EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2010
EMA/MB/194352/2010

Minutes of the 66th meeting of the Management Board

Held in London on 17-18 March 2010

The two-day meeting started on 17 March with a presentation on decision making. Specifically, the sessions presented how to extend human capabilities in decision making and also demonstrated case studies where models were applied to extend and improve human judgement. Prof. Lawrence Phillips of the London School of Economics led the sessions. This topic links to the Agency's work on the methodology for the assessment of benefit/risk balance of medicinal products.

1. Draft agenda for 18 March 2010 meeting

[EMA/MB/3790/2010] The agenda was adopted.

The Chair invited members to volunteer as topic coordinators for the assessment of the Executive Director's annual activity report 2009. The report will be sent to the topic coordinators by the end of April. The members will have three weeks to draft an analysis and assessment, which will be submitted to the Management Board for adoption around 20 May 2010.

The Chair also informed the Board that the Chair of the Audit Advisory Committee is preparing a reflection paper for the Board, which will set out options for the future of the Committee. The discussion is foreseen for the October meeting.

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.

3. Minutes from the 65th meeting, held on 10 December 2009

[EMA/MB/806136/2009] The Management Board adopted the minutes with the following changes under point 12 (payment system to Member States): The Board clarified that only those countries which participated in the pilot demonstrated ability to identify hourly rates for services provided and to record time spent on centralised applications. A number of countries chose not to participate in the pilot. The Board also stressed that Member States continued to have reservations as to the ability to record time on an ongoing basis.

The Board noted that the topic coordinators will continue reflecting on the payment system. The following colleagues put their names forward to assist in this task: Chair, Austria, Estonia, Ireland,

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Germany, Spain, The Netherlands and Mike O'Donovan. Other members were invited to join. The group will examine in greater detail the requirement put forward by the Court of Auditors. If needed, the Court of Auditors will be contacted for further clarification. A number of additional changes were made to the minutes as part of the written procedure which preceded this adoption.

4. **Highlights**

Visit of the Commissioner for Health and Consumer Policy

Commissioner John Dalli visited the Agency on 5 March 2010. Mr Dalli had extensive meetings with key staff of the Agency, and also outlined his priorities and replied to the questions of staff members. Mr Dalli stressed that patients' interests are at the heart of his and our work. It was emphasised that there should be the right balance between the interests of patients and of industry. The Commissioner was satisfied with the work of the Agency, including achievements in the area of communication and the involvement of patients and healthcare professionals.

Evaluation of the Agency by the European Commission

The Board noted that the evaluation of the Agency commissioned by the European Commission and carried out by Ernst & Young has been completed. A joint conference organised by the European Commission and the Agency will take place on 30 June 2010. The conference will address the topics raised in the evaluation and will also be an opportunity to discuss key issues proposed in the Agency's draft road map to 2015. The Agency's partners and stakeholders will be invited to participate.

H1N1 pandemic update

The Board noted that a number of non-EU countries used EU authorisation to grant authorisation of pandemic vaccines in their own countries. The H1N1 pandemic continues to affect Africa, and EU vaccine stock is being exported to affected countries. Information on the use of vaccines in those countries will add to the pool of knowledge on the safety and effectiveness of these vaccines.

The Agency will now work to identify lessons learned from the pandemic situation to identify improvements for future situations of this nature. The Executive Director and the Board thanked the staff of the Agency and the national authorities for their deep commitment and highly effective performance in the face of this public-health threat.

The Board expressed its support for the vaccination strategies adapted by Member States in the wake of a potentially severe pandemic threat. Members stressed that a very short lead time from identification of the threat to the start of vaccination was only possible due to cooperation of regulators and industry. This cooperation was a prerequisite for the successful response to the threat. A common statement by the Heads of Medicines Agencies could help to communicate with national parliaments and bodies in light of the ongoing debate on national strategies applied during the crisis.

Expiry of the building lease in 2014

The Agency began to identify options for a future location of the Agency in London, once its current lease expires in 2014. When available, the options will be presented to the Management Board. The agreement on an option may be needed as early as this autumn. Depending on the outcome, the European Commission and the European Parliament will be informed about a preferred option.

Term of office of the Chair of the Board

It was pointed out that the term of office of the current Chair of the Management Board will expire in June. The Executive Director will write to members of the Board before June concerning the appointment of a Chair.

Meeting of the chairs of the management boards of EU agencies

The first meeting of chairs of the management boards of EU agencies took place to share best practices and discuss common issues and challenges. The group plans to meet twice a year. A representative of the European Commission will attend the next meeting to outline details of the recent evaluation of EU agencies and the Commission's response.

5. **Annual report 2009**

[EMA/MB/69923/2010] The Management Board adopted the Agency's annual report 2009. The report shows that the Agency's performance with regard to the growing core business remained at a high standard, despite the fact that significant resources were dedicated to pandemic work throughout the year. The Agency delivered opinions within legislative timelines and achieved the majority of set targets. A few deviations occurred, notably in the field of herbal medicinal products. The proportion of new marketing authorisation applications for human medicines with negative outcomes increased to 33% last year, compared to 20-25% in previous years. For new active substances the negative outcome rate last year was 40%. Data indicate that small companies suffer higher rates of negative outcomes. There is also a correlation between compliance with scientific advice and positive outcomes. The Board also commented that the quality of dossiers may be a significant factor, and it is likely that a number of the products that received a negative opinion could have been approved if the dossiers had been of a higher standard.

The above trends underline the importance of the operation of policies that support small and medium-sized enterprises. The Board also stressed that the Agency's guidance relating to new and emerging therapies is highly important in the light of scientific development. Timely engagement between regulators and industry is needed to assure that more products pass the regulatory assessment.

The Board suggested looking at the adequacy of some of the key performance indicators. This is particularly true for areas where targets are self-set, as for example in the area of European public assessment reports (EPARs), where a number of self-set targets are not achieved due to circumstances outside of the Agency's reach. With regard to EPARs, the Board suggested that work should continue to promote them in the medical and scientific community, as these documents contain very valuable information about the evaluation of medicines and the decision-making process. In the meantime, the network needs to continue developing a coherent approach to the provision of information to patients and healthcare professionals across the EU. The Board also requested that the Agency send for information copies of scientific articles that are written by the Agency's staff.

6. **Draft work programme and budget 2011**

[EMA/MB/6505/2010; EMA/MB/68936/201; EMA/MB/125880/2010] The Management Board adopted the preliminary work programme, preliminary draft budget (PDB) and draft staff policy plan for 2011. The Board thanked the topic coordinators (Chair, Austria and the Netherlands) for their contribution in preparing these documents.

Preliminary work programme 2011

The operations of the Agency and its work programme are shaped by various trends in the scientific and business environment of the Agency, including globalisation, scientific progress, and growing demand for openness and communication with stakeholders. The priorities for 2011 are consistent with previous years and the Road Map to 2010. The Agency will also start preparing for the implementation of legislation on pharmacovigilance and falsified medicines. The adopted preliminary work programme will be further modified in the course of 2010 to take into account the outcome of the evaluation of the Agency and its Road Map to 2015. The impact of the recent legislation on variations should be seen in 2010 and will need to be taken into account in 2011.

Preliminary draft budget 2011 (PDB)

The PDB for 2011 totals €218.9 million, in line with the work programme. The budget represents an increase of €20.7 million (10.5%) over the 2010 budget. The budget includes estimated fee revenue of €163 million and a requested Community contribution of €47.1 million, which the Commission representative indicated was beyond the current EU financial perspectives. The draft budget also includes resource needs for the implementation of the future pharmacovigilance and counterfeit medicines legislation, which were challenged by the Commission as being higher than estimated. The Commission also stated that any deficit in the EU contribution compared to the request should not lead to cuts in the telematics expenditure intended for the implementation of the proposed legislation.

The PDB includes an increase of 48 posts in the establishment plan, to a maximum number of 615 temporary agents. All newly requested staff posts are financed through fee revenue. Fourteen of the new posts are requested due to increased workload and/or new activities. Following the discussion of the Management Board at the December meeting about the gap between workload and the number of temporary agents, the Agency requested 34 posts to replace existing contract agent positions with temporary agent positions. As a consequence, the number of contract agents will decrease by 35 in 2011 compared to 2010. The Management Board supported the conversion of these contract agent posts to temporary agent posts as essential in the Agency's efforts to recruit and retain scientific and highly specialised expertise. The Commission representative stated that the Agency's justification for the request to convert these posts was inappropriate, taking into account the Staff Regulations.

7. Preparation for a written procedure on adoption of amending budget No 1/2010

[EMA/MB/75924/2010] A written procedure will be launched in April or May to amend the budget 2010. The amendments may concern the reduction of fee income due to revised inflation rate, possible use of part of the surplus from 2008, increase in orphan medicinal products budget, financing ICT expenditure, and consultancy services aimed to identify options for future accommodation for the Agency.

8. Amendments to fees payable to the European Medicines Agency and other measures

[EMA/MB/818152/2009] The Management Board adopted the amendments to the Fee Regulation implementing rules. The amendments concern the adjustment of fees to inflation (increase by 1%), establishing reduced fees for applications for marketing authorisation for multi-strain dossiers, adapting the fees for extensions of marketing authorisations and clarifying reporting requirements for national competent authorities. The revised implementing rules will enter into force on 1 April 2010.

8bis. **Revised delegate reimbursement rules**

[EMA/MB/183091/2010] The Management Board adopted the amendments to the reimbursement rules for delegates, whereby an allowance, corresponding to 35% of the maximum cost of a hotel night (€60 for London), is introduced to provide financial support to delegates where no accommodation invoices can be provided. This provision is in line with reimbursement rules of other EU institutions. The revised rules will enter into force on 1 April 2010.

9. **Management Board Telematics Committee (MBTC)**

a) Update

The Committee watched presentations by the chairs of the telematics implementation groups. The Committee discussed the overall governance arrangements of the telematics programme. It will review the existing governance structures and consider alternative arrangements to optimise the governance of the programme. The MBTC and Heads of Medicines Agencies telematics group will work to ensure optimum collaboration.

b) Terms of reference

[EMA/MB/64422/2010] The Management Board adopted the terms of reference of the Management Board Telematics Committee.

10. **New website of the Agency**

The new website of the Agency, which is under development, was demonstrated to the Management Board. The Board had an opportunity to test the website during the break.

11. **Revised Management Board consultation procedure for CHMP and CVMP nominations**

[EMA/MB/281553/2007Rev.2] The Management Board adopted the revised procedure. The amendments clarify, among others, that the procedure does not apply to re-nominations of members/alternates for which the Management Board was already consulted.

12. **Committee on Herbal Medicinal Products: update from the Chair**

The Management Board welcomed the presentation of the Chair of the Committee on Herbal Medicinal Products. A number of issues were raised, relating to the availability of genotoxicity data by Member States, distribution of rapporteurships among Member States, and the impact of the strict requirements of the conflicts-of-interest policy on the availability of scientific expertise. A number of suggestions for future developments in the field were provided.

The Board discussed the need to enhance the number of list entries, but noted the hurdles posed by the unavailability of genotoxicity data. The adequacy of available genotoxicity data should be judged on a case-by-case basis and the request for new data should be made when there is a specific concern for safety.

With regard to output of the Committee, the members also regretted that Member States do not have adequate resources to allow additional support for the work of the Committee. In this respect, the Board welcomed the Norwegian model, where the agency has involved universities in producing draft monographs.

13. **Action plan for herbal medicines for 2010-2011**

[EMA/MB/142837/2010] The Management Board endorsed an action plan for herbal medicinal products. The action plan will now be discussed at the Heads of Medicines Agencies in April. Some of the objectives of the action plan include:

- collecting information on the uptake of the traditional use registration scheme in Member States;
- improving the output of the Committee;
- responding to any Commission request for enhanced cooperation between the Agency and the European Food Safety Agency (EFSA) in the area of health claims for food containing herbal ingredients.

The Board was concerned that few applications are submitted to national competent authorities in many Member States in light of the approaching deadline for registration of herbal medicinal products in Member States (April 2011)[1]. The Board also noted that issues exist in the area of the registration of traditional herbal medicinal products which can lead to products being marketed under another classification, e.g. food supplements. The Board proposed to develop a harmonised approach for use by all Member States after the expiry of the transitional period.

14. **Report from the European Commission**

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

- The move of the Pharmaceutical Unit F2 (and Unit F3, cosmetics and medical devices) to DG Sanco. The change took place on 1 March 2010.
- Progress on the pharmaceutical package (legislative proposals on pharmacovigilance, falsified medicines and the proposal on provision of information to patients).
- Visits of Commissioner Dalli to EMA and EFSA.
- Completion of the evaluation of the Agency and the upcoming conference on the report; the Board asked to see the report before its publication.
- Future revision of the transparency directive, with a view to promoting competitiveness of industry and innovation.
- Creation of a task force on corporate social responsibility of the pharmaceutical industry.

With respect to the selection procedure for the appointment of the Agency's new Executive Director, the Commission expects to produce a shortlist of candidates before the summer or in early September. The Board asked to accelerate the procedure to enable members to consider candidates in June. The Commission will write to the Chair to confirm specific dates for the shortlist of candidates to enable the Board to plan for an extraordinary meeting.

Board members raised concerns about the process by which DG Sanco has apparently decided to give the mandate for vigilance of cells and tissues to ECDC. Concern was expressed that the decision was taken prematurely, without due examination of the issue and discussion with all stakeholders. Members considered that the decision should take into account the fact that cells and tissues can be raw materials for medicinal products. Although the Commission confirmed that the decision had already been taken, the Board called for further debate on this matter.

[1] Directive 2004/24/EC of 31 March 2004.

15. **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:

- implementation of the e-submissions system across the EU and the future workshop on this topic;
- the work of the HMA task force on improvement of veterinary legislation;
- progress with the HMA/EMA training strategy;
- Benchmarking of European Medicines Agencies (BEMA).

Additional information was provided in a written report.

Documents for information

- [EMEA/MB/115245/2010] Annual report 2009 of the Agency's Audit Advisory Committee.
- [EMEA/MB/115301/2010] Annual report 2009 of the Agency's Internal Audit.
- Performance of the Agency's scientific procedures:
  - [EMA/78873/2010] Survey 2009 for medicinal products for human use;
  - [EMA/MB/117221/2010] Note on veterinary products.
- [EMA/61092/2010] Update report on the Agency's implementation of the EU telematics strategy.
- [EMA/MB/84539/2010] Outcome of written procedures during the period from 21 November 2009 to 25 February 2010.
- [EMEA/MB/617640/2009] Summary of transfers of appropriations in the budget 2009.
- [EMA/MB/121058/2010] Minutes from the first MBTC meeting, held on 9 December 2009, adopted on 9 February 2010.

Tabled documents

- Agenda point 8bis_Amendment of the reimbursement rules for delegates.
- Note on the outcome of the selection procedure for patients'/consumers' representatives to participate as observers in the PhVWP.
- HMPC presentation.
- Action plan for herbal medicines 2010-2011 presentation.
- Capabilities & limitations of human judgement presentation.
- Extending & improving judgement presentation.

List of participants at the 66th meeting of the Management Board, held in London, 17-18 March 2010

Chair: Pat O'Mahony

	Members	**Alternates and other participants**
Belgium	Xavier De Cuyper	
Bulgaria		Jasmina Mircheva
Czech Republic	Lenka Balážová	Jiří Deml
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		Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	Gyntautas Barcyc	
Luxembourg	Apologies	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Wojciech Matusewicz	Grzegorz Cessak
Portugal		Nuno Simoes Hélder Mota Philipe
Romania	Daniel Boda	
Slovenia	Martina Cvelbar	
Slovakia		Dagmar Stará
Finland		Pekka Järvinen
Sweden	Christina Åkerman	Christian Ifvarsson
United Kingdom	Kent Woods	
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Isabel de la Mata Georgette Lalis	Lenita Lindström
Representatives of patients' organisations	Mike O'Donovan	
Representative of doctors' organisations	*Apologies*	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Rannveig Gunnarsdóttir (Iceland)	

	Members	Alternates and other participants
	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 Hans-Georg Eichler Martin Harvey Allchurch	Anthony Humphreys Isabelle Moulon Frances Nuttal Agnès Saint-Raymond Bo Arronson Mario Benetti Yoshikazu Hayashi Arielle North Nerimantas Steikūnas Sarah Weatherley