10 August 2011
EMA/MB/465305/2011Adopted

Minutes of the 72nd meeting of the Management Board

Held in London on 8-9 June 2011

8 June 2011 meeting

The two-day meeting of the Management Board of the European Medicines Agency (EMA) commenced with an afternoon extraordinary session held on Wednesday, 8 June 2011, to nominate an Executive Director-designate. The vice-chair chaired the session.

Members deplored the fact that confidential information about the proceedings of the previous meeting of 5 May, held behind closed doors, was leaked and appeared in the press. Members were kindly reminded that the 8 June session was again a closed session and details of the meeting should remain confidential.

1. Draft agenda for 8 June 2011 meeting

[EMA/MN/234822/2011] The agenda was adopted without amendments.

2. Minutes from the 71st extraordinary meeting

[EMA/MB/417000/2011] The Management Board adopted the minutes from the 71st extraordinary meeting of the Management Board, held on 5 May 2011. The Board noted the legal note of 7 June 2011 of the Legal Service of the Commission which was tabled and presented at the meeting.

3. Announcement of votes by proxy

The Vice-Chair announced the following proxy votes:

- Lisette Tiddens (representative of doctors' organisations) and Claude Hemmer (Luxembourg) to Aginus Kalis (Netherlands).
- Henk Vaarkamp (representative of veterinarians' organisations) to Mary Geraldine Baker (representative of patients' organisations).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

4. Appointment of tellers

The Board appointed Brigitte Batliner and Gro Ramsten Wesenberg, observers from Liechtenstein and Norway, to act as tellers.

5. Announcement of the candidates

The Vice-Chair announced the following candidates on the shortlist presented by the European Commission:

[redacted]

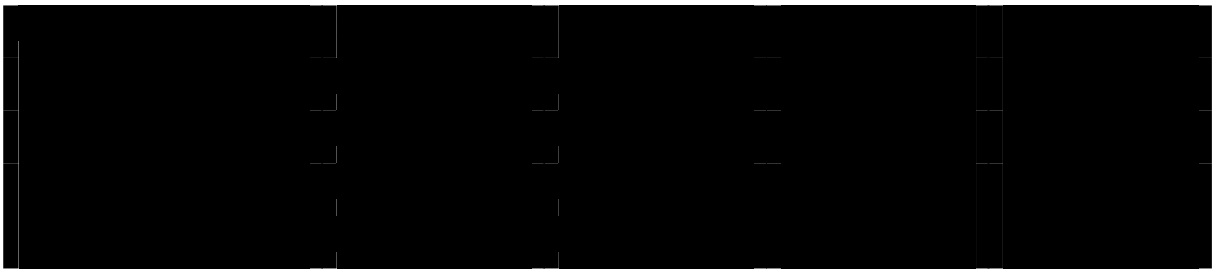
6. Declaration by Members

Kent Woods, the Board's observer in the pre-selection procedure appointed in December 2009, addressed the Board before the vote, emphasising the obligation of the Board on behalf of the Agency and EU public health to reach a decision and the repercussions should this decision not be reached. This position was supported by other members.

7. Vote

The Management Board vote took place by secret ballot in accordance with the revised procedure for appointment of the Executive Director (EMA/MB/400828/2009 Rev.1), adopted on 5 May 2011.

The results of the vote were as follow:



8. Announcement of the final result

The Vice-Chair announced the Management Board nomination of Mr. Guido Rasi as the EMA Executive Director-designate.

The Vice-Chair and the Acting Executive Director informed the candidates of the outcome of the selection by telephone after the meeting.

Tabled documents

- Comments to draft Management Board minutes of the 5 May 2011 meeting

- Note to the EMA Management Board from DG Sanco on selection procedure of the EMA Executive Director

9 June 2011 meeting

The meeting congratulated Guido Rasi as the Executive Director-designate. Mr Rasi thanked the Board for the confidence and the support and was looking forward to working with the Board and the network in the new capacity.

Mr Rasi announced his resignation as a member of the Management Board.

This was the last Management Board meeting for Steve Dean, the alternate of the United Kingdom, and Panayiota Kokkinou, the member of Cyprus. The Board thanks them for their past contributions.

1. Draft agenda for 9 June 2011 meeting

[EMA/MB/234822/2011] The agenda was adopted with the following change: item 23 'Update report on the Agency's implementation of the EU Telematics strategy' was withdrawn from the agenda.

2. Declaration of conflicts of interest related to current agenda

No interests were declared in relation to items on the agenda.

3. Election of the Management Board Chair

The Management Board received one nomination from Kent Woods (United Kingdom). Members noted the procedure for the election of the Chair. The Vice-Chair announced votes by proxy:

- Dominique Maranichi (France) to Belén Crespo Sánchez-Eznarriaga (Spain)
- Lisette Tiddens (representative of doctors' organisations) and Claude Hemmer (Luxembourg) to Aginus Kalis (Netherlands)
- Mary Geraldine Baker (representative of patients' organisations) to Mike O'Donovan (representative of patients' organisations)
- Henk Vaarkamp (representative of veterinarians') to Jytte Lyngvig (Denmark)

The Board appointed Brigitte Batliner and Gro Ramsten Wesenberg, observers from Liechtenstein and Norway, to act as tellers. The vote took place by secret ballot.

The results of the vote were as follow:

The Vice-Chair announced unanimous election of Kent Woods as Chair of the Board for a three-year term. Following the election, Prof. Woods stressed that continuing to protect public health and maintaining public trust are the two principles underlying the work of the Board. As a chairman he will work to provide strategic leadership to achieve these goals. Prof. Woods expressed his thanks to former Chair Pat O'Mahony for his contribution and his role over the recent years. Prof. Woods also thanked Vice-Chair Lisette Tiddens for her support and chairmanship during the past meetings.

Following the election Kent Woods chaired the meeting.

4. Minutes from the 70th meeting

[EMA/MB/232704/2011] The Management Board noted minutes from the 70th meeting, held on 16-17 March 2011, adopted via written procedure on 19 May 2011.

5. Minutes from the extraordinary 71st meeting

[EMA/MB/417000/2011] The Management Board minutes from the 71st meeting, held on 5 May 2011, were adopted on 8 June 2011.

6. Highlights from the Acting Executive Director

The Executive Director updated the Management Board on a number of issues, including:

- Positive opinions on a number of important medicines: a first new antibiotic, a new treatment for hepatitis C and a new product to treat multiple sclerosis.
- The launch of the EU clinical trials register and publication of the report on lessons learned from the influenza pandemic, as part of the ongoing work to increase transparency.
- Adoption of the strategy on antimicrobial resistance, and international cooperation in this domain.
- Increased cooperation with the European Commission aiming to improve the scientific review process, quality and consistency of opinions.
- Establishment of the expert group on geriatric medicines.
- Arrangements for the 2012 Olympic period to ensure that the Agency's key activities continue uninterrupted.
- Impact of the Mediator case.
- Issues relating to the 2009 discharge for the Agency.
- Progress on the future accommodation of the Agency.

Among other topics, the Board discussed that the Agency has the opportunity to take stock of its activities and to further clarify the division of work and responsibilities between the Agency, its scientific committees and the partners in the network. The Agency also needs to continue to ensure the transparency and robustness of management of conflicts of interests to continue to enjoy positive perception and trust of the pubic.

7. EMA Annual Report 2010

[EMA/306870/2011] The Management Board adopted the Annual report 2010. Last year, many areas have seen an increase in the volume of activities. Every effort was made to improve outputs of the work of the Agency. Some of the highlights include the launch of the new website which improved significantly the way in which information is provided to the public. A lot of effort went into and good results were achieved in areas of managing conflicts of interests, improving the transparency of the activities and providing access to the Agency's documents. The meeting provided a number of comments on the annual report which will be included before the document is published.

8. Acting Executive Director's Annual Activity Report 2010

[EMA/MB/416690/2011, EMA/292936/2011] The Management Board adopted the analysis and assessment of the Acting Executive Director's Annual Activity Report (AAR) and noted the AAR. The Board was satisfied with the performance of the Agency and included a number of specific points in the analysis and assessment. No reservations for the declaration of assurance were recommended.

The Board highlighted the fact that the national competent authorities contributed to the successful performance of the Agency. The Board however voiced concern over the fact that a number of activities which do not have fees are not compensated while the workload in those areas is steadily increasing. The meeting also discussed the pressures on one hand to increase controls in areas where incidents of mistakes or human errors occurred, and on the other hand the need to maintain proportionate relationship between controls and resources deployed.

The Board thanked the topic coordinators Kristin Raudsepp (Estonia), Mike O'Donovan (Patients' organisations), Rannveig Gunnarsdóttir (Iceland), and Lisette Tiddens for their work in preparing the analysis and assessment.

9. From Vision To Reality: Implementing the EMA Road Map to 2015

[EMA/743205/2010] There was detailed discussion on the level of ambition in the document and the extent to which this was achievable in a time of zero growth of staff and budget restrictions. The link between core business activities and the activities under the strategic areas was also discussed. The Agency clarified that this was not a request for additional resources and that many of the activities had already been agreed as part of other work programmes.

The European Commission representatives stressed that in the light of the current and future financial perspectives no additional resources will be granted to the Agency. Additional resources through fees or EU subsidy will only be available for new tasks required by legislation.

The Agency will review the document in line with the discussion. Since the implementation plan is a living document the direction of travel was agreed but the document itself was not endorsed. The plan will be revised on the basis of comments received, and updated on a regular basis to reflect the progress of the implementation of Road Map activities, trends affecting the core business and changes of legislation.

10. Preparation for written procedures

The Board noted that the following written procedures will be launched ahead of the next meeting:

a) Opinion on the Agency's annual accounts for the year ended 31 December 2010

[EMA/MB/173649/2011] The Board was briefed about the observations included in the draft opinion of the European Court of Auditors for the financial year 2010. Once the final opinion is received, the Agency will finalise its accounts and will launch a written procedure requesting the Board's opinion on the Agency's annual accounts for the year ended 31 December 2010.

b) Amending Budget 2011

[EMA/MB/370030/2011] The amending budget will concern possible changes in the forecast level of fee revenue, additional appropriations for the Agency's accommodation project and possible amendments to the establishment plan. With regards to the last, the European Commission is in

contact with the budgetary authority in the context of resources required for the implementation of the pharmacovigilance legislation. At this stage it is not likely that the fee legislation will be modified in 2012 in time for the implementation of the pharmacovigilance legislation. A bridging financing facility will be needed.

c) Appointment of the Executive Director

The Board was also advised of the next steps following the nomination of the Executive Director-designate. The Executive Director-designate will be invited to make a statement to the European Parliament and to answer any questions put by its members on 13 July 2011. It is expected that the Parliament will write to the Agency confirming the outcome of this hearing in September 2011, following which a written procedure by the Management Board to formally appoint the Executive Director will take place.

11. Amending Budget 01-2011 for changes to entry grades

[EMA/MB/373047/2011] The Board adopted the amending budget 01-2011 changing the entry grades for five posts. The adopted changes are within the 10% limit set out in the Financial Regulation (change to five posts out of 567). The amendments do not affect the staff appropriations corresponding to a full financial year and do not alter the limit of the total number of posts authorised by the establishment plan.

11bis EMA Discharge 2009

The Management Board discussed the European Parliament resolution to postpone the discharge for the budget year 2009. The Board noted the letter it had received from the Agency's Audit Advisory Committee [EMA/424437/2011] in which the committee provided comments on a number of issues raised in the Parliament's resolution. The Board also noted the tabled response on all of the points raised by the Parliament. The Board will write to the European Parliament outlining its views on some of the issues raised and actions taken. Members were asked to provide comments to the tabled draft letter by Wednesday 15 June, after which time the chair and vice-chair will finalise the letter and submit it to the Committee on Budgetary Control. The Commission representative stressed the need to implement the recommendations of the European Parliament.

[EMA/422080/2011] The Board also nominated its representatives to the group which will look at how the Agency's procurement procedures operate and will consider proposed actions for improvement. The nominated members are Björn Lemmer and Jytte Lyngvig. The European Commission will nominate a representative following the meeting. The Agency will inform the European Parliament about the group.

12. Extension of mandate of the Acting Executive Director

[EMA/MB/376449/2011] Members adopted the proposal to extend the current mandate of the Acting Executive Director for a further 6 months from 1 July 2011 to 31 December 2011 or until the new Executive Director takes up office, whichever is the shorter period.

13. Management of conflicts of interests

a) Draft implementing rules on handling of staff declared interests

[EMA/390118/2011] Draft implementing rules on handling of staff declared interest

The Board adopted the draft rules for the management of conflicts of interests of staff which are subject to approval by the European Commission. The rules are in line with those applicable to the members of scientific committees and experts with only minor differences stemming primarily from the Staff Regulations. The level of allowable conflicts of interests of staff will depend on the role of a staff member in question and the type of procedure the staff member will be involved in. Direct interests (e.g. shares, patents) will not be allowed and those staff members who have them will have to dispose of those interests within six months of the adoption of the rules.

The meeting discussed that the new rules also impact on the network. It was stressed that the right balance between consideration of conflicts of interests and availability of expertise is important to ensure high quality assessments. Availability of expertise is particularly acute in the veterinary sector. The transparency of decisions to seek opinions of experts with conflicts of interests is of particular importance.

The Agency will send the rules to the Commission for approval. Following comments received, the rules will be amended and resubmitted to the Board for the final adoption. The Agency will commence the implementation of the procedure already at this stage, on a provisional basis. The Board thanked Management Board coordinators Xavier De Cuyper and Kent Woods.

b) Common methodology of management of conflicts of interests within the network

[EMA/MB/400852/2011] The Agency and national authorities had agreed to the Memorandum of Understanding which clarifies responsibilities in managing conflicts of interests of assessment team experts. In addition, the Internal Audit Service (IAS) recommended that the Agency supports the introduction of experts' assessment methodology for all national competent authorities. The IAS suggests that the Agency should also monitor the consistency of checks carried out by national competent authorities and check the correctness of content of declarations of interests. The Agency considered that these proposals fall outside of the remit of the Agency. EMA informed the HMA of the IAS recommendation at the HMA in April 2011. The HMA agreed to provide their feedback for the July 2011 meeting.

The Board considered that it would be appropriate to request the European Medicines Agencies Cooperation on Legal and Legislative Issues (EMACOLEX) Working Group to carry out a review of how Members States deal with staff and expert conflicts of interests. This review would help to understand whether there is an issue which the network needs to address. The value of having a harmonised declaration of interest form was also mentioned. The meeting was reminded that the network's benchmarking exercise (BEMA) can also be used to facilitate the introduction of a more harmonised approach within the network. The meeting concluded that a further discussion at the HMA should take place.

c) Preparation for the review of the policy applicable to the members of the Management Board

The Board nominated topic coordinators Xavier De Cuyper, Walter Schwerdtfeger and Lisette Tiddens to review the current procedure for the management of conflicts of interests of the Board members and make a proposal at a future meeting. The current procedure on the management of conflicts of interests will continue to apply until the new procedure is adopted.

14. Authorisation for the Acting Executive Director to sign documents for new EMA headquarters

[EMA/MB/424329/2011] The Board adopted the decision giving a mandate to the Acting Executive Director to sign the lease and associated documents for the new headquarters building for the Agency.

15. MBTC Meetings and Communications

[EMA/MB/399835/2011] Members adopted the proposal from the Management Board Telematics Committee for meetings, virtual meetings and alternative ways of communicating and noted the report on the use of virtual meetings at the Agency. The Board's decision requires that the chair and the coordinator of every planned meeting where one or more individuals need to travel should consider, and justify, why virtual meeting technology cannot be used for the meeting in question. The Board also requested each group to propose a communication and meeting strategy specifying which of its meetings need to be held face-to-face and which not. The Board also suggested that benchmarking of the committees and working parties should be carried out with regards to the use of virtual meetings.

16. Substances of Human Origin

The Management Board endorsed the proposal on how responsibilities for vigilance and traceability of substances of human origin (SoHO) will be distributed between DG SANCO, European Centre for Disease Prevention and Control (ECDC) and EMA. German and Dutch delegations expressed their concerns with the proposal with regards to the distribution of tasks between the two agencies and the fact the European Commission did not allocate additional resources to the agencies. The European Commission expects the agencies to allocate internal resources through redeployment and efficiency gains. Taking into account that the Board had discussed this subject already at length and that the revised proposal was supported by both agencies, in combination with the fact that no further alternatives are envisaged and that an urgent mechanism for the protection of public health is required, the Board endorsed the proposal. The experience will be reviewed after 1-2 years. In a post-discussion note the German delegate wished to minute that the agreement to proceed according to the proposal was not supported by Germany.

16bis Harmonisation of transparency

There were a number of articles expressing views that the Agency has to further increase transparency in the area of clinical trials held by the Agency and to provide more details on the rationale of its decisions. Individual approaches taken by agencies within the network when replying to similar calls put additional strains on the network's resources. The Board is in favour of a full rather than partial disclosure policy. Members discussed that once assessment of a medicinal products is completed and a decision is taken, non-confidential information, including that related to clinical trials, needs to be made available to the public. However, this approach needs to be agreed within the network and consequences of such a policy assessed. The Board reiterated that the network should agree on what constitutes commercially confidential information and personal data to facilitate and enable a harmonised release of information to the pubic.

17. Annual EudraVigilance status report 2010

[EMA/78235/2011] The Board endorsed the EudraVigilance status report for human medicinal products for publication on the website with a number of amendments. The report provides information on how EudraVigilance contributes to the conduct of pharmacovigilance in the EU. In future information on further actions taken by rapporteurs for each signal will be included in the public report. In the context of the new pharmacovigilance legislation, information on signals kept under monitoring will also be provided in future. Likewise, information on compliance with the legal timeframes for reporting will be included in the future.

[EMA/422934/2011] The Board noted the EudraVigilance status report for veterinary medicinal products. Several Member States have submitting their product data thus allowing for the post-marketing surveillance of not only centrally authorised products but also of nationally authorised products on the EudraVigilance Veterinary Data Warehouse. The EudraVigilance veterinary 3 project is on track and a major milestone has been reached with the closure of the inception phase.

18. Report from the European Commission

The European Commission provided an update on a number of items including:

- The formal adoption of the falsified medicines legislation by the Council on 27 May 2011. The publication of the directive is imminent.
- On the basis of the first reading at the European Parliament of the legislative proposal on information to patients the Commission will prepare a modified proposal which will also include the following three points which emerged from a recent evaluation of the 2010 pharmacovigilance legislation in the light of the Mediator case ('stress test'):
  - If a Member State takes action on a marketing authorisation of a medicinal product, this product will be automatically referred for assessment at EU level;
  - If a marketing authorisation holder takes voluntary measures to withdraw a medicinal product from a market, the holder will have to specify the reasons to a national competent authority;
  - The new public list of medicinal products which are subject to additional monitoring will include all medicinal products subject to post-authorisation safety conditions will be prepared.
- In respect of the revision of the clinical trials directive (public consultation on the concept paper having been completed), the Commission is now preparing an impact assessment with a view to adopt the legislative proposal in the 2nd quarter of 2012.
- Recently, the Committee on Agriculture and Rural Development in the European Parliament adopted a resolution on antibiotic resistance. The European Commission and the Agency are having discussions notably on further work to assess the data on the use of antimicrobials collected from Member States and on how to ensure the necessary funding of this important project.

19. Report from the Heads of Medicines Agencies

The Management Board noted the report from the HMA meeting of 28 and 29 April 2011, including an HMA response on the public consultation by the European Commission on the Clinical Trial Directive.

List of written procedures during the period from 23 February 2011 to 16 May 2011:

- No 05/2011 – the appointment of Arantxa Sancho-Lopez as CHMP alternate, proposed by Spain, finalised on 3 March 2011.
- No 06/2011 – the appointment of Reynir Arngrímsson as CHMP alternate, proposed by Iceland, finalised on 3 March 2011.
- Written procedure for adoption of the draft minutes of the 70th Management Board meeting, adopted on 19 May 2011.

Documents for information:

- Report on discharge in respect of the implementation of the budget of EMA 2009
- Internal Audit Service annual audit report
- Pandemic report: lessons learnt
- Outcome of written procedures during the period from 23 February 2011 to 16 May 2011.
- Summary of transfer of appropriations in the budget 2011
- Minutes of the Management Board Telematics Steering committee

Tabled documents

- Draft letter from the Management Board to the European Parliament; Committee on Budgetary Control
- EMA Draft reply to the European Parliament
- Preliminary observations from the European Court of Auditors with a view to a report on the annual accounts of the European Medicines Agency for the financial year 2010
- Implementing rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the EMA
- From Vision to Reality: Implementation of the EMA Road map to 2015: The Agency's contribution to science, medicines and health
- Copies of correspondence sent to Dr. Fionna Godlee of the British Medical Journal dd. 31 May 2011 and 1 June 2011

List of participants*

Chair: Elizabeth Tiddens and Kent Woods[1]

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	*Apology received*	Meri Peycheva
Czech Republic	Jiří Deml	
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland	*Apology received*	Rita Purcell
Greece	Ioannis Tountas	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	*Apology received*	Marc Mortureaux[2] Miguel Bley[3]
Italy		Silvia Fabiani Guido Rasi[4]
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	*Apology received*	Beatrix Horváth
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal	Jorge Torgal	Nuno Simoes[5]
Romania	Daniel Boda	
Slovakia	Jan Mazag	
Slovenia	Martina Cvelbar	
Finland		Pekka Kurki
Sweden		Johan Lindberg
United Kingdom	Kent Woods	Steve Dean[6] Jonathan Mogford[7]
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Paola Testori Coggi *Apology received (Pedro Ortum Silvan)*	Giulia del Brenna Lenita Lindstrom[8] Stefaan van der Spiegel[9]

[1] Kent Woods chaired on Thursday, 9 June 2011
[2] Marc Mortureaux participated on Wednesday, 8 June 2011
[3] Miguel Bley participated on Thursday, 9 June 2011
[4] Guido Rasi participated at the start of the meeting on Thursday, 9 June 2011, where he resigned his membership
[5] Nuno Simoes was present during the meeting on Thursday, 9 June 2011
[6] Steve Dean participated on Thursday, 9 June 2011.
[7] Jonathan Mogford was present during the meeting on Thursday, 9 June 2011
[8] Lenita Lindstrom was present during the meeting on Thursday, 9 June 2011
[9] Stefaan van der Speigel was present during the meeting on Thursday, 9 June 2011

	Members	Alternates (and other participants)
Representatives of patients' organisations	Mary Geraldine Baker[10] Mike O'Donovan	
Representative of doctors' organisations	Elizabeth Tiddens	
Representative of veterinarians' organisations	*Apology received (Henk Vaarkamp)*	
Observers	*Apology received (Rannveig Gunnarsdóttir, Iceland)* Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway)	

*Participation during the 2-day meeting varied, variations are recorded in the footnotes.

European Medicines Agency attendees

- Andreas Pott
- Patrick Le Courtois
- David Mackay
- Hans-Georg Wagner
- Noël Wathion
- Hans-Georg Eichler[11]
- Peter Arlett[11]
- Sylvie Benefice[11]
- Sabine Brosch[11]
- Frances Nuttall[11]
- Martin Harvey Allchurch
- Agnes Saint Raymond[11]
- Vincenzo Salvatore
- Emer Cooke[12]
- Jean-Claude Brival[11]
- Sabine Haubenreisser[11]
- Jos Olaerts[12]
- Zuzana O'Callaghan

[10] Mary Geraldine Baker participated on Wednesday, 8 June 2011
[11] Present during the meeting on Thursday, 9 June 2011
[12] Participated on Thursday, 9 June 2011