



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# Handling competing interests: revised rules for Management Board members

Policy effective from 1 May 2016

The European Medicines Agency (EMA) has published its revised policy on handling competing interests for members of its Management Board. The Board adopted the revised policy at its December 2015 meeting.

The revision aligns EMA's Management Board policy with the Agency's policy on handling declarations of interests for scientific committee members and experts which underwent a major overhaul and became effective in January 2015.

"The effective management of competing interests of Management Board members is critical to ensuring the independence of the decisions of the Board," said Noël Wathion, EMA's Chief Policy Adviser. "The updated policy brings the rules for Board members in line with those for scientific experts, whilst also taking into account the specific role of the Board, without lowering the bar on the independence of its work."

In order 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, EMA, over recent years, has continuously reviewed and fine-tuned its policies taking into account experience obtained.

The Management Board takes strategic decisions and oversees corporate activities of the Agency, such as setting EMA's budget and approving its annual work programme. It does not give recommendations on marketing authorisations of medicines.

The Agency will apply a 'risk-based' approach, to determine the level of involvement in activities of the Management Board for a Board member with a declared interest. This approach is based on four factors:

- the nature of the declared interest;
- the timeframe during which the interest occurred;
- the type of Management Board activity and the likely impact of the Board's decision on the pharmaceutical, or other industry; and



- the type of action requested by the Management Board, e.g., whether a decision such as approval or endorsement has to be taken by the Board or not.

The new policy will enter into force on 1 May 2016.

### **Breach of trust procedure**

The current 'breach of trust' procedure on declarations of interests for Management Board members has also been revised and was approved by the Board in December 2015. Changes are aligned with those introduced in 2015 for the breach of trust procedure for the scientific committee members and experts. The breach of trust procedure was developed in 2012 to deal with cases of incorrect or incomplete declarations of interests of Board members.

The revised breach of trust procedure came into effect on 1 January 2016.

### **Notes**

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1. This press release, together with all related documents, is available on the [Agency's website](#).
2. Revised policy: [Handling of competing interests of Management Board members](#).
3. Revised procedure: [EMA breach of trust procedure on declarations of competing interests for Management Board members](#).
4. All Management Board members must submit a declaration of interests every year, or as soon as their interests change. These are available on the EMA website under [Management Board members](#).
5. More information on [handling conflicts of interests](#) at EMA.
6. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

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