EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholder Division

Press release

EMA Management Board: highlights of December 2016 meeting

Board adopts work programme and budget 2017 and hears Brexit update

Update on Brexit preparations

The Management Board of the European Medicines Agency (EMA) heard from Executive Director Guido Rasi how the Agency is preparing for the possible exit of the United Kingdom (UK) from the European Union (EU). The extent of the impact of Brexit on the Agency's operations and location is uncertain and will depend on the future relationship between the EU and the UK. Depending on the outcome of the negotiations, this could cause significant disruption to the Agency's operations and business continuity plans will need to be in place. As part of its preparedness, the Agency will continue carrying out impact assessments to identify the main risks and propose possible mitigating measures to maintain the Agency's ability to protect public health.

Work programme and budget for 2017 adopted

Despite the uncertainties brought about by the outcome of the referendum, EMA's work programme 2017 signals that the Agency is committed to carrying on with its responsibilities as usual. The Board adopted a budget of 322 million Euros for 2017, a 4.4% increase over the previous year. This is expected to cover the expected 5.4% increase in its fee-financed workload and will also allow the Agency to focus on priority areas such as antimicrobial resistance, supporting innovation and access to both human and veterinary medicines, increasing and improving regulatory capacity and capability as well as its continued commitment to increased transparency. The work programme is being finalised and will be published by the end of January 2017.

Multinational assessment teams extended to post-authorisation procedures

The Board endorsed an extension of the concept of multinational assessment teams to post-authorisation assessments. EMA has been encouraging the formation of assessment teams not by country but by expertise since 2013, initially for the assessment of new medicines. Following the endorsement by the Board, assessment teams made up of experts from several member states will also be able to evaluate applications for extensions of marketing authorisations of existing medicines as of April 2017.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Multinational assessment teams enable the involvement of a wide range of Member States in the work of EMA's scientific committees. They contribute to optimising the use of resources throughout the European regulatory system for medicines and encourage cross-border fertilization of scientific expertise for high quality work of the committees.

Revision of EMA's access to documents policy

The Board also gave its green light for the launch of a public consultation to revise the Agency's existing policy on access to documents. The revision seeks to take account of the experience gained since the current policy entered into force in 2010, and to extend its scope to include both access to documents that relate to human or veterinary medicines as well as to corporate information.

The launch of the consultation including the publication of the consultation documents is foreseen for January 2017.

Updated framework for interaction with healthcare professionals

The Board endorsed an update to the existing framework of interaction with healthcare professionals. The main aim of the update was to align the framework with the Agency's overarching framework for stakeholder interaction. It also places new focus on the involvement of general practitioners and family physicians, who play a key role in patient care as they often have the first contact with the patient and accompany them throughout the life of their condition. Involving them in the Agency's activities can greatly enrich the knowledge and experience on how a medicine is used in real life for better decision making.

Notes

1. This press release, together with all related documents, is 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

Contact our press officer

Monika Benstetter
Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu

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