

30 September 2011
EMA/794549/2011
Press Office

Press release

European Medicines Agency launches new database of European experts

New database gives access to declarations of interests of all experts

Coinciding with the entry into force of new rules on how to handle conflicts of interests of scientific experts, the European Medicines Agency today launched its new experts database. The database allows the public for the first time to directly search for the declarations of interests of all experts who have been nominated by competent authorities for medicines regulation across the European Union to be involved in the Agency's activities.

The launch of the new database is a major building block of the Agency's new rules on the handling of conflicts of interests of its scientific experts, which aim at protecting the Agency's scientific opinion-making processes from the influence of any improper interests.

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 provide a signed declaration of interests form detailing any direct or indirect financial or other interests that could affect their impartiality. The declarations of interest are displayed on the website as submitted by the experts.

On the basis of the declarations of interests, the Agency takes decisions on whether or not to include an expert as a member of a working party or other group. Experts 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 or even excluded, taking into account the nature of the interest declared, the time passed since the interest occurred and the type of activity in which the expert will be involved.

According to the new rules, 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 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, with the new experts database as a key element.

The new database contains the names of approximately 5,000 experts. New declaration of interest forms have been received and published for around half of them. Declarations of interests of experts who have not yet submitted or signed their forms will continue to be received and published over the coming weeks and months, so that all experts have a valid and signed declaration of interest published together with their name on the Agency's website. Involvement in the Agency's activities is subject to the availability of a signed declaration of interests form and assessment of declared interests.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/09/news_detail_001352.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1
2. The experts database is accessible on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/experts.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac058043244a
3. Previously, declarations of interests of experts were available only upon request.
4. The experts database will replace the List of European Experts which previously was published on the Agency's website.
5. More information on the Agency's rules on conflicts of interests is available on the website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78#section1
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu