EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2011
EMA/MB/828587/2011 Adopted
Management Board

Minutes of the 73rd meeting of the Management Board

Held in London on 6 October 2011

1. Draft agenda for 6 October 2011 meeting

[EMA/MB/650168/2011] The agenda was adopted.

2. Declaration of conflicts of interest related to current agenda

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.

The Chair informed the Board that he had reviewed declarations of interests of Board members and alternates and will send a number of letters to clarify certain issues.

The Management Board topic coordinators Xavier De Cuyper (Belgium), Walter Schwerdtfeger (Germany) and Lisette Tiddens (Vice-chair) are revising the conflicts of interests policy applicable to the Board. The group will aim to propose a draft for discussion at the December 2011 meeting.

The Board was informed that the European Court of Auditors is conducting an audit on systems and policies for managing conflicts of interest in several EU agencies. Best practices among the audited agencies will be identified. The parties involved recognise that the area of conflicts of interests is complex, and requires managing a variety of scenarios as well as public perception of 'factual' and 'perceived' conflicts of interests.

3. Minutes from the 72nd meeting, held on 8-9 June 2011

[EMA/MB/465305/2011] The Management Board noted the final minutes, adopted by written procedure on 11 August 2011.

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3bis Appointment of Guido Rasi as Executive Director

The Board appointed Guido Rasi as Executive Director of the Agency. The Committee on Environment, Public Health and Food Safety gave a positive opinion after the hearing of Mr Rasi on 13 July 2011, following which the Conference of Presidents of the European Parliament took the decision on 7 September 2011 to endorse the nomination of Mr Rasi for the position of Executive Director of the Agency.

Following the appointment, Guido Rasi joined the meeting of the Management Board.

Guido Rasi will take office on 16 November 2011.

This is the last meeting of the Board for Andreas Pott in his capacity as the Acting Executive Director of the Agency. The Board thanked him for the excellent results achieved during his time in this role, and fruitful cooperation with the Board, national competent authorities and the European Commission, and wished him well in continuing in his position as Head of the Administration Unit.

4. Highlights from the Acting Executive Director

New premises for the Agency

The Board was informed that the Agency has signed a contract for lease of a new building. The Agency will move to the new premises following the expiry of the current lease in 2014.

Discharge for the budget year 2009

The Committee on Budgetary Control of the European Parliament has made a proposal to grant the discharge to the Executive Director of the Agency for the budget year 2009. The Board was reminded that the group on procurement is reviewing the Agency's procedures and will make recommendations to reinforce procurement practices at the Agency. Members of the group are: Björn Lemmer, Jytte Lyngvig, Guido De Clercq and Vincenzo Salvatore. Jytte Lyngvig, the chair of the group, informed the Board that the work takes place in the areas of negotiated procedures, centralised oversight of tendering and use of exceptions. The group aims to provide its recommendations for the December Management Board meeting.

European Anti-Fraud Office (OLAF) investigation

The Board was informed that OLAF will visit the Agency as part of its investigation into the Agency's role in the medicinal product 'Mediator'. The date of the visit is to be confirmed.

Visit by the delegation of the European Parliament Committee on Environment, Public Health and Food Safety

The delegation visited the Agency in June 2011 to discuss the operations of the Agency and the environment impacting on the work of the Agency.

Review of meeting practices

The Acting Executive Director stressed the need to increase the use of virtual meeting technologies. Experts who need to contribute only during a part of a meeting should be given the possibility to participate through audio-visual means.

The Agency is reviewing working parties in order to further streamline their activities and participation. It is hoped that the number of missions for delegates and staff will decrease, which will in turn increase capacity and save resources.

Launch of a new human resources management system

Earlier in the year, the Agency had launched the SAP system for accounting and financial transactions, which replaced a number of internal databases. Now a new human resource module of the system has been launched, which replaced a further three databases. Overall, the new system has streamlined activities and improved resource use in the concerned areas.

Operational excellence programme - OpEx

The Agency is implementing the so-called OpEx programme that aims, amongt other objectives, to further increase efficiency of processes through their redesign. Processes that are subject to this approach are Type I variations, validation, management of requests to access documents and information.

Olympics 2012

The meetings which cannot be cancelled or postponed during the peak Olympic period in the months of July and August 2012 will be hosted at other locations. A number of national authorities, including those from Sweden, Germany, Malta and the Netherlands, have agreed to host such meetings. More video-conferencing will be held during the Olympic period. A parallel project is ongoing to organise the work of staff.

5. EMA mid-year report 2011 from the Acting Executive Director (January - June 2011)

[EMA/MB/653974/2011] The Management Board noted the mid-year report 2011. The document provides detailed information on progress against objectives and performance indicators set in the work programme 2011. The Agency is on track to implement agreed objectives. The revenue is in line with the forecast, while expenditure is lower than planned. These savings are needed for the implementation of pharmacovigilance legislation and to finance the move to the new premises.

A highlight for the first half of the year is the significant increase in activities in the wake of the Mediator case in France. The Agency hosted visits of many interested parties, including the French Senate, The French National Assembly and the IGAS inspectorate, and responded to enquires of committees conducting investigations into the circumstances surrounding the product, as well as to enquiries from the media.

The above case and the overall transparency policy had an impact on the number of requests for access to documents, which totalled 800,000 pages in the first half of the year.

The Mediator case also contributed to a larger number of referrals, since the environment has become more risk averse.

With regard to herbal products, the Board raised the issue that genotoxicity data remain inaccessible to the HMPC, which impedes the work of the Committee. The situation is such that it becomes increasingly difficult for the committee to achieve its work targets, despite the action plan that had been put in place earlier.

With regard to initiatives in the field of transparency, it was reiterated that the Agency will aim to implement a policy for proactive release of milestone documents emanating from the opinion-making process. An exercise to define commercially confidential information is ongoing, in cooperation with the HMA. The Management Board will review in greater detail ongoing activities in the area of transparency at the next meeting.

6. Implementation of the EMA road map to 2015

[EMA/MB/550544/2011] The Management Board endorsed the implementation plan for the 'Road map to 2015'. The Board provided final comments about the Agency's role in the area of clinical trials and in responding to European health threats. The updated document will be published on the website following the meeting. The Agency will draw on this multiannual implementation plan to prepare its annual work programmes, at which point final decisions will be taken as to which activities will be taken forward in line with resources available. The Board thanked the topic coordinators (Christina Åkerman, Aginus Kalis, Jytte Lyngvig, Marcus Müllner, Giuseppe Nisticó and Lisette Tiddens) for their role in preparing this document.

7. Implementation of the pharmacovigilance legislation

The Management Board noted the presentation summarising the discussions on the implementation of the pharmacovigilance legislation which were held during the meeting of the Heads of Medicines Agencies on 5 October 2011. The objectives of the meeting were to address strategic issues requiring HMA orientation, with particular focus on challenging aspects impacting on the NCAs; and to raise awareness on specific areas. The meeting noted that the budgetary situation has evolved since the March 2011 Management Board meeting when the preliminary draft budget 2012 was adopted. This required reviewing options for the implementation of the legislation. As a consequence, the implementation has been reprioritised in the following way: activities contributing to public health were given the highest priority, followed by activities increasing transparency and improving communication, followed by simplification measures.

7bis EU telematics projects report

[EMA/MB/793453/2011] The Management Board noted the report on the implementation of telematics projects. The format of the report has been changed at the request of the Management Board Telematics Committee. Members discussed that the governance of the EU telematics programme needs further strengthening. Historically, a complex governance structure, loss of knowledge during the implementation phase, loss of continuity between projects and inadequate representation of business users were among the negative factors that partly affected delivery of projects.

8. First update on the implementation of conflicts of interests policy for experts and staff

The Management Board noted the presentation on the implementation of the policies on conflicts of interests for experts and for staff. The policy for experts was implemented on 29 September 2011, with declarations of experts published on 30 September. The policy does not cover staff and experts working in national competent authorities. These are addressed in the Memorandum of Understanding that has been signed by all Member States. At the time of the report, 2,600 of 5,000 experts who are included in the database had signed their declarations of interest.

Those experts who work with the EMA but have not yet updated their declaration of interests in line with the new policy were reminded that they will not receive documents and/or invitations to the October meetings of scientific committees unless a signed declaration of interests is received. It must be noted that the majority of experts who have not submitted their declaration of interests are not involved in EMA activities. It was agreed that the website information on this topic would be made more specific to explicitly confirm that any experts who have not submitted a valid, signed declaration will not be involved in any EMA activities.

An overview of the impact of the new policy on scientific committees was presented. Members discussed that for the majority of experts who had direct interests, it was not an issue to discontinue those interests. However, members recognised that it may be disadvantageous for experts specialising in a narrow scientific area to discontinue their involvement, since stepping down from some of their activities may affect their level of expertise long term. Such members, however, will have to make a considered choice in light of the current policy.

The draft staff rules on conflicts of interests were adopted in June and the implementation started immediately. The implementation progresses according to plan. Staff updated their declaration of interests during the summer and the risk-level assignment is ongoing. The rules were sent to the European Commission for approval and the dialogue is ongoing.

9. Membership of the Management Board Telematics Committee

[EMA/MB/751210/2011] The Management Board appointed Sir Kent Woods as a member of the Management Board Telematics Committee following the departure of Pat O'Mahony from the committee earlier this year.

10. Personnel matter

11. Management Board decision-making process

[EMA/MB/746083/2011] The Management Board discussed whether to review the decision-making process in cases where there is evidence of a lack of consensus. The current practice has been to adopt decisions by consensus. Apart from elections, the Board generally only votes in exceptional situations.

The Board decided to clarify this point in the rules of procedure, stating that in situations where there is absence of obvious consensus, the Chair will ask members whether they wish to vote following the closure of a debate. Such a vote will be open and meeting minutes will indicate members who voted in favour, against or abstained. In cases where discussions are controversial, meeting minutes shall provide further details of the discussion and shall record dissenting opinions.

The revised rules of procedure will be submitted for adoption at the December meeting.

12. Reinstatement of the Accounting officer

[EMA/MB/729369/2011] The Management Board reinstated Gerard O'Malley as the Agency's accounting officer, effective 6 October 2011, following his return from long-term absence.

13. Implementing rules for Staff Regulations

[EMA/MB/742275/2011; EMA/MB/751326/2011; EMA/MB/742295/2011; EMA/MB/752482/2011] The Management Board adopted the following implementing rules:

- leave;
- part-time working scheme;
- parental and family leave.

The Board was informed that EU agencies no longer have the flexibility to adapt implementing rules to their specific circumstances following prior positive opinion of the European Commission. All rules now have to follow the rules as they are adopted by the Commission. The Board therefore has adopted the decision to delegate to the Chair the power to sign such implementing rules on behalf of the Board without presenting them at the plenary meetings.

14. Management Board meeting dates

[EMA/MB/376489/2011] The Management Board adopted the following meeting dates in 2012:

- Wednesday, 21 March & Thursday, 22 March;
- Thursday, 7 June;
- Thursday, 4 October;
- Thursday, 13 December.

The Board also noted the proposed meeting dates in 2013.

15. Substances of human origin (SoHO)

The Management Board noted the oral report by the Chair on the progress made following the last meeting. Two representatives of the Board, Walter Schwerdtfeger and Lisette Tiddens, were appointed to the steering group set up by the European Commission to provide support to the implementation of arrangements in the area of traceability of tissues and cells. Management Board Members of the European Centre for Disease Prevention and Control (ECDC) and representatives of national competent authorities (NCAs) also participate in the work of the group. The group will aim to clarify any concerns raised by the management boards of the two bodies and the needs and expectations of national competent authorities. The first meeting is scheduled for 27 October 2011.

Members noted the report from the Chair about significant differences as to how responsibilities for substances of human origin are allocated at the level of Member States. More specifically, in five Member States responsibility for SoHO is given to NCAs responsible for medicinal products, in a further ten some of the responsibility in the field is given to NCAs responsible for medicinal products, while in twelve Member States responsibility for SoHO is given to NCAs that are not responsible for medicinal products.

With regard to the request to open the group to a larger number of representatives from Member States, the European Commission confirmed that the steering group should remain small, representing the three settings EMA, ECDC and NCAs for tissues and cells, considering also that this group is doing the preparatory work.

16. Fourth report on progress of the interaction with patients

[EMA/MB/744981/2011; EMA/632696/2011] The Management Board noted the report on the interactions with patients' and consumers' organisations within the framework agreed in 2005. The report concludes that there was a significant increase in the interactions between the Agency and patients' and consumers' organisations. The future revised framework will focus on the role of patients in the scientific committees, the involvement of patients in benefit/risk evaluation and the implementation of a strategy for training and support. Regarding the frequency of preparation of these reports, the Board considered that the reports should remain annual; however, members would be content to receive a lighter version of such reports.

17. Revised criteria to be fulfilled by patients' and consumers' organisations involved in EMA activities

[EMA/MB/744342/2011; EMA/MB/24913/2005/rev.1] The Management Board adopted the revised criteria that have to be fulfilled by patients' and consumers' organisations involved in EMA activities. The revised criteria, among other changes, broaden the involvement of the organisations and revise the transparency criterion regarding the provision of information about funding sources.

18. Minor use minor species (MUMS) policy: Annual report 2011

[EMA/MB/743894/2011; EMA680110/2011] The Management Board noted the report on the implementation of the MUMS policy. The aim of the policy is to increase availability of veterinary medicines by stimulating applications for minor uses and minor species. The Board thanked the Agency, the national authorities and colleagues who were directly responsible for putting in place this very successful initiative. The policy was seen as another good example of how joint activities between the national agencies and the EMA contribute to bringing to the market products whose development could otherwise be discontinued.

The scheme will continue in 2012. It was suggested to have a closer look at minor species in future. It was also discussed that coordination with the DISCONTOOLS project (a joint initiative with industry and other stakeholders conducted under the European Technology Platform for Global Animal Health) could be explored, e.g. by including diseases identified in the DISCONTOOLS project within the policy. The next report will be prepared in 2013.

19. EudraVigilance status report for veterinary medicinal products

[EMA/MB/744682/2011] The Management Board noted the regular update report on the status of implementation of the European database for the collection of adverse events related to veterinary medicines.

20. Report from the European Commission

The European Commission provided an update on a number of items, including the following.

- The implementation of the cross-border health care directive (implementation by October 2013, a number of implementing measures will need to be adopted).
- European networks of reference for rare diseases (setting the criteria to identify networks, their financing, functioning).
- eHealth (legal basis to establish a voluntary network of Member States which can adopt guidelines; work is taking place in areas of patient registries, interoperability of national systems).
- Establishment and functioning of health technology assessment bodies and arrangements to grant financial support to HTA activities.
- Falsified medicines directive (the date of implementation is January 2013; the three areas of activity for implementing measures are the implementation of the safety feature, control of import of active pharmaceutical ingredients and preparing a logo for online pharmacies).
- The revised proposal on information to patients is expected to be adopted on 11 October 2011.
- A proposal on health security to better protect citizens against serious cross-border threats to public health (the European Commission expects the adoption of the proposal in July 2012).
- The Commission is preparing an impact assessment for the revision of the legislation on clinical trials (the aim is to prepare a proposal in the third quarter of 2012).
- The Innovation Partnership on Active and Healthy Ageing (first areas of work have been identified).
- A call for expressions of interest for membership of some EMA committees and of its Management Board (published on 30 September 2011; the call is open till the beginning of December 2011).
- The review of the legislation on veterinary medicinal products (the proposal will be made as a package with the legislation on medicated feed; the timeline for the proposal is to be set).
- Amendments of the fee regulation to include fees foreseen in the pharmacovigilance legislation (a European Commission proposal is expected later in 2012. The need for a bridging budget for EMA is being discussed).

21. Report from the Heads of Medicines Agencies

The Management Board noted the update on a number of items, including the following.

- HMA initiatives in the area of clinical trials in the context of the review of clinical trials legislation (voluntary harmonisation procedure).
- HMA paper published in the context of the review of the veterinary legislation.
- HMA work in the area of support to innovation (health technology assessment, discussions on medical devices and the impact of the recast of the related legislation).
- The next stage of the Benchmarking of European Medicines Agencies initiative.

List of written procedures during the period from 17 May 2011 to 14 September 2011

- No 07/2011 – the appointment of Helder Mota-Filipe as CHMP alternate, proposed by Portugal, finalised on 5 July 2011.
- No 08/2011 – the appointment of Janne Komi as CHMP member, proposed by Finland, finalised on 14 July 2011.
- No 09/2011 – the appointment of Michel Tougouz Nevessignsky as CHMP alternate, proposed by Belgium, finalised on 9 September 2011.
- Written procedure for adoption of the Agency's Final Accounts for the financial year 2010, adopted on 28 June 2011.
- Written procedure for adoption of the draft minutes of the 72nd Management Board meeting, adopted on 10 August 2011.

Documents for information

- [EMA/MB/793451/2011] EU telematics Operations Report.
- [EMA/MB/711444/2011; EMA/MB/711456/2011; EMA/MB/711459/2011] Minutes from the Management Board Telematics Committee (MBTC) from its March, May and June meetings.
- [EMA/MB/714970/2011] Outcome of written procedures during the period from 17 May 2011 to 14 September 2011.
- [EMA/MB/730141/2011] Summary of transfers of appropriations in the budget 2011.

Tabled documents

- Revised draft Agenda version 4.0.
- Letter from the president of the European Parliament.

List of participants at the 73rd meeting of the Management Board, held in London on 6 October 2011

Chair: Sir Kent Woods

	Members	Alternates (and other participants)
Belgium	Xavier De Cuyper	
Bulgaria		Meri Peycheva
Czech Republic	Jiří Deml	
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland	Pat O'Mahony	Rita Purcell
Greece	Ioannis Tountas	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	Dominique Maraninchi	Miguel Bley
		Jean-Pierre Orand
Italy	Luca Pani	Paolo Siviero
		Silvia Fabiani
Cyprus		George Antoniou
Latvia	Inguna Adoviča	
Lithuania	Gyntautas Barcys	
Luxembourg	*Apologies*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	Gavril Flores
The Netherlands	Aginus Kalis	Birte Van Elk
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal	Jorge Torgal	Nuno Simoes
Romania		Simona Bãdoi
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland		Pekka Kurki
Sweden		Christer Backman
United Kingdom	Kent Woods	Jonathan Mogford
		Jonathan Hafferty
European Parliament	Giuseppe Nisticó	
	Björn Lemmer	
European Commission	Paola Testori Coggi	Lenita Lindström
Representatives of patients' organisations	*Apologies from Mary Baker*	
	Mike O'Donovan	
Representative of doctors' organisations	Lisette Tiddens-Engwirda	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Rannveig Gunnarsdóttir (Iceland)	
	Brigitte Batliner (Liechtenstein)	
	Apologies from Norway	

European Medicines Agency	Andreas Pott
	Patrick Le Courtois
	David Mackay
	Hans-Georg Wagner
	Noël Wathion
	Sylvie Bénéfice
	Riccardo Ettore
	Martin Harvey Allchurch
	Isabelle Moulon
	Frances Nuttall
	Vincenzo Salvatore
	Emer Cooke
	Karen Quigley
	Zuzana O'Callaghan
	Nerimantas Steikūnas