# More work needed on new EMA conflicts of interest policy

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In late November, the European Medicines Agency (EMA) published a revised policy on conflicts of interest. For many, the revised policy came as a bit of a surprise, not least because its Management Board had endorsed it about eight months earlier, in March. The main objective of the revised policy, according to the EMA's press release, was to ''reflect a more balanced approach to handling conflicts of interest that aims to effectively restrict the involvement of experts with possible conflicts of interest in the Agency's work while maintaining [the] EMA's ability to access the best available expertise". While some aspects of the new policy have been strengthened, most areas present opportunities for much-needed improvement, which we hope the EMA will consider in future revisions. The policy comes into effect for members of scientific committees and involved experts on 30 January, 2015.

***Improvements that have been made***

We applaud the EMA for including a broader definition of what comprises a pharmaceutical company and close family members in the revised policy. We're also pleased that if an individual plays an executive, or lead, role in the development of a medicine during his/her previous employment with a pharmaceutical company, this will result in a lifetime non-involvement with the concerned company or product.Both of these new proposals improve the comprehensiveness of the policy and take into account scenarios that should also be considered conflicts of interest.

***Areas for improvement***

While some improvements have been made, we're disappointed that the EMA has reduced the 'cooling off period' to three years (from five years) for the majority of declared interests, and that there is still no cooling-off period for financial interests. This is a clear weakening of the policy. The EMA needs to embrace a more precautionary approach to ensure that decisions—particularly, scientific-related assessments—are free of undue influence.

The revised policy also continues to make an arbitrary distinction between direct and indirect interests with the latter allowing a more permissive involvement with the EMA's activities. Being a principal investigator or an investigator involved in a pharmaceutical industry instigated/sponsored trial is, for example, considered an indirect interest, as is belonging to an institution or organisation that receives funding from a pharmaceutical company, which, in turn, is used to support any expert activities. Sponsorship and funding by pharmaceutical companies to an organisation (such as patient and healthcare professional organisations) cannot be considered a *minor* conflict. The corresponding restrictions should be applied.

In addition, while we welcome the commitment of the EMA to develop a proactive approach

with respect to the search of alternative experts in the field, we encourage it to find the needed independent experts within research centres, universities, patient, consumer and healthcare organisations. This could be done by distributing information materials to raise awareness about their important contribution to the EMA's work.

We also encourage the EMA to invite independent researchers to future workshops on conflicts of interest, organised by the Agency, to explain the results of their studies and how conflicts of interest influence behaviour. These kinds of exercises have shown to be very useful to medicine students and healthcare professionals. Experts engaged in the EMA's activities, particularly those with declared interests, would likely learn a great deal.

Finally, we urge the EMA to make the ongoing revision process for this policy more open and transparent. It was rather unfortunate that a public consultation was not held on this subject. This could have further strengthened this very important policy that benefits public health decision making.