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Press release

EMA Management Board: highlights of June 2016 meeting

New civil society representatives join the Board; EMA multiannual work plan to 2020 and overarching stakeholder relations management framework adopted

New civil society representatives join the Board

At its June meeting, the European Medicine Agency's (EMA) Management Board welcomed new representatives of civil society who are joining the Board as members.

Ilaria Passarani, Head of the Food and Health Department at the European Consumer Organisation (BEUC), and Yann Le Cam, Chief Executive Officer and co-founder of the European Organisation for Rare Diseases (Eurordis), will represent patients' organisations.

Wolf-Dieter Ludwig, Head of the Department of Hematology, Oncology, Tumor Immunology and Palliative Care at Helios Klinikum Berlin-Buch, a hospital in Germany, has been reappointed to represent healthcare professionals' organisations.

Nancy De Briyne, Deputy Executive Director of the Federation of Veterinarians of Europe, is the new representative for veterinarians' organisations.

The civil society members have full voting rights at the Board; their role is to ensure that the views and needs of patients, healthcare professionals and veterinarians are taken into account. Their mandate lasts for three years.

In addition, Tonio Borg has been appointed to represent the European Parliament. Mr Borg is a former European Commissioner for Health. He will serve as the Parliament representative together with Björn Lemmer, who has been re-appointed to this role. Björn Lemmer is a former member of the National Commission on Prescription of Drugs in Germany.

EMA multiannual work plan to 2020 adopted

The Board adopted EMA's multiannual work programme to 2020. This programme supports the implementation of the joint strategy to 2020 for the European medicines regulatory network developed by EMA and the Heads of Medicines Agencies (HMA). The multiannual work programme outlines the

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main initiatives and activities that the Agency will undertake in the coming years to support the achievement of common goals.

The document will be published shortly on the EMA website and will be reviewed annually.

Overarching framework for stakeholder relations management adopted

The Board adopted EMA's framework for stakeholder relations management, a high level document which outlines the overarching principles for managing EMA's key stakeholder interactions. The framework builds on the Agency's experience in interacting with stakeholder associations representing patients and consumers, healthcare professionals, the pharmaceutical industry and, more recently, academia. The aim of this overarching framework is to streamline interaction activities across the various stakeholder groups and align working methodologies where possible.

The Board also adopted the criteria to be fulfilled by industry stakeholder organisations to be eligible for direct involvement in the Agency's activities. These eligibility criteria stem from the Agency's framework for interaction between EMA and industry stakeholders that was adopted last year, and will come into effect on 15 January 2017.

Positive assessment of EMA 2015 operations

The Board gave a positive assessment of EMA's operations in 2015, and of its management and internal control system.

Areas of work highlighted by the Board included: the common strategy to 2020 for the European medicines regulatory network that was adopted by EMA and the Heads of Medicines Agencies for the first time in 2015, the Agency's efforts to improve timely access to promising medicines for patients and the establishment of the European Network Training Centre to ensure that good scientific and regulatory practice is promoted across the European medicines regulatory network.

Update on implementation of the EudraVigilance system

The Board approved an updated schedule for the implementation of the new EudraVigilance system. The new system that will offer enhanced functionalities for the reporting and analysis of suspected adverse drug reaction to all stakeholders, is now expected to go live in November 2017. The four-month delay is mainly due to the need to optimise the performance of the new system prior to its launch. The system processes very large numbers of reports and transactions every day and its use will increase significantly with the new functions being made available, so a high level of system performance is crucial.

Further information on the EudraVigilance project and its implementation can be found on the EMA website.

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. Following a call for expressions of interest, the four civil society Board members are appointed by the Council of the European Union, after consultation of the European Parliament and based on a list drawn up by the European Commission.
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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