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Press Office

Press release

EMA Management Board: highlights of October 2015 meeting

Focus on mid-year report and interactions with key stakeholders

Mid-year report: continuous increase in parallel advice with HTA bodies

The Management Board heard an update on the European Medicines Agency's (EMA) activities in the first half of 2015. Overall, the mid-year report for 2015 shows that the Agency's operations were largely in line with its forecast. There was a notable increase in the Agency's activities supporting innovation and development of medicines compared to the same period in 2014. Of the marketing authorisation applications for medicines containing a new active substance and for biosimilars that were submitted in the first half of 2015, 77% had received scientific advice. This demonstrates that EMA's efforts to encourage medicines developers to seek interaction and dialogue with the Agency are paying off. Early dialogue supports the development of high-quality, effective and safe medicines that meet patients' needs.

The number of requests for scientific advice and protocol assistance rose by 6% compared to the same period last year. Among these, the number of requests for parallel scientific advice with health technology assessment (HTA) bodies more than tripled (21 in the first half of 2015 compared to six in the first half of 2014). This procedure enables medicine developers to gain feedback from regulators and HTA bodies at the same time, early in the development of a medicine. This can streamline the generation of evidence needed to determine both a medicine's benefit-risk balance and its relative effectiveness so that patients can access new medicines in a timely manner.

In the area of veterinary medicine, the number of scientific advice requests in the first half of the year was at the same level as in 2014. The number of requests for classification of medicines for minor-use-minor-species (MUMS) / limited-market increased compared to the first half of 2014.

Adoption of formal framework for interaction with industry stakeholders

The Board adopted a framework for interaction between EMA and industry associations. The aim of the framework is to formalise and structure EMA's interaction with industry stakeholder groups to:

- facilitate exchange of views and promote dialogue;
- improve delivery of efficient, targeted and timely communication;

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- enhance understanding of the European Union (EU) medicines regulatory framework by pharmaceutical companies;
- increase transparency of EMA's engagement with stakeholders from pharmaceutical industry and report on these interactions annually.

The framework covers a broad range of industry association types, including industry trade associations, organisations engaged early on in the innovation lifecycle, associations of service providers or professionals supporting the industry, and associations with multi-stakeholder membership including industry. An action plan is included in the framework.

Integrating the views of patients and healthcare professionals in EMA's activities

The Board received the 2014 annual report on the Agency's interaction with patients, consumers and healthcare professionals. The report shows that integrating the views of patients, consumers and healthcare professionals in a wide range of EMA activities has become an established part of the Agency's work. In 2014, patients, consumers and healthcare professionals brought their life experiences and clinical practice perspectives to the evaluation of medicines on more than 900 occasions.

The key highlight of 2014 was that patients were involved for the first time in discussions on the benefits and risks of a new medicine with the Committee for Medicinal Products for Human Use (CHMP) during a plenary meeting. This is part of a pilot project that started in 2014 to explore how patients can be involved systematically and effectively in discussions of the CHMP. The pilot has been extended into 2016 to allow more patients to participate.

Update on development of a clinical trial portal and database

The Board endorsed the addendum to the functional specifications of the EU portal and database, which describes the practical implementation of the transparency rules of the European Clinical Trial Regulation.

According to the Regulation, EMA is responsible for the development and maintenance of a portal and database for the submission of clinical trial applications and authorisations within the EU.

The public will be able to access extensive details of each trial including the major characteristics of the trial, the start and end of recruitment, end date of the trial and substantial modifications to the trial. A summary of results and lay summary will normally be published 12 months after the end of the trial.

The document endorsed by the Board sets out the rules for the publication of this information. It is the outcome of a large public consultation exercise. In addition, EMA also held meetings with different stakeholder groups.

The Board was also updated on the timeline for the implementation of the clinical trial portal and database. The plan is to have the system available for an independent audit by the end of the third quarter of 2016. If the portal and database get a green light from the audit, the Regulation will come into application by the end of 2017. From that point onwards the portal and database will be operational for sponsors and Member States to use for all new clinical trial applications in the EU, and the information from the database will be publically available.

Herbal medicines: achievements and challenges

Dr Werner Knöss, Chair of the EMA Committee on Herbal Medicinal products (HMPC) and Head of the Complementary and Alternative Medicines and Traditional Medicinal Products department of the

Federal Institute for Drugs and Medical Devices (BfArM), presented the achievements and ongoing challenges in the area of herbal medicines.

According to Dr Knöss, "The work of the Committee since its establishment 10 years ago has led to a high level of harmonisation of the conditions of use of herbal medicines across the European Union". So far, the Committee has issued 140 scientific opinions, known as EU monographs, which contain recommendations on the conditions of use and potential side effects associated with the use of herbal substances. These opinions can be used by EU Member States when evaluating marketing authorisation and registration applications submitted by companies and by the companies themselves as part of their applications. Reflecting on the challenges posed by traditional medicines of non-European origin, Dr Knöss said, "Chinese and Indian herbal substances are already a reality in the EU market. We need harmonised standards to protect public health and the Committee is working towards this aim."

Notes

1. This press release and all relevant documents adopted at the Management Board meeting are available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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