



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2014
EMA/709353/2014
Press Office

Press release

Conflicts of interests: revised EMA policy reflects more balanced approach

Experts to submit updated declarations of interests by end January 2015

The European Medicines Agency (EMA) has published its revised policy on handling declarations of interests for scientific-committee members and experts. The revisions reflect a more balanced approach to handling conflicts of interests that aims to effectively restrict the involvement of experts with possible conflicts of interests in the Agency's work while maintaining EMA's ability to access the best available expertise.

The revised policy, which was endorsed by the Management Board in March 2014, takes into account input from stakeholders at the Agency's September 2013 public workshop "Best expertise vs conflicts of interests: striking the right balance".

"The priority of EMA is to ensure that the integrity of our scientific assessments of medicines is not compromised by private interests in the pharmaceutical industry," said Noel Wathion, EMA's Chief Policy Adviser. "But over recent years we also have recognised that an overly-rigid approach may limit the availability of expertise needed to ensure the robust scientific assessment of medicines. The updated policy should now allow a level of involvement better tailored to the interest profile of each expert."

The revised policy includes a number of measures which better take into account the nature of the declared interest before determining the length of time any restrictions may apply:

- an executive role, or a lead role in the development of a medicine during previous employment with a pharmaceutical company now results in a lifetime non-involvement with the concerned company or product;
- for the majority of declared interests a three-year cooling-off period is foreseen. Restrictions to involvement decrease over time and make a distinction between current interests and interests within the last three years;
- for some interests, such as financial interests, there continues to be no cooling-off period required when the interest is no longer present.



Overall, requirements for experts who are members of scientific committees remain stricter than for those participating in EMA advisory bodies and ad-hoc expert groups. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than requirements for the other committee members.

Public scrutiny and transparency

All EMA scientific committee members and experts are required to submit their updated declarations of interests by the end of January 2015. The Agency will screen each expert's declaration and assign an 'interest level'. The interest level assigned and the nature of his or her involvement in EMA activities will determine the restrictions applied.

To ensure that this process is transparent, the updated declaration of interest and the assigned interest level of each expert will be published on the EMA website.

The new policy enters into force on 30 January 2015.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Updated policy: European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177253.pdf
3. Procedural guidance on inclusion of declared interests in the EMA's electronic declaration of interests form (for scientific committees' members and experts):
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/11/WC500177570.pdf
4. European experts list:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/experts.jsp&mid=WC0b01ac058043244a
5. Handling conflicts of interests at the EMA:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&mid=WC0b01ac0580029338#section1
6. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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