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WORKING DOCUMENT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Giovanni La Via

EXPLANATORY STATEMENT

The European Medicines Agency (EMA) is an important EU decentralised Agency, responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.

The EU's health and safety needs are constantly evolving, resulting in an increasing demand of information and of a risk and evidence-based perspective.

Therefore, EMA's mission to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union, is and will be of utmost importance.

The Agency, currently based in London, has to be relocated in the context of the UK's withdrawal from the EU. On 22 June 2017, in the margins of the European Council, the EU27 leaders endorsed a specific procedure for the relocation of this agency and EBA's. EU27 ministers voted in the margins of the General Affairs Council meeting on 20 November 2017, assigning the location with a draw to Amsterdam, the Netherlands.

On 29 November 2017, the European Commission proposed a legislative amendment for the relocation of the European Medicines Agency, under the ordinary legislative procedure, asking the co-legislators (the European Parliament and the Council) to give priority to the handling of the legislative proposal, which is strictly limited to confirming the new seat of the Agency in the founding Regulation.

The offer from the Netherlands indicates one proposed building, the Vivaldi Building (31,855 m²), which according to the offer, has a planned delivery of the conference centre as well as some of the workplaces by 1 April 2019, with consecutive office floors becoming available up to 6 months later. The offer also indicates temporary back up premises to be used as of 1st January 2019 until all EMA staff has moved to the Vivaldi Building, with a detailed layout to be agreed with the Agency.

The Rapporteur regrets that the European Parliament, and ultimately the EU citizen representatives, were not fully involved in the procedure to select the new seat of EMA, which was eventually concluded by a draw, despite it being such an important decision.

The rapporteur intends, therefore, to propose to work towards a Declaration, as an annex to the report to be voted in ENVI Committee and in plenary, in order to modify the Joint Statement of the European Parliament, Council and European Commission on decentralised agencies and the Common Approach annex to the document, signed in 2012, which are legally non-binding, as written in the Statement itself, and agreed without prejudice to the legislative power of the Institutions.

The rapporteur intends to defend the prerogatives of the European Parliament and believes that all decisions in relation to the location of EU bodies and agencies need and have to legally- 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.