European Medicines Agency

EMEA/MB/642672/2009/EN/Adopted
13 November 2009

Minutes of the sixty-fourth meeting of the Management Board

London, 1 October 2009

1. Draft agenda for 1 October 2009 meeting

[EMEA/MB/358420/2009] The agenda was adopted.

Item 11 (rules on attachment of staff) was taken off the agenda taking into account the interpretation of the Staff Regulations provided by the European Commission whereby the proposed rules may not be applied to govern the attachment of EMEA staff.

2. Declaration 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 conflicts of interests were declared.

The Management Board was notified of the letter received about a former member of the Management Board and a CHMP alternate Member concerning their past activities. The letter informed the Board, inter alia, that these persons were members of an editorial team for a book, which was sponsored by a pharmaceutical company. The Agency will consider this information in the context of the ongoing revision of the Agency's policy governing the handling of conflicts of interest and will inform the corresponding parties accordingly.

3. Minutes from the 63rd meeting, held on 11 June 2009

[EMEA/MB/366757/2009] The Management Board noted the adoption of the minutes by written procedure on 28 July 2009. A correction was introduced under point 16 of the minutes (rules on attachment of staff). The text should read: "The Board discussed the EMEA rules on attachment of staff. The rules will be submitted for adoption after a positive opinion of the European Commission. The proposed rules transpose the rules that are applied in the European Commission for secondment of their staff to organisations outside the EU."

4. EMEA highlights from the Executive Director

Pandemic vaccines
The Committee for Medicinal Products for Human Use (CHMP) has given a positive opinion on two pandemic vaccines. The approval of vaccines was based on the concept of H5N1 mock-up vaccines developed by the Agency in 2003. A robust system to monitor the safety and efficacy of vaccines has been put in place, in cooperation with the European Centre for Disease Prevention and Control. The CHMP has provided an explanatory note about the rationale for benefit-risk assessment of the vaccines, and published the information on the Agency's website.

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The Executive Director has recently attended the European Parliament, where he discussed the topic of pandemic-influenza vaccines. Members of the Parliament raised a number of questions, including ones about the use of single versus two doses of the approved vaccines and the use of the vaccines in children and pregnant woman.

The Board thanked the Agency, its staff and the members of the scientific committees for their effective work and the timeliness of the scientific opinions in light of the public-health benefits of the H1N1 pandemic vaccines.

EMEA long-term strategy – the Road Map
The Agency's current road map covers the period up to 2010. The Agency is in the process of developing a new road map. The first draft is undergoing internal consultation with the Agency's staff, members of the scientific committees and the working parties.

The Agency's long-term strategy will be coordinated with the strategy paper of the Heads of Medicines Agencies (HMA). The first discussion on the draft road map at the HMA level is planned for later this year, in time to submit the document for discussion at the EMEA Management Board in December.

The EU (European Commission/EMEA) - FDA meeting
The meeting took place on the 27-29 September. Having reviewed the level of cooperation between the EU and FDA, all parties concluded that the cooperation between the two regulators is successful and both parties regard each other as primary international partners in the regulatory field.

5. EMEA mid-year report 2009

[EMEA/MB/503751/2009] The Management Board reviewed the progress of the implementation of the Agency's work programme 2009. The Agency is largely on track with the implementation of its main objectives and is adhering to the majority of its performance indicators. The number of applications is also in line with forecasts. The Agency's revenue and expenditure is in line with the plans.

There is a significant increase in applications for authorisation of generic medicinal products, with 31 applications received. A significant amount of resources was allocated to work relating to the H1N1 pandemic. Good progress was made in the field of international collaboration on inspections. The Agency's Committee for Advanced Therapies, inaugurated at the beginning of the year, has issued its first opinions.

Some deviations from the work programme were recorded, relating to the number and complexity of referrals in the veterinary field, which requires significant scientific resources, and to lower-than-planned productivity of the Committee on Herbal Medicinal Products (HMPC). The latter seems to be due to the difficulty experienced by the Member States in allocating scientific resources to work in the field of traditional medicinal products. The Management Board proposed to invite the chair of the HMPC to present the work of the Committee and the challenges it encounters at its December meetings.

6. Budget 2010 update

In March 2009, the Management Board adopted a preliminary draft budget for 2010 of €211m. The Board heard that the current estimate for revenue from fees is €8.5m lower than originally forecast, due to a decrease in the proportion of fee-earning applications expected to be received.

The requested Community contribution of €46m will be reduced to €37m. The Budget Committee of the European Parliament indicated that the fee-earning agencies would have access to the surplus revenue from previous years.

In view of the reduction of planned revenue, the Agency's senior management is reviewing areas where savings could be made and projects scheduled for 2010 be cut. The findings will be presented to the EMEA Management Board topic coordinators and to the Management Board in December.

7. Telematics master plan 2009-2013

[EMEA/69619/2009] The Management Board adopted the 2009 part of the telematics master plan. The document contains amendments discussed and agreed by the telematics steering committee in relation to the new pharmaceutical package and the funding gap. The Board will be asked to approve the 2010 part of the plan as part of the work programme and budget discussion 2010 in December. It was asked that for future versions of the telematics master plan the document should be tabled with track changes for a more easy comparison with previous versions. The Board reiterated the need to agree on telematics projects well in advance, to enable the national competent authorities to develop their IT systems in line with the needs at the EU level.

8. Vacancy notice for the Executive Director's function

Management Board members reviewed and provided written comments on the proposed vacancy notice for the Executive Director's post. The Board's substantial concern remains that the grading level proposed by the European Commission is too low. The Management Board wrote to the Commission regarding this issue in June and provided a response to the European Commission's letter in August. While the Management Board is awaiting a reply from the Commission to its latest correspondence, the Board considers that this issue remains open, and expects that the publication of the vacancy notice will not proceed without the outstanding issue being resolved. The Board expressed its willingness to meet with Commissioners to discuss the concerns expressed.

The Board will send a summary of this discussion to the Director General of DG Enterprise and Industry. The Commission representative agreed to inform the European Commission of the concerns raised, and reiterated the need to find a timely solution enabling the appointment procedure to be completed by mid 2010.

9. Update on the pilot project on revision of the payment system

The pilot on the assessment of evaluation costs in the national competent authorities is ongoing. Fifteen national competent authorities participate in the work of the costing group, and ten of them have submitted costing data. The data is provided in line with the costing methodology agreed by the Management Board.

The Agency is now preparing a report based on the data received, and will submit the report to the December Management Board meeting, at which time the Board will also be able to discuss options for a possible decision in the future. It was reiterated that the overall objective of the exercise is to bring the system better in line with the requirements of good governance and ensure that the remuneration system is justified, manageable and transparent.

10. Setting up a subgroup of the Management Board to replace the Telematics steering committee

[EXT/548688/2009] Further to the decision of the Telematics steering committee and the proposal of the European Commission, the Management Board adopted the decision to create the EMEA Management Board Telematics Committee (MBTC) as a subgroup of the Management Board. The proposal aims to simplify the governance structure, rationalise reporting lines and confirm the appropriate representation of the network. The composition of the new MBTC is as follows:

- 3 members of the Management Board, plus 1 representative of the patients' organisations which are members of the Management Board;
- 3 members of the Heads of Medicines Agencies;
- 2 members of the EMEA;
- 1 member of the Commission.

The Board nominated the following members:

- Marcus Müllner;
- Lisette Tiddens-Engwirda;
- Pat O'Mahony;
- Mike O'Donovan (representative of the patients' organisations).

The EMEA nominated the following representatives:

- Thomas Lönngren;
- Hans-Georg Wagner.

Lisette Tiddens-Engwirda was nominated as chair of the committee. The Board asked to convene the committee and present its terms of reference at the December meeting.

A request will be sent to the Heads of Medicines Agencies and the European Commission to nominate representatives to the committee.

11. Implementation of Staff Regulation: Rules on attachment of staff

The item was taken off the agenda.

12. Amendments to the fee implementing rules

[EMEA/MB/170391/2009/Rev.3] The Management Board adopted the revisions to the fee implementing rules. The revisions concern the fees for consultation on line-extensions for ancillary substances, including blood derivates, incorporated in medical devices; and the implementation of the new regulation on maximum residue limits.

The Board noted that at present there is no legal basis to request fees for site visits or to compensate national competent authorities for the work carried out for site visits in the context of advanced therapy medicinal products. This topic will be addressed during the future review of the Fee Regulation.

[EMEA/MB/565964/2009] The Board also noted the proposed future amendment of the fee implementing rules in relation to the new legislation on variations. Amendments to the implementing rules based on this proposal will be submitted to the Board in December 2009. The Board was invited to send comments with regards to the outlined proposal ahead of its presentation in December.

13. Meeting dates for 2010 and provisional meeting dates for 2011

[EMEA/MB/518171/2009] The Board adopted the following meeting dates for 2010: 17 and 18 March, 10 June, 7 October and 16 December.

The Board noted the proposed dates for 2011 as follows: 16 and 17 March, 16 June, 6 October and 15 December.

14. Mandate of the Ad Hoc Pharmacovigilance Inspectors Working Group

[EMEA/MB/575748/2009] The Board noted the mandate and the report on the first year of operation of the Ad Hoc Pharmacovigilance Inspectors Working Group. The mandate has been endorsed by the Heads of Medicines Agencies.

15. Report from the Task force on scientific qualifications of CHMP and CVMP members

[EMEA/MB/517929/2009] The Board adopted the proposals aiming to improve the consultation process on nomination of scientific committee members. Amendments to the CV template for experts and to the EMEA letter inviting nominations were introduced. The experience with the revised CV template will be reviewed in the future.

The Board also endorsed the proposal to establish a procedure for advanced screening of potential conflicts of interests ahead of the nomination. The procedure will enable the Agency to inform the nominating authority of a potential conflict of interests of a nominee at the start of the nomination procedure. The authority will then decide whether to continue with the nomination in the light of the feedback received from the Agency. The information on conflicts of interests will also constitute a part of the documentation submitted during the formal consultation process. The changes to the procedure will be introduced in the future revision of the EMEA policy on the handling of conflicts of interests.

The Board asked the task force to further elaborate its proposal on the training of experts involved in the work of the committees in the light of the significant training already provided by the Agency. The proposal also links to the ongoing work at HMA-EMEA level, where a joint training team looks into a strategy aimed at further enhancing skills of the regulators.

16. Consultation on appointment of a CVMP member

[EMEA/433259/2009] The Board noted the outcome of the written procedure on consultation on the nomination to the CVMP and considered the nomination as insufficient. The authority will be informed about the concerns expressed by the Board with regards to the suitability of the nominee. The Board stated, however, that the final decision as to the nomination lies with the Member State.

17. Simplification of the contractual arrangements between the EMEA and the national competent authorities of the Member States: development of a cooperation agreement

[EMEA/MB/589426/2009] The Board further considered the proposal on contractual arrangements following the discussion in June and a subsequent round of consultation. The present proposal contains comments received and also includes a new proposal for quantitative performance indicators – compliance with set timelines. The work to develop and introduce qualitative indicators will commence. The topic coordinators, Jean Marimbert and Marcus Müllner, have reviewed the proposal and gave positive feedback. The Board generally supported the introduction of quantitative indicators.

Some members of the Board requested additional time to review the proposal ahead of its approval. Feedback form the members is expected in a week's time, following which the proposal will be

finalised and re-presented at the October Heads of Medicines Agencies meeting, and later submitted for adoption by the Board in December.

18. Report on interaction with patients' organisations

[EMEA/MB/589426/2009] The Management Board noted the report on interaction with patients' and consumers' organisations. A reflection paper, which will be presented at the December meeting, will provide proposals on further involvement of patients' and consumers' organisations in the Agency's activities, including in the scientific review process. The patients' representative on the Board asked to address in the reflection paper the increasing difficulty of patients' representatives to participate in the Agency's activities due to resource constraints.

While recognising that the interests of the healthcare professionals (HCP) organisations are more diverse than those of the patients, the Board asked to continue to explore ways on how to best develop interaction with healthcare professionals. A proposed framework on the interaction with HCPs' organisations will be discussed at the October meeting of the working group. The proposal should be finalised for the March 2010 Management Board meeting.

19. Report from the European Commission

The members noted the update report from the European Commission on a range of topics, including: the European Commission's work in the field of pandemic influenza, progress on the inter-service consultation on the variations regulation, the entry into force of the new regulation on maximum residue limits, and work in the field of health technology assessment.

The Management Board discussed that currently there is a lot of duplication in the area of health technology assessment (HTA) among Member States. Work-sharing and collaboration among the Member States is necessary, since the evaluation of added therapeutic value is scientific work whose results can be used by all interested Member States. The assessment of cost-effectiveness and subsequent decisions on reimbursement, on the other hand, should be left at the level of individual Member States. Collaboration between the regulators and the HTA bodies also needs to be developed, in order to reduce avoidable differences in requirements in both fields.

20. Report from the Heads of Medicines Agencies

The members noted the update report from the Heads of Medicines Agencies (HMA) on a number of topics, including: the development of the new HMA strategy paper, expected to be completed by the end of 2010; the ongoing discussion on transparency issues, with focus on commercially confidential information; and the reflection on the future of the veterinary medicines legislation.

Documents for information

- [A6-0162_2009_EN] European Parliament decision on discharge to the Executive Director of the EMEA
- [EMEA/MB/528743/2009] Update report on EMEA implementation of EU telematics strategy.
- [EMEA/MB/472819/2009*; EMEA/MB/569756/2009] Reports on EudraVigilance implementation for human medicines and medicines for veterinary use.
- [EMEA/MB/517930/2009] Outcome of written procedures:
  - On consultation on changes in the membership of the CHMP and CVMP scientific committees;
  - Final accounts 2008;
  - Minutes of the 64th meeting of the Management Board;

- Amending Budget 01-2009.

- [EMEA/MB/320040/2009] Summary of transfers of appropriations in the budget 2009.

Participants at the sixty-fourth meeting of the Management Board
London, 1 October 2009

Chair: Pat O'Mahony

	Members	Alternates and other participants
Belgium	Xavier De Cuyper	
Bulgaria	*Apologies*	
Czech Republic	Lenka Balážová	
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	*Apologies*	
Spain	Cristina Avendaño-Solà	
France	Jean Marimbert	Miguel Bley Patrick Dehaumont
Italy	Guido Rasi	Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	Mindaugas Būta	
Luxembourg	*Apologies*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	Christian Kalcher
Poland	*Apologies*	
Portugal		Nuno Simões
Romania	Daniel Boda	Stefania Simionescu Roxana Mustata
Slovenia	Martina Cvelbar	
Slovakia	Jan Mazaq	
Finland		Pekka Järvinen
Sweden		Christer Backman
United Kingdom	Kent Woods	
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Heinz Zourek	Lenita Lindström-Rossi
	Isabel de la Mata	
Representatives of patients' organisations	Mike O'Donovan	

Representative of doctors' organisations	Lisette Engwirda-Tiddens	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Rannveig Gunnarsdóttir (Iceland) Gro Ramsten Wesenberg (Norway) Brigitte Batliner (Liechtenstein)	
EMEA	Thomas Lönngren Patrick Le Courtois David Mackay Andreas Pott Hans-Georg Wagner Noël Wathion Sylvie Benefice Riccardo Ettore Martin Harvey Allchurch Frances Nuttall John Purves	Fergus Sweeney Mario Benetti Claus Christiansen Hans-Georg Eichler Anne-Sophie Henry-Eude Xavier Luria Arielle North Nerimantas Steikūnas Spiros Vamvakas