European Medicines Agency

EMEA/MB/319028/2009Adopted

Analysis and assessment of the 2008 annual activity report of the Executive Director

The Management Board,

- having regard to the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,
- having regard to the Financial Regulation applicable to the budget of the European Medicines Agency and in particular Article 40 thereof,
- having regard to the 2008 Work programme of the Agency adopted by the Management Board at its meeting of 11 December 2007,
- having regard to the Annual report 2008 of the Agency adopted by the Management Board at its meeting of 5 March 2008,

1. Welcomes the results presented in the Annual Report 2008 and the strong contribution of the EMEA to EU-wide efforts in support of making high-quality, safe and effective medicines available for use in human and animal populations.

2. Congratulates the Agency for achieving all the main objectives it had set for 2008 and once more demonstrating good performance results across the entire spectrum of its activities.

3. Welcomes that in terms of the core assessment work of the Agency, 2008 was once again a highly productive year with the number of positive opinions adopted on marketing-authorisation applications for medicines for human use higher than in any year to date. As a result, 66 new medicines will become available to European citizens.

4. Notes that the number of inspections has increased and also the co-ordination work on quality defects has significantly increased in 2008.

5. Notes the increased activity in assessment work in relation to paediatric medicines, rare-disease medicines, herbal medicines and veterinary medicines during 2008.

6. Welcomes the Agency's continued application of a proactive approach to safety of medicines throughout their lifecycle.

7. Welcomes the work undertaken in the context of the European Risk Management Strategy (ERMS) included the development of an EU Regulatory System Incident Management Plan.

8. Welcomes in light of the lower priority in 2007 of this project, the continued implementation and development of EudraVigilance Veterinary (EVVet) in 2008 and the sharp increase in the number of entered reports observed in 2008.

9. Notes the new EU regulation on advanced therapy medicinal products which entered into force on 30 December 2008 and congratulates the Agency that all necessary preparations were carried out in 2008 so that the Committee for Advanced Therapies (CAT) was able to hold its first meeting on 15/16 January 2009.

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10. Welcomes the continued policy of the Agency to support applications for products indicated for Minor Use/Minor Species (MUMS) and limited markets and the acceptance of one application for marketing authorisation and one application for post-authorisation activities for such products with a reduced fee.

11. Welcomes the Agency's statement that the European medicines network, a partnership of more than 40 medicines regulatory authorities in the European Union (EU), is the basis of the EMEA's success and the Agency's continued activities during 2008 to further strengthen and improve the day-to-day operation of the network including an early notification system alerting the Member States of envisaged communication activities on (emerging) safety related concerns, a draft EU Regulatory System Incident Management Plan, and draft key principles for signal management in the EU.

12. Welcomes the better planning and monitoring of the implementation of the Telematics programme and invites further improvements, having regard to the level of investment involved and the effect of the IT systems on the work of the entire network and, specifically, regarding Eudrapharm encourages that a clear decision be arrived at to either conclude the project or stop the adding of additional resources till it will be clear if it is possible at all to finalise it as presently envisioned.

13. Having regard to resource constraints through out the network notes the Agency's continued focus on reducing costs per activity and encourages renewed focus on this topic.

14. Welcomes the number of training days provided by the Agency together with the increase in the training budget, and the efficiency gain demonstrated.

15. Notes other initiatives looking at the way meetings are run by the EMEA and looks forward to improvements in the organisation of working parties and also the increased use of video- and teleconferencing facilities in order to reduce the need for experts to travel to the EMEA.

16. Welcomes the publication in December 2008 for public consultation of a draft "EMEA policy on the practical operation of access to EMEA documents" and the decision of the Management Board in December 2008 to publish Management Board meeting documents.

17. Welcomes the enhanced contribution of the Agency to international regulatory activities as instanced by the appointment of an International Liaison Officer to oversee and develop further the Agency's cooperation with its international partners, progress on the implementation of confidentiality arrangements with the USA, Japanese and Canadian Authorities and the Agency's continued collaboration with the World Health Organisation (WHO) on medicinal products intended for markets outside the EU.

18. Notes that on the basis of the findings from the audits carried out by the Internal Audit function in 2008 and the findings of the European Court of Auditors and the European Commission's Internal Audit Service, the Agency's Internal Audit function is of the opinion that the Quality system is well-implemented, procedures in general adhered to, and the controls in place provide a reasonable level of assurance.

19. Notes the Agency response to the 2006 report of the Court of Auditors regarding the matter of the payment of costs incurred by rapporteurs, and notes the Management Board endorsement in June 2008 of a proposal of the Executive Director for a pilot phase of a new system with a view to be in a position to discuss a new remuneration proposal by the end of 2009. Notes also the commitment that payment for activities which at present attract no remuneration and the non-paid participation of civil society representatives will be further considered within the ongoing discussions.

20. Notes the Court of Auditors welcome for the steps the Agency has made in order to address the issue of the evaluation of the costs and the Court's calls for further progress.

21. Regrets the European Commission intention relating to all agencies to cancel the arrangement which allowed the Commission to treat any positive balance of an agency's outturn account as 'earmarked revenue', which can then be made available in subsequent years to cover negative fluctuation of the fee revenue for that agency. As this intention creates a major risk for the Agency should the actual fee income decline unexpectedly, welcomes the Agency's discussions with the European Commission regarding the possibility to maintain the mechanism in line with the recommendation from the European Parliament to allow a flexibility instrument for agencies that largely depend on fee income.

22. Welcomes the Agency's continued development of the business continuity management plan.

11 June 2009

Pat O'Mahony
Chairman of the Management Board