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Press Office

Press release

European Medicines Agency's Management Board endorses revised policy on handling of declarations of interests

The Board also reviewed the Agency's 2013 activities and looked ahead to 2015

The European Medicines Agency's (EMA) Management Board endorsed the Agency's draft revised policy on handling of declarations of interests for scientific-committee members and experts. This revision aims at maintaining a pool of high-quality scientific experts while ensuring that experts are free from undue financial or other interests. The revised policy takes into account the outcome of the 6 September 2013 EMA public workshop "Best expertise vs conflicts of interests: Striking the right balance".

The main changes to the current policy will be explained in the revised policy and a guidance document which will be published within the next few weeks. These changes focus on looking at the nature of the declared interest before determining the length of time any restrictions may apply and aim to better differentiate rules that apply to experts involved in decision-making bodies versus experts involved in advisory bodies, and similarly between chairpersons and lead persons versus other members.

Management Board reviews the Agency's 2013 activities and looks ahead to 2015

The Management Board adopted the Agency's 2013 annual report. The document will be published in April 2014.

The Agency recommended a total of 81 new medicines for approval in 2013. Among those were recommendations for marketing authorisation of two new advanced therapies, 11 orphan medicines and the first two biosimilar monoclonal antibodies. Of note, among the 81 medicines were 14 benefitting from special regulatory pathways that facilitate market access to medicines which either fulfil unmet medical needs, present a major therapeutic interest or could not be made available under a standard approval because the disease they target is too rare. These mechanisms include accelerated assessment, conditional marketing authorisation and approval under exceptional circumstances.

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In the area of veterinary medicines the Agency received a record number of 23 marketing-authorisation applications in 2013, almost twice as many as in 2012, reflecting the growing interest in the development of new veterinary medicines.

Among the 12 veterinary medicines recommended for marketing authorisation in 2013 was the first vaccine for authorisation at European Union (EU) level against foot-and-mouth disease, a debilitating disease that causes significant loss of agricultural productivity.

The Management Board also endorsed the draft EMA work programme for 2015. The Agency forecasts a stable number of marketing authorisation applications for new non-orphan medicines and a steady increase in orphan medicines applications in the area of human medicine. This would continue the anticipated trend reported in the work programme for 2014, which was published last week. The number of generic applications is expected to remain low over the next two years, at a similar level as in 2013. The number of applications for marketing authorisations for veterinary medicines over 2014 and 2015 is expected to remain at the relatively high level seen in 2013.

Presentation by the CHMP Chair

Tomas Salmonson, the Chair of the Agency's Committee for Medicinal Products for Human Use (CHMP), presented his reflections on the recent achievements and current projects of the committee. He expressed his support for the direction taken by the Agency to reorganise its processes in order to better support the work of the scientific committees. He also highlighted the strengthened interaction with health technology assessment (HTA) bodies and the efforts made by the CHMP to structure its assessments so that they can also be used by HTA bodies for their evaluation of the cost-effectiveness of medicines. The CHMP Chair also noted the success of the EMA-HTA workshop on parallel scientific advice held at the Agency in November 2013. The workshop demonstrated the shared interest of all stakeholders in this area. Tomas Salmonson also welcomed the initiative to allow the formation of multinational teams for the assessment of medicines, which allows sourcing the best expertise across the EU for each application. The CHMP Chair emphasized the strength and the rich resources in terms of scientific expertise of the European medicines regulatory network.

Update on draft policy on publication and access to clinical trial data

The Board was updated on the progress made on the draft policy on proactive publication of clinical-trial data. Based on the set of key principles endorsed by the Management Board at its December 2013 meeting, efforts were made to identify redaction criteria for those parts of clinical-trial data that exceptionally contain commercially confidential information, on a consultation process with the concerned data owners and on user-friendly technical measures to make the data accessible under the new policy, whilst addressing the need to reasonably protect against unfair commercial use of the data. The final policy and an implementation plan will be presented to the Management Board for endorsement at its June 2014 meeting.

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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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