

19 March 2015  
EMA/MB/99041/2015 Noted  
Management Board meeting of 19 March 2015

## Renewal of the Cooperation Agreement between the NCAs and the EMA

### Issues for consideration

A Cooperation Agreement between the NCAs and the EMA, which governs the services provided by the NCAs to the EMA, came into force on 1 January 2011. The duration of the Agreement expires on 31 December 2015.

The agreement has been updated 4 times since January 2011 in order to incorporate all legislative changes adopted from the date it entered into force until now.

A substantial legislative reform, i.e. a revision of the legislation for veterinary medicines is currently ongoing and will, once it applies, impact on the arrangements between the EMA and the NCAs, including the content of the Cooperation Agreement. There will also be an impact on the current General Fee Regulation.

Taking into account the above upcoming changes, the EMA proposes to renew the Cooperation Agreement as it stands, and to review its content at a later stage once the new legal provisions are adopted. Article 2(2) of the Cooperation Agreement foresees the following in this respect:

*“The duration of the Agreement shall not exceed 60 months (5 years). This period and all other periods specified in the Agreement are calculated in calendar months. If no objection has been raised by either party within 6 months before such period elapses, the Agreement shall be renewed tacitly”. (emphasis added)*

The topic was presented at the 4 February 2015 HMA meeting in Riga. HMA supported the EMA proposal to renew the Cooperation Agreement.