it resides in the temporary location. The delays that the Dutch government has already announced, which have pushed back the handover of the permanent building, on which construction work has not yet started, raise concerns about potential further delays. The relocation to the temporary building should be limited to 10,5 months to ensure that the Agency will be able to operate again at its full capacity as of 16 November 2019 and avoid further loss of expertise.

Amendment 5

Proposal for a regulation

Article 1 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

In Regulation (EC) No 726/2004, the following Article 71a **and Article 71b are** inserted:

Amendment 6

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004

Article 71a

Text proposed by the Commission

Article 71a

The Agency shall have its seat in

Amendment

Article 71a

The Agency shall have its seat in

Amsterdam, the Netherlands.

Amsterdam, the Netherlands.

The Commission and 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 Commission and 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.

Amendment 7

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004

Article 71 b (new)

Text proposed by the Commission

Amendment

Article 71b

A headquarters agreement allowing the Agency to take up its duties at the premises approved by the European Parliament and the Council shall be concluded within three months from ... [date of entry into force of this Regulation].

Amendment 8

Proposal for a regulation

Article 2 – paragraph 2

Text proposed by the Commission

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.***

Amendment

This Regulation shall apply from 30 March 2019.

Amendment 15

**Proposal for a regulation
Statement (new)**

Text proposed by the Commission

Amendment

***‘ATTACHMENT TO REGULATION
2018/...***

***STATEMENT OF THE EUROPEAN
PARLIAMENT***

The European Parliament regrets that its role of co-legislator has not been duly taken into account since it was not involved in the procedure leading to the selection of the new seat of the European Medicines Agency.

The European Parliament wishes to recall its prerogatives as co-legislator and insists on the full respect of the ordinary legislative procedure in relation to the location of bodies and agencies.

As the only directly elected Union institution and representative of the Union’s citizens, it is the first guarantor of the respect of the democratic principle in the Union.

The European Parliament condemns the procedure followed for the selection of the new location of the seat, which has de facto deprived the European Parliament

of its prerogatives since it was not effectively involved in the process, but is now expected to simply confirm the selection made for the new location of the seat by means of the ordinary legislative procedure.

The European Parliament recalls that the Common Approach annexed to the Joint Statement of the European Parliament, Council and European Commission on decentralised agencies signed in 2012 is legally non-binding, as acknowledged in the Statement itself and that it was agreed without prejudice to the legislative powers of the institutions.

Therefore, the European Parliament insists that the procedure followed for the selection of a new location for the agencies will be revised and not used anymore in this form in the future.

Finally, the European Parliament wishes to recall as well that in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making¹ the three institutions committed to sincere and transparent cooperation while recalling the equality of both co-legislators as enshrined in the Treaties.

¹ OJ L 123, 12.5.2016, p. 1.'