



Brussels, 30 October 2018
(OR. en)

13316/18

Interinstitutional File:
2017/0328(COD)

CODEC 1723
ECO 88
AGRILEG 159
SAN 334
PREP-BXT 39
PE 133

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 first reading
(Strasbourg, 22 to 25 October 2018)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure ¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

¹ OJ C 145, 30.6.2007, p.5

In this context, the rapporteur, Giovanni LA VIA (EPP, IT), presented two amendments (amendment 16 and amendment 17) to the proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety. These amendments had been agreed during the informal contacts referred to above.

II. VOTE

When it voted on 25 October 2018, the plenary adopted two amendments (amendment 16 and amendment 17) to the proposal for a Regulation. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto².

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

² The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

Relocation of the European Medicines Agency ***I

European Parliament legislative resolution of 25 October 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2017)0735),
 - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0421/2017),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the provisional agreement approved by the committee responsible under Rule 69f(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 17 October 2018 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Constitutional Affairs (A8-0063/2018),
1. Adopts its position at first reading hereinafter set out³;
 2. Denounces the Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies of 19 July 2012 and the Common Approach annexed to it and calls for close involvement of the European Parliament in the decision-making process on the location and relocation of agencies and bodies in view of its prerogatives as co-legislator under the ordinary legislative procedure;
 3. Approves its statement annexed to this resolution;
 4. Takes note of the statement by the Council annexed to this resolution;
 5. Regrets that the European Parliament - and ultimately the representatives of the Union's citizens - were not fully involved in the procedure to select the new seat of the European

³ This position replaces the amendments adopted on 15 March 2018 (Texts adopted, P8_TA(2018)0086).

Medicines Agency (EMA), which was eventually concluded by drawing lots, despite it being such an important decision; decisions in relation to the location of bodies and agencies need, and legally must, be taken under the ordinary legislative procedure, fully respecting the European Parliament's prerogatives, whereby the European Parliament and the Council are equal co-legislators;

6. Regrets the decision of the Council which leads to a deepening of the geographical disproportionality with only 9 out of 37 EU decentralised agencies being located in new Member States contrary to the European Council Conclusions 5381/04 and 11018/1/08 which both give priority to new Member States.
7. Calls on the budgetary authorities and the Commission to ensure that the costs relating to the change in the seat of EMA will be fully covered by the current host country; points out that some of the costs of the relocation from the current location will have to be pre-financed by the Union budget, prior to the financial settlement with the current host country;
8. Calls on the budgetary authorities and the Commission to ensure that the additional costs relating to the double transfer of the seat of EMA, first to a temporary location, and then to the Vivaldi Building, will be fully covered by the Dutch government and thus will not adversely affect the general budget of the Union;
9. Calls on the budgetary authorities and the Commission to ensure that the double transfer will not jeopardise the normal operational needs of EMA, and will guarantee business continuity and EMA's smooth functioning, without disruption, beyond March 2019;
10. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
11. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Position of the European Parliament adopted at first reading on 25 October 2018 with a view to the adoption of Regulation (EU) 2018/... 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 point (c) of Article 168(4) 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 Committee⁴,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure⁵,

Whereas:

⁴ OJ C 197, 8.6.2018, p. 71.

⁵ Position of the European Parliament of 25 October 2018.

- (1) In the context of the United Kingdom's notification on 29 March 2017 of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union (“TEU”), the other 27 Member States, meeting on 20 November 2017 in the margins of the Council, selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency (“*the Agency*”).
- (2) Having regard to Article 50(3) TEU, the █ Agency should take its new seat as of █ 30 March 2019 █ .
- (3) To ensure the proper functioning of the Agency in its new location, a headquarters agreement should be concluded between the Agency and the Netherlands before the Agency takes up its new seat.

- (4) *It is to be welcomed that the authorities of the Netherlands 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.*
- (5) *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.*
- (6) To give the Agency sufficient time to relocate, this Regulation should enter into force as a matter of urgency.
- (7) Regulation (EC) No 726/2004 of the European Parliament and of the Council⁶ should therefore be amended accordingly,

⁶ 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

The following Article is inserted in Regulation (EC) No 726/2004:

“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 is able to move to its temporary location no later than 1 January 2019 and that it is able to 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 adaptations to the temporary premises and on the construction of the permanent building by ... [three months after the entry into force of this amending Regulation], and every three months thereafter, until the Agency has moved to its permanent location.”.

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 30 March 2019 **■** .

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

Done at ...,

For the European Parliament

For the Council

The President

The President

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 on Better Law-Making of 13 April 2016⁷ the three institutions committed to sincere and transparent cooperation while recalling the equality of both co-legislators as enshrined in the Treaties.

⁷ OJ L 123, 12.5.2016, p. 1.

Council statement EBA/EMA

Recalling the commitment of the European Parliament, the Council and the Commission to sincere and transparent cooperation, and in the light of the process followed for the relocation of the EMA and EBA, which was specific to the situation and did not constitute a precedent for location of agencies in the future,

While recalling the Treaties, the Council acknowledges the value of enhanced exchange of information from the initial stages of future processes for the location of agencies.

Such early exchange of information would make it easier for the three Institutions to exercise their rights according to the Treaties through the related procedures.

The Council takes note of the request by the EP to revise, as soon as possible, the 2012 Joint Statement and Common Approach on decentralised Agencies. As a first step, it invites the Commission to provide, by April 2019, an in-depth analysis of the implementation of the Joint Statement and Common Approach as regards the location of decentralised Agencies. This analysis would serve as a basis to assess the way forward in engaging with the process of such a revision.