22 March 2011
EMA/MB/232704/2011
Management Board

Minutes of the 70th meeting of the Management Board

Held in London on 16-17 March 2011

The two-day meeting of the Management Board of the European Medicines Agency (EMA) started on 16 March 2011 with presentations and an exchange of views on the following topics:

- implementation of the new pharmacovigilance legislation, presented by Noël Wathion, of the EMA;
- outcome and recommendations from the Agency's evaluation and the stakeholder conference (Ernst & Young report), presented by Nerimantas Steikūnas, of the EMA;
- impact of health-technology assessment on the work of regulators, presented by Kent Woods, of the Medicines and Healthcare products Regulatory Agency (MHRA).

1. Agenda for 17 March 2011 meeting

[EMA/MB/19969/2011] The agenda was adopted.

The Chair invited the Board members to volunteer as topic coordinators for the analysis and assessment of the Acting Executive Director's Annual Activity Report 2010.

Following the appointment of Marcus Müllner as Heads of Medicines Agencies (HMA) representative to the Management Board Telematics Committee (MBTC), the Chair invited members to express their interest to represent the Management Board at the MBTC.

2. Declarations of conflicts 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 69th meeting, held on 7 October 2010

[EMA/MB/808316/2010] The Management Board noted the minutes adopted by written procedure on 7 February 2011. The minutes have been published on the Agency's website.

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4. Highlights from the Acting Executive Director

Discharge

The European Parliament Budget Control Committee received the proposal to postpone the discharge for the financial year 2009 for the Agency, although both the European Parliament Committee on the Environment, Public Health and Food Safety and the European Court of Auditors recommended the discharge. The Agency will receive a list of questions to which the Agency will reply in order to receive the discharge in June.

Budget 2011

The Agency has not received new posts for 2011 and has difficulty recruiting scientific staff as contract agents, due to the short term of the contracts and lower remuneration level. However, the Agency expects that the Budgetary Authority will grant some posts later this year.

The Board was also informed that the Agency is reviewing the efficiency of its procedures and is introducing changes in other areas where savings can be made.

Audit reports

The Board was informed that the Director-General for DG SANCO has written to remind the Agency that audit reports need to be provided to the Board. Currently, the Agency provides annual reports drawn up by the internal audit capability and by the Audit Advisory Committee (AAC), as well as final reports from the European Court of Auditors, with the Agency's replies. The Management Board has its representative at the AAC.

Mediator

The Acting Executive Director updated the Board on the issue of products containing benfluorex, saying that the Agency had provided a platform for discussion but had not had a mandate to deal with national products.

Meeting with Commissioner Dalli

The Acting Executive Director met with Commissioner Dalli on 11 March 2011. They discussed a number of topics pertinent to the Agency. With regard to the staffing for 2011, the Commissioner indicated that the Agency may receive some of the posts requested for 2011. With regard to the structural problems of the budget, Commissioner Dalli was of the opinion that the Agency should be allowed to retain the surplus revenue from fees.

With regard to financing the implementation of the new pharmacovigilance legislation, the Agency requires significant financial and human resources to accomplish the work. The European Commission has initiated a review of the Fee Regulation. In case the review will be completed later than the implementation work is due, the Agency requested the European Commission to provide for additional financial resources in the interim period.

The Acting Executive Director has also informed the Commissioner about 'project 2014'.

Update from the meeting of Chairs of the EU agencies

At the last meeting, the EMA Chair handed over the chairmanship for the group to the Chair of EFSA. Two new agencies joined the meeting. The group is currently working on a set of documents, including one on the role of the chairs of management boards, to set out best practice in the area. The document should be agreed in two weeks' time. It was also agreed that chairs may ask for the possibility to sit as observers in the meetings of the boards of other agencies.

5. Annual report 2010

The Board noted the oral report on the activities of the Agency in 2010. The full annual report will be submitted to the Board in May 2011 for adoption at the June 2011 meeting.

The Board noted that the number of new chemical entities and the number of opinions were lower than those received in the previous three years. This may be due to the decrease in the number of applications and to fluctuations in submission of applications during the year. A gradual shift from chemical to biological products, and from general to more specialised types of medicines, has also been observed, as has an increase in the number of applications from small and medium-sized enterprises. A smaller number of generic medicines in the centralised procedure comes as a result of the European Commission's policy on multiple applications for centrally authorised products. The Board also noted the high level of activity in the area of variations. However, it remains to be seen whether this is a temporary increase or the level of activity will remain high for a longer period. There has been a significant increase in the numbers of paediatric procedures (around 20% higher than in 2009) and inspections (a 30% increase), and a very high increase in veterinary scientific advice applications (21 applications received, which is a 90% increase).

6. Work programme and preliminary draft budget 2012

- [EMA/MB/805742/2011] Preliminary work programme.
- [EMA/MB/784841/2011] Preliminary draft budget.
- [EMA/MB/62985/2011] Information technology.

The Management Board adopted the preliminary work programme and the preliminary draft budget 2012. The Board noted the paper providing more detail about the ICT projects and budget for 2012.

The main set of new activities for the Agency derives from the implementation of the pharmacovigilance legislation, which comes into effect in July 2012. The Agency also anticipates that the adoption of the legislation on falsified medicines and the conclusion of the discussions on substances of human origin will also impact on activities in the near future. The Board stressed that the increase in pharmacovigilance and other activities at the Agency's level will mean a higher workload for the national authorities.

The Board asked for information on the management of procurement and recruitment procedures, and on its work in the area of the management of conflicts of interests, to be included in the final work programme. Information on the Agency's cooperation with the World Organisation for Animal Health (OIE) will also be added.

The provisional draft budget (PDB) 2012 amounts to EUR 238.4 million, representing an increase of EUR 29.5 million over the 2011 budget. This increase is mainly due to the increase in requested EU contribution to finance the implementation of the pharmacovigilance legislation in 2012, as well as an increase in fee income due to the expected increases in workload. The Board adopted the

establishment plan of 612 posts, which represents an increase of 45 posts required for the preparation and implementation of the pharmacovigilance legislation. Any budgetary requirements concerning the implementation of the pharmacovigilance legislation were only provisionally adopted, and need to be made fully plausible in the following months. The total staffing needed for the full implementation of the legislation (phased over five years) may be higher. The Board asked, therefore, to be informed of further details on pharmacovigilance implementation, requirements for IT expenditure and staffing needs.

The European Commission drew the attention of the Board to the fact that the EU contribution is still under discussion in the Commission, and that any increase in budget or staff needs to be duly substantiated, particularly in crisis periods. In the field of IT, a more strategic approach with clear prioritisation is called for. As regards pharmacovigilance implementation, the Commission is starting a review of the Fee Regulation in order for the Agency to charge fees for pharmacovigilance activities as foreseen in the pharmacovigilance legislation.

Implementation of the pharmacovigilance legislation

The Board discussion focused on the implementation of the new legislative provisions in relation to EudraVigilance and EU Telematics Controlled Terms. The Board agreed on the following strategic steer, allowing for the preparation of the implementation to proceed without delay, while asking the Agency to monitor the situation on an ongoing basis as the implementation of the legislation progresses. The Board supported that the EudraVigilance audit should take place by Q4 2014 at the latest. The Board supported the development of a subset of functionalities required for the EudraVigilance audit that would meet predefined high-level requirements. The Board supported the proposed transitional measures for the pharmaceutical industry to comply with the 2 July 2011 deadline for the electronic submission of information on medicinal products for human use. The Board also supported the proposals for maintaining the EudraVigilance system until the new functionalities are implemented (in relation to data-quality management, support of EVDAS and the revised implementation of the EudraVigilance Access Policy).

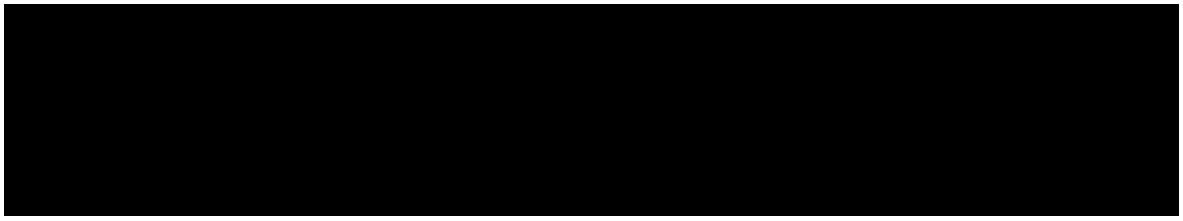
7. Amendments to the Management Board implementing rules on the Agency's fees

[EMA/MB/757388/2011] The Board adopted the amendments to the implementing rules on the Agency's fees. The document will be published on the Agency's website.

8. Amendments to the delegate reimbursement rules

[EMA/MB/149825/2011] The Board adopted the amendments to the delegate reimbursement rules which allow flight tickets to be changed if a meeting ends two hours earlier or later than planned. The document will be published on the Agency's website.

9. Accommodation of the Agency



[redacted]

[redacted]

10. Request of the former Executive Director for authorisation of external activities after leaving the service

[EMA/MB/218686/2011] The Management Board adopted a decision giving its approval for the currently declared activities of Thomas Lönngren, who stepped down as Executive Director of the Agency on 31 December 2010.

The discussion was held behind closed doors and focused on two areas of potential conflict of interests: firstly, whether any activity risked the misuse of confidential or privileged information gained during his leadership of the Agency; and secondly, whether any activity risked improper influence on decisions taken by the Agency. The Board concluded that none of the activities as communicated presented a conflict of interests.

In adopting its decision, the Board imposed a set of limitations on these and any future activities for a period of two years after leaving the Agency, including prohibitions on taking managerial and executive positions in the pharmaceutical industry, and on providing product-related advice with regard to activities falling within the remit of the Agency. The conditions set by the Board also require that Mr Lönngren should neither have contact with Agency staff or committee members in the context of his professional activities, nor represent or accompany third parties at meetings with the Agency.

Members regretted the late notification by Mr Lönngren of details of his activities. The Board stressed its role in protecting the public interest and the reputation of the Agency. It attaches great importance to transparency, and, acting in the public interest, requested the Acting Executive Director to publish its decision, together with supporting documents on the EMA website.

The Board indicated that it expects the next Executive Director to inform it of their intentions before the end of their mandate.

The Board adopted the decision with two votes against.

[redacted]

The representatives of the European Parliament on the Board requested the following statement to be entered in the minutes of the meeting:

"We believe that Thomas Lönngren's advisory role regarding strategic development of the companies, as well as business plans and investment opportunities are strictly connected with privileged information and confidential data that he gained during his mandate as EMA Executive Director. Therefore we cannot give our approval for current activities of Thomas Lönngren."

11. Revision of 'Charter of tasks and responsibilities of the Agency's accounting officer'

[EMA/MB/80540/2011] The Management Board adopted the revised charter of the accounting officer, which clarifies the accounting officer's obligations and responsibilities in line with the Financial Regulation. The document follows the revised rules laid down by the European Commission.

12. Management Board consultation procedure for CHMP and CVMP nominations: follow-up from December 2010 discussion

[EMA/MB/105478/2011] The Board adopted the revised consultation procedure and the revised CV template. The revised procedure now foresees that unless five or more members expressed their reservations with regards to the nomination, the candidate is considered accepted and the procedure is closed. If five or more members express their reservations, the chair of the committee concerned[1] will be approached and his/her views sought before finalising the procedure. The Board also discussed that the training programme for regulators is an important element to ensure that high-quality assessors are available. In this context, reference was made to the joint HMA/EMA training strategy. The Management Board also suggested considering how the training needs of regulators can be reflected in the projects undertaken under the Innovative Medicines Initiative (IMI). A formal letter can be issued to the IMI board as part of the process to improve prospects of obtaining funding.

15. Report on the performance of the Agency's scientific procedures: key performance indicators (KPIs) for medicinal products for human and veterinary use

[EMA/MB/146523/2011] The Management Board noted the report on performance of national competent authorities with respect to a subset of KPIs, which had been agreed by the Board in June 2010. The KPIs enable the performance of the newly established cooperation agreements with national competent authorities to be monitored. The report identified areas where some delays occurred. The reason for the delays will need to be clarified over time. The Agency will provide national competent authorities with individual line listings to enable them to review their own performance.

16. Report from the European Commission

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

- The Mediator case (a stress test was conducted in the context of the new pharmacovigilance legislation).
- The new legislation on falsified medicines (the text of the legislation is likely to be published in the Official Journal in May 2011).
- The legislative proposal on information to patients (the discussions will restart at the Council level).
- The revision of the clinical trials legislation (target for the proposal is the second quarter of 2012).
- Preparation for the revision of the Fee Regulation, which will be carried out in two steps: first, amending the Fee Regulation to allow the EMA to charge fees for pharmacovigilance activities (in

[1] Committee for Medicinal Products for Human Use (CHMP) or Committee for Medicinal Products for Veterinary Use (CVMP).

view of the urgency), followed immediately by a broad review of the entire Fee Regulation.

- Plans for limited and targeted amendement to the Penalties Regulation (focusing on the scope of the Regulation; a public consultation will be launched in spring 2011).
- The continued work to clarify the tasks of the EMA and ECDC in the area of substances of human origin (a concept paper is under development; a proposal will be made at the June Management Board meeting).
- The procedure for the appointment of the Executive Director (the 5 May 2011 meeting of the Board will be maintained as planned).
- The progress on the five calls within the process on corporate responsibility in the field of pharmaceuticals: coordinated access to orphan medicinal products, capacity building on contractual agreements for innovative medicines, market access for biosimilars, facilitating supply in small markets and promoting a good governance for non-prescription medicines.
- The public consultation on the Transparency Directive (a proposal for the review of the Directive may be made by the end of 2011).

17. Report from the Heads of Medicines Agencies

The members noted the update report from the Heads of Medicines Agencies on a range of topics, including the following:

- The process for the implementation of the strategy paper (the HMA meetings will be reorganised to facilitate the implementation of the strategy paper).
- The meeting with the European Commission to discuss principles of a future fee regulation (including the issue of non-remunerated tasks).
- The next cycle of the Benchmarking of the European Medicines Agencies (BEMA) exercise (the BEMA cycle will follow the five-year period of the HMA strategy and the EMA road map).
- A meeting with the medical device authorities.
- The task force on the availability of medicines, which has completed its mandate.
- The enquiry by MEPs into off-label use of medicines in the EU (the MEPs' letters will be included on the April HMA agenda).

Other business

With regard to the transparency of application dossiers, the Board repeated the need to reach an agreement at the EU level among the stakeholders as to what information is considered commercially confidential or constitutes personal data. Following such a uniform position at the EU level, a proposal can be made at the level of te International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), with a view to changing the format of the dossier to enable automatic publication of application information without releasing information that is commercially confidential or contains personal data.

Written procedures

During the period from 25 November 2010 to 15 March 2011, the Board finalised eight written procedures.

These comprised six consultations on new membership in the CHMP and CVMP, the adoption of the non-automatic carryover of appropriations from 2010 to 2011, and the adoption of the minutes of the 69th meeting of the Management Board from 16 December, as indicated below:

- No 32/2010 – the appointment of Dana Gabriela MARIN as CHMP alternate, proposed by Romania, finalised on 20 December 2010.
- No 33/2010 – the appointment of Dalibor VALÍK as CHMP member, proposed by the Czech Republic, finalised on 3 January 2011.
- No 01/2011 – the appointment of Helen JUKES as CVMP member, proposed by the United Kingdom, finalised on 11 January 2011.
- No 02/2011 – the appointment of Miloslav SALAVEC as CHMP alternate, proposed by the Czech Republic, finalised on 4 February 2011.
- No 03/2011 – the appointment of Zanda AUCE as CVMP member, proposed by Latvia, finalised on 4 February 2011.
- No 04/2011 – the appointment of Lyubina TODOROVA as CHMP alternate, proposed by Bulgaria, finalised on 22 February 2011.
- Non-automatic carryover of appropriations from 2010 to 2011, finalised on 13 January 2011.
- 69th Management Board minutes from 16 December 2010, finalised on 11 February 2011.

Documents for information

- [EMA/786515/2010] Annual report 2010 of the Agency's Audit Advisory Committee.
- [EMA/807799/2010] Annual report 2010 of the Agency's Internal Audit.
- [EMA/MB/66833/2011] Performance of the Agency's scientific procedures: Survey 2010 for medicinal products for human use.
- [EMA/MB/78578/2011] Update report on the Agency's implementation of the EU telematics strategy.
- [EMA/634206/2010] Minutes from the latest Management Board Telematics Committee meeting 2010-11-002.
- [EMA/MB/105462/2011] Outcome of written procedures during the period from 17 October 2010 to 24 November 2010.
- [EMA/MB/111120/2011] Summary of transfers of appropriations in the budget 2010.

Tabled documents

- Road map to 2015.
- Presentation: The EMA in 2010 - highlights.
- Report from BNP Paribas Real Estate.
- Presentation: Project 2014; Update to the Management Board.

List of participants

Chair: Pat O'Mahony

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	*Apology received*	
Czech Republic	Jiří Deml	
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	*Apology received*	
Ireland		Rita Purcell
Greece	*Apology received*	
Spain	Belén Crespo Sánchez-Eznarriaga	
France		Miguel Bley
Italy	Guido Rasi	
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	*Apology received*	
Luxembourg	*Apology received*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	Christian Kalcher
Poland	Grzegorz Cessak	
Portugal	Miguel Oliveira Cardo	Nuno Simões
Romania	Daniel Boda	
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland		Pekka Kurki
Sweden		Johan Lindberg
United Kingdom	Kent Woods	Jonathan Mogford
European Parliament	Guiseppe Nisticó Björn Lemmer	
European Commission		Andrzej Ryś Giulia Del Brenna Lenita Lindström Stefaan Van Der Spiegel
Representatives of patients' organisations	Mary G. Baker (morning session) Mike O'Donovan	
Representative of healthcare professionals' organisations	*Apology received*	

	Members	Alternates (and other participants)
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway)	Rannveig Gunnarsdóttir (Iceland)

European Medicines Agency attendees

- Andreas Pott.
- Patrick Le Courtois.
- David Mackay.
- Hans-Georg Wagner.
- Noël Wathion.
- Sylvie Bénéfice.
- Riccardo Ettore.
- Martin Harvey Allchurch.
- Sara Mendosa.
- Vincenzo Salvatore.
- Emer Cooke.
- Zuzana O'Callaghan.
- Nerimantas Steikūnas.