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Press release

EMA Management Board: highlights of March 2016 meeting

New chair elected, report from Paediatric Committee and update on policy on veterinary medicines for minor use minor species / limited market

Christa Wirthumer-Hoche elected as new chair of the Management Board

At its 17 March meeting in London, the European Medicines Agency's (EMA) Management Board elected Christa Wirthumer-Hoche as chair of the Board for a three-year period. Dr Wirthumer-Hoche is Head of the Austrian Medicines and Medical Devices Agency, a post she has held since October 2013. She has served as vice-chair of EMA's Management Board since March 2015. For further information, please see separate announcement.

Medicines for children: achievements and challenges

Dr Dirk Mentzer, chair of EMA's Paediatric Committee (PDCO) and Head of Pharmacovigilance at the German national agency for vaccine and biomedicinal products (Paul-Ehrlich-Institut), presented the achievements, challenges and priorities of the PDCO regarding medicines for children.

The chair recalled that the EU Paediatric Regulation came into force 10 years ago to improve the health of children in Europe by stimulating high quality research and promoting the development and authorisation of paediatric medicines in the EU.

Dr Mentzer highlighted areas where the therapeutic landscape for children has significantly improved over the past few years. These include rheumatologic diseases, conditions that affect the joints, muscles, bones and immune system, for which children had extremely limited therapeutic options a few years ago. "Thanks to the EU Paediatric Regulation which has enforced the study of new innovative treatments in paediatric rheumatology, a number of biological medicines for rheumatologic conditions are now authorised for use in children," explained Dr Mentzer. "Children also have access to new and innovative treatments for hypertension and hypercholesterolaemia as well as for infectious diseases, such as HIV and hepatitis C. All these medicines were authorised on the basis of studies conducted as part of paediatric investigation plans (PIP) agreed with the PDCO."

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Dirk Mentzer mentioned ongoing challenges in areas such as neonatology, neurology, congenital defects and paediatric rare cancers in which it is difficult to study medicines, in particular due to the rarity of these children-only indications or the high toxicity of the medicines, e.g. in cancer.

In future, the PDCO will focus on the integration of innovative clinical trial methodology, such as modelling, simulation and extrapolation of data, in its decisions. "These tools are very helpful to avoid unnecessary studies in children, one of the objectives of the Paediatric Regulation," explained Dirk Mentzer. Strengthening collaboration between EMA committees and increasing the involvement of patients in PIP decisions, for example to collect their views on the feasibility of clinical trials, are also among the PDCO's key priorities for the years ahead.

Veterinary medicines for minor use minor species / limited market

The Board endorsed the 2015 report on the policy 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.

EMA has observed a continued high level of interest from stakeholders in the policy with 28 requests for classification received in 2015. Almost one in two requests originated from micro-, small- or medium enterprises (SMEs).

Among the 28 requests received, 23 were classified as MUMS, the highest number in a year. A wide range of species, both minor and major, were represented and the number of medicines for food-producing species receiving financial incentives increased (seven in 2015 compared to two in 2014).

One MUMS medicine for mineralocorticoid deficiency or Addison's disease in dogs was recommended for marketing authorisation at EU level in 2015. It was noted that many MUMS medicines are authorised at national level.

Veterinary medicines that are classified as intended 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 for animal or public health.

Other meeting highlights:

- Endorsement of draft rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC) following a public consultation. Adoption by PRAC scheduled for April 2016.
- Adoption of EMA annual report 2015. Publication planned in April 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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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