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PROPOSAL

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 30 November 2017

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: COM(2017) 735 final

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

Delegations will find attached document COM(2017) 735 final.

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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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Reasons for and objectives of the proposal

The European Medicines Agency has been established by Regulation (EEC) No 2309/93, which has been replaced by Regulation (EC) No 726/2004¹. In accordance with Article 1 of 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 Europol², the European Medicines Agency has its seat in London, United Kingdom.

On 29 March 2017 the United Kingdom notified to the European Council its intention to leave the Union, pursuant to Article 50 of the Treaty on European Union.

On 20 November 2017, the 27 remaining Member States, in the margins of the General Affairs Council (Art. 50), selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The act to be amended being based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union ("TFEU"), the amending act should be founded on that basis.

- **Choice of the instrument**

This proposal seeks the amendment of Regulation (EC) No 726/2004. The corresponding amendment is therefore proposed as an amending Regulation.

- **Subsidiarity and Proportionality**

The issue of the location of the seat of the Agency falls within the exclusive competence of the Union. The measure is proportionate to the purpose of the proposed Regulation, namely to confirm the new seat of the Agency within Regulation (EC) No 726/2004.

4. BUDGETARY IMPLICATIONS

The relocation of the European Medicines 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 for the negotiation of an agreement with the United Kingdom setting out the arrangements for its withdrawal from the European Union, the

¹ 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).

² OJ C 323, 30.11.1993, p. 1.

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 may have to be pre-financed by the EU budget, prior to the financial settlement. In this respect, the Commission will assess possible additional funding needs to be channelled through the EU budget in cooperation with the European Medicines Agency. As necessary, the Commission will present relevant proposals to the European Parliament and the Council in the context of the annual budgetary procedure for 2019, and if necessary for 2018. This concerns for instance the costs related to the move itself. 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 Regulation³, 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).

³ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

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 Committee⁴,

Having regard to the opinion of the Committee of the Regions⁵,

Acting in accordance with the ordinary legislative procedure,

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 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.

⁴ OJ C , , p. .

⁵ OJ C , , p. .

- (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 Council⁶ should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

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

“Article 71a

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

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

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).