26 March 2010
EMA/169371/2010
Press Office

Press release

European Medicines Agency's Management Board emphasises the importance of the European medicines network

Management Board meeting 17-18 March 2010

The European Medicines Agency's Management Board noted the outstanding performance of the European medicines regulatory network in 2009 during the pandemic H1N1 influenza. Thanks to the strength of the network, the European Medicines Agency was able to contribute to the EU-wide response to the pandemic by providing timely scientific opinions leading to the approval of three pandemic vaccines and new recommendations for antiviral medicines. Despite the fact that many resources were diverted to deal with this public health issue, the Agency was also able to deliver very good results across the range of its activities, which were conducted to a high level of quality, and regulatory timelines were consistently met.

During 2009, substantial increases were seen across many of the core activity areas, including scientific-advice requests (20%), orphan designations (38%), type II variations (20%) and safety-related activities. In all, 96 applications for marketing authorisations for medicines for human use were received (7% less than in 2008), of which 50 % were for generic and hybrid medicines and informed consent applications. The number of these applications is over 60 % higher than the initial forecast.

In opening budget discussions for 2011, the Executive Director presented the priorities and main objectives for the Agency next year: efficient management of the core business; monitoring of the safety of medicines and ensuring continuous positive benefit-risk balance; continued involvement of patients and healthcare professionals; responding to globalisation of manufacturing and research activities; responding to public health needs, such as antimicrobial resistance and medicines for the elderly. The Agency will further increase transparency in the daily operation of its activities. Agendas and minutes of scientific committee and working party meetings will be gradually published, and interested parties will have access to certain information contained in clinical trials and EudraVigilance databases. The year 2011 will also focus on the implementation of the new pharmacovigilance legislation, including the creation of a new pharmacovigilance committee.

The Agency forecasts 52 applications for new medicines and 56 applications for generic and hybrid medicines; and 170 applications for orphan designation. The Management Board adopted a preliminary

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draft budget for 2011 of € 218.9 million (2010: € 198.2 million). Further discussions will take place throughout the year to refine the budget.

The Management Board endorsed a number of actions aimed at improving the availability of herbal medicines in Europe and emphasised the importance of coordinated actions within the European medicines regulatory network. This is in view of the April 2011 deadline, which marks the end of the transition period for Member States to apply provisions of Directive 2004/24/EC to traditional herbal medicinal products on the national markets. For herbal medicines that were on the market in Europe on 30 April 2004 this Directive offers the possibility to apply for marketing authorisations using the simplified registration procedure.

The Management Board also adopted amendments to the implementing rules on fees payable to the Agency. The changes adapt fees for extensions of marketing authorisations, establish reduced fees for applications for multi-strain veterinary immunological products and reflect the 1% inflation rate. The revised rules will come into effect on 1 April 2010.

Notes

1. The 2009 Annual Report of the European Medicines Agency and the Agency's action plan on herbal medicines for 2010-2011 will be published shortly.
2. All other relevant documents adopted at the Management Board meeting can be found here: http://www.ema.europa.eu/htms/general/manage/MB/MB_overview.html.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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