EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Analysis and assessment of the 2009 annual activity report of the Executive Director

Management Board meeting 10 June 2010

Background note

Article 40 of the Financial Regulation, applicable to the budget of the European Medicines Agency, requires the Executive Director to prepare a report to the Management Board in the form of an annual activity report on performance of his duties together with financial and management information on the previous financial year.

The Financial Regulation also requires the Management Board to carry out an analysis and an assessment of the annual activity report and forward it to the Budgetary Authority and the Court of Auditors by 15 June.

Matters for consideration

The Management Board's topic coordinators group, set up for the purpose of drafting the analysis and assessment on behalf of the Management Board, consisted of:

- Jytte Lyngvig
- Kristin Raudsepp
- Pat O'Mahony.

The group's drafted document is hereby submitted for discussion and adoption by the Management Board. The full Annual Activity Report 2009 is also attached for information.

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Analysis and assessment of the 2009 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 2009 Work programme of the Agency adopted by the Management Board at its meeting of 11 December 2008,
- having regard to the Annual Report 2009 of the Agency adopted by the Management Board at its meeting of 18 March 2010,

1. Welcomes the results presented in the Annual Report 2009 and the strong contribution of the EMA 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 on the coordinated response to the A/H1N1 influenza pandemic. The preplanning conducted by the agency allowed for a rapid response once the pandemic was declared and an intensive concentrated scrutiny of product applications leading to the approval of the pandemic vaccines.
3. Notes the enhanced system of pharmacovigilance of antivirals and vaccines used during the pandemic influenza as set out in the European Strategy for influenza A/H1N1 vaccines benefit/risk monitoring in close collaboration with the European Centre for Disease Control and Prevention (ECDC) and the Heads of Medicines Agencies (HMA).
4. Welcomes the extensive inter-agency and international collaboration which the agency has nurtured and developed, apparent in the A/H1N1 case, but also in other areas such as joint inspections with international partners and activity in the area of tackling the development of anti-microbial resistance.
5. Welcomes the adoption of the Action Plan on paediatric pharmacovigilance based on EudraVigilance data in order to further strengthen the intensive monitoring of paediatric use of medicines.
6. Congratulates the Agency for achieving all the main objectives it had set for 2009 and consistently meeting all regulatory timelines despite the A/H1N1 related workload.
7. Notes the increased activity in assessment work in relation to scientific advice requests, orphan designations, variations and safety related activities.
8. Notes the considerable increase in the number of requests for scientific advice and in pharmacovigilance activities for veterinary medicines and the progress made with EudraVigilance Vet.

9. Welcomes the conducting of joint inspections with US FDA and Australian Therapeutic Goods Administration (TGA) inspectors with inspectors from EU NCAs.

10. Welcomes the development of the work of the Committee for Advanced Therapies (CAT) and the receipt of three applications for marketing authorisations for Advance Therapy Medicinal Product (ATMPs), and the adoption of the first positive opinion by CAT and the Committee for Medicinal Products for Human Use (CHMP).

11. Welcomes the continued policy of the Agency to support applications for veterinary products indicated for Minor Use/Minor Species (MUMS) and limited markets and the introduction of a range of measures to support this.

12. Welcomes the efficient handling of an increase in activities in all corporate and administrative areas in line with the overall increased activity across the organisation.

13. Notes that the Agency successfully implemented the last necessary steps of the implementation plan for electronic-only submissions and eCTD. In line for the deadline (1st of January 2010) by which application can only be submitted electronically.

14. Notes that the EudraVigilance Support Programme was initiated end of January 2009 to assist Member States in their signal detection and evaluation activities. The European Pharmacovigilance Issues Tracking Tool (EPITT) is now routinely used to support the signal management process.

15. Having regard to resource constraints throughout the network urges the Agency's continued focus on reducing costs per activity and encourages renewed focus on this topic.

16. Welcomes the establishment of the Management Board Telematics Committee and notes that in addition to oversight of Telematics programmes, this committee will also promote the more efficient conduct of EMA meetings by developing the use of video- and teleconferencing facilities in order to reduce the need for experts to travel to the EMA.

17. Welcomes the enhanced focus and activities in the area of transparency, having regard to stakeholder expectations in this area, and looks forward to the deliveries of the activities and their implementation.

18. Stresses again that allocating new tasks to the Agency without providing for the appropriate resource base may lead to risk for the implementation of such tasks and may lead to substantial difficulties for the national competent authorities and the civil society representatives on the Agency's committees.

19. The Management Board notes that discussions concerning a revised payment system have been on going throughout 2009 and that a proposal based on a pilot will be presented in 2010.

20. Notes that there was no further development of EudraPharm in 2009.

21. Welcomes the new visual identity for the Agency, launched on 8 December 2009.

22. Welcomes the appointment of an International Liaison Officer to oversee and develop further the Agency's cooperation with its international partners, and the signing of the confidentiality agreement with the Australian Therapeutic Goods Administration (TGA).

23. Welcomes the enhancement in bilateral relations with the US FDA and the Japanese authorities with the appointment of liaison placements from US FDA and the Japanese authorities at EMA and the appointment of an EMA staff member as a liaison officer to the FDA in July 2009.

24. Welcomes the evaluation of the Agency and the Network conducted by Ernst and Young on behalf of the European Commission, as required by Regulation (EC) No 726/2004, the Implementing Measures of the Financial Regulation and by the European Parliament and looks forward to considering the findings, and recommendations.

25. Notes that on the basis of the findings from the audits carried out by the Internal Audit function in 2009 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.

26. Welcomes the apparent progress reported by the Court of Auditors in relation to previous findings regarding procurement and recruitment.

27. Welcomes the considerable work undertaken on the development of a strategic plan for 2011 to 2015 and the publication of the draft Roadmap for public consultation by year end.

28. Thanks to the Executive Director for his exceptional commitment and leadership of the organisation throughout the year.

London, 10 June 2010

Signature on file

Pat O'Mahony
Chairman of the management Board