EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2011
EMA/MB/416690/2011 Adopted

Analysis and Assessment of the Executive Director's Annual Activity Report 2010

Management Board meeting 9 June 2011

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 Lisette Tiddens, Kristin Raudsepp, Mike O'Donovan and Rannveig Gunnarsdóttir.

The group's drafted document is hereby submitted for discussion and adoption by the Management Board. The full Annual Activity Report 2010 is also attached for information.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Analysis and assessment of the 2010 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 2010 Work programme of the Agency adopted by the Management Board at its meeting of 16 December 2009,
- having regard to the draft Annual Report 2010, and
- having regard to the Annual Activity Report 2010, the Management Board;

1. Welcomes the results presented in the Annual Activity Report 2010 and the strong contribution of the EMA to EU-wide efforts in support of making high-quality and effective medicines available for use in human and animal populations.
2. Welcomes the considerable work undertaken on the development of a strategic plan and the adoption of the Agency's new Road Map to 2015 in December 2010, including the ideas raised in the evaluation of the EMA and the European medicines network as a whole carried out by Ernst & Young on behalf of the European Commission.
3. Welcomes the preparation for implementation of new legislation which includes the assessment of the impact of the legislation on the Agency's human and financial resources in the area of the new Pharmacovigilance legislation and the Falsified Medicines legislation.
4. Welcomes the preplanning conducted by the agency and the coordinated activities to the A/H1N1 influenza pandemic.
5. Welcomes the Agency's efforts in the area of minimising the risk of antimicrobial resistance arising from use of veterinary medicine. Notes intensified activities in cooperation with the European Commission and other stakeholders. Major progress has been achieved with the Agency project to coordinate at a European level the collection by Member States of harmonised data on use in the EU of antimicrobials in food-producing species and companion animals.
6. Notes the further steps on the consultation process on the Agency's 'Reflection Paper on ethical and Good Clinical Practice (GCP) aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA'.
7. Welcomes the progress in raising transparency. Notes especially the launch of the Agency's website on 15 July 2010, following a complete re-design to optimise usability for the Agency's

key online audiences, new adopted Access to Documents Policy and revised EudraVigilance Access Policies for human and veterinary medicines which were adopted by the Management Board in December 2010.

8. Congratulates the Agency and the National Competent Authorities for achieving all the main objectives set for 2010 and consistently meeting all main regulatory timelines.

9. Notes the increased activity in assessment work in relation to scientific advice requests, orphan designations, variations and safety related activities.

10. Notes the small decrease of 5.5% in the total number of applications for marketing authorisation for human medicines.

11. Notes the Agency adopted a total of 53 opinions on initial evaluation applications in 2010, a sharp drop compared to the record number of 125 opinions adopted in 2009. In line with its objective to reinforce the regulatory and scientific consistency and transparency of the CHMP's opinions on initial evaluation, all applications started in 2010 underwent improved documented quality control in line with agreed criteria.

12. Notes the level of activity remained high in the area of referrals and there was an increase of applications in the area of medicines for children.

13. Notes the considerable increase in the number of requests for scientific advice, in post-authorisation activities as well as pharmacovigilance activities for veterinary medicines.

14. Notes a 30% increase of inspections carried out in 2010 compared to 2009 and that all the inspections were handled within the legal deadline.

15. Notes the launch of the EU Clinical Trials register was delayed.

16. Has serious concerns about the possibility for the Agency to fulfil its role in the area of Telematics. Pharmacovigilance, e-Application Form, EudraCT are only examples in the telematics area that require full attention and resources.

17. Welcomes the development of the work of the Committee for Advanced Therapies (CAT), notes well advanced discussions between the CHMP, the PDCO and the CAT and welcomes preparing the CAT work programme 2010-2015 to help bring more advanced-therapy medicines to the market.

18. Notes the Agency's total budget for 2010 was EUR 208.387.000, a 7,2 % increase compared to 2009. Raises concern about the trend in dependency on fees for the Agency that is increasing year on year with the decrease in the relative percentage income from contribution from the EU budget (from 23% in 2006 to 14% in 2010).

19. Welcomes the well-functioning internal control system of the Agency.

20. 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 like further developing the use of Vitero /video or telephone conference meetings.

21. Raises concern about several activities for which payment to Member States is not provided. New tasks are allocated to the Agency without providing for the appropriate resource base which may put the implementation of such policies at risk and may lead to substantial difficulties for the national competent authorities and the civil society representatives on the Agency's committees. Examples of non-financed activities through fees include: paediatric, orphan designation, herbal medicines and referrals as well as work-sharing on variations to decentralised products.

22. Notes there was no significant increase in the number of herbal medicines, for which herbal monographs or list entries were finalised. At the same time the cost for that activity (ABB - activity based budgeting) increased by 6,5% in comparison to year 2009 and more than 57% in comparison to year 2007.

23. Notes the annual audit report of the Agency's 2009 accounts adopted on 5 October 2010 by the European Court of Auditors.

24. Thanks the Executive Director for his exceptional commitment and leadership of the organisation and to all the staff of the Agency for their hard work throughout the year.

London, 9 June 2011

Signature on file

Kent Woods
Management Board Chair