16 December 2010
EMA/MB/628133/2010

Minutes of the 68th meeting of the Management Board

Held in London on 7 October 2010

1. **Draft agenda for 7 October 2010 meeting**

[EMA/MB/398075/2010] The agenda was adopted with the following item added: Draft Council conclusions on innovation and solidarity in the pharmaceutical sector.

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 67th meeting, held on 10 June 2010**

[EMA/MB/404038/2010] The Management Board noted the final minutes, adopted by written procedure on 4 August 2010.

4. **Highlights**

Product suspension

The Committee for Medicinal Products for Human Use recommended the suspension of Avandia. The management were satisfied that both the Agency and the US Food and Drug Administration cooperated in this matter and made a coordinated announcement of respective decisions. This practice reflected well on both agencies and needs to be maintained in future.

The Board discussed that transparency of deliberations leading to the decision need to be improved and more information has to be provided to the public at different stages of the decision. The Agency's transparency policy due to be finalised next year will address this aspect. The Board stressed that a collective approach to transparency of the decision making process is needed in the network.

An international workshop in the area of GCP and ethical requirements for clinical trials

The Agency held an international workshop, on 6-7 September 2010 as part of the public consultation on the draft Reflection paper on GCP and ethical requirements for clinical trials conducted in third countries and submitted in marketing authorisation applications to the Centralised Procedure. The

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workshop was successful with 170 delegates from around 50 countries attending. The Agency will publish a summary report with slides on the meeting and will finalise the paper in 2011.

European Commission initiative on vigilance of substances of human origin

EU legislation on Substances of Human Origin sets out responsibilities for the EU Member States and the Commission in this area. The European Commission is seeking a solution for the support and coordination of the EU level tasks. All three concerned parties - European Commission, ECDC and EMA - have been working together to propose a solution. A report proposing an operational level solution will be prepared following these discussions and will be presented to the Management Boards of the ECDC and EMA in November and December 2010 respectively.

The EMA's involvement in this process relates to the fact that a part of substances of human origin are processed to advanced therapies, which are then covered by specific legislation. There should be an EU level interconnectivity between these areas to ensure a comprehensive approach to vigilance and traceability of products. The traceability is a complex issue, particularly for medicinal products due to their wide distribution. Resource consequences, should new responsibilities be granted, need to be examined.

The European Parliament hearing on H1N1 pandemic

Executive Director briefed the Management Board about the hearing at the European Parliament. All bodies which had a role in responding to the pandemic participated. The hearing addressed such topics as coordination of procurement of vaccines, adequacy of the mechanisms to declare a pandemic, risk assessment, arrangements to manage of conflicts of interest and other.

Financing of the Agency

The Agency anticipates that the EU contribution for the Agency will not increase and is likely to decrease as a proportion of the Agency's budget. The existing and new responsibilities, notably the new responsibilities in the field of pharmacovigilance, will increase pressure on financial resources. The fee system should be re-examined to assure appropriate financing of the Agency and the network. The work has started whereby the Agency has communicated its experience of the fee system to the European Commission and presented the topic to its stakeholders at the conference in June 2010. The political process to examine the fee system will be lengthy and therefore it is important to proceed as soon as possible and envisage interim solutions.

Update from the group of chairs of EU agencies

The last meeting of the group discussed the ongoing inter-institutional review of the EU agencies with the participation of the chair of the EU executive directors group. The meeting also considered future interactions between the two groups and a concept of performance indicators applicable to members of a management board.

5. EMA Mid-year report 2010

[EMA/MB/511582/2010] The Management Board noted the mid-year report 2010. The Agency demonstrated good performance against objectives set in the work programme. The Agency's revenue and expenditure for 2010 are also on target. The Management Board provided comments with regards to the reasons for the decline in the number of applications for human medicinal products, the increase in applications for paediatric investigation plans and the previous discussions of the Board on the payment system to national competent authorities. Proposed changes will be introduced and the report will be published on the website.

6. **Appointment of the Executive Director**

Management Board procedure for the selection of the Executive Director

[EMA/MB/400828/2009] The Board noted that the vacancy notice for the selection of the Executive Director of the EMA will be published on 27 October 2010 with a closing date for applications on 24 November 2010. The European Commission anticipates that an extraordinary meeting can be convened for the last week of February 2011.

The Management Board adopted the procedure for the selection of the Executive Director. Kent Woods, the Board's observer in the Commission part of the selection process, together with a few members will prepare questions for the interview, assuring that the selection criteria were adequately explored.

Appointment of Acting Executive Director

[EMA/MB/578243/2010] Taking into account that a new Executive Director will not be selected in time to take office from 1 January 2011, the Board discussed the appointment of an acting Executive Director and recommended the appointment of Andreas Pott, Head of Administration. The European Commission had been informed of the proposal. The current Executive Director will make the appointment.

The Board also endorsed the publication of the meeting document with a few amendments. The publication will take place after the official announcement has been made.

7. **Access to documents**

[EMA/MB/581808/2010; EMA/MB/581875/2010] The Management Board endorsed the EMA Policy on access to documents (related to medicinal products for human and veterinary use) and noted the document outlining outputs of the policy. The latter outlines how principles set out in the policy will be interpreted. By introducing the new policy, the Agency aims to ensure the widest possible access to its documents whilst respecting a number of principles set out in the policy, including the protection of commercial confidential information and personal data. The endorsed document follows the public consultation launched in December 2008 and takes into account recommendations from the European Ombudsman. The policy will be published in November 2010.

It was suggested that, in future, an agreement with the industry on the format of marketing authorisation applications in a way that would facilitate access without the need for redacting of commercial confidential and information containing personal data throughout the document should be explored. . It was also put forward that a world-wide arrangement could be envisaged, e.g. within the context of ICH.

8. **Audit Advisory Committee contribution paper to the Management Board**

[EMA/MB/575243/2010] The Executive Director had established the Audit Advisory Committee to oversee and advice him on internal controls, financial and risk management, and audits in order to help secure good governance and effective accountability and transparency. The Board endorsed the AAC approach to its remit in March 2005.

The Management Board discussed ways to establish closer relation between the Committee and the Management Board. The Board nominated the vice-chair, Lisette Tiddens-Engwirda, as the Board representative to the Committee. The Board also agreed to the proposal that the Chair of the Management Board will be invited to attend one meeting of the AAC per year and the Chair of the Committee will be invited to attend one meeting of the Board per year. In addition to the annual report, any other reports from the AAC will be presented to the Board.

9. **Revision of EMA Financial Regulation and its Implementing Rules**

[EMA/MB/528780/2010; EMA/MB/216485/2009; EMA/MB/281870/2010] The Management Board adopted the revised EMA Financial Regulation and implementing rules. The new EMA Financial Regulation follows the revision of the Framework Financial Regulation (EC, EURATOM) No 2343/2002 in 2008 and takes into account comments made by the European Commission. The regulation replaces the version provisionally adopted by the Board on 11 December 2008.

9bis **Transfer of appropriations in the budget 2010 in accordance with Article 23 (2) of the Financial Regulation**

[EMA/MB/603657/2010] The Management Board adopted the transfer of € 4.4 million of 'provisional appropriation' (€ 5.4 million) that was set aside for possible variations in fee income. The transfer follows the evaluation of its budgetary situations as at 31 August 2010 which showed favourable budget trend. The released part of the provisional appropriation will be used to finance and bring forward ICT projects that might be insufficiently financed in 2011 due to reductions in the EU contribution for 2011.

10. **Amendment to the Agency's internal control standard on sensitive functions**

[EMA/MB/568706/2010] The Management Board adopted the proposed revision to the Agency's internal control standard on sensitive functions. The amendment concerns the replacement of mandatory mobility with ex-post controls and/or focused audits every two years for sensitive functions. The amendment takes into account the size of the Agency and specialisation of staff.

11. **Preparation for written procedure on adoption of the Agency's policy on protecting the dignity of the person and preventing any form of psychological or sexual harassment**

[EMA/MB/575364/2010] The Management Board noted the proposal for a written procedure for the adoption of the aforementioned policy which will be launched after the Agency receives the opinion of the European Data Protection Supervisor. The European Commission already gave its agreement to the draft policy in accordance with Article 110 of the Staff Regulations.

12. **Amendments to Fees payable to the European Medicines Agency and other measures**

[EMA/MB/818152/2009] The Management Board adopted the amendments to the implementing rules on the Agency's fees. The amendments concerns extensions of marketing authorisation, Type II variations, annual fees, variations to plasma master files and vaccine antigen master files. The proposal received a favourable opinion from the European Commission. The rules come into effect on 7 October 2010 and will be published on the Agency's website.

13. **Minor Use Minor Species policy: Annual report 2010**

[EMA/MB/577848/2010; EMA/577855/2010] The Management Board endorsed the annual report on the operation of the Minor Use Minor Species (MUMS) policy and the proposal to continue with the scheme for an additional year. The report concluded that the new scheme is achieving the objective of incentivising the development and authorisation of new veterinary medicinal products for MUMS. The financial impact of the scheme was in excess of € 140,000. The financial and workload impact of the scheme and the Agency's and the network's ability to respond will continue to be monitored and reviewed if needed. As experience is gathered, the CVMP may need to further clarify the borderline between MUMS and other products.

14. **Future accommodation of the Agency**

The Management Board was given a presentation on the current options available to the Agency in respect of its future accommodation and the criteria applied to evaluate the options. The Board discussed that due to the nature of the Agency's operations any future options should provide for a maximum degree of flexibility for expansion or reduction. A further discussion will take place at the December meeting. The Board was informed that contacts were established with the European Commission on the matter. The topic coordinators will continue to work with the Agency on this matter which is expected to be ready for the decision by the end of 2010 or beginning of 2011.

15. **Revised policy on the handing of conflicts of interests**

[EMA/MB/588579/2010; EMA/MB/589332/2010] The Management Board endorsed the Agency's updated policy on the handling of conflicts of interests of Scientific Committee members and experts, and noted the document providing an overview of the allowable interests for the EMA scientific activities. The new policy is built with three principles in mind: robustness, efficiency and transparency. It aims at balancing out the need to secure Europe's best scientific experts for the evaluation and supervision of medicines while ensuring that these experts have no financial or other interests in the pharmaceutical industry that could affect their impartiality.

Members discussed whether the new policy may restrict participation of representatives of patients and academia in EMA activities, particularly in cases of smaller organisations. It was emphasised that the same principles are applied for all experts, those from national authorities, academia and civil society representatives, working in the EMA's committees. The Agency will meet with patients/consumers' and healthcare professionals' representatives to explain how the policy will be applied.

The policy will be implemented in the second quarter of 2011 once practical arrangements have been put in place. The effects of the policy will be monitored and further changes introduced as needed. The Board will review an interim report on experience with the revised policy in 6 months time and a full report in 18-24 months time.

Lisette Tiddens-Engwirda and Jean Marimbert will act as topic coordinators for the revision of the rules applied to members of the Management Board and will take into account experience gained with the above policy.

16. **Sponsoring of patients' organisations by pharmaceutical industry – proposed actions**

[EMA/MB/531926/2010] The Management Board discussed the issue raised in the report by the Health Action International which suggested that not all patient and consumer organisations fulfil the Agency's financial transparency criteria. The Board noted that the conclusions in the HAI report are based only on information found on the internet. The Agency receives financial statements of each of the organisations during the evaluation of their eligibility to work with the EMA. The organisations are also subject to regular re-evaluation of their eligibility. However, to further increase transparency in the area, the Board endorsed the proposal to make further improvements in related procedures and suggested including links to the websites of the concerned organisations to enable easier consultation by the public.

17. **Third report on the progress of the interaction with Patients' and Consumers' Organisations during 2009**

[EMA/MB/579729/2010] The Management Board noted the report. The document describes the on going progress of the interaction between the European Medicines Agency and Patients' and

Consumers' Organisations (PCOs) during 2009 and includes information about the status of implementation of the actions and recommendations that were identified in previous reports. Amongst further activities, the Agency plans to revise the "Framework of Interaction" between the EMA and PCOs and to explore how patients and consumers can be involved in the benefit/risk assessment of medicinal products. The role of patients and consumers in the different scientific committees of the Agency will also be defined.

18. **The establishment of a Joint CVMP/CHMP ad-hoc Expert Group on the application of the 3Rs (Replacement, Reduction and Refinement) in the development of medicinal products**

[EMA/MB/559867/2010] The Management Board endorsed the proposal to establish a joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs in the development of medicinal products. The group will contribute to the work aiming to encourage the development and regulatory acceptance of alternative approaches to animal testing, will reinforce the role of the Agency in the area of animal welfare and will facilitate communication with stakeholders. It is anticipated that the first meeting of the group will take place towards the end of 2010 or in early 2011.

19. **2009 EudraVigilance Human Status Report 2009**

[EMA/MB/599720/2010] The Management Board endorsed the EudraVigilance status report for Human medicinal products for 2009. The Board discussed that in future information about signal management activities will need to be provided. This aim can be achieved in the context of the transparency policy and the implementation of the pharmacovigilance legislation.

20. **Nomination to the CVMP**

[EMA/MB/578660/2010] The Board noted the nomination to the CVMP. In the context of the Management Board consultation procedure on nominations to the scientific committees, the Board discussed the level of scientific competence of nominees to the committees and the desired scientific and regulatory qualifications and experience of members. A number of Board members felt that, while the final decision on appointment of a member lies with the Member State in accordance with Art. 61 of Regulation (EC) No 726/2004, only appropriately scientifically qualified members should be accepted.

21. **Report from the European Commission**

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

- The progress on the "pharmaceutical package"; pharmacovigilance legislation which is due to become applicable in mid-2012), legislative proposals on preventing entry into legal supply chain of falsified medicines and information to patients).
- Revision of the clinical trials directive.

22. **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:

- The upcoming meeting with the European Generics Association (EGA) in the margins of the HMA meeting on 26 October.

- The HMA's endorsement of the draft Memorandum of Understanding on the monitoring of the scientific level and independence of the evaluation carried out by the NCAs for the Agency.
- The adoption of the draft Strategy Paper II 2011-2015 for public consultation.
- Wider application of teleconferencing tools involving larger number of participants.
- The preparation for the third cycle of Benchmarking of European Medicines Agencies and endorsement of its continuation.

AOB

Following the request from the Spanish Member of the Board, the Members noted the Draft Council conclusions on Innovation and Solidarity in the Pharmaceutical Sector prepared by the Presidency. The draft conclusions concern the issue of relative effectiveness. The meeting considered that a special session is needed at the Management Board to gain a more thorough overview of work done in the area of health technology assessment at the level of the Council and the European Parliament.

Documents for information

- [EMA/496888/2010] Update report on the Agency's implementation of the EU telematics strategy
- [EMA/MB/539466/2010] MBTC's Telematics Implementation Group: Chair's appointment procedure and role
- [EMA/MB/535239/2010] Outcome of written procedures during the period from 7 June 2010 to 4 October 2010.
- [EMA/MB/528844/2010] Summary of transfers of appropriations in the budget 2010.

Tabled documents

- The final English version of the announcement for the selection procedure for the Executive Director
- Presentation on the EMA accommodation strategy
- Presentation on the EMA Policy on the Handling of Conflicts of Interest for Scientific Committee Members and Experts
- Letter from the European Parliament representative to the Board and the Representative of Doctors' organisations to Commissioner John Dallli on the proposed revised EMA Policy on the Handling of Conflicts of Interest for Scientific Committee Members and Experts
- Nomination form and CV for the nomination to the CVMP
- Draft Council conclusions on Innovation and Solidarity in the Pharmaceutical Sector prepared by the Presidency

List of participants at the 68th meeting of the Management Board, held in London, 7 October 2010

Chair: Pat O'Mahony

	Members	Alternates (and other participants)
Belgium	Xavier De Cuyper	
Bulgaria	*Apology reveived*	
Czech Republic	Jiří Deml	
Denmark	Jytte Lyngvig	
Germany	Walter Schwerdtfeger	
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	Ioannis Tountas	
Spain	Cristina Avendaño-Solà	
France		Miguel Bley
Italy	Guido Rasi	Silvia Fabiani
Cyprus	Panayiota Kokkinou	
Latvia	Inguna Adoviča	Dace Ķikute
Lithuania	Gyntautas Barcys	
Luxembourg	Claude A Hemmer	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal	Jorge Torgal	
Romania	*Appology reveived*	
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland		Pekka Järvinen
Sweden		Johan Lindberg
United Kingdom	Kent Woods	
European Parliament	Giuseppe Nisticó	
	Björn Lemmer	
European Commission	Isabel de la Mata	Andrzej Rýs
		Lenita Lindstrom
Representatives of patients' organisations	Mary G. Baker	
	Mike O'Donovan	
Representative of doctors' organisations	Lisette Tiddens-Engwirda	
Representative of veterinarians' organisations	Henk Vaarkamp	
Observers	Brigitte Batliner (Liechtenstein)	
	Gro Ramsten Wesenberg (Norway)	
	Apology received from Iceland	

European Medicines Agency	**Thomas Lönngren**	**Sara Mendosa**
	Patrick Le Courtois	**Isabelle Moulon**
	David Mackay	**Frances Nuttal**
	Andreas Pott	**Agnès Saint Raymond**
	Hans-Georg Wagner	**Arielle North**
	Noël Wathion	**Nerimantas Steikūnas**
	Peter Arlett	**Zuzana O'Callaghan**
	Sylvie Bénéfice	
	Jean-Claude Brival	
	Riccardo Ettore	
	Martin Harvey Allchurch	
	Anthony Humphreys	