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Press release

European Medicines Agency strengthens rules on Conflicts of Interests of its scientific experts

New rules aim for a more robust, efficient and transparent process

The European Medicines Agency has published new rules on how the Agency will be handling potential conflicts of interests of its scientific experts, following endorsement by its Management Board on 7 October 2010. The new rules aim at balancing out the need to secure Europe's best scientific experts for the evaluation and supervision of medicines while ensuring that these experts have no financial or other interests in the pharmaceutical industry that could affect their impartiality.

"Providing independent, high-quality scientific opinions about medicines to the European Commission and EU Member States is the core function of the European Medicines Agency. We take this work seriously and review our processes continuously to be sure that we take all steps necessary to protect our scientific opinion-making against the influence of any improper interests", says Noel Wathion, Head of Patient Health Protection at the European Medicines Agency.

The new rules are based on three pillars: robustness, efficiency and transparency. Conflicts of interests are classified into three categories – direct, indirect and no interests. Experts and members of the scientific committees provide a signed declaration of interests form detailing any financial or other interests that could affect their impartiality. Following this they are assigned corresponding risk levels, with direct interests leading to the highest risk-level. According to the risk level assigned, involvement of the expert may be restricted taking into account the nature of the interest declared, the time passed since the interest occurred and the type of activity the expert will be involved with.

The Agency will apply a more proactive approach both in identifying potential conflicts of interests and in searching for alternative experts. As part of this, the Agency will screen all declared interests of proposed members of its scientific committees prior to their formal nomination. In areas where conflicts of interests may limit the availability of experts, e.g. in relation to some rare diseases, the Agency will look proactively for alternative experts by using its established relationships with academia and learned societies.

All of this is underpinned by an increased level of transparency on declared conflicts of interests throughout the whole scientific review process. In addition, the declarations of interests of all members

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of the Agency's scientific committees are published on the Agency's website. The new rules foresee that the declarations of all other experts included in the Agency's database, which are currently available on request, will be gradually published on the Agency's website.

It is expected that the new policy will enter into force by the second quarter of 2011.

Notes

1. The European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts, together with an 'overview of the allowable interests of EMA scientific activities' as endorsed by the Management Board on 7 October 2010 is available on the Agency's website.
2. Implementation of the policy is subject to a number of practical arrangements which are expected to be in place by the second quarter of 2011.
3. More information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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