EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

European Medicines Agency Management Board strengthens conflicts of interest policies and transparency

Strengthened policies on handling of conflicts of interest

Following its implementation in September 2011, the Management Board reviewed the initial experience with the Agency's revised policy on the handling of conflicts of interest for scientific-committee members and experts.

The Board endorsed a proposal from the Executive Director to further strengthen the policy taking into account the last 6 months' experience. The amendments clarify involvement in academic trials and in publicly funded research/development initiatives, align risk and related restrictions for the different roles in the scientific decision process and tighten the rules in the case of grants from pharmaceutical industry.

The Board also endorsed proposals for additional measures to further increase the quality assurance, such as the introduction of a 'breach of trust' procedure in case of incorrect or incomplete declarations of interests, and the introduction of ex-post cross checks on the correctness of the declared conflicts of interest, and of the risk mitigation measures.

The Board also adopted a revised policy on the handling of conflicts of interests for its members which follows largely the approach taken for the scientific committee members and experts while acknowledging the fundamentally different role of the Board. The new policy outlines specific restrictions when Board members do not take part in discussions and decision making. However, since the Board does not deal with product-specific topics, the type and the nature of restrictions differ from scientific committees. The new policy enters into force immediately.

New transparency initiatives discussed

The Management Board dedicated a large part of the meeting to the new pharmacovigilance legislation, which will significantly increase the transparency of all pharmacovigilance activities of the Agency and national authorities. The Agency will increase the transparency of its processes and procedures by publishing the agendas, recommendations, opinions and minutes from its scientific

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committees, including the Pharmacovigilance Risk Assessment Committee (PRAC), the human medicines Coordination Group (CMDh) and the Committee for Medicinal Products for Human Use (CHMP). The Agency will organise public hearings allowing the public to engage with the Agency on safety issues, and will strengthen its current role in ensuring coherent and consistent messages on safety issues across Europe.

The Board considered patients' expectations for hearings on medicines in Europe and discussed the purpose and added value of public hearings in the context of benefit-risk assessment. The Agency will prepare a paper for discussion by the PRAC at its inaugural meeting on 19-20 July 2012. This paper will provide the basis for the rules of procedure on the organisation and conduct of public hearings.

Management Board reviews the Agency's activities during 2011

The Management Board adopted the annual report for 2011, noting that that despite a challenging environment, the Agency was able to deliver a growing volume of core business in 2011. There was a 10 % increase in the number of applications for initial marketing authorisations for medicines for human use, from 91 applications in 2010 to 100 applications in 2011. This included 62 applications for new medicines, an increase of 35 % as compared to 2010. While the number of applications received for initial marketing authorisation for veterinary medicines declined slightly, the rise seen in veterinary scientific advice is an indicator that interest remains high in bringing innovative veterinary medicines to the market through the centralised procedure.

The Agency together with the consistently strong European medicines network met a number of milestones throughout the year 2011. Significant progress was made in terms of transparency, including the launch of the EU clinical trials register and a new online database of European experts. The Board also heard that the preparation for the implementation of the new pharmacovigilance legislation progressed according to plan.

Looking ahead to 2013

In opening budget discussions for 2013, the Executive Director presented the priorities and main objectives for the Agency next year: the continued implementation of the legislation on pharmacovigilance and on falsified medicines, further development of the communication activities of the Agency with increased transparency and better explanation of why decisions are made, ensuring efficient interactions between the committees and increasing the efficiency of the Agency's operations.

The Agency forecasts 110 applications for marketing authorisations for medicines for human use. The Management Board adopted a preliminary draft budget for 2013 of € 239.1 million (2012: € 222.5 million). The final budget will be proposed once the level of European Union contribution has been decided by the European Parliament and Council.

Notes

1. This press release, together with all relevant documents adopted at the Management Board meeting are available on the Agency's website.
2. More information on the implementation of the new pharmacovigilance legislation is available on the Agency's website.
3. The Agency's policy on the handling of conflicts of interest for scientific-committee members and experts was implemented on 29 September 2011, with electronic declarations of interests (eDoIs) published on 30 September 2011. Currently, 3600 experts are included in the EMA experts' database and their signed eDoIs and automatically assigned risk levels are available on the EMA

website. More information on the Agency's conflicts of interest policies is available on the Agency's website.

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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