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

(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 point (c) of Article 168(4) 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 Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) In the context of the United Kingdom's notification on 29 March 2017 of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union ('TEU'), 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 ('the Agency').

(2) Having regard to Article 50(3) TEU, the Agency should take its new seat as of 30 March 2019.

(3) To ensure the proper functioning of the Agency in its new location, a headquarters agreement should be concluded between the Agency and the Netherlands before the Agency takes up its new seat.

(4) It is to be welcomed that the authorities of the Netherlands 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.

(5) 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.

(6) To give the Agency sufficient time to relocate, this Regulation should enter into force as a matter of urgency.

(7) Regulation (EC) No 726/2004 of the European Parliament and of the Council ([3]) should therefore be amended accordingly,

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([1]) OJ C 197, 8.6.2018, p. 71.

([2]) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and decision of the Council of 9 November 2018.

([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).

HAVE ADOPTED THIS REGULATION:

Article 1

The following Article is inserted in Regulation (EC) No 726/2004:

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

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 30 March 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 14 November 2018.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	K. EDTSTADLER