17 June 2013
EMA/MB/302752/2013 Adopted
Management Board

Analysis and assessment of the Executive Director's annual activity report 2012

Background note

Article 40 of the Financial Regulation, applicable to the budget of the European Medicines Agency (EMA), 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 for 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 Belén Crespo Sánchez-Eznarriaga and Christina Åkerman.

The group's drafted document is hereby submitted for discussion and adoption by the Management Board. The full annual activity report and annual report 2012 are also attached for information.

The Management Board,

- having regard to 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 2012 work programme of the Agency adopted by the Management Board at its meeting of 15 December 2011,
- having regard to the annual report 2012 of the Agency adopted by the Management Board at its meeting of 22 March 2013,

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1. Welcomes the results presented in the annual report 2012 and the strong contribution of the Agency in support of making high-quality and effective medicines available for use in human and animal populations not only at EU-level but also underlining the efforts of the EMA to contribute to this goal at international level.

2. Notes that the success of the orphan incentives is underlined by the steady increase in the number of orphan designations: 107 designations were granted in 2011, 148 in 2012, and more than 150 are expected in 2013. Of note, 72% of the medicines that received a positive opinion for orphan designation concerned medical conditions affecting children. This is a very welcome trend as it increases the availability of medicines for rare diseases and demonstrates the importance of the orphan-medicines policy.

3. Welcomes the Agency's considerable efforts in implementing the new EU pharmacovigilance legislation, as this new legislation is an opportunity to improve public-health promotion and protection.

4. Underlines that the occurrence of shortages of medicines has increased over the last few years, owing to a large extent to the globalisation of manufacturing and supply chains, and notes with satisfaction that the Agency, in collaboration with the national competent authorities and the European Commission, developed a short and medium-term plan to help the European medicines regulatory network prevent, mitigate and manage shortages of important medicines resulting from manufacturing problems. This plan was published in November 2012.

5. Notes that the Agency's initial budget for 2012 totalled EUR 222,489,000, representing a 6.52% increase over the 2011 budget (EUR 208,863,000).

6. Notes the well-established risk-management system that is subject to annual review, and also notes that for significant risks, mitigating actions are in place to reduce the risks to an acceptable level.

7. Welcomes that, in the area of involvement with civil society, the Agency moved forward in 2012 by establishing a procedure for systematic participation of patients in scientific advisory group (SAG) meetings. This represents the first pillar in the involvement of civil society in the benefit-risk evaluation at the Agency. The publication of the 5th annual report on interaction with patients' and consumers' organisations saw a big increase in participation (423 interactions as compared to 307 in the previous year).

8. Welcomes the results of the study conducted for the European Parliament's Committee on Budgets, set to analyse the impact on both EU and national budgets of a transfer of responsibilities/tasks from the national to the European level following the creation of EU agencies, which concluded, among other things, that the Agency has strongly harmonised and increased scientific and technical standards across the EU-27 Member States, playing an important role in consumer protection, and that the Agency has become a powerful and respected key player in medicines evaluation worldwide.

9. Notes with satisfaction that the Agency has implemented a new approval process for projects. The process aims to better align projects with strategic objectives, which will improve the way projects are managed.

10. Notes the work of the task force for project prioritisation to develop a methodology for prioritising ongoing and proposed projects to support efficiency gains.

11. Welcomes the well-functioning internal control system of the Agency, as demonstrated by the building blocks of assurance, which include: audits by the European Court of Auditors, the Internal

Audit Sector of the European Commission and the Agency's internal audit capability; management reviews; and ex ante and ex post controls.

12. Welcomes the positive results of an external assessment of the activities of the Audit Advisory Committee and Internal Audit sector. The assessment confirmed that good audit practices are in place and that the activities of the sector comply with the International Professional Practices Framework of the Institute of Internal Auditors.

13. Acknowledges that the mandate of the current members of the Audit Advisory Committee expired at the end of 2012, and that the Agency is currently taking the opportunity to evaluate the structure and performance of the Committee in its present form, taking into consideration the external assessment report of the work of the Committee.

14. Takes note that no delays occurred and all transactions without exception were checked by applying appropriate checklists, in line with the financial regulations.

15. Underlines that, overall, the 2012 ex post controls programme showed no significant weaknesses in EMA internal controls, that no financial errors have been identified, and that actions are planned to address the administrative errors highlighted, which have no potential impact on the Agency's activities.

16. Welcomes the Agency's initiative to conduct an internal exercise, under the name of 'Review and Reconnect', to analyse and review its key processes of pharmacovigilance, marketing authorisation and clinical trials within the Human Medicines and Evaluation unit and the Patient Health Protection unit, and looks forward to hearing the results of this review.

17. Notes that the conclusions of the staff-engagement survey determined that the staff engagement across the Agency remained at the same level as previous years and that no major actions were required.

18. Gives full support to the newly created Advisory Committee on Procurements and Contracts, created following the request of the European Parliament to remedy the shortcomings in procurement procedures.

19. Notes that there is a new Head of the ICT unit, and expects further development of IT in such a way that the network can increasingly benefit from IT systems and data held by the Agency. Welcomes in this context the initiative of the Agency to reduce the current high number of Agency-hosted websites used by our various stakeholder groups (industry, patients, staff, delegates, etc.) to just three main websites.

20. Welcomes the launch of the new Scientific Coordination Board to deal with the increasing complexity of the system and to ensure that there is sufficient coordination between the committees, so that the standards they set for the development of medicines are consistent across the whole product lifecycle, for increased robustness and predictability of the benefit-risk assessment of medicines.

21. Welcomes the notable progress the Agency made during 2012 in its approach to transparency — an effort that was highlighted by the European Parliament in its discharge decision.

22. Welcomes the Agency's proposals on a way forward for proactive publication of clinical-trial data, and congratulates the Agency for organising the workshop on access to clinical-trial data.

23. Is firmly convinced that necessary steps have to be taken to make progress on costing of evaluation activities, to introduce a cost-based system of remuneration for services provided by Member State authorities.

24. Notes the results of the audit of the European Court of Auditors confirming the reliability of the 2011 accounts and the legality and regularity of the transaction underlying the accounts.

25. Notes the result of the audit on conflict of interests by the European Court of Auditors. Is aware that a number of shortcomings of varying degrees had been identified in Agency policies and procedures, as well as in their implementation, and acknowledges the fact that, since the audit, the Agency has taken various initiatives addressing the recommendations in the Court's report to further strengthen the managing of conflicts of interests of the Agency's experts, Committee members, Management Board members and staff, taking care to ensure that they do not have any financial or other interests that could affect their impartiality and at the same time ensuring the right level of expertise.

26. Notes with satisfaction that all recommendations relative to the Internal Audit Service audit on "Selected administrative procedures supporting the provision of scientific evaluation for human medicines" have been rectified.

27. Highlights that the review of the recommendations issued by the Internal Audit Sector shows that the Agency has made a significant effort to reinforce the systems and processes in place by continuously implementing required actions. Out of 235 total recommendations issued for the period 2009 to 2012, 186 (79.1%) have been successfully completed.

28. Takes note of the fact that, on leaving the Agency, staff members are required to seek permission to engage in an occupation within a period of two years after leaving the Agency, increasing the level of control of possible conflicts of interests.

29. Notes that business-continuity plans are in place to ensure that the Agency is able to continue operating to the extent possible, whatever the nature of a major disruption, and that the open recommendations stemming from the audit carried out by the Internal Audit Sector of the Commission will be rectified in 2013.

30. Acknowledges the Agency's efforts to deal with the expected disruptions during the 2012 London Olympic Games, and notes with satisfaction that no issue or disruption was reported during this period, and that the core business activities were carried out as planned.

31. Welcomes the review of the pandemic-influenza management plan and associated manual from the lessons-learnt exercise, and notes the publication of such plans on the Agency's website.

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

London, 13 June 2013

Signature on file

Sir Kent Woods
Management Board Chair