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Press Office

Press release

European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

In-depth analysis of more than 1000 stakeholders' comments received on draft policy currently underway

The European Medicines Agency is currently reviewing and analysing more than 1,000 comments received during the public consultation on its draft policy on publication and access to clinical-trial data, which ran from June to end of September 2013.

The public consultation on the policy has generated input from an unprecedented range of stakeholders. Patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies and a range of others sent their comments to the Agency. Many of the contributors provided detailed in-depth comments, some of them substantial, some of them technical, including suggestions relating to methodological and technical aspects of the implementation of the policy.

The Agency is grateful for this exceptional contribution from its stakeholders. As part of its collaborative approach to developing a methodology for the release of clinical-trial data with its stakeholders, the Agency is currently devoting attention to all comments received and reaffirms its commitment to transparency and the principles of publication and access to clinical-trial data.

In order to conduct the appropriate in-depth analysis required, the Agency will spend additional time in this reviewing phase which may therefore delay the finalisation of the policy initially planned for the end of 2013. An update on timelines will be provided at the latest following the EMA Management Board meeting on 11-12 December 2013.

The Agency has embarked on the development of a policy on publication and access to clinical-trial data because it believes that the release of data is about establishing trust and confidence in the system. The Agency is also firmly of the opinion that availability of data broadens the scientific knowledge base, fosters innovation and encourages investment in the development of medicines and ultimately benefits public health.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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