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Press release

Management Board completes framework for conflicts of interests

New breach of trust procedure for Management Board members completes Agency's rules on dealing with potential conflicts of interests

The European Medicines Agency's (EMA) Management Board adopted a new 'breach of trust procedure' to deal with cases of incorrect or incomplete declarations of interests of Board members. The adoption of the latest procedure completes the Agency's framework on dealing with potential conflicts of interests of its scientific experts, committee members, Management Board members and staff.

The European Medicines Agency takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests in the pharmaceutical industry that could affect their impartiality. As part of these efforts, the rules on how the Agency deals with conflicts of interests have been strengthened over the last year.

Some Board members recognised the difficulties to balance the independence of scientific experts with the need to ensure that the best scientific experts in the European Union remain available for the evaluation and supervision of medicines. The Board will keep the implementation and the impact of the rules under regular review.

Countdown to entry into force of the new pharmacovigilance legislation

With less than a month to go until the entry into force of the new pharmacovigilance legislation, the Board was informed of all activities supporting the establishment and functioning of the new Pharmacovigilance Risk Assessment Committee (PRAC), in preparation for its inaugural meeting on 19 and 20 July 2012.

The Board noted that all Member States have nominated members and alternates for the PRAC, and that only nominations for civil-society members representing healthcare professionals and patients are still awaited. The focus during the PRAC's inaugural meeting, which will be chaired by the Agency, will be on procedural aspects of the new Committee, including the adoption of the new rules of procedure. Election of the PRAC chair and vice-chair is scheduled for the Committee's second meeting in September 2012.



The Board will continue to hear regular updates on the implementation of the new legislation.

Notes

- 1. This press release, together with all related documents, is available on the Agency's website.
- 2. The inaugural meeting of the PRAC will be held in Brussels on 19 and 20 July 2012.
- 3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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