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Press Office

Press release

European Medicines Agency's Management Board formally appoints Guido Rasi as new Executive Director

Board also endorses implementation plan for Agency's 'Road map to 2015'

At its 6 October 2011 meeting in London, the European Medicines Agency's (EMA) Management Board formally appointed Guido Rasi as the new Executive Director of the Agency. This follows his nomination by the Board on 8 June 2011, a successful hearing in front of the European Parliament's Committee on Environment, Public Health and Food Safety on 13 July 2011 and the endorsement of his nomination on 7 September 2011 by the Conference of Presidents of the European Parliament. Mr Rasi is expected to take up office at the EMA in London on 16 November 2011.

Implementing the Agency's Road map to 2015

The Management Board endorsed the Agency's implementation plan for its 'Road map to 2015'. This implementation plan provides information on how the vision outlined in the road map, adopted by the Board on 16 December 2010, will be developed.

Efficient operation of the Agency's core business activities continues to be the primary focus for the Agency over the next five years. Performing and delivering on its tasks in line with current and upcoming legislation is the fundamental cornerstone on which all of the Agency's activities are based. The Agency's road map and this implementation plan are intended to optimise the Agency's performance in three strategic areas: addressing public-health needs, facilitating access to medicines and optimising the safe and rational use of medicines.

Taking into account the current economic climate the road map will be implemented gradually through annual work programmes up to 2015.

Implementing revised policies on handling of conflicts of interests

The Management Board welcomed the progress in the implementation of the revised policy on the handling of conflicts of interest for scientific-committee members and experts and draft rules applicable to the Agency's staff members. The policy and draft rules had been endorsed by the Board in October 2010 and June 2011, respectively, and are aimed at achieving a more robust system.

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As one of the measures of the new policy the Agency launched its new experts' database on 30 September 2011. The database allows the public for the first time to directly search online for the declarations of interests of all experts who have been nominated by competent authorities for medicines regulation across the European Union to be involved in the Agency's activities. Previously, declarations of interests of experts were available only upon request. The new database contains the names of approximately 5,000 experts. So far, new declaration of interests forms have been received and published for around half of them. Member States have been informed that experts that have not submitted a new signed declaration of interests form will not be invited to participate in activities of the Agency and will not receive any documents.

Progress of EMA interaction with patients' and consumers' organisations

The Management Board congratulated the Agency to the increased involvement of patients' and consumers' organisation representatives at all levels of the Agency's work, including more participation of patient experts in scientific advisory group meetings, an increase in the number of Committee for Medicinal Products for Human Use consultations, participation of patient representatives within the Pharmacovigilance Working Party and an enhanced participation in the review of EMA documents, including package leaflets for new medicines prior to authorisation, European public assessment report summaries, question & answer documents and press releases for safety issues. In 2010 the number of patients' and consumers' organisation representatives who have been involved in EMA activities has increased to 307 (as compared to 213 in 2009, 165 in 2008 and 77 in 2007).

The Board also adopted revised criteria to be fulfilled by patients' and consumers' organisations involved in EMA activities. The revised criteria broaden the involvement of organisations in the EMA scientific committees and clarify the transparency criterion with regards to funding sources of the organisations.

The focus during the next two years will be on revising the 'Framework of interaction' which will include the role of patients within the scientific committees, the involvement of patients in benefit/risk evaluation and a strategy for training and support.

Success of minor use minor species policy

The Management Board congratulated the Agency for the success of the minor use minor species/limited markets (MUMS) policy for veterinary medicines introduced in September 2009. This is a joint activity between the Agency and the European regulatory network aiming at facilitating the access to market of medicines indicated for MUMS as part of measures to promote the availability of veterinary medicines. The policy has been well received by the veterinary medicines industry and 26 separate applications were recorded in the second year of operation. This is a 30% increase on the 20 requests in the previous year.

The Board supports the continuation of this policy for another year.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The press release dated 8 June 2011, together with Mr Rasi's curriculum vitae and his declaration of interests, are available on the Agency's website.
3. The Agency's 'Road map to 2015' is available on the Agency's website. The Agency's core business is defined as the Agency's involvement in the authorisation and supervision of medicines for human

and veterinary use, in accordance with EU legislative provisions, including the processes supporting these tasks.

4. The new policy on handling conflicts of interests for scientific-committee members and experts is available on the Agency's website.
5. The press release dated 30 September 2011 on the launch of the European experts' database is available on the Agency's website.
6. All relevant documents adopted at the Management Board meeting will be published on the Agency's website.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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