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Press Office

Press release

European Medicines Agency's Management Board endorses work programme 2014

The Board also clears the way for publication of EMA Committees' agendas and minutes and endorses key principles for revision of conflicts-of-interests policy

The European Medicines Agency's Management Board, at its meeting on 11-12 December 2013, adopted the Agency's work programme and budget for 2014.

In addition to delivering core business activities to a high level of quality and consistency, implementing new legislation and increasing transparency and communication, new priorities for 2014 include:

- enhancing cooperation within the European medicines network through training, expansion of national experts programmes and IT systems that deliver value to the network;
- facilitating early stages of medicines development by promoting and integrating the range of procedures available to medicine developers;
- improving the quality, integration and accessibility of data held by the Agency for the network and stakeholders;
- reinforcing international cooperation with emphasis on inspection cooperation and capability building to ensure that clinical trials conducted outside the European Union (EU) and medicines destined for EU citizens are of the required high quality;
- tackling the issue of antimicrobial resistance and availability of anti-infective treatment options both in the human and veterinary areas;
- improving operational effectiveness and efficiency of the Agency as part of the reorganisation of the Agency.

Forecast and budget

In 2014, the Agency expects a slight general increase in its assessment activities for human medicines compared with 2013. Activities in the early stages of medicines development remain at a high level; these activities, which provide support to sponsors, include scientific advice on clinical development,

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orphan designation and support to micro-, small- or medium-sized enterprises. A 16% increase in the number of extensions of indication and variations applications is expected. A 12% decrease in the number of initial marketing-authorisation applications received is forecasted, which is mainly due to a lower number of generic applications. The number of applications for new medicines containing a new active substance is expected to be stable.

In the veterinary area, the Agency expects an overall steady level comparable to previous years of the assessment activities, following a high level of applications in 2013.

The work programme is accompanied by a budget of €297.2 million, which comprises fee revenue of €236.2 million, an EU contribution of €39.2 million and €20 million for the EMA's relocation.

Revision of conflicts-of-interests policy

The Board endorsed draft principles that will guide the revision of the Agency's conflicts-of-interests policy for scientific-committee members and experts. This revision aims at maintaining a pool of high-quality scientific experts while ensuring that experts are free from undue financial or other interests. The principles discussed by the Board stem from discussions that took place during a workshop organised by the Agency in September 2013 and include:

- considering the nature of a declared interest within the frame of a specific EMA activity before determining how long it takes for the interest to be over;
- further differentiating rules for experts involved in decision-making bodies versus experts involved in advisory bodies;
- making involvement with EMA more attractive to experts by recognising experts' involvement in EMA activities, developing a framework of interaction with academia and exploring the possibility for shorter- or longer-term incentives.

A revised policy and an implementation plan will be presented to the Board at its March 2014 meeting.

Go-ahead for the publication of agendas and minutes of all EMA scientific committees

The Board cleared the way for the publication of the agendas and minutes of the Agency's Committee for Medicinal Products for Human Use (CHMP), Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Advanced Therapies (CAT).

Today, the Agency will publish for the first time the agendas of the December meetings of these three committees. The minutes of the meetings will be published once they have been adopted in January. It will then become standard practice to publish all Committees' agendas at the start of the meetings.

The Agency announced in July 2012 its plan to publish the agendas and minutes of all seven scientific committees before the end of 2013. This is the final step of this process that has already been implemented, in a phased approach, for the other four committees of the Agency.

Similarly, the agenda of the Management Board meetings will now be published ahead of the meeting as of 2014.

Update on next steps towards publication and access to clinical-trial data

The Board agreed on a set of key principles which will guide the finalisation of the policy on publication and access to clinical-trial data. The policy and an implementation plan will be discussed at the March 2014 Management Board meeting.

Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release is available on the Agency's website.
2. The press release on next steps towards publication and access to clinical-trial data is available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/12/news_detail_001991.jsp&mid=WC0b01ac058004d5c1
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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