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Press Office

Press release

EMA Management Board: highlights of December 2015 meeting

Focus on adoption of multi-annual work programme and 2016 budget, timeframe for the development of the EU clinical trial portal and database, and personnel changes

Looking towards 2016

At its December meeting, the European Medicines Agency's (EMA) Management Board adopted the Agency's programming document which includes a multi-annual programme, EMA's work programme and budget for 2016 and a preliminary draft programme and budget for 2017.

The single programming document is required by the new EU Financial Regulation and was developed for the first time.

EMA expects a stable level of pre-authorisation activities for human medicines in 2016. According to the forecast, around 546 requests for scientific advice on medicine development will be received, compared to 510 in 2015. Among these, EMA expects approximately 33 requests for parallel advice with heath technology assessment (HTA) bodies, an important tool for the Agency to facilitate timely access to medicines for patients.

The number of applications for initial marketing authorisation in 2016 is expected to remain constant with 110 applications in 2016 versus 112 in 2015. The number of applications for medicines containing a new active substance should remain stable.

In the area of veterinary medicines, EMA is expecting a moderate increase in the number of applications for initial marketing authorisation (18 in 2016 versus 14 in 2015).

EMA's budget for 2016 is forecast to rise by 5.4% to a total of €324,711 million.

EMA's work programme for 2016 will be published on the EMA website in the first quarter of 2016.

Timeframe for development of EU clinical trial portal and database endorsed

The Board endorsed the timeframe for the implementation of the EU clinical trial portal and database.

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The Clinical Trials Regulation involves a very significant overhaul of the processes for authorisation and oversight of clinical trials. This ambitious project is underpinned by the services of the EU clinical trial portal and database. It will provide a single portal for submission and maintenance of clinical trial applications and authorisations, and support their coordinated assessment and supervision. The portal and database will also serve as the source of public information on the full lifecycle of all clinical trials conducted in the EU, from their initial review up to publication of their results.

The Board emphasised that it is of critical importance that the EU system provides the required functionalities to all stakeholders in the most efficient and stable way from the start of its operations. This is to ensure delivery of the benefits foreseen by the Clinical Trial Regulation for researchers, patients and the public as a whole.

The development of the portal and database, which is underway, is guided by the functional specifications agreed by the Board in December 2014. The timeframe endorsed by the Board enables the robust development and testing of the system and allows resolving unforeseen difficulties and potential issues. The timeframe foresees that the database and portal are available for independent audit by August 2017. If the system gets a green light from the audit, the EU Clinical Trial Regulation will come into effect by October 2018 at the latest.

The Board stressed that this is a maximum timeframe and that all possible efforts must be made to shorten it and bring the Regulation into operation as soon as possible.

Management Board Chair stands down

Sir Kent Woods announced that he will step down as Chair of the Board effective as of the end of December 2015.

Management Board Vice-Chair, Christa Wirthumer-Hoche, Head of the Austrian Medicines and Medical Devices Agency (AGES), will take the role until the election of a new Chair takes place at the next meeting of the Board on 17 March 2016.

In his announcement to the Board, Sir Kent, who has served as Chair of the Board since 2011, said: “It has been a privilege to serve as chairman of EMA’s Management Board. Together, EMA and the regulatory authorities in Member States have achieved a lot in recent years and the development of a shared strategic plan for the coming five years is a major landmark.” He added “I am confident that under Guido Rasi’s leadership the Agency today is in a strong position to move forward to serve patients and protect public and animal health in Europe.”

Sir Kent, who led the UK’s Medicines & Healthcare products Regulatory Agency (MHRA) as Chief Executive from 2004-2013, was recently appointed as senior medical trustee and chairman of the Advisory Council of the British Heart Foundation.

EMA’s Executive Director, Guido Rasi, said: “I would like to extend my heartfelt thanks to Sir Kent for more than four years of exceptional stewardship of the Management Board. He has expertly guided the Board through a key and sometimes challenging time for the Agency. We wish Sir Kent all the very best in his new position.”

Organisational changes

EMA Executive Director Guido Rasi announced to the Board that Noël Wathion, EMA Chief Policy Adviser and ad interim Head of EMA’s Stakeholders & Communication Division, has been appointed to follow Andreas Pott in the role as Deputy Executive Director of the Agency. This appointment will be effective as of 1 February 2016. Andreas Pott and Noël Wathion will be working closely together over the coming months to ensure a smooth transition of responsibilities before Mr Pott retires.

Among other responsibilities, Noël Wathion will be in charge of policy development and preparation for new legislation, emergency/ crisis management, liaison with EU Institutions, access to documents and proactive publication of clinical data, as well as fostering integration of EMA activities across the Agency.

Melanie Carr, Head of the Corporate Stakeholders Department, has been appointed as ad interim Head of the Stakeholders & Communication Division.

Other meeting highlights:

- Adoption of EU Medicines Agencies Network Strategy to 2020 – see separate press release.
- Adoption of Revised EudraVigilance Access Policy – see separate press release.
- Endorsement of reliance on the Article 57 database for Qualified Person Responsible for Pharmacovigilance (QPPV) contact details and Pharmacovigilance System Master File (PSMF) location – see separate news item
- Adoption of revised policy on the handling of competing interests of Management Board members and revised breach of trust procedure on declarations of competing interests for Management Board members – separate communication and documents to be released in January 2016.

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 Clinical Trials Regulation (EU) No. 536/2014 was published in the Official Journal of the EU in May 2014.
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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