Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2017/0328(COD)	Procedure completed
European Medicines Agency (EMA): location of the seat Amending Regulation (EC) No 726/2004 2001/0252(COD) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20.04 Pharmaceutical products and industry 8.40.08 Agencies and bodies of the EU	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		10/01/2018
		LA VIA Giovanni	
		Shadow rapporteur	
		BORZAN Biljana	
		KRUPA Urszula	
		RIES Frédérique	
		AUKEN Margrete	
		PEDICINI Piernicola	
		MÉLIN Joëlle	
	Committee for opinion	Rapporteur for opinion	Appointed
	AFCO Constitutional Affairs		26/02/2018
		BRESSO Mercedes	
	AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	
	CONT Budgetary Control		
	BUDG Budgets	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Foreign Affairs	3647	09/11/2018
European Commission	Commission DG	Commissioner	
	Health and Food Safety	ANDRIUKAITIS Vytenis Povilas	
European Economic and			

Social Committee European Committee of the Regions	

Key events

29/11/2017	Legislative proposal published	COM(2017)0735	Summary
11/12/2017	Committee referral announced in Parliament, 1st reading		
12/03/2018	Vote in committee, 1st reading		
12/03/2018	Committee report tabled for plenary, 1st reading	A8-0063/2018	Summary
15/03/2018	Results of vote in Parliament		
15/03/2018	Decision by Parliament, 1st reading	T8-0086/2018	Summary
15/03/2018	Matter referred back to the committee responsible		
17/10/2018	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE629.511 GEDA/A/(2018)008294	
25/10/2018	Decision by Parliament, 1st reading	T8-0427/2018	Summary
09/11/2018	Act adopted by Council after Parliament's 1st reading		
14/11/2018	Final act signed		
14/11/2018	End of procedure in Parliament		
16/11/2018	Final act published in Official Journal		

Technical information

Procedure reference	2017/0328(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 726/2004 2001/0252(COD)
Legal basis	Rules of Procedure EP 59-p4
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/11697

Documentation gateway

Legislative proposal		COM(2017)0735	29/11/2017	EC	Summary
Economic and Social Committee: opinion, report		CES0004/2018	17/01/2018	ESC	

Committee draft report		PE615.463	18/01/2018	EP	
Amendments tabled in committee		PE616.891	31/01/2018	EP	
Committee opinion	AFCO	PE616.913	27/02/2018	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0063/2018	12/03/2018	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T8-0086/2018	15/03/2018	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2018)008294	17/10/2018	CSL	
Text agreed during interinstitutional negotiations		PE629.511	17/10/2018	EP	
Text adopted by Parliament, 1st reading/single reading		T8-0427/2018	25/10/2018	EP	Summary
Draft final act		00040/2018/LEX	14/11/2018	CSL	
Commission response to text adopted in plenary		SP(2018)755	21/11/2018	EC	

Final act

Regulation 2018/1718
OJ L 291 16.11.2018, p. 0003 Summary

European Medicines Agency (EMA): location of the seat

PURPOSE: to relocate the seat of the European Medicines Agency (EMA) following the notification by the United Kingdom to the European Council of its intention to leave the Union.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the European Medicines Agency has been established by Regulation (EEC) No 2309/93, which has been replaced by Regulation (EC) No 726/2004.

In accordance with the Decision of 29 October 1993 taken by common agreement between the representatives of the governments of the Member States, meeting at Head of State and Government level, on the location of the seats of certain bodies and departments of the European Communities and of Europol, the European Medicines Agency has its seat in London, United Kingdom.

Following the notification by the United Kingdom of its intention to leave the Union, the 27 remaining Member States, in the margins of the General Affairs Council (Article 50), selected Amsterdam, the Netherlands, as the new seat for the European Medicines Agency.

CONTENT: the Commission proposes to amend Regulation (EC) No 726/2004 in order to confirm the new seat of the European Medicines Agency in Amsterdam, the Netherlands.

The Agency should occupy its new seat from the date on which the Treaties cease to apply to the United Kingdom or from 30 March 2019, whichever is the earlier.

It is proposed that the Regulation shall enter into force as a matter of urgency in order to give the Agency sufficient time to relocate.

BUDGETARY IMPLICATION: the relocation of the Agency will have budgetary implications, in particular in view of the costs related to the early termination of its current rental contract in London as a consequence of the withdrawal, the costs related to the move itself and the costs related to the installation in the new premises in Amsterdam.

As set out in the negotiation directives of the Council of 22 May 2017, the United Kingdom should fully cover the specific costs related to the withdrawal process, such as the relocation of the agencies based in the United Kingdom.

Some of the relocation costs (e.g. costs related to the move itself) may have to be pre-financed by the EU budget prior to the final financial settlement. If necessary, the Commission will submit the relevant proposals to the European Parliament and the Council in the framework of the annual budgetary procedure for 2019 and, if necessary, for 2018.

In addition, the costs related to the installation in the new premises will also be presented in the context of the building procedure set out in Article 203 of the Financial Regulation, which requires prior approval from the European Parliament and the Council before contracts related to building projects are concluded. This procedure is expected to be launched as soon as possible (at the latest in early 2018).

European Medicines Agency (EMA): location of the seat

The Committee on the Environment, Public Health and Food Safety adopted the report Giovanni LA VIA (EPP, IT) 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.

As a reminder, the Commission proposal aims at amending Regulation (EC) No 726/2004 in order to confirm the seat of the European Medicines Agency in Amsterdam, the Netherlands.

The committee recommended that the European Parliaments position adopted at first reading under the ordinary legislative procedure should amend the Commission proposal as follows.

According to Members, 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 headquarters agreement shall include the most appropriate terms and conditions for the successful relocation of the European Medicines Agency and its staff members to Amsterdam.

In order to ensure the Agencys 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. The Commission and the Dutch authorities shall take all the 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.

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 the date this Regulation enters into force.

In a statement annexed to this resolution, Parliament regretted 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 (EMA). It recalled its prerogatives as co-legislator and insisted on the full respect of the ordinary legislative procedure in relation to the location of bodies and agencies, while insisting that the procedure followed for the selection of a new location for the agencies will be reformed and not used anymore in this form in the future.

European Medicines Agency (EMA): location of the seat

The European Parliament adopted by 507 votes to 112, with 37 abstentions, amendments to 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.

The matter was referred back to the committee responsible for interinstitutional negotiations.

As a reminder, the Commission proposal aims at amending Regulation (EC) No 726/2004 in order to confirm the seat of the European Medicines Agency in Amsterdam, the Netherlands.

The main amendments adopted in plenary concern the following issues:

Precise timeline: Members suggested the Commission and the Dutch authorities shall take all the 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.

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 the date this Regulation enters into force.

Respect for the prerogatives of the Parliament: in a statement, the Parliament condemned 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.

Under these circumstances, Parliament insisted 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.

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

European Medicines Agency (EMA): location of the seat

The European Parliament adopted by 425 votes to 71 with 56 abstentions a legislative resolution 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 (EMA).

The European Parliaments position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Following the United Kingdom's notification on 29 March 2017 of its intention to withdraw from the Union, 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 (EMA).

Timeline: the amended text specifies that 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.

Members regretted 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 which both give priority to new Member States. They called 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.

Parliaments role: in a statement, Parliament condemned 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 wishes to recall as well that in the Inter-institutional Agreement on Better Law-Making of 13 April 2016 the three institutions committed to sincere and transparent cooperation while recalling the equality of both co-legislators as enshrined in the Treaties.

In a statement to the legislative resolution, Parliament recognised the commitment of 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.

The Council took note of the request by Parliament to revise, as soon as possible, the 2012 Joint Statement and Common Approach on decentralised Agencies. As a first step, it invited 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.

European Medicines Agency (EMA): location of the seat

PURPOSE: to relocate the seat of the European Medicines Agency (EMA) following the notification by the United Kingdom to the European Council of its intention to leave the Union.

LEGISLATIVE ACT: Regulation (EU) 2018/1718 of the European Parliament and of the Council of 14 November 2018 amending Regulation (EC) No 726/2004 as regards the location of the seat of the European Medicines Agency.

CONTENT: this Regulation amends Regulation (EC) No 726/2004 to establish the seat of the European Medicines Agency (EMA) in Amsterdam, the Netherlands.

Following the United Kingdom's notification of its intention to withdraw from the Union, the other 27 Member States, meeting on 20 November 2017 in the margins of the Council, chose Amsterdam, the Netherlands, as the new seat of the European Medicines Agency.

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.

They 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 17 February 2019, and every three months thereafter, until the Agency has moved to its permanent location.

ENTRY INTO FORCE: 16.11.2018.

APPLICATION: from 30.3.2019.