

**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**

COMMISSION PROPOSAL COM(2017)0735	EP AMENDMENTS (as adopted 15 March 2018)	COUNCIL	COMMENTS / SUGGESTIONS
RECITALS			
(2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines Agency should take its new seat <i>as from the date on which the Treaties cease to apply to the United Kingdom or</i> from 30 March 2019, <i>whichever is the earlier.</i>	AM 1 (2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines Agency (" <i>the Agency</i> ") should take its new seat from 30 March 2019.	Could accept the Commission proposal as is.	<i>Agreed</i> (2) Having regard to Article 50(3) of the Treaty on European Union, the European Medicines Agency (" <i>the Agency</i> ") should take its new seat from 30 March 2019.
(3) To ensure the proper functioning of the <i>European Medicines</i> Agency in its new location, a headquarters agreement should be concluded <i>before</i> the <i>European Medicines</i> Agency <i>takes up its new seat.</i>	AM 2 (3) To ensure the proper functioning of the Agency in its new location, a headquarters agreement should be concluded <i>as soon as possible. The headquarters agreement should include the most appropriate terms and conditions for the successful relocation of the Agency and its staff members to Amsterdam.</i>	Could accept the Commission proposal as is.	<i>EP drops this AM</i>

	<p>AM 3 <i>(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.</i></p>		
	<p>AM 4 <i>(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</i></p>		<p><i>Commission proposal:</i> <i>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 during and after the relocation. Nevertheless, given the extraordinary situation, However, the double relocation of the Agency to Amsterdam means that the Agency will 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. and taking into account 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</i></p>

	<i>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.</i>		<i>it resides in the temporary location.</i>
<i>Article 1 – paragraph 1 – introductory part</i>			
In Regulation (EC) No 726/2004, the following Article 71a is inserted:	AM 5 In Regulation (EC) No 726/2004, the following Article 71a and Article 71b are inserted:	Could accept the Commission proposal as is.	<i>EP drops this AM</i>
<i>Article 1 – paragraph 1 Regulation (EC) No 726/2004 – Article 71a</i>			
Article 71a The Agency shall have its seat in Amsterdam, the Netherlands.	AM 6 Article 71a The Agency shall have its seat in Amsterdam, the Netherlands. <i>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.</i>	Could accept the Commission proposal as is. Preliminary comments on the amendment: The provisions put forward by the amendment are of a temporary effect which will expire with the completion of the relocation process. No issue of substance but the amendment should be made to the amending regulation, not to the amended one (726/2004).	<i>Commission proposal:</i> <i>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.</i> <i>The Commission—and—the competent authorities of the Netherlands shall submit a</i>

	<p><i>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.</i></p>		<p><i>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.</i></p> <p>New recital: <i>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.</i></p>
<p><i>Article 1 – paragraph 1 Regulation (EC) No 726/2004 - Article 71b (new)</i></p>			
	<p>AM 7 Article 71b</p> <p><i>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].</i></p>	<p>Preliminary comments on the amendment:</p> <p>While it is useful to set a deadline for the signature of the headquarter agreement as indeed noted in recital 3 of the Commission proposal, neither this agreement nor the premises (building) of EMA can be subject to the approval of the Council or the Parliament. Clarification of the drafting and intention of the</p>	<p><i>EP drops this AM</i></p>

		amendment is therefore needed.	
<i>Article 2 – paragraph 2</i>			
This Regulation shall apply from <i>the date on which the Treaties cease to apply to the United Kingdom or from 30 March 2019, whichever is the earlier.</i>	AM 8 This Regulation shall apply from 30 March 2019.	Could accept the Commission proposal as is	<i>Agreed</i> This Regulation shall apply from 30 March 2019.

*Proposal for a regulation
Statement (new)*

AM 15

***‘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

Council's preliminary comments:
This is a unilateral statement which should therefore not be published as an integral part to the legislative act. Besides, the statement refers to procedures that concern future selection processes, which are out of the scope of the current Regulation.

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-Making ¹ 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.*