7 February 2011
EMA/MB/808316/2010 corr.

Minutes of the 69th meeting of the Management Board

Held in London on 16 December 2010

This was the last Management Board meeting for Thomas Lönngren as the Executive Director of the Agency. Thomas Lönngren ends his 10-year mandate on 31 December 2010. The Board recognised the significant achievements made during his term of office and thanked him for leading the Agency successfully over the last ten years.

1. Draft agenda for 16 December 2010 meeting

[EMA/MB/660138/2010] The agenda was adopted with amendments. Point 6 (budget 2011) was changed from 'for endorsement' to 'for adoption'. Points 8 (Implementation of budget 2011 with provisional twelfth) and 10 (transfers of appropriations in accordance with Article 23 (2) of the Financial Regulation) were cancelled.

Members added a new point about potential quality defects of certain medicinal products for peritoneal dialysis.

In March, the Management Board plans to hold a two-day meeting. The Management Board noted the proposal for the following two sessions for 16 March 2011: health technology assessment and the implementation of the pharmacovigilance legislation. Members were invited to provide their comments and alternative proposals for the 16 March meeting.

2. Declarations of conflict of interests

Members were asked to declare any specific interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflict of interests was declared.

3. Minutes from the 68th meeting, held on 7 October 2010

[EMA/MB/628133/2010] The Management Board adopted the minutes. The minutes will be published on the Agency's website.

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
An agency of the European Union

4. Highlights from the Executive Director

Transparency

The Board was informed that the European Ombudsman gave a positive evaluation of the Agency's access-to-documents policy. The Board noted that the Agency is experiencing an increase in the number and complexity of requests for access to documents, which puts pressure on limited resources. This is a common challenge for the network, and ways to manage workload in this area need to be found. As discussed at earlier meetings, one of the options is to amend the format of application dossiers in such a way that publication of non-confidential information can be done without redaction.

The next step in the transparency process will be agreeing on a common approach for deletion of commercially confidential information from application files. This will be discussed at the Heads of Medicines Agencies meeting and then with stakeholders.

The Board noted that the Agency plans to complete an overarching transparency policy in 2011.

Court of Auditors

The Executive Director informed the Board that the Agency has received a qualified opinion from the Court of Auditors for the first time. The opinion relates to procurement cases. The detected mistakes were not systematic and a control mechanism has been established to reinforce the procedure. The Agency will be invited to the Council and the Committee on Budgetary Control of the European Parliament to answer questions from the members as part of the discharge process.

Evaluation of the Agency

Following the conference at which the outcomes of the evaluation of the Agency were discussed, a report has been prepared and submitted to the European Commission. The Agency expects to publish the report at the beginning of 2011.

The members stressed that remuneration of national competent authorities for non-fee related activities is particularly acute, and needs to be addressed to assure sustainable performance of the network. The review of the Fee Regulation is a good opportunity to address the issue. Coupled with this is the need to continue addressing areas where there is duplication of work within the network.

5. Work programme 2011

[EMA/MB/482208/2010] The Management Board adopted the work programme 2011. The priorities for 2011 are in line with the 'Road map to 2015' and ensure continuity from the previous years. One of the key priorities for the Agency is the implementation of the new pharmacovigilance legislation, including the establishment of the seventh scientific committee. With the adoption of the new road map, the Agency increasingly emphasises the importance of a balanced view of benefits and risks of medicines. This concept is emphasised in the work programme and will become more prominent in future years.

In its work programme, the Agency also addresses the expectations of closer collaboration between the regulators and health technology assessment bodies. Initiatives are planned in this field, while ensuring that cost/benefit assessment remains separate from the licensing process. Other priority areas remain similar to the previous years'.

6. Budget, establishment plan and staff policy plan 2011

[EMA/MB/784261/2010; EMA/MB/132208/2010; EMA/MB/637740/2010] Following the adoption of the EU budget, this agenda point was presented to the Management Board for adoption.

The Board adopted the Agency's budget, establishment plan and staff policy plan for 2011. The budget is in line with the work programme and totals €208.9 million (0.23% increase over the 2010 budget), which includes a general EU contribution of €28 million, the 2009 surplus of €5.4 million and the €4.9 million orphan medicinal products fund. The budget is €10.1 million lower than the preliminary draft budget adopted in March 2010. The reduction is largely due to a lower than requested Community contribution (-€8.64 million) and reduced fee revenue estimates (-€1.96 million). The Board noted that the positive outturn from 2009 was included in the budget. As a consequence, the Agency will not be able to draw on reserve funds in case of decrease of forecast fee revenue or to use these funds to finance EU telematics.

The Budgetary Authority did not authorise the requested 48 staff positions. The Agency had to compensate these positions by increasing the levels of contract agents and national experts for 2011.

The Board thanked the topic coordinators (the Chair, Austria and the Netherlands) who reviewed the Agency's work programme and budget ahead of the meeting and provided their recommendations.

7. ICT planning and priorities 2011

[EMA/MB/691944/2010] The Board noted that the Agency will continue the development of all projects planned during the preliminary draft budget stage, in spite of significant reduction of available appropriations in the draft budget 2011. This was made possible by reducing the planned expenditure for hardware and software by bringing certain procurements forward. The budget does not cover adequately the costs of ICT projects needed for the implementation of the pharmacovigilance legislation. The European Commission representatives stressed the need for proper planning of ICT, clarified that the development of the EudraVigilance database should remain a priority, and informed that work is in progress on a review of the Fees Regulation.

8. Implementation of budget 2011 with provisional twelfth

The agenda point was cancelled.

9. Preparation for written procedure on non-automatic carry-over of appropriations from 2010 to 2011 for Project 2014

[EMA/MB/703910/2010] The Management Board noted that it will be requested to adopt the non-automatic carry-over of appropriations by written procedure.

The Board also noted that the Agency will make an advance payment of the 2010 salary adjustment to all eligible staff by the end of December. Since these appropriations cannot be subject to non-automatic carry-over, it is essential for the Agency to make the payment using the earmarked appropriations from the 2010 budget to avoid a major strain on the 2011 budget next year.

10. Transfers of appropriations in the 2010 budget in accordance with Article 23(2) of the Financial Regulation

The agenda point was cancelled.

11. Implementation of pharmacovigilance legislation

The Management Board heard the presentation on how the Agency is preparing for the implementation of the pharmacovigilance legislation. The legislation vests new or extended responsibilities on the Agency in various areas, including periodic safety update reports, adverse drug reactions, communication, risk management and audits of pharmacovigilance systems. A new Pharmacovigilance Risk Assessment Committee will be established. This will be the seventh committee of the Agency. Given the complexity of the new tasks and the timelines for implementation, the Agency has prepared a prioritised implementation plan, in collaboration with the European Commission. Together with the Member States, the Agency has set up project teams, which are working under the leadership and supervision of the project oversight committee and the coordination group.

12. Road map to 2015

Road map

[EMA/MB/761407/2010] The Management Board adopted the 'Road map to 2015', which outlines the Agency's vision for the coming years. The Agency's core activities remain the overall priority for the Agency. In addition, the Agency sets out its long-term objectives in the following three domains: addressing public-health needs, facilitating access to medicines, and optimising the safe and rational use of medicines.

The road map underwent extensive public consultation, during which 71 contributions were received from EU Institutions, Member State competent authorities, European patients/consumers' organisations, European healthcare professionals' organisations and other stakeholders. A number of meetings with stakeholders took place.

The road map will be published in January 2011. The Agency will also publish comments received during the consultation phase.

From vision to reality

The Agency is preparing the road map implementation plan, entitled 'From vision to reality'. The plan will be presented to the Board for adoption in March 2011.

13. EudraVigilance access policies for medicinal products for human and veterinary use

[EMA/MB/754407/2010; EMA/MB/777113/2010] The Management Board adopted the EudraVigilance access policies for medicinal products for human and veterinary use. The policies had been endorsed by the Heads of Medicines Agencies. The adoption follows the public consultation, and takes into account comments received from the European Data Protection Supervisor (EDPS) and the European Ombudsman (EO) and provisions of the recently adopted pharmacovigilance legislation, which requires the Agency to improve access for stakeholders. Once implemented, the policies will provide stakeholders with different levels of access to suspected adverse reaction reports contained in the EudraVigilance database. Both policies follow the same principles. The access policies will be implemented gradually, taking into account the availability of ICT tools.

14. Nominations to the Agency's scientific committees

Management Board consultation procedure for nominations to Committees for Medicinal Products for Human and Veterinary Use (CHMP and CVMP)

[EMA/MB/739310/2010] The Management Board discussed ways to streamline the consultation procedure. Specifically, the meeting focused on issues such as handling of observations and comments received from members during the consultation procedures, whether or not it is practical to suspended certain procedures and defer them for discussion to the Management Board plenary meetings, and whether chairs of committees need to be consulted. The Board was unanimous in its opinion that the procedures should not be suspended in all cases where observations from members are received. The Board also highlighted that the Board should consider the individual circumstances of national competent authorities, and the fact that committee members are supported by multidisciplinary expertise in the national competent authorities.

Members also reflected on what could be a desirable professional profile (scientific, regulatory, other) of members of the scientific committees, and how this can be demonstrated. Members were of the opinion that committees should consist of a mixture of expertise (scientific and expertise in evaluating benefit/risk balance). Those competencies should be clearly reflected in the CVs of nominees, and an explanation given in cases where the relevance of the expertise of proposed candidates is not obvious.

The Management Board asked the group of topic coordinators to consider opinions that have been put forward, and to make a proposal to streamline the procedure at a future meeting. The following members agreed to participate in this work: Aginus Kalis, Marcus Müllner, Björn Lemmer, Tamás Paál, Rita Purcell, Guido Rasi, Lisette Tiddens and Gro Wesenberg.

Nomination to the CVMP

[EMA/MB/739310/2010] Following the comments received during the written consultation procedure, the Management Board endorsed the nomination to the CVMP and concluded the consultation procedure. Members did not raise additional questions.

15. Financial compensation for Member States' participation in linguistic checking - fixed flat hourly cost for 2011

[EMA/MB/751837/2010] The Management Board endorsed the hourly cost for 2011 of €40 (the same rate as in 2009 and 2010).

16. Future accommodation of the Agency

The Management Board was given a presentation about the outcome of the feasibility study, and continued its reflection on options for the accommodation of the Agency following the expiry of the current lease. Taking into account the opinion of topic coordinators, the Board gave a mandate to the Executive Director to look in more detail at options. Further information will be provided for the next meeting, when the Management Board will be asked to take a decision.

17. Relationship with the European Centre for Disease Prevention and Control (ECDC)

Working arrangements

[EMA/MB/783955/2010; EMA/520678/2010] The Management Board endorsed the working arrangements with ECDC. This is an overarching document that will be supplemented by specific annexes related to the operational areas in the future. The arrangements outline the areas in which enhanced cooperation may take place, make provision for mutual consultation and coordination, and address confidentiality issues. The arrangements had been endorsed by the Management Board of ECDC, and will enter into force once signed by the Directors of both agencies.

Cooperation on substances of human origin (SoHO)

[EMA/MB/784727/2010; EMA/MB/791259/2010] According to the legislation, the European Commission has to set up a system for vigilance and traceability of SoHO. ECDC had prepared a paper outlining the management of operational EU-level tasks related to substances of human origin. The European Medicines Agency's comments had been included in the document. The Board endorsed the document that was prepared following a teleconference with the Management Board topic coordinators (the Chair, Austria, Denmark and France).

The Board reflected on the question of leadership for the identified tasks. During the discussion, it was noted that the vast majority of SoHO are used in the area of transplantation and only a small number of them are used for the manufacturing of advanced therapy medicinal products (ATMPs). However, the German member highlighted that, although the majority of products are used locally, the German national competent authority detects most problems in the area of quality defects, rather than in the area of contamination by infectious agents. The Board therefore stressed that the European Medicines Agency should take a more prominent role in the vigilance and traceability of SoHO. However, the Board considers it to be important to understand the actual scope of tasks required by the legislation before a decision is taken about how the two agencies will be involved and leadership decided. Care should be taken not to extend the scope unjustifiably. The Board was concerned that resources for the new tasks will not be made available by the European Commission.

The Board mandated the Executive Director to engage in further discussions with the Commission and with ECDC. The Commission's proposal will be presented to the Management Board in March 2011.

18. Report from the European Commission

The members noted the update report from the European Commission on a range of topics, including the following:

- Pharmacovigilance legislation (the publication is imminent and the new legislation will be applicable mid 2012).
- Legislative proposal on falsified medicines (agreement is expected in the first reading; publication is expected by March and entry into force 18 months later).
- Legislative proposals on information to patients (the European Parliament adopted its resolution in November 2010, and on this basis the Commission will present a modified proposal).
- Development of the new strategy to control antimicrobial resistance (announcement by the Commission in November 2010 of its intention to develop a five-year strategy).

- Progress in the selection procedure for the Executive Director. (The Board noted that a shortlist of candidates will be presented to the Board by the end of March 2011 at the earliest. The extraordinary meeting for interviewing and nominating the Executive Director is scheduled for 5 May 2011. The earlier announced date of 24 February 2011 has been cancelled.)
- European Innovation Partnership on Active and Healthy Ageing.
- Progress on review of the veterinary medicines legislation. (It will be presented with medicated feed in a package in 2012.)
- Sustainable and responsible competitiveness: the Process on Corporate Responsibility in the field of Pharmaceuticals.
- Review of the Transparency Directive. (An impact assessment has been launched, to be followed by a public consultation by March 2011, before issuing a final report by June 2011.)

19. Report from the Heads of Medicines Agencies

The members noted the written update from the Heads of Medicines Agencies (HMA).

AOB

Members exchanged information about the handling of the quality defects of certain medicinal products for peritoneal dialysis. The meeting reflected on a wider issue: potential risks to supply of medicines in cases where patients become dependent on special delivery systems that lack intercompatibility across products. If an issue arises, the replacement of products becomes difficult in such situations. Problems may occur particularly where the manufacturer has a quasi-monopoly on the market. The availability of contingency arrangements and ensuring that companies are prepared to solve such situations are essential. A lessons-learned exercise, based on the experience of the ongoing quality defect situation, will be completed, and the Agency will explore this issue with the European Commission.

Documents for information

- [EMA/MB/821069/2010] Periodic report on signal detection activities and EudraVigilance – Interim report – 01/01/10 to 30/06/10.
- [EMA/674449/2010] Update report on the Agency's implementation of the EU telematics strategy.
- [EMA/MB/719548/2010] Ash cloud impact report.
- [EMA/MB/743560/2010] Update report from the Management Board Telematics Committee.
- [EMA/MB/739297/2010] Outcome of written procedures during the period from 17 October 2010 to 24 November 2010.
- [EMA/MB/694689/2010] Summary of transfers of appropriations in the budget 2010.

Tabled documents

- Presentation: Implementation of the new pharmacovigilance legislation.
- Presentation: Road map to 2015.
- Presentation: From vision to reality: Implementing the road map to 2015.

- Presentation: Project 2014 – Feasibility study on the future accommodation of the European Medicines Agency.
- Presentation: Developing a vigilance system for substances of human origin (SoHO) at European level – Technical introduction.

List of participants

Chair: Pat O'Mahony

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	*Apology received*	
Czech Republic	Jiří Deml	Lenka Balážová
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	*Apology received*	
Ireland		Rita Purcell
Greece		Catherine Moraiti
Spain	Belén Crespo Sánchez-Eznarriaga	
France		Jean-Pierre Orand Miguel Bley
Italy	Guido Rasi	Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	Dace Ķikute
Lithuania	Gyntautas Barcys	
Luxembourg	*Apology received*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal	Jorge Torgal	Nuno Simões
Romania		Nela Vilceanu
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland	Sinikka Rajaniemi	
Sweden		Johan Lindberg
United Kingdom	Kent Woods	Jonathan Mogford
European Parliament	Björn Lemmer	
European Commission	Paola Testori Coggi Pedro Ortun Silvan	Andrzej Ryś Lenita Lindstrom Stefaan Van Der Spiegel
Representatives of patients' organisations	Mary G. Baker Mike O'Donovan	
Representative of healthcare professionals' organisations	Lisette Tiddens-Engwirda	
Representative of veterinarians' organisations	Henk Vaarkamp	

	Members	**Alternates (and other participants)**
Observers	Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway)	Rannveig Gunnarsdóttir (Iceland)
European Medicines Agency	Thomas Lönngren Patrick Le Courtois David Mackay Andreas Pott Hans-Georg Wagner Noël Wathion Peter Arlett Sylvie Bénéfice Jean-Claude Brival Riccardo Ettore Martin Harvey Allchurch Anthony Humphreys	Sara Mendosa Agnès Saint Raymond Vincenzo Salvatore Hans-Georg Eichler Emer Cooke Arielle North Nerimantas Steikūnas Zuzana O'Callaghan
Other	Fred Hargreaves of BNP Paribas Real Estate (point 16)	
	Maarit Kokki of ECDC (point 17)	