9 February 2012
EMA/MB/33634/2012 Adopted
Management Board

Minutes of the 74th meeting of the Management Board

Held in London on 15 December 2011

The Management Board expressed its condolences to the family and its deepest regret following the death of its valued member Henk Vaarkamp who represented veterinary organisations on the Board for almost 3 years.

The mandates of the current civil society members of the Board expire on 4 March 2012. Members expressed regret and dissatisfaction regarding the delay in the nomination process. A number of interim arrangements will be made pending the completion of the process. In particular, the Board decided to defer the election process for the Vice-chair of the Board and the Chair of the Management Board Telematics Committee (MBTC) until after the civil society nominations have been made, which is anticipated in June 2012. The Board also decided to invite the current civil society representatives – Mary Baker, Mike O'Donovan and Lisette Tiddens – to participate at the next meeting as observers, to enable them to provide valuable input to the work of the Board.

Members raised concern that the legislation does not provide for alternate members of the civil society representatives on the Management Board.

Members welcomed Guido Rasi, the Executive Director of the Agency, for whom this was the first Management Board meeting in this capacity.

1. Draft agenda for 15 December 2011 meeting

[EMA/MB/826035/2011] The agenda was adopted.

2. Declaration of conflicts of interest related to current agenda

The Chair informed the Board that he had examined declarations of interests of members together with the Vice-chair and the secretariat, and concluded that there were no conflicts of interest that could interfere with the topics of the meeting.

In addition, 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 additional conflicts of interests were declared.

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3. Minutes from the 73rd meeting, held on 6 October 2011

[EMA/MB/828587/2011] The Management Board noted the final minutes, adopted by written procedure on 23 November 2011. The document had been redacted and published on the Agency's website.

4. Highlights from the Executive Director

Changes in management

Andreas Pott had been appointed as Deputy Executive Director of the Agency effective 1 December 2011. Andreas had been in charge of the Agency as acting Executive Director since January 2011 and has demonstrated his leadership, personal judgement and dedication by leading the organisation in a complex environment throughout 2011. In addition to his responsibilities as Deputy Executive Director, Andreas will continue in his position as Head of Administration Unit.

This was the last Management Board meeting for Hans-Georg Wagner, Head of Information and Communications Technology (ICT) Unit, who was shortly to retire after serving with the Agency since May 2002. The Management Board thanked Hans-Georg for his leadership, skill and contribution to achieving the Agency's objectives over this period, and wished him all the best for his future plans.

Meeting with Commissioner John Dalli and Director-General Paola Testori

The Executive Director briefed the Board about a range of topics discussed at the meeting, among which were the communication strategy of the Agency and the implementation of the pharmacovigilance legislation.

With regard to communication, the Board was informed that the Agency plans to reassess and further improve its communication activities with a view to providing the Agency's stakeholders with information about how the Agency and EU institutions contribute to public health.

Project 2014 - move to new premises

The Agency signed a lease agreement for new premises in October 2011. The process to prepare detailed plans and fitting-out requirements is ongoing and should finish in February 2012.

Discharge for the 2009 budget

The European Parliament granted the discharge for the implementation of the Agency's 2009 budget on 25 October 2011. The Agency had taken action to remedy shortcomings identified earlier in the process. Significant improvements have been made in the area of management of potential conflicts of interests of experts and staff members. Work is ongoing on improving procurement procedures.

Nomination to the new Pharmacovigilance Risk Assessment Committee (PRAC)

The Board was informed that the Agency had sent letters to respective Member States' Permanent Representations in Brussels inviting nominations to the Committee with the deadline of 15 January 2012.

Substances of human origin (SoHO)

The European Commission has decided to take over the responsibilities for SoHO activities. The decision was taken following a long period of discussions between the Commission, the European

Medicines Agency and the European Centre for Disease Prevention and Control, during which it was not possible to reach an agreement on how to distribute the responsibilities between the two agencies. The Board noted the letter from Paola Testori, Director-General of the DG for Health and Consumers, on the subject.

5. Planning 2012

a.) The work programme 2012

[EMA/MB/554514/2011] The Management Board adopted the work programme 2012. The main focus of the work programme is the implementation of the new pharmacovigilance legislation and the legislation on falsified medicines. The Agency forecasts that the numbers of applications within most of its activity areas will remain largely similar to those of the previous year.

Other important areas of activity will include further strengthening the quality of the Agency's scientific work. A number of projects are under way that will see streamlining of certain procedures and the introduction of more quantifiable elements in the assessment process. Effort will also be made to enhance the coordination of the scientific committees in light of the increasing complexity of interaction following the establishment of the seventh committee, which will deal with pharmacovigilance topics. Communication, transparency, future veterinary legislation, interactions with health technology assessment (HTA) bodies, process reengineering to increase efficiency of operations, and assuring functioning of the Agency during the busy Olympic period in London will be other areas of focus for 2012.

The Management Board thanked the topic coordinators Aginus Kalis, Marcus Müllner, Pat O'Mahony and Kent Woods for their contribution in preparing the topics on the work programme and the budget for the discussion. New topic coordinators were requested.

b.) Implementation of the Pharmacovigilance legislation

[EMA/MB/901680/2011; EMA/901869/2011] The Management Board endorsed the implementing activities for 2012. The implementation of a number of activities will continue in 2013 and subsequent periods, depending on the availability of further funds. Early in 2012, information on activities to be taken forward in 2012 will be provided through the Agency's website and a new workshop for industry will be organised.

The Management Board discussed at length the implementation of the provision on public hearings in the context of the revised urgent Union procedure. The meeting was cautious about the implementation of public hearings at an early stage. Members were concerned that this is a new initiative for the regulatory system and therefore requires thorough preparation in order to meet the significant expectations of stakeholders. The Board agreed to discuss a first draft proposal on public hearings at the next meeting.

With regard to the financing of the implementation of the pharmacovigilance legislation, the European Commission intends to present a 'bridging budget' for the year 2013. The Agency will not be able to pay rapporteurs until pharmacovigilance fees are introduced with the amendment of the Fee Regulation. However, the Board wishes to return to this question by the end of 2012.

c.) Draft budget and establishment plan 2012

[EMA/MB/143451/2011] The Board adopted the Agency's budget and the establishment plan for 2012. The budget is in line with the work programme and totals €222.5 million (6.5% increase over the 2011 budget), which includes a general EU contribution of €23 million, the 2010 surplus of €9.9 million and the €6 million orphan medicinal products fund. The planned fee revenue is increased by 7.5% over the 2011 budget to €173 million, in line with the increased number of applications and workload. Overall, the budget is €15.9 million lower than the preliminary draft budget adopted in March 2011. The reduction is largely due to a lower than requested EU contribution. The Board noted that the surplus from 2010 was included in the budget.

The Management Board adopted the establishment plan for 2012 of 590 posts, which increases the number of temporary agent (TA) posts by 23 for the implementation of the pharmacovigilance legislation. These TA posts will be financed bythe Agency's own resources (not from the EU contribution). However, the overall staffing of the Agency will remain at the previous year's level since the Agency will reduce the number of contract agents and seconded national experts by 23 full-time equivalents.

The Management Board also adopted a revision of the grading of the 23 posts in accordance with Article 32 of the Agency's Financial Regulation.

Topic coordinators were satisfied with the way the Agency is preparing for the Olympic period, both from the organisational and budget perspective. They were also content with the fact that the meeting budget remains stable even though a new committee will be established in the middle of 2012. The European Commission reminded the Board of the fact that the EU contribution to the Agency's budget is a balancing contribution. In the current financial situation, the contribution is not likely to be increased. The European Commission also pointed out that the ICT budget should be revisited and that there is scope for reducing meetings and missions. The meeting discussed that the Agency has to continue to review the scope of its activities and, when relevant, to reallocate resources from activities that are not strictly required by legislation. Members also stressed that the austerity environment should be seen as an opportunity for the whole network to rationalise the way it operates.

d.) ICT budgets and projects for 2012

[EMA/MB/856505/2011] The Management Board noted the information on the ICT budget and the projects planned for 2012. The ICT budget continues to show an increase in expenditure, which results in the decrease in the project development budget. As more systems go into production, the fixed ICT costs will continue to increase. The Agency and the network will need to consider ways of reducing the burden of fixed costs through the review and introduction of new technologies that have a cost-saving effect.

e.) Staff policy plan 2012

[EMA/MB/643417/2011] The Management Board noted the revised staff policy plan, in line with the reduced staffing and budget compared to the 2012 preliminary draft budget.

6. Amendments to Management Board implementing rules on the Agency's fees

[EMA/MB/239263/2011] The Management Board adopted amendments to the fee implementing rules. The amendments concern the following areas: inspections, plasma master files, certificates for

medicinal products, type II variations to MUMS marketing authorisations for non-food-producing species, and core dossiers for medicinal products to be used in a human pandemic situation.

7. EMA conflicts of interests policies

a.) Second update on the implementation of the conflicts of interests policy for experts

[EMA/MB/924270/2011; EMA/914836/2011] This item (for information) was deferred to the next meeting.

b.) Second update on the implementation of the conflicts of interests policy for staff

This item (for information) was deferred to the next meeting.

c.) The revised Management Board conflicts of interests policy

[EMA/MB/834867/2011] The Management Board welcomed the proposed revisions to the Management Board policy on conflicts of interests. Members raised a number of considerations in this respect. In their discussion, members stressed that the role of the Board and the types of decisions taken are significantly different from those of the scientific committees. This requires the Management Board to have a specific policy that differs in a number of aspects from that of the scientific committees.

The Board discussed the proposal to introduce restrictions in certain cases where potential conflicts of interests can be perceived. In this area, it was suggested to extend the period during which restrictions apply from two years to five years following the expiry of the conflict.

The meeting also considered whether additional provisions should be included in respect of attendance at meetings and conferences sponsored by the pharmaceutical industry. However, it was explained that the definitions in this policy mirror those adopted for the policy on conflicts of interests of experts, and it would be appropriate to keep both policies in line. With regard to this particular concern, the meeting was reminded that the issue was discussed when preparing the experts' policy. As an example, the Agency's staff do not attend events organised by the industry. But it was felt that the Agency is not in a position to impose further restrictions on the network, with a condition that any such participation can entail no more than a compensation of reasonable expenses. Members also stressed that with regard to Management Board members, the majority are also covered by similar conflicts of interests policies of their national authorities. The meeting was also informed that the Agency is preparing further guidance to experts about its policies on conflicts of interests. Members underlined that transparency is of significant importance in this area.

The Board decided to vote on whether to adopt the policy as proposed. The Chair announced the proxies held by members present. The outcome of the vote was as follows: 22 members in favour; 7 against; 2 abstained; 4 members sent their apologies for the meeting (votes by delegation and proxies can be found in the Annex). The Board requires 24 votes in favour to adopt a decision. The document was not adopted in its current form, and a revised policy will be submitted at the March 2012 meeting.

The Board took the opportunity to thank the topic coordinators (Xavier De Cuyper, Walter Schwerdtfeger and Lisette Tiddens) for preparing this topic for the discussion, and will look forward to a further discussion at the next meeting.

7bis Personnel matter

8. Report on the Agency's procurement procedure and a proposed improvement action plan

[EMA/MB/811207/2011] The Management Board endorsed the report on the Agency's procurement procedure and the proposed improvement action plan. The report follows the request of the European Parliament during the discharge procedure in 2011 to review the Agency's procurement practices. The proposed action plan focuses on the following areas: centralised multi-annual procurement planning, use of negotiated procedures in exceptional circumstances, and the Advisory Committee on Procurement and Contracts.

9. IAS strategic audit plan for 2012-2014

[EMA/MB/915206/2011; Ares(2011)992230 – 20/09/2011] The Management Board endorsed the IAS strategic audit plan for 2012-2014. If only one audit engagement can take place in 2012, the Management Board expressed a preference for the audit on planning and budgeting.

10. Revised Management Board rules of procedure

[EMA/MB/115339/2004/Rev.3] The Management Board adopted changes to the Management Board rules of procedure. The amendments clarify voting arrangements in cases where there is no clear consensus on a topic put forward for adoption.

Members also asked to revise the wording of Article 2 (5) of the rules of procedure to clarify that civil society representatives can be elected as chair.

11. Management Board Telematics Committee (MBTC)

a.) Revised terms of reference

[EMA/907384/2011] The Management Board adopted a change to the terms of reference of the Committee. A new member of the Committee is introduced to represent the business activities of the Agency. Members were also informed that a study to assess the governance of the telematics programme is ongoing. Results of the study are expected in March 2012.

b.) MBTC chairmanship arrangements

Taking into account that the current memberships on the Board of Lisette Tiddens and Mike O'Donovan expire on 4 March 2012, as do their mandates as Chair and a member of the MBTC respectively, and pending new appointments of the civil society representatives to the Board, the meeting decided to appoint Kent Woods as interim Chair of the MBTC effective 5 March 2012.

11bis Preparation for written procedures: Non-automatic carry-over 2011-2012

[EMA/MB/882002/2011] The Management Board noted that a written procedure for non-automatic carry-forward will be launched for adoption no later than 15 February 2012. The carry-over will concern funding of the relocation project, and the implementation of the next phase of the human resource database. Most of the preparatory stages of the commitment procedures relating to the two projects have been completed.

12. Draft reflection paper on ethical and GCP aspects of clinical trials

[EMA/MB/886045/2011; EMA/121340/2011] The Management Board endorsed the reflection paper. The Board discussed the importance of sharing the contents of the European clinical trials database with the countries with which the Agency cooperates in the area of clinical trials. This aspect will be addressed in the ongoing discussion about the review of the Clinical Trials Directive. The extended information sharing is important to enable effective and reliable cooperation for handling various situations and to contribute to an effective use of international inspection resources. Work on cooperation and capacity-building with the Agency's international partners is ongoing. Additional confidentiality arrangements would help to go further in this domain. The meeting also stressed that a mechanism to effectively address unethical behaviour should be put in place and would be an important instrument to ensure compliance with the requirements. The Board asked to include aspects of today's discussion in the report in order to clarify relevant issues. The European Commission stated the importance of not raising expectations among the public in view of the resource constraints; the Commission will look at what can be addressed in the revision of the Clinical Trials Directive.

13. Interaction between the Agency and healthcare professionals

a.) Framework for interaction between the Agency and healthcare professionals, and

b.) Criteria to be fulfilled by healthcare professionals' organisations involved in Agency activities

[EMA/MB/903626/2011; EMA/688885/2010; EMA/161137/2011] The Management Board endorsed the new framework for interaction with healthcare professionals (HCPs) and the criteria that apply to HCP organisations wishing to be involved in the Agency's activities. The Board welcomed the framework that aims to strengthen the already existing cooperation with HCPs and to fill remaining gaps.

The framework focuses on the following areas of interaction: accessing the best-possible expertise, contributing to a more efficient and targeted communication to healthcare professionals, and enhancing HCP organisations' understanding of the role of the Agency and of the network.

The adopted framework focuses on the interaction in the area of human medicines. The Board therefore asked to consider expanding this approach to veterinary medicines. The meeting also noted that both the network of HCPs and that of patients' and consumers' organisations will work together on topics of common interest.

The Management Board welcomed the Agency's efforts in this domain and recognised the contribution of staff in establishing fruitful and exemplary cooperation with its stakeholders.

14. Financial compensation for Member States' participation in the linguistic checking of product related information: Fixed flat hourly cost for 2012

[EMA/MB/880875/2011] The Management Board endorsed the adaptation of the fixed hourly cost to €41 for the year 2012 (the cost had been €40 since 2009).

15. 2011 EudraVigilance-Human mid-year report

[EMA/MB/902165/2011] The mid-year report showed positive trends in the area of signal detection and management. The Agency carries out the validation of signals and informs rapporteurs. This is then followed by a signal management procedure. The report confirmed that the response time from rapporteurs on communicated signals shortened compared to the same period in 2010. This improved response time reflects stronger collaboration between the Agency secretariat and the CHMP and its Pharmacovigilance Working Party, especially in terms of increased awareness of the current signal management process. The report also showed an increase in requests for data from EudraVigilance, a significant increase of Member States working with the EudraVigilance Data Analysis System, and improved compliance with the legal timeframes for the transmission of individual case safety reports.

16. Reflection paper on medicinal product supply shortages caused by manufacturing/GMP compliance problems

[EMA/MB/899250/2011; EMA/INS/GMP/774201/2011] The Board discussed the issue of supply shortages, considering it to be of importance to public health. There are many underlying drivers creating the problem, and many of those are not linked to globalisation. Some of the factors

contributing to supply shortages are trade issues, concentration and economics of manufacturing, and the drive for cost savings in healthcare systems. These factors are beyond the reach of regulators.

The Board also discussed the fact that management of supply shortages is equally complicated and involves various parties, such as the Agency, national competent authorities (NCAs), healthcare professionals, health ministries, companies and other bodies, all of which should work in a way that is efficient and responsive. It is equally important to acknowledge that the organisation and management of such issues varies in different Member States due to diverse healthcare settings and alternatives that are available.

European and international collaboration on these issues is important in order to achieve a positive outcome on this topic. It was recognised that a further debate with the European Commission and within the network should continue. The Commission pointed out that the focus should be on what can be done within the current legislative framework in view of the resource implications. The Board wished to return to this topic at a future meeting.

This reflection paper focuses only on supply shortages in the area of human medicines. Similar issues could also happen in the area of veterinary medicines, and this could have important consequences (human health, animal health or economical concerns). A reflection paper on veterinary product supply shortages should be discussed.

17. Report from the European Commission

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

- The implementation of the pharmacovigilance legislation (seven implementing measures are being prepared; public consultation finished in November 2011; the most relevant measure, which is relevant for national authorities, sets out minimum requirements for the pharmacovigilance system applied at NCA level).
- The implementation of the falsified medicines legislation (the Commission has launched public consultation on the following two implementing measures: the unique identifier and the assessment of the GMP status for active substances from non-EU countries).
- The proposal on information to patients (the provisions related to the pharmacovigilance legislation are now dissociated from the proposal on information to patients; progress on the latter proposal remains slow).
- The cross-border directive (progress has been achieved in setting up a voluntary cooperation structure with Member States in the area of health technology assessment; a network of Member States in the e-health area was established; a new proposal on cross-border health threats was adopted).
- Substances of human origin (the Commission will establish an information system on the substances; the Agency and ECDC will have an advisory role within their areas of competence).

18. Report from the Heads of Medicines Agencies (HMA)

The Chair of the HMA management group provided an update on a number of items, including the following:

- Progress on identifying commercially confidential information (a revised guidance document will be presented at the next HMA meeting in February 2012).

- EU database for veterinary medicines (in light of the revision of the veterinary legislation, the HMA reflected on a global strategic direction with regard to its IT infrastructure, particularly in the area of medicinal products databases).
- Communication about the network during international meetings, emphasising the complementarity of the EU system.

List of written procedures during the period from 15 September 2011 to 30 November 2011

- No 10/2011 – the appointment of Eva Persson as CVMP alternate, proposed by Sweden, finalised on 19 October 2011.
- No 11/2011 – the appointment of Frederic Klein as CVMP alternate, proposed by Belgium, finalised on 19 October 2011.
- No 12/2011 – the appointment of Alia Michaelidou-Patsia as CVMP alternate, proposed by Cyprus, finalised on 28 November 2011.
- Adoption of 73rd Management Board meeting minutes finalised on 25 November 2011.

Documents for information

- Minutes from the 1st meeting of the working group on substances of human origin.
- [EMA/907269/2011] EU telematics projects report; [EMA/907270/2011] EU telematics operations report; [EMA/907383/2011] Minutes from the Management Board Telematics Committee meeting held on 22 September 2011.
- [EMA/876327/2011] EMA preparations for the impact of the Olympic Games 2012.
- [EMA/MB/868582/2011] Outcome of written procedures during the period 15 September 2011 to 30 November 2011.
- [EMA/MB/902317/2011] Summary of transfers of appropriations in the budget 2011.

Tabled documents

- Revised draft agenda version 3.0.
- Letter from the European Commission, Paola Testori Coggi, regarding EU level support in the field of tissues and cells.

List of participants at the 74th meeting of the Management Board, held in London on 15 December 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	
Greece		Katerina Moraiti
Spain	Belén Crespo Sánchez-Eznarriaga	
France		Miguel Bley Jean-Pierre Orand
Italy	Luca Pani	Daniela Salvia
Cyprus	*Apologies*	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apologies*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal		Nuno Simoes
Romania		Simona Bãdoi
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland		Pekka Kurki
Sweden		Johan Lindberg
United Kingdom	Kent Woods	Jonathan Mogford Jonathan Hafferty
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Paola Testori Coggi *Apologies from Pedro Ortum Silvan*	Lenita Lindström Patrick Deboyser
Representatives of patients' organisations	Mary Baker *Apologies from Mike O'Donovan*	
Representative of doctors' organisations	Lisette Tiddens-Engwirda	
Representative of veterinarians' organisations		

	Members	Alternates (and other participants)
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Gro Wesenberg (Norway)	

European Medicines Agency	Guido Rasi Andreas Pott Patrick Le Courtois David Mackay Hans-Georg Wagner Noël Wathion Martin Harvey Allchurch Isabelle Moulon Frances Nuttall Vincenzo Salvatore Fergus Sweeney Zuzana O'Callaghan Nerimantas Steikūnas	

Annex

Vote on the adoption of agenda item 7c - MB conflicts of interests policy

Proxies announced by the Chair

1. Mike O'Donovan gives his vote by proxy to Mary G Baker.
2. Pedro Ortun Silvan (DG Enter) gives his vote by proxy to Paola Testori-Coggi (DG Sanco).
3. George Antoniou (Cyprus) gives his vote by proxy to Patricia Vella Bonanno (Malta).
4. Claude Hemmer (Luxembourg) gives his vote by proxy to Aginus Kalis (Netherlands).
5. Ioannis Toutas (Greece) gives his vote by proxy to Pat O'Mahony (Ireland).

	In favour	Against	Abstained	Not represented
1	Giuseppe Nistico	Paola Testori-Coggi	Czech Republic	Bulgaria
2	Bjorn Lemmer	Pedro Ortun Silvan by proxy	Hungary	France
3	Belgium	Austria		Portugal
4	Cyprus by proxy	Luxembourg by proxy		Veterinarian organisations
5	Denmark	Netherlands		
6	Estonia	Poland		
7	Finland	Spain		
8	Germany			
9	Greece by proxy			
10	Ireland			
11	Italy			
12	Latvia			
13	Lithuania			
14	Malta			
15	Romania			
16	Slovakia			
17	Slovenia			
18	Sweden			
19	United Kingdom			
20	Mary Baker			
21	Mike O'Donovan by proxy			
22	Lisette Tiddens			

Vote on the adoption of agenda item 7bis – Personnel matter

[redacted]

[redacted]