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Press release

European Medicines Agency agrees policy on publication of clinical trial data with more user-friendly amendments

EMA Management Board to formally adopt policy in coming weeks

The European Medicines Agency Management Board on 12 June 2014 agreed the policy on publication of clinical trial data, together with more user-friendly amendments proposed by EMA Executive Director Guido Rasi, that will not only allow the Agency to proactively publish clinical trial data that are submitted as part of marketing authorisation applications, but also give the possibility to download, save and print the trial data for academic and non-commercial research purposes.

In light of discussions at the Board, the wording of the policy, including practical arrangements for academic and non-commercial research users, will now be finalised with a view to its adoption by the Board through written procedure by mid-July 2014, and will be effective from 1 October 2014. Importantly, the Agency will ensure that the policy will not prejudice citizens' rights under existing access to documents legislation and the new clinical trials regulation.

Since embarking on its plans for the proactive publication of clinical trial data, the Agency has aimed to achieve the broadest possible consensus among its stakeholders and their often competing views and interests. After an extensive consultation phase that took place between June and September 2013, the Agency carried out a second round of targeted consultation in May 2014 that showed broad support for the policy, but highlighted concerns over the proposed view-on-screen-only access.

The Agency's policy is an important step forward towards achieving increased transparency in the regulation of medicines in Europe. It takes the Agency beyond its legal obligations and provides an unprecedented level of access to clinical trial data that are used as part of decision-making for new medicines.

Enhanced support to innovative veterinary therapies

The Board endorsed a proposal for the creation of an ad hoc Working Group on Veterinary Novel Therapies (ADVENT). The working group will address the need expressed by stakeholders for more guidance on new classes of veterinary medicines, such as cell therapies, monoclonal antibodies and bacteriophages. A novel approach is proposed for this group in view of the need to rapidly produce guidance on a range of topics using the minimum possible resources in recognition of the scarcity of experts within the network with knowledge of novel veterinary therapies. ADVENT will be composed of



a small core group of experts which can be supplemented with groups of experts in the specific scientific area covered by the new guidance document.

This initiative is in line with the Agency's efforts to support development of innovative medicines. It follows the opening up in November 2013 of the Agency's Innovation Task Force to provide support to veterinary medicines during the early stages of their development.

More transparent criteria for involvement of patients and healthcare professionals

The Management Board also adopted a revised process for assessing the eligibility of patients' and healthcare professionals' organisations to provide input to the Agency on general issues related to medicines. This process allows the Agency to identify the most appropriate organisations acting in the interests of European civil society. The eligibility criteria have been updated to align with increased transparency requirements, in particular on sources and level of funding and a code of conduct on their relationship with pharmaceutical industry.

Positive assessment of last year's operations

The Board gave a positive assessment of the Agency's operations in 2013, and of its management and internal control system. This analysis and assessment of the Executive Director's annual activity report is carried out by the Board annually, as required by the Financial Regulation. The analysis highlights, among other topics, the Agency's initiatives towards stronger interaction with health technology assessment bodies to facilitate patients' access to medicines and the Agency's new organisational structure designed to better support the scientific work of the EMA's committees, improve partner and stakeholder relations, and facilitate data-sharing among the European medicines regulatory network.

Notes

- 1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release is available on the Agency's website.
- 2. European Medicines Agency responds to concerns on its publication of clinical trial data policy: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news and events/news/2014/06/news det ail 002120.jsp&mid=WC0b01ac058004d5c1
- 3. Rules of Procedure of the Management Board: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500038065.pdf
- 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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