



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# European Medicines Agency's conflicts of interests handling recognised in European Court of Auditors report

## Many recommendations already implemented; some scope for further improvements identified

A review by the European Court of Auditors of the management of conflicts of interests in four independent agencies of the European Union found that the European Medicines Agency has some of the most advanced policies and procedures for declaring, assessing and managing potential conflicts of interests in place.

The report, which is based on policies and rules in place a year ago when the Court began its work, also makes a number of recommendations, many of which have already been implemented by changes made to the Agency's policies on dealing with conflicts of interests.

Professor Guido Rasi, the Agency's Executive Director, said that the Agency "is committed to continuous review and improvement of its handling of conflicts of interests. We will look carefully at the recommendations of the Court, together with the European Commission, the other EU agencies and our national counterparts in the European medicines network."

The Agency was one of four EU agencies included in the European Court of Auditors' review on the effectiveness of the policies and procedures they have adopted to manage potential conflicts of interests. The three others were the European Aviation Safety Agency (EASA), the European Chemicals Agency (ECHA) and the European Food Safety Agency (EFSA).

Protecting the scientific decision-making from undue financial or other interests is enshrined in the Agency's legislative framework, and policies have been in place to deal with conflicts of interests since its creation in 1995. The Agency has continuously strengthened the way it deals with conflicts of interests over the past years. Following a careful review of the experience gained, the Agency undertook a major revision of its policy on dealing with conflicts of interests at the end of 2010. Implementation of the new rules began from September 2011.

The main challenge in operating the new procedures is to find the right balance between ensuring the impartiality and independence of experts involved in the Agency's work versus the need to secure the best possible scientific expertise to continue to deliver top-quality scientific assessments. The Court



recognised in its report that this is often the case in highly specialised organisations, "where expertise is in limited supply and industry 'competes' for the same experts".

Additional Agency independence mechanisms not considered by the Court in their evaluation include collegial decision-making and peer review, and the recording and publication of all dissenting views.

Full details of the [policies, guidance and practical handling of declared interests](#) are published on the Agency's website.

The Agency has also conducted a number of controls to check that the policies are working. A review of potential conflicts of interests of experts involved in selected procedures at the Agency confirmed that there were no interests that constituted a potential conflict of interests in accordance with the policy applicable at the time of involvement.

## Notes

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1. This press release, together with all related documents, is available on the Agency's website.
2. Key characteristics of the Agency's rules on conflicts of interests:
  - Current employment with a pharmaceutical company is incompatible with involvement in Agency activities (no change compared to previous policy). Likewise, current financial interests in the pharmaceutical industry (not only shares) are incompatible with involvement in Agency activities (stricter than the previous policy).
  - Requirements for membership of decision-making bodies (scientific committees) are stricter than for advisory bodies (scientific advisory groups). Requirements are also stricter for chairs versus lead members (rapporteurs) versus other members.
  - Concept of 'expert witness' introduced for highly conflicted experts (including financial interests) who give specialist advice by providing information and replying to questions only.
  - Clear guidance on experts' involvement in academic trials and in publicly funded research/development initiatives. Restrictions in case of a pharmaceutical company giving a grant or other funding to the institution/organisation.
  - Restrictions in cases where current direct interests of household members have been declared.
  - A breach of trust procedure for members of the Agency's scientific committees and experts came into effect in April 2012.
  - All of this is accompanied by increased transparency, including publication of declarations of interests of all experts, including their assigned risk levels on the Agency's website.
3. [European Court of Auditors report on Management of conflict of interest in selected EU Agencies](#).
4. 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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