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Press release

EMA Management Board: highlights of March 2017 meeting

Focus on veterinary medicines

At its March 2017 meeting, the Management Board of the European Medicines Agency (EMA) focussed on the Agency's activities in relation to veterinary medicines.

Veterinary medicines: achievements and challenges

Dr David Murphy, chair of EMA's Committee for Medicinal Products for Veterinary Use (CVMP), presented the achievements and ongoing challenges in the area of animal health. Dr Murphy highlighted a number of innovative new medicines for animals that EMA has recently recommended for marketing authorisation. These included the first DNA vaccine in the European Union, to protect Atlantic salmon against a serious pancreatic disease; the first monoclonal antibody veterinary medicine, to treat atopic dermatitis in dogs; and a new medicine to protect honey bees against a serious parasitic infestation affecting honey bees worldwide.

"In addition to establishing maximum residue limits (MRLs) for new substances, the CVMP reviews all the scientific opinions on MRLs for substances that are already in use in light of any emerging safety concerns," Dr Murphy stressed. "This is an important activity to ensure that foodstuffs of animal origin are safe for consumers."

The CVMP chair also provided an update on activities in the area of antimicrobial resistance, in particular he emphasised the collaboration between EMA and the European Food Safety Authority (EFSA) on measures to reduce the need for antimicrobial use in animals. "Our recently published joint opinion will influence future policy on measures to be taken in the veterinary sector to address the public health risk associated with antimicrobial resistance," said David Murphy.

The CVMP chair pointed out that the Committee had only limited resources to deal with a wide variety of tasks, ranging from the assessment of marketing authorisation applications to referrals and scientific opinions. In this context, he welcomed the recent creation of the EU Network Training Centre and recognised the importance of this initiative to maintain and further improve the expertise available in the network.

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Increasing availability of veterinary medicines for minor species and minor use

The Board endorsed the 2016 report on the implementation of the policy on veterinary medicines for minor use minor species (MUMS) / limited markets. 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.

EMA has observed stakeholders' continued high level of interest in the policy. 178 requests for classification as a MUMS medicine were received since the policy entered into force, including 25 requests received last year.

The MUMS scheme grants developers access to specific incentives and has proved successful in facilitating the authorisation of new treatments for animals. In 2016 alone, four MUMS medicines were recommended for marketing authorisation, including the above-mentioned medicines for honey bees and Atlantic salmon.

Veterinary medicines that are classified for MUMS / limited market can benefit from two types of assistance: reduced data requirements and financial incentives for applications. The financial incentives are restricted to medicines for food-producing species as these can have an important impact on animal or public health.

Framework for reinforced collaboration with academia adopted

The Board adopted a framework of collaboration between EMA and academia. The framework aims to reinforce and further develop the collaboration between the Agency and academia by clarifying the scope, and by formalising and structuring interactions in the wider context of the European medicines regulatory network. Further information, including the framework document, an action plan, and dedicated webpages on the EMA website will be made available in early April.

Other meeting highlights:

- Adoption of a new policy on EMA's handling of information disclosed by external sources on alleged improprieties concerning EMA activities in the area of the authorisation, supervision and maintenance of human and animal medicinal products. Publication of the policy and associated document is planned for the end of March 2017.
- Adoption of EMA annual report 2016. Publication is planned for April 2017.

Notes

1. This press release is available on the Agency's website.1.All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course.
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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