



2017/0328(COD)

31.1.2018

AMENDMENTS

1 - 51

Draft report

Giovanni La Via

Location of the seat of the European Medicines Agency

Proposal for a regulation

(COM(2017)0735 – C8-0421/2017 – 2017/0328(COD))

Amendment 1
Luke Ming Flanagan

Draft legislative resolution
Citation 5 a (new)

Draft legislative resolution

Amendment

- *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, provided the new premises are fit and ready for purpose; if not, and to avoid unnecessary further disruption for those involved, allowances should be made for those services of the European Medicines Agency for which offices have not been fully readied to remain based in London until the new premises are ready.*

Or. en

Amendment 2
Piernicola Pedicini, Eleonora Evi, Marco Valli

Draft legislative resolution
Citation 5 a (new)

Draft legislative resolution

Amendment

- *whereas decisions regarding the establishment of decentralised EU agencies cannot taken on a random basis but only and exclusively by a democratic process based on measurable criteria of merit;*

Or. it

Amendment 3
Elisabetta Gardini

Draft legislative resolution
Paragraph 1

Draft legislative resolution

1. ***Adopts its position at first reading, taking over*** the Commission proposal;

Amendment

1. ***Rejects*** the Commission proposal;

Or. it

Amendment 4
Simona Bonafè, Patrizia Toia

Draft legislative resolution
Paragraph 1

Draft legislative resolution

1. ***Adopts its position at first reading, taking over*** the Commission proposal;

Amendment

1. ***Rejects*** the Commission proposal;

Or. it

Justification

The EP was in no way involved in the procedure for selecting the new seat of the EMA, thereby detracting from its role under the Treaties. A Joint Statement issued without the approval of the majority in plenary sitting cannot be allowed to deprive it of its role as co-legislator. MEPs were not informed about the selection criteria, making it impossible to assess objectively whether they have been properly weighed up and not invalidated by incomplete information, thereby detracting from the full effectiveness of the Agency and endangering the health of citizens.

Amendment 5
Piernicola Pedicini, Eleonora Evi, Marco Valli

Draft legislative resolution
Paragraph 1

Draft legislative resolution

1. Adopts its position at first reading, ***taking over*** the Commission proposal;

Amendment

1. Adopts its position at first reading, ***amending*** the Commission proposal, ***which makes choices of decisive importance for the health of European citizens on the basis of nothing more than random criteria that are equivalent to the***

toss of a coin;

Or. it

Amendment 6
Annie Schreijer-Pierik

Draft legislative resolution
Paragraph 1 a (new)

Draft legislative resolution

Amendment

1a. Reiterates that this Regulation will apply from the date on which the Treaties cease to apply to the United Kingdom or from 30 March 2019, whichever is the earlier.

Or. nl

Amendment 7
Annie Schreijer-Pierik

Draft legislative resolution
Paragraph 2

Draft legislative resolution

Amendment

2. 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 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 should, 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;

deleted

Or. nl

Amendment 8
Frédérique Ries

Draft legislative resolution
Paragraph 2

Draft legislative resolution

2. 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 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 *should*, 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;

Amendment

2. 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 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;

Or. en

Amendment 9
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft legislative resolution
Paragraph 2

Draft legislative resolution

2. ***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 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 should, be taken under the ordinary legislative procedure, fully respecting the European Parliament's prerogatives,

Amendment

2. ***Deplores the fact that*** the procedure to select the new seat of the European Medicines Agency (EMA) ***was left to chance, the*** drawing of lots, despite it being such an important decision; decisions in relation to the location of bodies and agencies need, and legally should, 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;

whereby the European Parliament and the Council are equal co-legislators;

Or. fr

Amendment 10

Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Draft legislative resolution

Paragraph 2

Draft legislative resolution

2. **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 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 should, 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;

Amendment

2. **Deplores the fact that the conclusion** of the procedure to select the new seat of the European Medicines Agency (EMA) **was left to chance through the** drawing **of** lots, despite it being such an important decision; decisions in relation to the location of bodies and agencies need, and legally should, 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;

Or. it

Amendment 11

Mireille D'Ornano

Draft legislative resolution

Paragraph 2

Draft legislative resolution

2. 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 Medicines Agency (EMA), which was eventually concluded by drawing lots, despite it being such an important decision;

Amendment

2. 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 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 should, 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;

a method that disregards democratic rules and is ill-advised, given the respective qualities of each application; decisions in relation to the location of bodies and agencies need, and legally should, 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;

Or. fr

Amendment 12
Catherine Bearder

Draft legislative resolution
Paragraph 2 a (new)

Draft legislative resolution

Amendment

2 a. Notes that while expertise will be developed over time, the loss of the UK's national competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA), to the joint pool of expertise available under the EMA could be detrimental to the scientific approval of medicines for the EU market in the interim. In 2016, the MHRA led 20 per cent of scientific evaluations of new medicines for the EMA.^{1b}

^{1b} <http://www.nhsconfed.org/regions-and-eu/nhs-european-office/brexit/brexit-health-alliance/access-to-medicines-and-medical-technologies>

Or. en

Amendment 13
Nicola Caputo, Simona Bonafè

Draft legislative resolution
Paragraph 2 a (new)

Draft legislative resolution

Amendment

2a. *Regrets that the procedure for the selection of the new EMA headquarters was concluded by drawing lots, despite the importance of this decision; considers that a decision of such vital importance for Europe cannot be left to chance and that the European Parliament, as co-legislator, must be involved in the selection of the new EMA headquarters;*

Or. it

Amendment 14
Annie Schreijer-Pierik

Draft legislative resolution
Paragraph 2 a (new)

Draft legislative resolution

Amendment

2a. *Welcomes the fact that the new location of the EMA is in line with the preferences of its current staff members,^{1a} thereby minimising the loss to the agency of valuable experience, knowledge and expertise;*

Or. nl

Amendment 15
Miroslav Mikolášik, József Nagy, Biljana Borzan, Kateřina Konečná, Daciana Octavia Sârbu, Andrzej Grzyb

Draft legislative resolution
Paragraph 2 a (new)

Draft legislative resolution

Amendment

2 a. *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.

Or. en

Amendment 16
Nicola Caputo, Simona Bonafè

Draft legislative resolution
Paragraph 2 b (new)

Draft legislative resolution

Amendment

2b. *Considers that the details of the two-stage transfer process, entailing operational restrictions during the transition period, were unclear and lacking transparency and that such obfuscation adversely affected the position of the other Member States during consideration of their applications and the procedure for selecting the new EMA headquarters;*

Or. it

Amendment 17
Catherine Bearder

Draft legislative resolution
Paragraph 2 b (new)

Draft legislative resolution

Amendment

2 b. *Regrets that the relocation of the EMA to Amsterdam has meant that the agency has had to temporarily de-prioritise certain activities, such as its work on paediatric medicines and public health issues. This includes its work on anti-microbial resistance and flu pandemics.^{1a}*

1a

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/10/WC500236

Amendment 18
Luke Ming Flanagan

Draft legislative resolution
Paragraph 3

Draft legislative resolution

3. ***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;***

Amendment

3. ***Regardless of the negotiating directives of the Council of 22 May 2017 for the negotiation of an agreement with the United Kingdom setting out the arrangements for its withdrawal from the European Union, which states the the United Kingdom should fully cover the specific costs related to the withdrawal process; given that the United Kingdom withdrawal is partially the result of the European Union's own refusal to listen to reasoned and reasonable argument against the direction in which it is headed, towards a full federal USA-style union, arguments now likewise being heard from various other Member States across the European Union, and likewise being ignored, and in line with the Joint report on the Brexit withdrawal negotiation approved on December 08th, where paragraph 86 reads as follows: “The Commission welcomes the United Kingdom Government's offer to discuss with Union Agencies located in London how they might facilitate their relocation, in particular as regards reducing the withdrawal costs”, the cost of this relocation should be shared between the United Kingdom and the European Union, proportionate to Gross National Product.***

Amendment 19

Biljana Borzan

Draft legislative resolution

Paragraph 3

Draft legislative resolution

3. 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;

Amendment

3. 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 may have to be pre-financed by the EU budget, prior to the financial settlement with the current host country;***

Or. en

Amendment 20

Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Draft legislative resolution

Paragraph 3

Draft legislative resolution

3. 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;***

Amendment

3. 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 ***general budget of the Union;***

Or. it

Amendment 21

Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft legislative resolution

Paragraph 3

Draft legislative resolution

3. 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***

Amendment

3. 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 ***Union***

host country;

budget;

Or. fr

Amendment 22
Mireille D'Ornano

Draft legislative resolution
Paragraph 3

Draft legislative resolution

3. ***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;

Amendment

3. ***Urges*** 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;

Or. fr

Amendment 23
Rory Palmer

Draft legislative resolution
Paragraph 3

Draft legislative resolution

3. 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;

Amendment

3. Calls on the budgetary authorities and the Commission to ensure that the costs relating to the change in the seat of ***the*** EMA will be fully covered by the current host country;

Or. en

Amendment 24
Rory Palmer

Draft legislative resolution
Paragraph 3 a (new)

Draft legislative resolution

3 a. Calls upon the UK Government to

Amendment

work with both the Commission and the EMA to ensure all measures are taken to make the transition as smooth as possible; further calls upon them to ensure adequate support is in place for EMA staff throughout the relocation;

Or. en

Amendment 25

Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft legislative resolution

Paragraph 4

Draft legislative resolution

4. 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;

Amendment

4. Calls on the budgetary authorities and the Commission to ensure that ***any unexpected*** costs relating to the transfer of the seat of EMA will not adversely affect the general budget of the Union;

Or. fr

Amendment 26

Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Draft legislative resolution

Paragraph 4

Draft legislative resolution

4. 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;

Amendment

4. Calls on the budgetary authorities and the Commission to ensure that ***any unexpected*** additional costs relating to the transfer of the seat of EMA will not adversely affect the general budget of the Union;

Amendment 27
Mireille D'Ornano

Draft legislative resolution
Paragraph 4

Draft legislative resolution

4. ***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;

Amendment

4. ***Urges*** 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, ***which is already high, and the contributions to which weigh heavily on Member States' finances, particularly those of the net contributors;***

Or. fr

Amendment 28
Frédérique Ries

Draft legislative resolution
Paragraph 4 a (new)

Draft legislative resolution

4a. Is alarmed by the serious delays that the Dutch Government has already announced, which have pushed back the handover of the Vivaldi building, construction work on which has not yet started, by more than seven months; is concerned about the consequences that the delays will have for the EMA's work, and the resulting need to prioritise some activities over others and repeated changes to its moving schedule to take account of the delays;

Amendment

Or. fr

Amendment 29
Annie Schreijer-Pierik

Draft legislative resolution
Paragraph 4 a (new)

Draft legislative resolution

Amendment

4a. Welcomes the saving to the general budget of the Union resulting from the undertaking by the Dutch Government to shoulder, from January 2018, the additional costs relating to the double transfer of the seat of EMA, first to a temporary location in the Spark Building and then to the Vivaldi Building in Amsterdam;

Or. nl

Amendment 30
Nicola Caputo, Simona Bonafè

Draft legislative resolution
Paragraph 4 a (new)

Draft legislative resolution

Amendment

4a. Considers that the two-stage transfer procedure will prolong the period during which the EMA will be unable to operate to capacity; urges, therefore, that the decision regarding the location of the EMA be reconsidered in the light of the delays occurring in Amsterdam, which are undermining the right to health of our citizens, infringing the principle of continuity and incurring additional costs for the European budget;

Or. it

Amendment 31
Mireille D'Ornano

Draft legislative resolution
Paragraph 5

Draft legislative resolution

5. ***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;

Amendment

5. ***Urges*** 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;

Or. fr

Amendment 32
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft legislative resolution
Paragraph 5

Draft legislative resolution

5. 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;

Amendment

5. Calls on the budgetary authorities and the Commission to ensure that the 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; ***calls on the Member States to anticipate disruption to pharmacovigilance operations and to take the requisite measures to cope with the disruption at their national health agencies;***

Or. fr

Amendment 33
Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Draft legislative resolution
Paragraph 5

Draft legislative resolution

5. Calls on the budgetary authorities

Amendment

5. 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;

and the Commission to ensure that the 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;

Or. it

Amendment 34

Rory Palmer

Draft legislative resolution

Paragraph 5

Draft legislative resolution

5. 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;

Amendment

5. 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, ***including the current work being undertaken to set up the European Portal and Database for Clinical Trials, as required under the Clinical Trials Regulation EU No 536/2014;***

Or. en

Amendment 35

Annie Schreijer-Pierik

Draft legislative resolution

Paragraph 5 a (new)

Draft legislative resolution

Amendment

5a. Welcomes the spirit of close cooperation shown by the Dutch Government in responding to the requests of the EEA administration to make the Vivaldi Building available by mid-November 2019 and the fact that EMA meetings can be organised centrally in a

provisional location between April and November 2019, as well as the efforts being made by the Dutch authorities to ensure that the double transfer will not jeopardise the operational effectiveness, continuity and uninterrupted functioning of the EMA;

Or. nl

Justification

The concentration of all EMA activities on a provisional basis in the Spark Building is an improvement on the initial Dutch bid.

Amendment 36
Luke Ming Flanagan

Draft legislative resolution
Paragraph 5 a (new)

Draft legislative resolution

Amendment

5 a. 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; the building contract should include an 'end of lease' clause which stipulates that should the Member State leave the European Union, the contract is automatically terminated on the exit date; this should become standard practice for all such building leases henceforth, and should also be negotiated into all existing building leases;

Or. en

Amendment 37
Rory Palmer

Draft legislative resolution
Paragraph 5 a (new)

Draft legislative resolution

Amendment

5 a. *Calls on the budgetary authorities and the Commission to publish regular reports pertaining to the financial burden incurred as a result of the relocation;*

Or. en

Amendment 38
Kateřina Konečná

Draft legislative resolution
Paragraph 6 a (new)

Draft legislative resolution

Amendment

6a. *Calls on the Commission to use the changing of the Agency's seat to review its mandate, tasks and the powers conferred to it, and to immediately begin a dialogue with Parliament on this issue;*

Or. cs

Amendment 39
Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Proposal for a regulation
Recital 1

Text proposed by the Commission

Amendment

(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.

(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 **on 20 November 2017** in the margins of the General Affairs Council ('Article 50'), selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency. **However, the Executive Director was subsequently forced to acknowledge^{1a} that the Amsterdam headquarters would not enable the Agency to become fully**

operational on schedule. The new seat should therefore be located in Milan (Italy), which was initially unsuccessful purely as a result of a random draw but fully satisfies all the logistic requirements

Or. it

Amendment 40
Elisabetta Gardini

Proposal for a regulation
Recital 1

Text proposed by the Commission

(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.

Amendment

(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. ***However, it now emerges that the Amsterdam headquarters will not be ready when the transfer is due to take place and that the provisional location falls short of requirements in terms of space available and the sound administration of public funds; this could detract from the efficiency of the Agency, causing delays in the registration of innovative medicines and advanced life-saving treatments, resulting in enormous harm to European citizens.***

Or. it

Amendment 41
Patrizia Toia, Simona Bonafè, Damiano Zoffoli, Renata Briano, Nicola Caputo, Elena Gentile, Caterina Chinnici

Proposal for a regulation
Recital 1 a (new)

(1a) However, that decision must take into account the need to find a suitable headquarters by March 2019, and no suitable premises are yet available. Furthermore, the building chosen must be immediately fit for purpose to avoid inconvenience, additional costs and repercussions regarding citizens' right to health;

Or. it

Amendment 42
Giovanni La Via, Biljana Borzan

Proposal for a regulation
Recital 2

Text proposed by the Commission

Amendment

(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.***

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

Or. en

Justification

The date of 30 March 2019 is the date when the UK is expected to become a third country. Although the Commission's proposal reflects the legal possibility that the UK could leave the Union before the end of the 2 years period foreseen in Art 50, the Agency requires legal certainty as regards the official date of its departure from the UK for several practical reasons related to the planning of its relocation process. To avoid that the Agency would have to suddenly move earlier than currently planned, e.g. due to a collapse in the EU-UK negotiations, the Agency would not be in a position to complete all necessary relocation activities on time.

Amendment 43
Biljana Borzan

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 European Medicines 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 European Medicines Agency and its staff members to Amsterdam*.

Or. en

Justification

Having a precise timeline in the legislation for the signature of the headquarters agreement is required to prevent delays in the HQ agreement's negotiations and thus to support the preparatory activities for the relocation by 30 March 2019. The existence of an HQ agreement setting out a detailed framework for the Agency's installation in the new host country will reduce uncertainty and provide additional clarity to staff members, thus helping to guarantee business continuity during all phases of the relocation.

Amendment 44

Patrizia Toia, Simona Bonafè, Damiano Zoffoli, Renata Briano, Nicola Caputo, Caterina Chinnici, Elena Gentile, Brando Benifei, Goffredo Maria Bettini, Mercedes Bresso, Silvia Costa, Andrea Cozzolino, Nicola Danti, Paolo De Castro, Isabella De Monte, Enrico Gasbarra, Michela Giuffrida, Roberto Gualtieri, Cécile Kashetu Kyenge, Luigi Morgano, Alessia Maria Mosca, Pina Picierno, David-Maria Sassoli, Daniele Viotti, Renato Soru

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004

Article 71a

Text proposed by the Commission

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

Amendment

The seat of the Agency shall be located in a city of a European Union Member State on the basis of absolute assurance that:

- it meets, without any exception or limitation, as from January 2019, all requirements, conditions and criteria necessary to ensure that the Agency can function effectively;

- it ensures the full and immediate operational continuity of the Agency's activities, which are highly important to society and of great scientific value.

The Agency's remit shall relate to what is recognised as a fundamental right of European citizens to health protection.

Its headquarters shall be selected under the ordinary legislative procedure pursuant to Articles 114 and 168(4)(b) TFEU.

Or. it

Justification

The amendment seeks to underline the need for a suitable, functional and operational headquarters on the date of actual exit of the UK from the EU. The wording thereof is, moreover, intended to clarify the role and prerogatives of the European Parliament and the need for its full involvement as co-legislator.

Amendment 45

Elisabetta Gardini, Massimiliano Salini, Stefano Maullu, Lara Comi, Alberto Cirio, Aldo Patriciello, Fulvio Martusciello, Barbara Matera, Salvatore Domenico Pogliese, Salvatore Cicu, Alessandra Mussolini, Lorenzo Cesa, Herbert Dorfmann

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004

Article 71a

Text proposed by the Commission

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

Amendment

The Agency shall have its seat in ***a city of the European Union that meets the following criteria:***

- 1. the assurance that, at the time when the United Kingdom leaves the EU, the agency will remain operational in a suitable location, ensuring that its activities are not disrupted;***
- 2. accessibility of the location;***
- 3. schools for the children of the agency staff;***
- 4. access to the labour market and health care for employees' spouses and children;***

5. the assurance of operational continuity, given the need to protect the health and safety of EU citizens;

Its headquarters shall be selected under the ordinary legislative procedure pursuant to Articles 114 and 168(4)(b) TFEU.

Or. it

Amendment 46

Patrizia Toia, Simona Bonafè, Damiano Zoffoli, Renata Briano, Nicola Caputo, Caterina Chinnici, Elena Gentile, Brando Benifei, Goffredo Maria Bettini, Mercedes Bresso, Silvia Costa, Andrea Cozzolino, Nicola Danti, Paolo De Castro, Isabella De Monte, Enrico Gasbarra, Michela Giuffrida, Roberto Gualtieri, Cécile Kashetu Kyenge, Luigi Morgano, Alessia Maria Mosca, Pina Picierno, David-Maria Sassoli, Daniele Viotti, Renato Soru

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004

Article 71a

Text proposed by the Commission

Amendment

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

The Agency shall have its seat in ***Milan, Italy.***

Or. it

Justification

A number of official statements and press reports refer to the impossibility of finding suitable premises for the European Medicines Agency headquarters in Amsterdam by March 2019, leading to the conclusion that the Council decision cannot at present be implemented. The choice of Milan, which can offer an available, totally suitable and immediately operational headquarters, would make it possible to avoid inconvenience, additional costs and repercussions regarding the right to health of the citizens and would ensure business continuity.

Amendment 47

Elisabetta Gardini, Alessandra Mussolini, Alberto Cirio, Stefano Maullu, Lara Comi, Aldo Patriciello, Barbara Matera, Salvatore Domenico Pogliese, Salvatore Cicu, Massimiliano Salini, Lorenzo Cesa, Herbert Dorfmann, Fulvio Martusciello

Proposal for a regulation

Article 1 – paragraph 1

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Regulation (EC) No 726/2004
Article 71a

Text proposed by the Commission

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

Amendment

The Agency shall have its seat in *Milan,*
Italy.

Or. it

Amendment 48

Matteo Salvini, Angelo Ciocca, Mara Bizzotto, Mario Borghezio, Lorenzo Fontana

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EC) No 726/2004
Article 71a

Text proposed by the Commission

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

Amendment

The Agency shall have its seat in *Milan,*
Italy.

Or. it

Amendment 49

Biljana Borzan

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:

"Article 71b

***A headquarters agreement allowing the
Agency to take up its duties at the
premises approved by the European
Parliament and the Council must be
concluded within 3 months from the date
this Regulation enters into force."***

Or. en

Justification

Having a precise timeline in the legislation for the signature of the headquarters agreement is required to prevent delays in the HQ agreement's negotiations and thus to support the preparatory activities for the relocation by 30 March 2019. The existence of an HQ agreement setting out a detailed framework for the Agency's installation in the new host country will reduce uncertainty and provide additional clarity to staff members, thus helping to guarantee business continuity during all phases of the relocation.

Amendment 50

Piernicola Pedicini, Eleonora Evi, Marco Valli

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.

Or. it

Justification

A specific date for entry into force is the only way to guarantee that the transfer of the Agency is properly planned.

Amendment 51

Giovanni La Via, Biljana Borzan

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.

Or. en

Justification

The date of 30 March 2019 is the date when the UK is expected to become a third country. Although the Commission's proposal reflects the legal possibility that the UK could

leave the Union before the end of the 2 years period foreseen in Art 50, the Agency requires legal certainty as regards the official date of its departure from the UK for several practical reasons related to the planning of its relocation process. To avoid that the Agency would have to suddenly move earlier than currently planned, e.g. due to a collapse in the EU-UK negotiations, the Agency would not be in a position to complete all necessary relocation activities on time.