EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2014
EMA/415308/2014
Press Office

Press release

Management Board delays formal adoption of EMA publication of clinical trial data policy to October 2014

Further discussion required on wording and practical arrangements

The Management Board of the European Medicines Agency (EMA) has postponed formal adoption of the policy on publication of clinical trial data to its 2 October 2014 meeting. Further clarifications on wording and practical arrangements will be discussed by Board members, who have confirmed their general support to the overall aims and objectives of the policy, including the more user-friendly amendments proposed by EMA Executive Director Guido Rasi that would allow data to be downloaded, saved or printed for academic and non-commercial research purposes.

Further to the agreement reached with the European Commission in accordance with Article 80 of Regulation (EC) No 726/2004, the Board was not able to conclude on the final wording of the policy through a written procedure. Members of the Board have offered additional valuable contributions which will now be considered and addressed in the next few weeks, with a view to reaching final agreement at the next Management Board meeting in October.

The Agency welcomes this additional round of joint reflections and respects all opinions, as well as the views expressed by several Member States, which largely reproduce the complexity of the debate on both political and technical aspects which have emerged during the previous general and more targeted consultation phases. In the last 12 months the Agency has attempted to strike a balance between proactive data disclosure, the absolute need to protect personal data and the concerns relating to the protection of commercially confidential information.

The Agency management remains committed to introducing this additional measure towards transparency as soon as possible, so as to enhance citizens' awareness and confidence in the EU authorisation system for medicinal products. The Agency has also underlined several times that the new policy, if approved, will be without prejudice to the provisions of Regulation (EC) No 1049/2001 on access to documents and the new clinical trial Regulation (EC) No 536/2014, which will become applicable in 2016 at the earliest and, as also noted during the debate, will apply to clinical trials conducted in the European Union.

The Agency management is conscious that any delay prevents citizens, and in particular academics and non-commercial researchers, from enjoying the benefits of proactive publication of clinical trial data for a further period. The Agency will continue to work with the Management Board and the

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European Commission ahead of the 2 October meeting to ensure that members receive the clarifications requested and to facilitate the adoption of the policy.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The Management Board written procedure was announced on 12 June 2014: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002124.jsp&mid=WC0b01ac058004d5c1
3. Access to documents requests can be submitted to the EMA at www.ema.europa.eu/contact
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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