



Council of the European Union
General Secretariat
Task Force on the UK

SGS18/08192

Brussels, 17 October 2018

Mrs. Adina-Ioana VĂLEAN

Chairman, European Parliament Committee on Environment, Public Health and Food Safety
STRASBOURG.

Subject: Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 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 - 2017/0328 (COD)

Dear **Mrs. VĂLEAN**

Following the informal meeting between the representatives of the three institutions, a draft overall compromise package was agreed today by the Permanent Representatives' Committee.

I am therefore now in a position to confirm that, should the European Parliament adopt its position at first reading, in accordance with Article 294 paragraph 3 of the Treaty, in the form set out in the compromise package contained in the Annex to this letter, the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position, subject, if necessary, to revision by the legal linguists of both institutions.

On behalf of the Council I also wish to thank you for your close cooperation which should enable us to reach agreement on this dossier at first reading.

Yours sincerely,

Nikolaus Marschik

Chairman of the Permanent Representatives
Committee (Part 2)

copy to:

Jean-Claude Juncker, President, European Commission
Jyrki Katainen, Vice-President, European Commission
Vytienis Andriukaitis, Commissioner
Giovanni La Via, EP Rapporteur

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² 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 Council³ should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

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

³ 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).

“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

Draft 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 European Parliament 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."
