EUROPEAN MEDICINES AGENCY
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Press release

European Medicines Agency's Management Board supports plan to publish agendas and minutes of all committees

Board also discusses the 2013 mid-year report and the first year of the PRAC

At its meeting on 3 October 2013, the European Medicines Agency's (EMA's) Management Board expressed its support for the Agency's initiative for publishing the agendas and minutes of all its scientific committees. This project is part of the EMA's approach to increasing transparency and opening up its operations.

The Board agreed to proceed with the EMA's implementation plan for publishing the agendas and minutes of the Committee for Medicinal Products for Human Use (CHMP), Committee for Advanced Therapies (CAT) and Committee for Medicinal Products for Veterinary Use (CVMP) by the end of 2013.

This is the final step of a process that started in July 2012. The EMA then announced its plan for publishing the agendas and minutes of all its scientific committees by the end of 2013. This started with the Paediatric Committee (PDCO) and the Pharmacovigilance Risk Assessment Committee (PRAC) in July 2012, the Committee for Orphan Medicinal Products (COMP) in September 2012 and the Committee on Herbal Medicinal Products (HMPC) in September 2013.

Highlights of the EMA mid-year report

The Management Board also discussed the Agency's mid-year report for 2013. This report provides an overview of the Agency's progress from January to June in implementing its 2013 work programme.

- The number of marketing-authorisation applications for initial evaluation remains at around the same level as 2012 for all types of medicines, except for generics and biosimilars, for which there is a decrease; there are 24 applications for new non-orphan medicines (compared with 25 in first half 2012) and 5 applications for new orphan medicines (compared with 8 in first half 2012).
- The number of requests for scientific advice for human medicines is 11% below that of the first half of 2012; however, annual results for 2013 are still expected to be above the figures for 2012.

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- There were four multi-stakeholder scientific-advice requests received in the first half of 2013, compared with two in 2012; this procedure includes other organisations than the EMA, such as health-technology-assessment bodies.
- In the area of veterinary medicines, the report shows that the number of initial applications increased to 11, compared with 3 in first half 2012. The number of scientific-advice requests continues to increase.

Reflections on the first year of the PRAC

June Raine, Chair of the PRAC, presented to the Management Board her reflections on the first year of the Committee. She highlighted the progress made by the Committee to put in place a proactive approach to the safety monitoring of medicines for the benefit of public health, as well as the transparent approach of the PRAC, which has helped build up trust and confidence in the system. Dr Raine emphasised the strong role played by the experts of the European medicines network in applying their scientific expertise. The Board congratulated the Committee for the work accomplished, but also acknowledged that workload and resource management remain challenging for the network.

A more detailed account of the first year of the PRAC was published on the Agency's website in July 2013 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/07/news_detail_001850.jsp&mid=WC0b01ac058004d5c1).

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 at: <LINK>
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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