EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2013
EMA/183166/2013
Press Office

Press release

European Medicines Agency's Management Board welcomes new civil-society members

Discussions focus on regulatory science and new challenges posed by the fast-evolving area of drug development

The European Medicines Agency's Management Board held its first meeting in 2013 on 20-21 March 2013. The Board welcomed four new civil-society representatives as full members. Nikolaos Dedes from the European AIDS Treatment Group and Dr W.H.J.M. Wientjens from the International Diabetes Federation Europe will represent patients' organisation, and Dr Wolf-Dieter Ludwig from the Standing Committee of European Doctors and Dr Christophe Hugnet from the Federation of Veterinarians of Europe will represent healthcare professionals for a three-year mandate.

The first day of the two-day meeting was dedicated to reflections on regulatory science and on the best way to get the European medicines network ready to address the challenges of the fast-evolving area of drug development. The focus of the second day was on reporting on activities of the past year and forward planning for 2014 and beyond.

Reflection on regulatory science in the evolving drug-development environment

"Medicines regulation today is characterised by the increasing complexity of applications for new medicines, such as nanomedicines or personalised medicines, and the drug-development environment as a whole", explained the Agency's Executive Director Guido Rasi.

The Board agreed that there is a need to develop the capability of the European medicines network to assess innovative study designs. An innovative evaluation framework involving iterative phases of data gathering and regulatory evaluation is needed in order to align regulatory approval more closely with patients' needs for timely access to innovative medicines. This also includes the ability to integrate in the decision-making process multiple data sources — not only industry studies but also data from real-world use, as well as the views of patients on the level of risk acceptable for a given medical benefit.

Some initiatives to address these topics are already included in the Agency's 2013 work programme. The Board will continue to discuss them throughout the year in order to take them forward as part of the work programme for 2014.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Management Board reviews the Agency's activities during 2012

The Management Board adopted the annual report for 2012. For the past few years, the European Medicines Agency has received a stable number of applications for initial evaluation of medicines for human use, with 96 applications received in 2012. A 36% increase in the number of applications for medicines with orphan designation was observed in 2012 compared with 2011. This is a very welcome trend as it increases the availability of medicines for rare diseases and demonstrates the importance of the orphan-medicines policy.

Also of interest in 2012, the number of companies assigned micro, small and medium-sized enterprise (SME) status by the Agency increased by 58% compared to 2011. An increase in the number of applications for marketing authorisations from SMEs was also observed.

The Agency received 12 applications for the initial evaluation of new veterinary products last year. A trend towards a higher number of requests for scientific advice was confirmed in 2012, which is a result of the Agency's policy to support minor uses and minor species (MUMS). Since its introduction in October 2010, this policy has been highly successful in terms of increasing interest from the animal-health industry in submitting applications for MUMS products, as highlighted by the third annual report on the policy also endorsed by the Management Board.

The Agency, together with the consistently strong European medicines network, met a number of milestones throughout the year 2012, including major deliverables as part of the implementation of the pharmacovigilance legislation. Significant progress was made in terms of transparency, tightening rules for the handling of conflicts of interests and initiation of a process towards improvement in the effectiveness and efficiency of the Agency's operations.

Contribution to the 3Rs

The Management Board adopted the renewal of the mandate for the Joint CVMP/CHMP Expert Group on the 3Rs (replacement, reduction, refinement) in regulatory testing of medicinal products. Since October 2010, the expert group has provided a valuable forum for the development of strategies aimed at eliminating repetitious and unnecessary animal testing and promoting best practice in the implementation of the 3Rs across Europe.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The Agency's annual report for 2012 is expected to be published by mid April.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu