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Press release EMEA Management Board adopts the 2007 work programme and budget

At its final meeting for 2006, the Management Board of the European Medicines Agency adopted the work programme and budget in preparation for a sustained level of activity in 2007.

Adoption of the 2007 work programme

The EMEA work programme for next year has been structured to accommodate a number of planned developments, most notably the entry into force of new European Union legislation on paediatric medicines (expected in early 2007), which will give the Agency a significant role in stimulating the availability of safe and effective medicines for use in children. An attendant impact on the workload of the Agency is anticipated.

The second major development will be the accession to the EU of Romania and Bulgaria, on 1 January 2007, which will bring the number of countries participating in the work of the Agency up to 30 (27 EU Member States, plus Iceland, Liechtenstein and Norway).

According to the work programme forecast, the Agency will receive 85 initial marketing authorisation applications for human medicinal products, 65 of which are expected to concern new medicines, including orphan drugs (medicines for rare diseases). This figure is similar to the number of applications received in 2006 (89 applications, 65 of which concerned new medicines), indicating that the high level of activity seen this year will be maintained in 2007.

Similarly, activity relating to veterinary medicinal products is forecast to remain constant next year, with 14 initial marketing authorisation applications expected, including 10 for new medicines (2006: 14 applications received, 12 of which for new medicines).

A marked increase (25%) in the number of requests for scientific advice is expected in relation to both human medicines (due in part to the entry into force of the new paediatric legislation) and veterinary medicines.

Further increases, too, are expected in relation to post-authorisation activities performed by the Agency. These increases are mainly due to the natural increase over time in the number of centrally authorised products on the market.

Adoption of the 2007 budget

The Management Board also adopted the 2007 budget, totalling €154,538,000 (2006: €138,676,000).

The maximum permitted number of staff will increase from 424 to 441. The Board approved this increase primarily to allow for additional staff in areas relating to the new paediatric legislation and to the provision of information for patients and healthcare professionals.

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Notes

- 1. The 2007 work programme will be published on the EMEA website in January 2007.
- 2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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