2007 discharge: European Medicines Agency EMEA

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PURPOSE: to present the final accounts of the European Medicines Agency for the financial year 2007.

CONTENT: this document sets out a detailed account of the implementation of the European Medicines Agency's budget for the financial year 2007. It notes that the final budget amounts to EUR 163.1 million in 2007 (compared to EUR 138.7 million in 2006), representing a 24.3% Community subsidy (excluding subsidy for orphan medicines).

As regards the staffing policy, the Agency, whose head office is in London (United Kingdom), officially set out 441 posts in its establishment plan. 422 of these posts are currently occupied with 95 other posts (auxiliary agents, contract agents seconded national experts, employment agency staff) totalling 518 posts assigned to operational and administrative tasks.

Throughout 2007, the Agency concentrated on coordinating the scientific evaluation of medicinal products.

Concerning medicinal products for human use, the Agency:

- replied to 91 applications for marketing authorisations and delivered 58 favourable opinions taking an average evaluation time of 171 days;
- delivered 1 899 opinions after authorisation;
- drafted 150 188 pharmacovigilance reports and 313 periodic safety update reports;
- delivered 215 scientific opinions and 10 932 procedures for mutual recognition;
- made 85 applications for paediatric investigation plans relating to 202 indications (new task).

Concerning veterinary medicinal products, the Agency:

- replied to 14 new applications for marketing authorisations and 100 applications in respect of variants;
- carried out 185 inspections.

Concerning orphan medicinal products, the Agency replied to 125 applications and gave 97 favourable opinions.

Concerning SMEs, the Agency:

- replied to 212 requests for SME status;
- replied to 81 applications for fee reduction or deferrals.

The complete version of the final accounts may be found at the following address: www.emea.europa.eu