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Press Office

Press release

EMA Management Board: highlights of December 2014 meeting

The Board adopts EMA work programme 2015-2016

Looking towards 2015

During its two-day December meeting, the European Medicines Agency's (EMA) Management Board adopted the Agency's work programme and budget for 2015 and a preliminary draft programme and budget for 2016. Priorities for the next two years include:

- Ensuring that assessment activities are conducted to the highest standards of quality, regulatory and scientific consistency;
- Facilitating early stages of medicines development in both the human and veterinary areas;
- Enhancing cooperation within the European medicines regulatory network, as well as with European and international partners;
- Continuing the implementation of pharmacovigilance legislation and clinical trials legislation;
- Providing support to European institutions in the context of the revision of the veterinary medicines legislation;
- Ensuring efficient crisis management and responsiveness to public health threats, including addressing antimicrobial resistance and availability of anti-infective treatments;
- Further increasing transparency and access to data, and implementing stakeholder and communication strategies;
- Improving quality, integration and accessibility of data held by the Agency.

Forecast and budget for 2015

In 2015, EMA expects a general increase in pre-authorisation activities in the area of human medicines. In particular, a sustained increase in requests for scientific advice on clinical development, including parallel advice with heath technology assessment (HTA) bodies which aims to facilitate timely access to medicines for patients, is expected.

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The number of applications for initial marketing authorisation is expected to be as high as in 2014 (114 in 2015 versus 118 in 2014). More than 20% of these applications are for medicines for rare diseases (24 in 2015 versus 23 in 2014). The number of applications for medicines containing a new active substance should remain stable.

In the veterinary area, EMA also expects a slight increase in pre-authorisation activities as well as a higher number of applications for initial marketing authorisation (20 in 2015 versus 16 in 2014).

The budget for 2015 is €302,117 million, a 7% increase over 2014 (€282,474). This is mainly due to the overall higher number of applications expected in 2015 and to the application of pharmacovigilance fees.

EMA interaction with patients, consumers and their organisations – revised framework

The Board adopted a revised framework of EMA interaction with patients, consumers and their organisations. This framework was first established in 2006. One of the goals is to incorporate patients' and consumers' values and preferences in all evaluation activities to further ensure the safe and rational use of medicines. Consulting and listening to patients and consumers also improves plans and policies.

The revised framework allows the Agency to further build transparency and trust with patients' and consumers' communities through their active engagement in EMA's activities. The new framework foresees in particular:

- the establishment of a pool of disease-specific patient experts to make the process of involvement easier, particularly in product-related activities;
- the development of patients' capacities through training to facilitate their integration in the Agency's work;
- raising awareness about EMA and the European regulatory network activities to enhance understanding of the regulatory processes.

Clinical trial portal

The Board endorsed the functional specifications of a clinical trial portal and a database that will be developed by EMA as part of the implementation of the new European Union (EU) Clinical Trial Regulation.

These specifications were drawn up by EMA in collaboration with the Member States and the European Commission and have previously been released for public consultation. The final document will be published shortly on the EMA website.

The authorisation and oversight of clinical trials remains the responsibility of Member States. The portal, database and associated workspace are created to simplify and facilitate the approval of clinical trials in the EU by providing a single entry point for the submission of data and information relating to clinical trials. This is expected to improve the attractiveness of the EU as a research location and facilitate multistate trials. The user-friendly IT platforms will support sponsors and experts in Member States in all aspects related to clinical trials. The platforms will also provide for enhanced transparency on the conduct of trials in the European Economic Area, from the point of their authorisation to the publication of the results of those clinical trials.

EMA will present timelines for the development and deployment of the system at the March 2015 Management Board meeting.

EMA anti-fraud strategy

The Board adopted an EMA anti-fraud strategy, in line with the European Commission's initiative to develop a common approach for all EU decentralised agencies in the fight against fraud.

The strategy applies to EMA staff, delegates, contractors and suppliers in the conduct of their duties. The overall objective is to improve the prevention, detection and investigation of fraud and to achieve adequate reparation and deterrence.

The strategy is based on a fraud risk assessment and focuses on four areas: data security/theft; impartiality of assessment; procurement; and recruitment.

The EMA anti-fraud strategy will be published shortly on the EMA website.

Policy on veterinary medicines for minor use minor species / limited market revised

The Board adopted the EMA revised policy and supporting guidance on veterinary medicines for minor use minor species (MUMS) / limited market. The MUMS policy was introduced in September 2009 to stimulate the development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed under current market conditions. Two types of assistance are provided for veterinary medicines that are classified as intended for MUMS/limited market: reduced data requirements and financial incentives for applications. The financial incentives offered under the revised policy are restricted to medicines for food-producing species as these have the potential to be of most benefit to animal or public health.

The criteria for classification as MUMS/limited market have also been refined in light of the experience gained with the objective of providing greater clarity and predictability to potential applicants with regard to the classification of the medicines and the support they can obtain.

The revised policy went through a public consultation before being presented to the Board.

Guido Rasi offered role as Principal Adviser

The Management Board approved the amendment of Guido Rasi's current contract. As Principal Adviser in charge of strategy, he will continue to serve the Agency by ensuring strategic coordination among EMA's scientific committees and by shaping the Agency's strategy with respect to regulatory matters of international relevance.

The amendment of Guido Rasi's contract follows the November 2014 judgment of the EU Civil Service Tribunal that annulled in part the 2011 selection procedure for the position of Executive Director. While Guido Rasi no longer heads the Agency, his contract is still in operation. This will allow the Agency to benefit from his experience.

The European Commission published today a vacancy announcement for the position of EMA Executive Director.

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. Vacancy announcement for the position of EMA Executive Director: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000325.jsp&mid=WC0b01ac0580029400
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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