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Source: EMA

Subject: European Medicines Agency to push ahead in 2014 towards publication and access to clinical trial data

The European Medicines Agency (EMA) has now reviewed all comments received on its draft policy on publication and access to clinical trial data. While the comments received showed that there is large support for the Agency's plans to allow access to clinical trial data submitted as part of marketing authorisation applications, they also highlighted that there is a need for further analysis and clarification of certain aspects.

The Agency will continue to work with stakeholders, including industry, academia and civil society organisations, to further clarify and fine-tune the proposed rules to achieve the broadest possible consensus. This work will be guided by a set of key principles that were agreed with the Agency's Management Board on 12 December 2013. The policy on publication of and access to clinical-trial data and an implementation plan will be discussed at the March 2014 Management Board meeting.

The key principles include a stepwise approach for implementation with, as a first step, preparation for the publication of clinical study reports redacted as appropriate, the development of a methodology for de-identification of patients, and the definition of a standard format for the submission of data. The principles also foresee the introduction of preliminary steps prior to data access designed to address the risk of possible unfair commercial use of data while ensuring proactive and non-selective access ('use control' not 'access control').

The Agency reiterates its firm commitment to pursuing the objective of full transparency regarding clinical trial data. The Agency will continue to monitor progress in the Court cases brought by two pharmaceutical companies against the Agency and the on-going discussions on the new European clinical trials legislation. It recognises the need for consistency in the general approach to access to documents by EU institutions and bodies, while recognising the specificity of documents in the possession of the EMA and the Agency's primary duty to protect and foster public health.

The Agency's draft policy has prompted broad debate among an unprecedented range of stakeholders, including the important focus on the benefits to patients, and more generally to society of giving access to clinical trial data and on the best approach to achieve this. It has been the catalyst for various initiatives from the pharmaceutical industry, funding bodies and academia centres in this direction.

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

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/12/WC500158390.pdf

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