EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 March 2010
EMA/MB/806136/2009

Minutes of the 65th meeting of the Management Board

Held in London on 10 December 2009

1. Draft agenda for 10 December 2009 meeting

[EMEA/MB/672992/2009] The agenda was adopted.

2. Declaration 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 conflicts of interests were declared.

3. Minutes from the 64th meeting, held on 1 October 2009

[EMEA/MB/642672/2009] The Management Board noted the adoption of the minutes by written procedure on 13 November 2009.

4. Highlights from the Executive Director

Meeting with the Commissioner designate for health and consumer policy

The Executive Director met with Mr John Dalli to discuss the trends in the pharmaceutical environment and future challenges. The meeting comes ahead of Mr Dalli's hearing at the European Parliament and the Agency's move from the responsibility of the Directorate-General Enterprise and Industry to the Directorate-General Health and Consumers.

H1N1 pandemic update

The number of people vaccinated with the three vaccines is growing. The main goal for the Agency is to ensure safety of vaccines. The work in the Committee for Medicinal Products for Human Use and various groups is ongoing. The first report on pharmacovigilance of the three pandemic vaccines was published and was very well received by stakeholders. According to the data collected, the benefit/risk balance of the vaccines remains positive. The Agency will continue weekly publication of pharmacovigilance reports on the vaccines. The Executive Director thanked the European experts and the Committee for continuous work in the field of pandemic vaccines.

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Cooperation with the Swiss medicines authority

The Management Board was informed that a confidentiality arrangement is under preparation with Switzerland.

New visual identity

The Agency launched its new visual identity on 8 December 2009. A new logo has been adopted. As part of the new identity, the Agency will discontinue the use of the current acronym 'EMEA' and will use either the full name 'European Medicines Agency' or simply 'the Agency'. The acronym 'EMEA' is not well known amongst the Agency's stakeholders such as healthcare professionals and patients in the EU. It is expected that the strategy will further improve communication and awareness about the Agency amongst the stakeholders.

The new organisational structure has also been put in place as of 8 December 2009 and has had a positive impact on the activities of the Agency. It is expected that the new structure will increase the overall efficiency of the Agency's operations, improve the quality of its work and increase the effectiveness of its interaction with stakeholders.

The Agency is completing the development of an entirely new public website that offers much-improved content structure, user-friendliness and functionality for the Agency's audiences. The development takes into account specific needs of the user groups: healthcare professionals, patients and industry. The website will be launched in spring 2010.

March 2010 meeting

The next Management Board meeting will last two days. The first day will be dedicated to discussion on decision-making. Professor Larry Phillips of the London School of Economics will lead the discussions. Prof. Phillips is engaged with the Agency in the work on methodologies for benefit/risk assessment.

5. Work programme 2010

[EMEA/MB/203131/2009] The Board adopted the Work programme 2010. The presented priorities, objectives and projects follow proposals made to the Board in March 2009, and include:

- focus on core business (including addressing the growing volume of activities in such areas as post-authorisation activities and orphan medicinal products);
- further implementation of legislation on paediatric medicines and advanced therapy medicinal products (particular challenges relate to workload and availability of resources);
- strengthening the European medicines network;
- safety-monitoring of medicines;
- international cooperation (particularly important in light of the number of clinical trials and amount of manufacturing being done in countries outside the EU);
- transparency and interaction with stakeholders;
- support to research;
- availability of medicines.

The Board welcomed the work programme. The Board reiterated its earlier concern in the area of herbal medicinal products where work is progressing very slowly. The Board was concerned that large groups of herbal products may have to be removed from the market due to the very small number of

entries on the list of traditional herbal medicinal products. The Member States need to find ways to increase the availability of resources to work in the area of herbal medicinal products. A discussion on this topic will be planned during the March 2010 meeting.

The number of generic medicinal products for which authorisation is being sought through the centralised procedure is growing. However, this is only a fraction of the total number of generic products coming to the EU markets. The Board saw that the challenge in this area will be to assure consistency of the assessment of generic medicines across the EU. Work will be undertaken in 2010 to address this challenge.

5bis. ICT planning and priorities 2010

[EMEA/MB/727972/2009] The Board discussed this agenda point under the work programme and the EU telematics master plan 2010.

6. EU telematics master plan

[EMEA/768926/2009] The Board adopted the 2010 part of the telematics master plan, which forms part of the work programme and budget 2010. In addition to information provided in the previous version, the plan also looks at how to integrate EU telematics systems with those of the national competent authorities. The plan also takes into account the expected impact of upcoming legislative proposals on pharmacovigilance and falsified medicines.

The funding gap has reappeared and multi-annual funding solutions need to be found. The Board discussed the concern that a higher proportion of the telematics budget will be consumed by maintenance of the systems as more telematics systems come into operation over the years.

Members noted that the Management Board Telematics Committee has not yet discussed the telematics master plan since the committee has not yet been fully established. The meeting underlined that good coordination between the Management Board's and the Heads of Medicines Agencies' telematics committees is essential. A merger of the two committees should be considered.

7. Budget and establishment plan 2010 and staff policy plan

[EMEA/MB/628139/2009; EMEA/MB/700124/2009; EMEA/MB/579221/2008] The Board adopted the budget, the establishment plan and the staff policy plan for 2010, pending the budget decision by the European Parliament. The budget is in line with the work programme and totals €198.2 million (1.95% increase over the 2009 budget), which includes a general EU contribution of €32.6 million and the €4.5 million orphan medicinal products fund. The budget is €13.6 million lower than the preliminary draft budget adopted in March 2009. The reduction is due to lower than requested Community contribution and reduced fee revenue estimates due to the impact of the new regulation on variations and a shift to non-fee or reduced-fee applications. The establishment plan increases staffing numbers by 37 posts, brining the maximum permissible number of temporary agents to 567.

The budget topic coordinators (the Chair, Austria, Germany and the Netherlands) scrutinised the Agency's work programme and budget documents ahead of the Management Board, received responses to their questions and recommended that the Board adopt the documents.

The Board discussed the need to consider options for addressing the gap between the workload and the number of temporary agents. Currently, in order to match the resources with the workload originating from permanent tasks, the Agency recruits contract agents.

The European Commission reserved their position with regard to the expected total amount of the general EU contribution, pending the decision of the European Parliament. The representative of the

European Commission also referred to the need to reduce the surplus, and noting that the surplus of 2008 needs to be used in 2010.

8. Draft road map to 2015

[EMEA/MB/752624/2009; EMEA/MB/786453/2009] The Board discussed and adopted the draft road map to 2015 for public consultation. The strategy supersedes the road map to 2010, the implementation of which finishes next year, and outlines the Agency's strategic direction for the coming five years. An implementation plan is being prepared and will be finalised once the comments stemming from the public consultation on the road map have been reviewed and necessary amendments have been made. Both documents will then be presented to the Board.

Topic coordinators (the Vice-chair, Austria, Denmark, the Netherlands, Sweden and Prof. Nisticó) provided positive feedback on the vision outlined in the draft road map. It was acknowledged that pharmacovigilance and safety of medicines remains a priority area within which the focus should now be on looking into both risks and benefits throughout a medicinal product's lifecycle. Taking into account the recent change of responsibility for the Agency within the European Commission, the members asked to ensure that the road map takes into account DG Sanco's strategic directions.

The Board stressed that the national competent authorities are an integral part of the EU network, and highlighted the future role of patients in decision-making in the course of the assessment of medicines. Members discussed the needs to understand the relevant positions of regulators and health-technology assessment bodies and to ensure that cost-benefit analysis does not become a part of the regulatory assessment of medicines.

Public consultation on the road map will last three months, during which time meetings with stakeholders will be organised. The Board will receive the updated document one week before the start of the consultation, to allow for any final comments to be made.

9. Appointment of the Executive Director

The Chair thanked the members for the work done during the interactions and correspondence with the European Commission with regard to the vacancy notice and the grading of the Executive Director's post. The Board appointed Kent Woods as the Board's representative in the selection process at the European Commission.

The European Commission representative informed that the Commission has recently adopted the text of the vacancy notice and the grade AD14. The document has now been submitted for translation. The publication of the notice is expected in the second week of January 2010.

In light of the earlier discussions on the grade level and in view of the Agency's move to the responsibility of DG Sanco, the Board enquired whether the publication could be delayed to allow the new Commissioner to express his views with regards to the grading of the Executive Director's post. It was clarified by the representative of the European Commission that at this point the revision of the decision is no longer possible.

10(a) Management Board Telematics Committee

The Management Board Telematics Committee prepared and presented to the Board the draft terms of reference. The Board members were invited to review the document within the next few weeks and to provide comments. The terms of reference will be submitted for adoption at the March 2010 meeting. The Committee will meet the chairs of all of the telematics implementation groups ahead of the next Management Board meeting.

10(b) Amendments to the Management Board rules of procedure

[EMEA/MB/115339/2004] The Board adopted the revised Management Board rules of procedure, which now include a provision for the setting-up of Management Board committees and groups. The chairs and mandates of such committees shall be appointed/adopted by the Board.

11. Status report on EudraVigilance implementation

[EMEA/MB/761723/2009; EMEA/MB/736762/2009] The Board noted the status reports on the implementation of EudraVigilance for human and veterinary medicines. The Board was satisfied with the changes in the content and structure of the report on human EudraVigilance. The new report on human EudraVigilance now focuses on how EudraVigilance contributes to the conduct of pharmaco-vigilance in the EU. The report will in future also provide, for centrally authorised products for human use, information on signal management, from signal detection through to follow-up, including feedback provided by rapporteurs and any subsequent regulatory action taken. The new Human EudraVigilance report will now be produced twice a year, with the next report, which will be published, planned for June 2010. The EudraVigilance Veterinary (EVVet) status report will be made available to the Board at the same time. The EVVet status report is updated continuously and is also available on the EVVeT website.

12. Payment system to Member States

[EMEA/MB/780575/2009; EMEA/MB/762513/2009] The Management Board reviewed the outcomes of the pilot which aimed to assess the costs of assessment of centralised applications by national competent authorities. The pilot concluded that the national competent authorities, which participated in the pilot, are in a position to identify their hourly rates for services provided. Those national competent authorities also showed that they are able to record the hours spent on centralised applications. However, many countries expressed reservation regarding their ability to record on an ongoing basis.

Taking into consideration the outcomes of the pilot and the estimated impact on the Agency's budget, and in light of the observations made by the Court of Auditors and the European Commission, the Executive Director submitted for adoption a new remuneration system, based on the proposal presented in March and June 2008, which aims to align the remuneration system with the legislative requirements.

The Board recognised the Executive Director's efforts to revise the system and bring it more into line with the requirements. However, members decided to reject the proposal. The Board was concerned that not all national competent authorities provided data in the pilot phase (18 out of 46 invited), and that the data made available by the participating national competent authorities is still preliminary. The latter is due to a marked difference in the ability of national competent authorities to record time spent on procedures, the lack of full agreement on what constitutes costs, and the need for a longer observation period to capture the full assessment time for various procedures.

Moreover, members also meant that, whereas over the years the agencies have adapted to the current system, a change may adversely affect the financing of some of the national competent authorities and weaken their ability to contribute to the non-fee related activities, and consequently impact on the effectiveness of the network. The issue of using and reimbursing external experts was also raised. Members suggested engaging with the European Court of Auditors to explain the Board's concern and the benefits of the existing system. Some members proposed that, if the system were to be revised, this should be done at a political level.

The representative of the European Commission drew the attention of the Board to the fact that a decision of the Board is necessary notably in the light of the observations of the Court of Auditors (also noting that, for example, in the European Chemicals Agency, the reimbursement rate is based on the cost for the national agency involved (rapporteur) multiplied with a country coefficient).

The topic coordinators (the Chair, Austria and the Netherlands) proposed an alternative solution: to introduce, for a transitional period, a payment system based on Eurostat correction coefficients, and to continue collecting costing data for assessment of centralised applications. Topic coordinators will meet to further elaborate their proposal.

13. Amendments to the fee implementing rules in relation to the new legislation on variations

[EMEA/MB/170391/2009/Rev.4] The Board adopted the amendments to the fee implementing rules to come into effect on 1 January 2010. The proposed amendments were presented at the October meeting and no comments were received.

13bis. Financial compensation for Members States' participation in linguistic checks

[EMEA/MB/767563/2009] The Board endorsed the fixed, flat hourly cost for 2010, which is set at the same rate as in 2009.

14. Implementation rules regarding training for staff

[EMEA/MB/737155/2009] The Board adopted the implementing rules, subject to their formal approval by the European Commission. The attention of the Board was drawn to the amendments aimed at promoting language training of staff, to enable them to comply with the requirement of the staff regulations.

15. Reflection paper on the further involvement of patients and consumers in the Agency's activities

[EMEA/MB/753771/2009] The Board adopted the proposals aimed at more structured involvement of patients/consumers in the various activities of the Agency. The proposals include revising the current framework of interaction between the Agency and patients' and consumers' organisations, and providing financial support by doubling the daily allowance in defined cases.

A framework of interaction with healthcare professionals is under development and will be presented to the Board in 2010. The development of the framework has taken longer then planned due to the need to meet two sets of views: those of academia and learned societies on one hand, and those of prescribing physicians and pharmacists on the other.

At the request of the Board, the Agency will provide an estimated amount of resources that are needed to implement the future revised framework of interaction. The Agency also undertook to review in two years' time whether the doubling of the daily allowance meets financial requirements of patients/consumers' representatives.

16. Participation of patients/consumers' representatives as observers to the PhVWP

[EMEA/MB/752664/2009] The Board adopted the proposal whereby one patients/consumers' representative will be nominated to the Pharmacovigilance Working Party (PhVWP) as an observer and a second representative will be nominated as an alternate. The decision is taken following a very positive pilot phase, during which patients/consumers' representatives participated in three meetings of the PhVWP.

The representatives, with proven experience in medicines regulation, will be selected taking into account well-defined selection criteria, on the basis of a call for expressions of interest. The decision will be taken by the Executive Director on the basis of a shortlist of candidates.

Taking into account the mandate of the PhVWP, the proposal will now be put to the January 2010 HMA meeting for adoption. Once adopted, the Agency will proceed with the implementation.

17. Revised reimbursement rules for delegates

[EMEA/MB/728947/2009] The Board adopted the revised reimbursement rules for delegates. The amendments concern the doubling of the daily allowance for representatives of specific organisations, changes to the rules regarding hotel accommodation, and travel-ticket changes.

18. Report from the European Commission

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

- move of the Pharmaceutical Units F2 and F3 (cosmetics and medical devices) to DG Sanco;
- progress on the two legal proposals (pharmacovigilance and falsified medicines legislation);
- publication of the guidelines on variations;
- public consultation on the assessment of the functioning of the Clinical Trials Directive (closing date 8 January 2010);
- discussion on the Cross-border Healthcare Directive;
- work on the H1N1 pandemic, including initiatives to address the limited vaccine availability in some Member States, reflections on virtual stockpiling, and the communication challenges.

In view of changes within the European Commission of the responsibilities for the Agency, the Management Board expressed its thanks to Heinz Zourek, Director-General of DG Enterprise and Industry, for his significant contribution to the work of the Board and of the Agency.

19. 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: publication of information on e-readiness in each of the national competent authorities; the creation of the network of HMA contacts on medicines advertising; the veterinary SPC harmonisation project; and revision of the action plan in the field of antimicrobial resistance.

More information has been provided in the written report.

Documents for information

- Charter of the Internal Audit Service of the Commission.
- [EMEA/MB/528743/2009] Update report on EMEA implementation of the EU telematics strategy.
- [EMEA/MB/715154/2009] Outcome of written procedures:
  - On consultation on changes in the membership of the CHMP and CVMP scientific committees;
  - Minutes of the 64th meeting of the Management Board.
- [EMEA/MB/617640/2009] Summary of transfers of appropriations in the budget 2009.

Tabled documents

- Presentation on the Road Map to 2015.
- Letter from EURODIS (dated 7 December 2009).
- Supplement to Agenda point 12b.
- Draft terms of reference for the Management Board Telematics Committee.

Participants at the 65th meeting of the Management Board

London, 10 December 2009

Chair: Pat O'Mahony

Vice-chair: Lisette Engwirda-Tiddens

	Members	**Alternates and other participants**
Belgium	Xavier De Cuyper	
Bulgaria		Jasmina Mircheva
Czech Republic	Lenka Balážová	Jiří Deml
Denmark	Jytte Lyngvig	Paul Schüder
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	Apologies	
Spain	Cristina Avendaño-Solà	
France		Miguel Bley Patrick Dehaumont
Italy		Silvia Fabiani
Cyprus		George Antoniou
Latvia	Inguna Adoviča	
Lithuania	Mindaugas Būta	
Luxembourg	Apologies	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Wojciech Matusewicz	
Portugal	Vasco A J Maria	
Romania	Daniel Boda	
Slovenia	Martina Cvelbar	
Slovakia	Jan Mazaq	
Finland		Pekka Järvinen
Sweden		Johan Lindberg
United Kingdom	Kent Woods	
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Heinz Zourek Isabel de la Mata	Lenita Lindström
Representatives of patients' organisations	Mike O'Donovan	
Representative of doctors' organisations	Lisette Engwirda-Tiddens	
Representative of	Henk Vaarkamp	

	Members	Alternates and other participants
veterinarians' organisations		
Observers	Rannveig Gunnarsdóttir (Iceland) Gro Ramsten Wesenberg (Norway) Brigitte Batliner (Liechtenstein)	
European Medicines Agency	Thomas Lönngren Patrick Le Courtois David Mackay Andreas Pott Hans-Georg Wagner Noël Wathion Sylvie Benefice Riccardo Ettore Martin Harvey Allchurch Agnès Saint-Raymond	Vincenzo Salvatore Mario Benetti Emer Cooke Hans-Georg Eichler Sabine Haubenreisser Arielle North Nerimantas Steikūnas Janice Soreth Yoshikazu Hayashi