



Council of the
European Union

Brussels, 31 October 2018
(OR. it, en)

**Interinstitutional File:
2018/0328 (COD)**

**13598/18
ADD 1**

**CODEC 1810
ECO 91
AGRILEG 174
SAN 354**

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft 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 (First reading) - Adoption of the legislative act - Statements

Council statement EBA/EMA

"Recalling the commitment of the European Parliament, the Council and the Commission to 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,

While recalling the Treaties, the Council acknowledges the value of enhanced exchange of information from the initial stages of future processes for the location of agencies.

Such early exchange of information would make it easier for the three Institutions to exercise their rights according to the Treaties through the related procedures.

The Council takes note of the request by the European Parliament to revise, as soon as possible, the 2012 Joint Statement and Common Approach on decentralised Agencies. As a first step, it invites 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. This analysis would serve as a basis to assess the way forward in engaging with the process of such a revision."

Statement by Italy

Italy is unable to support the proposal amending Regulation (EC) No 726/2004 on the seat of the European Medicines Agency (EMA). As stated in the action it brought before the Court of Justice of the European Union on 30 January 2018 (Case C-59/18), the Italian Government considers that the decision, adopted in the margins of the meeting of 20 November 2017 of the Council of the European Union in its 'General Affairs' configuration, selecting Amsterdam as the new seat of the EMA amounts to misuse of powers through failure to investigate adequately and distortion of facts, owing to inaccurate or misleading information on the features of the new seat in Amsterdam and the time frame for making the new building operational. This is confirmed by the fact that the relocation to the premises of the new seat (the Vivaldi Building) is to take place with effect from 16 November 2019 rather than from 1 April 2019 as initially provided for in the Dutch bid and stated in the Commission report. Furthermore, the new conference centre, which is essential for the Agency's core activities, will not be ready on 1 April 2019 as initially planned but instead will only be operational at the same time as the new building, i.e. with effect from 16 November 2019.