EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency publishes 2012 annual report

The European Medicines Agency has published today its 2012 annual report. The report highlights the main trends recently observed in the Agency's activities. For the past few years, the Agency has received a stable number of initial marketing authorisation applications (MAAs) for human medicines, with a total of 96 applications received in 2012. The Committee for Medicinal Products for Human Use (CHMP) issued 59 positive opinions for the approval of new medicines, including a positive opinion for the first gene therapy in Europe.

In general, the Agency has observed an increasing complexity of the applications for new medicines received. A 36% increase in the number of MAAs for medicines with orphan designation was seen in 2012 compared with 2011, with 19 applications received in 2012. 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. The success of the orphan incentives is underlined by the steady increase in the number of orphan designations: 107 designations were granted in 2011, 148 in 2012, and more than 150 are expected in 2013. Of note, 72% of the medicines that received a positive opinion for orphan designation concerned medical conditions affecting children.

Also of interest in 2012, the number of companies assigned micro, small and medium-size enterprise (SME) status by the Agency increased by 58% compared to 2011, with a cumulative total of 1,098 active SMEs registered at year end. Concomitantly, an increase in the number of applications by SMEs was observed in 2012: almost 30% of initial evaluation applications were submitted by SMEs. The increase is particularly significant for applications for medicines with orphan designation, as 68% of these applications were submitted by SMEs, compared to just 27% in 2011.

There was a significant increase in the number of SMEs seeking scientific advice prior to filing an MAA in 2012 (64% compared to 41% in previous years). In 2012, for the first time, an SME requested biomarker qualification, another tool that supports the development of medicines that the Agency provides to companies, large and small.

Trends in the veterinary area

The Agency received 12 applications for the initial evaluation of new veterinary products last year. Only 25% of applications concerned food-producing animals while 75% were for medicines for companion animals, which represents a significant change compared to 2011 when the ratio was approximately 50/50.

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A trend towards a higher number of requests for scientific advice was confirmed in 2012 with 28 requests received.

Nine of the 12 referrals received in 2012 concerned products containing antimicrobial substances for food-producing animals. This reflects the high level of concern within the European Union to ensure that such products are authorised with appropriate conditions of use in order to reduce the risk of antimicrobial resistance development as much as possible.

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

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