



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency on track to meet core business targets for 2012

Executive Director reports to Management Board on first six months of 2012

The European Medicines Agency's Management Board discussed the Agency's annual mid-year report for 2012 at its meeting on 4 October. The mid-year report from the Executive Director to the Management Board provides an overview of the Agency's progress from January to June in implementing its 2012 work programme.

Presenting the report to the Board, Executive Director Guido Rasi said that the progress of the Agency's activities so far in 2012 was encouraging. "Our main performance indicators have been met. The mid-year report indicates that the Agency is on target to meet its core business objectives for 2012," he said.

Report highlights

- The number of new marketing-authorisation applications for new human medicines received so far is largely in line with 2011 figures for the same period (52). However, the forecast for applications to be submitted by the end of the year has been reduced from 112 to 101, owing mainly to a lower rate of submission of applications for generic medicinal products for human use than expected.
- The Board noted that requests for scientific advice and protocol assistance for new human medicines had increased by almost 14% and 24% respectively compared to figures from the same period in 2011, confirming the growing importance for pharmaceutical companies to seek early advice from the Agency on their medicines-development programmes.
- The report also showed a significant increase in the number of applications for orphan designation (30% above the same period in 2011).
- In the area of veterinary medicines the report shows that requests for classifications for minor use minor species (MUMS) was more than double compared to the same period in 2011.



- Applications for new veterinary medicines remain at around the same level as 2011. However, the forecast was revised to a total of 11 applications to be received by year-end, two more than initially forecast.

Pharmacovigilance legislation – implementation progresses as planned

The Board also noted that the implementation of the new pharmacovigilance legislation progressed as planned, in line with the prioritisation agreed by the Management Board in its December 2011 meeting. Since the Board's last meeting in June 2012, the Pharmacovigilance Risk Assessment Committee (PRAC) has been established and met three times. The Board will continue to monitor the implementation of the legislation carefully.

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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