

2008 discharge: European Medicines Agency

EMA

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PURPOSE: to present the final accounts of the European Medicines Agency for the financial year 2008.

CONTENT: this document sets out a detailed account of the implementation of the European Medicines Agency's budget for the financial year 2008. It notes that the final budget amounts to EUR 182.9 million in 2008 (compared to EUR 163.1 million in 2007), representing a 21.9% 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 481 posts in its establishment plan. 469 of these posts are currently occupied with 118 other posts (auxiliary agents, contract agents seconded national experts, employment agency staff) totalling 587 posts assigned to operational and administrative tasks.

Throughout 2008, the Agency concentrated on coordinating the scientific evaluation of medicinal products.

Medicinal Products for Human Use

- replied to 103 applications for marketing authorisations and delivered 68 favourable opinions. The average evaluation time dedicated was 184 days
- delivered 2 122 opinions after authorisation
- drafted 193 587 Pharmacovigilance reports and 391 periodic safety update reports
- delivered 263 scientific advice finalised: 263 and 14 522 procedures for mutual recognition
- made 271 applications for paediatric investigation plans and relating to 395 indication(new task).

Medicinal Products for Veterinary Use

- replied to 13 new applications and 100 applications in respect of variants
- carried out 253 inspections.

Orphan Medicinal Products

- made 119 applications and gave 86 favourable opinions.

SMEs

- replied to 242 requests for SME status
- replied to 84 applications for fee reduction or deferrals.

The complete version of the final accounts may be found at the following address: <http://www.emea.europa.eu/htms/general/manage/ar.htm>