28 July 2012
EMA/MB/394635/2012 Adopted
Management Board

Minutes of the 76th meeting of the Management Board

Held in London on 7 June 2012

This was the last Management Board meeting for Jytte Lyngvig. The Management Board thanked Jytte for her significant contribution to the work of the Board over many years. Members wished her all the very best for her future plans.

The Management Board will continue inviting the recent civil society members whose mandate expired to participate at the Board meetings as observers until the Council nominates new members.

1. Draft agenda for 7 June 2012 meeting

[EMA/MB/92770/2012] The agenda was adopted.

2. Declaration of conflicts of interests related to current agenda

This is the first meeting under the new conflicts of interests policy. In line with the previous practice, the Chair will continue reviewing interests declared by members before each meeting and will consider whether any of the declared interests pose conflicts with items on the agenda. The new policy provides for certain restrictions. Names of members concerned and restrictions will be indicated on future agendas.

The Chair informed the Board that he had examined declarations of interests of members together with the secretariat, and concluded that there were no conflicts of interests 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.

3. Minutes from the 75th meeting, held on 21-22 March 2012

[EMA/MB/221361/20124/2012] The Management Board adopted the minutes. The minutes contain amendments received during the consultation phase.

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Members discussed that it is important to balance the independence of scientific experts with the need to ensure that the best scientific experts in the European Union remain available for the evaluation and supervision of medicines. A negative trend resulting from strict rules is already seen in some Member States, where high-level scientists choose to step down from various committees. To avoid a negative impact of the rules, they need to be reviewed regularly, particularly with regard to definitions.

It was stressed that the role of the Management Board is very different from that of scientific committees in that it does not deal with product-specific issues but focuses on matters of governance and supervision. The Chair of the Management Board will play an important role in the balanced application of the policy.

4. Organisation of Management Board meetings

[EMA/MB/251300/2012] The Management Board decided to introduce changes to the future meetings. Beginning from October 2012, Board meetings will commence at 8:00 and finish at 15:00, with an option to extend to 16:00. Forty-five minutes will be allocated for lunch.

The agenda will be divided into three parts: items A, which are intended for adoption without presentation; items B, intended for adoption and/or discussion with presentation; items C, presented for information and not discussed unless requested by members. These changes are already introduced in this agenda.

March meetings will continue as two-day meetings. The Board will make further use of written procedures where appropriate.

The Board thanked topic coordinators (Marcus Müllner, Luca Pani, Kristin Raudsepp, Andrzej Rys, Gro Wesenberg and Kent Woods) for their proposed improvements.

A.1 Revised implementing rules to the Fee Regulation

This item was presented as preparation for the future written procedure under agenda point C.5.b.

B.1 Highlights from the Executive Director

Discharge for the budget 2010

The European Parliament has postponed the discharge for the 2010 budget. This is due mainly to two concerns: the handling of conflicts of interests by the Agency, and the past decision by the Management Board not to adopt a cost-based payment system to the national authorities. The European Parliament is now requesting the Agency to verify declarations of interests of experts, overturning the previous principle of 'burden of proof' and introducing a new approach for which a new methodology needs to be developed. A discussion about options for a new payment system will be held later in the year. With regard to managing conflicts of interests, the Management Board discussed the intrinsic challenges faced by the medicines system with regard to access to expertise and scientific knowledge, and emphasised the importance of transparency to address public perception in this area. It is seen to be of value to organise a symposium with the European Parliament to discuss these and other issues in the context of changing ethics and perception. The Commission representative stressed the importance of a strict approach to conflicts of interests and of adequate documentation of the outcome of the screenings of declarations of interests; also, after the identification of different levels of risk, the Agency needs to show that it acts accordingly.

Meeting with Matthias Groote, Chairman of the European Parliament Committee on Environment, Public Health and Food Safety (ENVI)

The directors of five agencies — the European Medicines Agency, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Environment Agency (EEA) and the European Chemicals Agency (ECHA) — met with Mr Groote on 30 May 2012. During the meeting he expressed appreciation for the agencies and proposed to meet twice a year to discuss common issues, such as transparency, handling of conflicts of interests and strain on resources.

Establishment of a Scientific Coordination Board

The Board has been created to facilitate the efficient and coordinated running of the scientific committees, working parties, working groups and scientific advisory groups. Its function is to improve interaction between committees, foster dialogue from the early stages of product assessment, and optimise the support to the committees from the secretariat, working parties and experts to move towards a more integrated procedure. The Scientific Coordination Board met for the first time on 23 April 2012 and is expected to meet four times a year, with further virtual meetings if necessary. It is composed of the chairs of the scientific committees, the chair of Scientific Advisory Working Party and senior staff of the Agency, and will be chaired by the Executive Director.

Launch of the ADR website

Stakeholders have welcomed the launch on 31 May of the database, which is directly fed by EudraVigilance, is fully searchable in compliance with the access policy and allows consultation of records relating to about 650 centralised products.

Resignations and new appointments

The Chair of the Committee for Medicinal Products for Human Use (CHMP), Eric Abadie, resigned as of 4 April 2012. The Committee is currently chaired by its Vice-Chair, Tomas Salmonson, pending the election of a new chair, expected in October.

Vincenzo Salvatore, Head of the Legal Service, will be leaving his role at the Agency on 15 June 2012 to return to his position as Professor of International Law at Università degli Studi dell'Insubria in Varese, Italy.

As part of the ongoing EU-Japan confidentiality arrangements and increased collaboration and cooperation with the Japanese Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), a new Japanese liaison official, Junko Sato, has joined the Agency for an initial period of one year, replacing Yoshikazu Hayashi.

Sabine Haubenreisser has been appointed as the Agency's liaison officer to the U.S. Food and Drug Administration (FDA), replacing Hilde Boone, who has now taken the post of EU Institutional Liaison Officer.

B.2 Executive Director's 'Annual activity report 2011'

[EMA/MB/878723/2012; EMA/MB/326427/2012] The Management Board discussed and adopted the analysis and assessment of the Executive Director's annual activity report for 2011. The final document takes into account comments made at the meeting.

The annual activity report is a reflection of the Agency's annual report, with particular focus on the use of resources to achieve objectives. The report highlights: work done to implement the new pharmacovigilance legislation; the successful achievement of core activities; initiatives to streamline

activities and reduce costs; the impact of the changing public view on conflicts of interests, and the Agency's initiatives in this domain; and the ongoing project to relocate the Agency to new premises.

When discussing the report, the Management Board wished to include in the analysis and assessment a reference to the Agency's operational excellence initiatives, and asked for information about the results of the initiatives to be provided at a future meeting. The Board may wish to include its concern about the need to provide adequate resources for the implementation of the legislation in the analysis of the 2012 activity report.

The Board thanked the topic coordinators (Xavier De Cuyper, Martina Cvelabar and Gro Wesenberg) for preparing the draft report for discussion.

B.3 Report from the European Commission

The European Commission reported on EU legislative and policy developments, specifically those listed here:

- Implementing measures for the pharmacovigilance legislation (vote in Standing Committee on 29 May 2012; planned adoption in June 2012).
- Appointment by the Commission of six independent experts for the Pharmacovigilance Risk Assessment Committee (PRAC), to be finalised shortly. The procedure for the appointment of representatives of civil society for the PRAC and the Committee for Advanced Therapies will be relaunched at the request of the European Parliament, due to the scarcity of candidates.
- Status of the appointment of the four representatives of civil society to the Management Board. These should be appointed by the Council and the European Parliament by October, and would be able to take part in the December meeting.
- Progress with the review of the Fee Regulation with regard to pharmacovigilance fees. A concept paper on fees for new pharmacovigilance activities has been drafted and a public three-month consultation procedure should be launched in June. This will be followed by an impact assessment, leading up to the presentation of a legislative proposal by the end of 2012. The subsequent legislative procedure is expected to take place over at least two years, terminating in 2014.
- Proposal by the European Parliament, supported by the Commission, to introduce fees related to pharmacovigilance activities by means of a time-limited delegated act. This approach has not been supported by the Council.
- Future joint action on pharmacovigilance for which, so far, 17 Member States have expressed interest. This aims at supporting Member States in implementing pharmacovigilance systems and can be co-financed by the Commission up to 70% of total costs.
- Impossibility for the Council to reach qualified majority on the proposal on information to patients and on the other workstreams for information to patients.
- Upcoming proposal on the revision of the clinical trials legislation, to take the form of a regulation (planned adoption: July 2012).
- Proposals for regulations on medical devices and in vitro diagnostics (to be presented by the Commission in Q3 2012).
- Proposal for revision of the veterinary medicines legislation (Q3 2013).

- Initiatives on antimicrobial resistance, with the Commission 'AMR Action Plan' adopted in November 2011 and the Council conclusions to be adopted in June, and an own-initiative report to be presented in Q3 by the European Parliament.
- Good progress of the initiative promoting good governance in the pharmaceutical sector, which will be submitted to the network of stakeholders and national competent authorities in July.
- New substantial phase of discussion around the Transparency Directive (three Working Group meetings have already taken place in the Council; under preparation at the European Parliament).

The Board expressed concern over the delays in the appointments of the representatives of civil society to the committees and to the Board, which might have repercussions on the ability of these bodies to operate at full capacity and to appoint members to internal organisational positions. The Board decided to proceed with the election of the vice-chair of the Management Board at the October meeting, regrettably ahead of the appointment of the civil society representatives. An invitation for nominations will be sent separately.

B.4 Management Board breach of trust procedure

[EMA/MB/309079/2012] The Management Board discussed and adopted the breach of trust procedure for Management Board members, taking into account comments raised by Members, in particular clarifying that the role of Agency staff in the process shall be that of a secretariat, and that the view of the nominating authority will be sought as part of the process.

The procedure deals with cases of incorrect or incomplete declarations of interests of Board members, and completes the Agency's framework on dealing with potential conflicts of interests of its scientific experts, committee members, Management Board members and staff.

The adopted procedure provides that it will be the responsibility of the Management Board to review individual cases and to decide whether a breach of trust took place. An appeal mechanism is provided.

Each newly appointed member will receive a copy of the rules, along with the conflicts of interests policy, with which they will be asked to familiarise themselves when completing declarations of interests.

The Board thanked the topic coordinators (Xavier De Cuyper, Walter Schwerdtfeger and Lisette Tiddens) for drafting this document.

B.5 Report from the Management Board sub-group on procurement procedures

[MB/EMA/2368595/2012; EMA/269255/2012; EMA/269247/2012] The Management Board had at its earlier meeting endorsed a report from the sub-group on procurement procedures, which contained a number of measures to strengthen and improve the Agency's layers of checks and controls. Recommendations from the European Parliament and from auditors have been taken into account, and new proposals for setting up the Advisory Committee on Procurements and Contracts and for its rules of procedure were presented for endorsement to the Board. General support was expressed for the Agency's approach; however, suggestions from the European Commission, which might further improve provisions, are awaited. The Board will be informed accordingly.

B.6 Pharmacovigilance legislation

a) Pharmacovigilance Risk Assessment Committee (PRAC) rapporteur appointment principles

[EMA/MB/347576/2012] The Board resumed the discussion on the principles for the appointment of rapporteurs to the PRAC, which was initiated in February 2012 at the meeting of the Heads of Medicines Agencies and in March at the Management Board. On these occasions, opinions on the necessity to introduce the so-called 'pair of fresh eyes principle' had been divided, with concerns expressed about discontinuity of knowledge, duplication of work and complication of the process. Many Member States did not express their views on the matter. All were invited to come forward with proposals and ideas.

Denmark/Sweden and Norway sent written proposals introducing the need for a differentiated approach for new applications, i.e. applications filed after 2 July 2012, and 'legacy' applications, which are only concerned with the need for a PRAC input in the post-authorisation phase. The proposal for PRAC co-rapporteurs was also put forward.

The proposal now presented by the Agency at the meeting took into consideration the feedback received by Member States during the previous discussions, as well as both proposals. It further introduced two principles that should guide the appointment of PRAC rapporteurs:

- robustness of opinion: scientific and specific knowledge (continuity);
- need for checks and balances.

For products submitted after 2 July 2012

PRAC rapporteurship in both pre- and post-authorisation phases is open to all PRAC delegates; the selection criteria are the best possible scientific expertise and, where possible, being from a different Member State to those whose delegates form the CHMP teams. A PRAC co-rapporteur would be appointed from the same team as the CHMP rapporteur.

For 'legacy' products

The proposal for legacy applications was different only in that the Agency left the option open on whether the new PRAC team would take the lead or not, in relation to the team that is linked to the CHMP rapporteur.

The Agency considered that this proposal builds on the newly introduced principles for appointment. Furthermore, it favours the creation of multinational rapporteur teams and avoidance of duplication of work.

The Board acknowledged positively the effort by the Agency to build the proposal stepwise, reflecting all contributions. The Commission advised the Agency and the Board to keep in mind the need to streamline work as much as possible when setting out provisions and procedures concerning the new Committee, giving due regard to resources. The Board appreciated the new principles and suggested the introduction of a third, i.e. to add a risk-based approach in order to tailor activities in proportion to real needs. Once implemented, the principles for appointment should be reviewed after an adequate timeframe.

b) Countdown to July 2012; the establishment and functioning of the PRAC

[EMA/MB/345767/2012; EMA/315258/2012] The Management Board discussed the status of the implementation of the PRAC. This is proceeding as scheduled, with some delays in the nomination of

PRAC members. At its inaugural meeting on 19 and 20 July, which will be chaired by the Agency, the PRAC will adopt its rules of procedure, to be implemented after a favourable opinion by the Commission and by the Management Board. To this purpose, a written procedure will be held. The election of the PRAC chair and vice-chair is scheduled for the Committee's second meeting in September 2012.

Good coordination of the interaction between the PRAC, CHMP and Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) will be crucial, to allow for the formal decision-making phase required by some of the PRAC output along short timelines. The Early Notification System to the EU Regulatory Network will be revised to provide advance warning on communications to be issued, as well as to assist the planning of subsequent discussions at CHMP/CMDh. The PRAC will work at a very high standard of transparency, publishing its agendas and minutes, high-level outcomes of its main scientific discussions, and its recommendations and advice.

In this last period of its operation, the Pharmacovigilance Working Party (PhVWP), which ceases to exist upon establishment of the PRAC, is examining all open files brought to its attention in order to entrust to PRAC the legally actionable issues. Should issues arise that require urgent discussion in the period between the July and September PRAC meetings, these will be handled in an extraordinary PRAC meeting chaired by the Agency.

The Board noted the progress in the establishment of the PRAC and underlined the importance to provide the public with clear and exhaustive information on the functioning of the system and on the role and responsibility of all its components.

c) Final composition of the PRAC

[EMA/329643/2012] The Management Board noted the current composition of the PRAC, which covers all areas of expertise required. Further nominations by the European Commission of six independent experts are awaited in the coming weeks, in time for the inaugural session, while there will be delays in the appointment of the civil society representatives due to the relaunch of the call for expressions of interest.

B.7 Management Board meeting dates 2013

[EMA/MB/325685/2012] The Management Board adopted the following proposed meeting dates for 2013:

- Wednesday, 20 March & Thursday, 21 March;
- Thursday, 13 June;
- Thursday, 3 October;
- Thursday, 12 December.

The Board also noted the following proposed meeting dates for 2014:

- Wednesday, 19 March & Thursday, 20 March;
- Thursday, 12 June;
- Thursday, 2 October;
- Thursday, 11 December.

B.8 Annual EudraVigilance status report 2011

a) Human medicines

[EMA/MB/144431/2012; EMA/144430/2012] The Management Board endorsed the EudraVigilance status report for human medicinal products for publication on the Agency's website with some amendments. The report highlights substantial increases in validated signals, requests for data from EudraVigilance and shorter response time by rapporteurs. Collection and management of EudraVigilance data has also progressed, with an increase of use of the EudraVigilance Data Analysis System by Member States and improved compliance with legal timeframes.

b) Veterinary medicines

[EMA/322615/2012] The Management Board noted the EudraVigilance status report for veterinary medicinal products. Development of EVVET 3 is progressing to plan. Its success is dependent on the availability of a single database for veterinary products. The long-term objective is to use EUTCT to house veterinary data as well as human. Good cooperation has been established with the Member States who support the development of a single database based on Eudrapharm.

B.9 Committee on Herbal Medicinal Products (HMCP); Report on action plan for herbal medicines 2010–2011

[EMA/MB/347231/2012; EMA/HMPC/45679/2012] In 2010, the Management Board had adopted an action plan for herbal medicinal products 2010–2011 to address concerns about the low number of monographs and list entries. At this meeting, the Chair of the Committee on Herbal Medicinal Products presented the results of the implementation of the plan.

The Committee achieved the continuous release of monographs, with over 100 monographs adopted, representing more than half of the expected 200 monographs of herbal substances with a European tradition. The Board also noted that the number of registrations granted based on monographs has grown significantly and now totals over 750. This confirms that monographs are an accepted European standard. The Board considers that list entries are a useful tool for herbal medicinal products. They are binding and can be used for combination products. However, the number of list entries remains low, due to lack of public data on genotoxicity. The HMPC is looking for solutions. Some members were of the opinion that the circumstances in which genotoxicity data are required could be reviewed.

The Committee remains concerned about borderline products. A trend is seen where manufacturers are choosing to reclassify their products as food, in which case the directive on traditional medicinal products does not apply. Cooperation with the European Food Safety Authority is essential in this area, as is the need to ensure that there is no overlap or duplication of activities, particularly in borderline areas.

Other tasks include the need for harmonisation of assessment of non-European traditional herbal substances, to avoid the application of diverse policies among Member States.

B.10 Management Board appointment to the Management Board Telematics Committee (MBTC)

The Management Board appointed the Italian Member, Luca Pani, to represent the Board at the MBTC. Noting that there are two further places to be filled by the Management Board, one of which is

assigned to the patients' representatives of the Board, Members were asked to express their interest for one nomination, which will be circulated for appointment at the next Board meeting.

Information items

- Report on the Agency's discharge 2010.
- Annual Internal Audit Report (IAS) 2011.
- EMA/MB/321840/2012 Agency's improvement action plan on open recommendations from the IAS audit.
- [EMA/310159/2012] EU telematics projects report; [EMA/310155/2012] EU telematics operations report; [EMA/310498/2012] Minutes from the MBTC meeting from March 2012.
- [EMA/MB/326836/2012] Outcome of written procedures during the period 1 March 2012 to 17 May 2012.
- [EMA/MB/323136/2012] Overview of implementing rules to Staff Regulations signed by the MB Chair during the period from 7 October 2011 to 29 February 2012.

List of written procedures during the period from 1 March 2012 to 17 May 2012

- Consultation No 04/2012 on the appointment of Walter Janssens as CHMP alternate, proposed by Belgium, ended on 9 March 2012. The mandate of the nominee commenced on 10 March 2012.
- Consultation No 05/2012 on the appointment of Maria Azevedo Mendes as CVMP alternate, proposed by Portugal, ended on 9 March 2012. The mandate of the nominee commenced on 10 March 2012.
- Consultation No 06/2012 on the appointment of Arvils Jakovskis as CVMP alternate, proposed by Latvia, ended on 9 March 2012. The mandate of the nominee commenced on 10 March 2012.
- Consultation No 07/2012 on the appointment of Chrysoula Ntaousani as CHMP alternate, proposed by Greece, 4 April 2012. The mandate of the nominee commenced on 5 April 2012.

List of participants at the 76th meeting of the Management Board, held in London on 7 June 2012

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria		Meri Peycheva
Czech Republic		Jiří Bureš
Denmark	Jytte Lyngvig	Else Smith
Germany		Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland	Pat O'Mahony	Rita Purcell
Greece	Ioannis Toutas	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	Dominique Maraninchi	Jean Baptiste Brunet
Italy	Luca Pani	Paolo Siviero Daniela Salvia
Cyprus	Arthur Isseyegh	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apologies*	
Hungary	Tamás L Paál	
Malta	Patricia Vella Bonanno	
The Netherlands	Aginus Kalis	
Austria		Sylvia Fuszl
Poland	Grzegorz Cessak	
Portugal	Jorge Torgal	Nuno Simoes
Romania	Petru Domocos	
Slovakia	Jan Mazág	
Slovenia	Martina Cvelbar	
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom	Kent Woods	Jonathan Mogford Sandor Beukers
European Parliament	*Apologies (Giuseppe Nisticó)* Björn Lemmer	
European Commission	Paola Testori-Coggi Salvatore D'Acunto	Patricia Brunko
Representatives of patients' organisations		Mike O'Donovan
Representative of doctors' organisations		
Representative of veterinarians' organisations		

	Members	Alternates (and other participants)
Observers	Luka Vončina (Croatia) Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Gro Wesenberg (Norway)	Viola Macolić Šarinić (Croatia)

European Medicines Agency	Guido Rasi Andreas Pott Patrick Le Courtois David Mackay Noël Wathion Vincenzo Salvatore Frances Nuttall Mario Benetti Silvia Fabiani Tomasz Jablonski Zuzana O'Callaghan Jos Olaerts Nerimantas Steikūnas	