EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Management Board

# Minutes of the 75th meeting of the Management Board

Held in London, 21-22 March 2012

## Wednesday meeting, held on 21 March 2012

Annually, the Management Board dedicates the first day of its March meeting to discussions on strategic topics. The meeting this year focussed on the following:

- A discussion on the concept of public hearing and transparency.
- Publication of agendas and minutes.
- Update on the implementation of the pharmacovigilance legislation.
- Pharmacovigilance Risk Assessment Committee (PRAC) rapporteur appointment.
- Adaptive licensing.

## Session 1: A discussion on the concept of public hearing and transparency

The new pharmacovigilance legislation, which enters into force in July 2012, introduces a provision that allows public hearings to be held, in the context of the assessment of medicinal products for human use. This is a new tool for the Agency, and the Management Board discussed this concept in order to provide guidance for a future procedure.

During the session, the Management Board heard expectations that patients – the main stakeholders in this process – have about public hearings. In his presentation, François Houÿez, of the European Organisation for Rare Diseases, stressed that patients are looking for greater involvement, better understanding of already reached regulatory decisions and participation in decision making. Mr Houÿez also shared his experience from public hearings at the US Food and Drug Administration and made a number of practical suggestions. He underlined that, among other considerations, such hearings should have a clear and defined structure, a clear and understandable list of questions, be transparent about sponsorship of participants, and ensure that contributions by participants add to the discussion.

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The legislation states that public hearings may be held in cases of safety concerns. However, patient representatives expressed their wish to see such hearings extended to other areas where patients have high expectations (e.g. unmet medical needs), where there is public concern (controversial media coverage), divergence between regulatory and HTA assessments, etc. Public hearings should address not just safety issues but also expected benefits of medicinal products.

The Management Board underlined that public hearings should be seen as a new way of engaging and communicating with the public, and not only as an additional tool for transparency. The hearings should see a 'real public participation'. The audience for the hearings should represent the right balance among the Agency's stakeholders in this area – patients, healthcare professionals, academia and industry. To be a communication tool, hearings should convey a clear and well-defined message. The issue of language was raised. It was suggested that such hearings could be streamed to national competent authorities and that the public could participate in hearings from their premises.

Another key opinion of the Board was that hearings should add value to the assessment process by offering views of the patient community or the general public. Future reflection should therefore consider at which stage of the decision process a public hearing would be most valuable (e.g. when addressing benefit-risk or borderline issues). Members stressed the importance of the quality and clarity of the questions asked, so that participants can offer their opinions and answers, and take the discussion forward. The use of case stories was suggested, as this is a useful tool to increase understanding of the matters raised.

With regard to the transparency of conflicts of interests, the Board underlined that the disclosure of participants' relations with industry or with others whose views they represent is very important, to ensure that the process is clear and trustworthy.

The Agency should also manage expectations about what the hearings will aim to achieve and what will not be tackled. Public hearings should initially cover a limited number of aspects only, but may over time be expanded to cover more complex issues. After initial experience, the process needs to be evaluated, to verify if the expected results are being achieved.

The Board agreed on a process to prepare for the procedure. The Agency will draft a reflection paper based on the guidance provided today, and will seek written comments from the Board. The paper will be discussed by the newly created PRAC, and a final proposal will be submitted to the Board later this year. The Board suggested organising a mock-up hearing at some stage, and using the experience gained from this when finalising the procedure.

# Publication of agendas and minutes

The legislation states that the Agency shall make public agendas and minutes of the Committee for Medicinal Products for Human Use (CHMP), the PRAC and the Coordination Group (CMD(h)) as regards pharmacovigilance activities, and the Board heard an update on preparations for the implementation of these provisions. Members agreed that all parts of agendas and minutes should be published. It was proposed that agendas and minutes of the PRAC meetings be published, initially, with those of the CHMP and CMD(h) being published in a second phase, once sufficient experience has been gathered.

The Board also supported the position of ensuring utmost transparency on post-authorisation matters, since these will have significant public interest. This means that adopted minutes will be published irrespective of whether a procedure is finished or still ongoing.

However, the issue that needs to be addressed in this scenario is making every effort to ensure that committee discussions on safety-related signals do not cause misunderstanding by the public. This is

particularly relevant due to the fact that the CHMP and CMD(h) may take a different view after the PRAC opinion has been put in the public domain.

With regard to pre-authorisation procedures, the general feeling was that minutes should only be published after procedures are finalised and the European Commission has taken its decision.

The meeting also noted the proposal about the timing between PRAC and CHMP/CMD(h) meetings. The underlying principle is to allow enough time for the CHMP/CMD(h) to review and debate the outcomes of the PRAC meetings. A gap of one week between PRAC and CHMP/CMD(h) meetings was proposed. The challenges in this approach are that there may be increased pressure from external parties on the CHMP/CMD(h) and that Member States may act prior to CHMP/CMD(h) outcomes.

## Session 2:
## An update on the implementation of the pharmacovigilance legislation in the run-up to 2 July 2012

The meeting noted a detailed update about progress on the implementation of provisions foreseen in the new pharmacovigilance legislation.

The discussion of the Board focused on the possible divergence of opinions between the PRAC and the CHMP/CMD(h). While members stressed that every effort needs to be made to avoid divergence of opinions, it was recognised that the possibility of having divergent opinions is also a strength of the European system, which is based on checks and balances. Such divergence can be seen as an opportunity to add new views to the scientific debate and to make the final outcome of such debate more robust and of better value.

The challenge for the Agency in this context is to ensure that the internal mechanisms to support the scientific committees – e.g. the rapporteurs, product teams, committee secretariats and systems for communication and cooperation among the committees – are effective at capturing early signals of possible divergence in the assessment process. These systems should then ensure that all knowledge about the reasons for a decision is shared among concerned committees in a timely manner. The committees should then have sufficient time to debate the cause for divergence and to identify any possibility to converge their views before the final decision is taken.

A second challenge for the Agency is to explain to the public the reason for the divergence and the impact this has. The Board stressed the importance of transparency in this context.

## A discussion on PRAC rapporteur appointment (follow-up to the February HMA meeting)

The Board continued discussions held at the meeting of the Heads of Medicines Agencies in February 2012. The debate focused around the issue of whether a PRAC rapporteur should be from the same Member State as the rapporteur in the initial evaluation stage, or from a different one.

The Board had divergent views about the two approaches. Although the appointment of a rapporteur from a different Member State could be seen as adding to the trust of the system, other members were convinced that this would unnecessarily increase the complexity and associated costs of the system. Some members argued that unless benefits of having a different rapporteur can be demonstrated and quantified, they would be unwilling to provide the additional resources needed.

It was also argued that the knowledge obtained about a product in the pre-authorisation stage is important for PRAC rapporteurship. On the other hand, it was stressed that product knowledge is one

aspect of PRAC rapporteurship, while specific expertise in risk management and independence from the pre-authorisation phase are other important considerations.

Another proposal offered, which would allow knowledge about a product that had been gathered at the pre-authorisation stage to be retained, was to appoint the PRAC rapporteur from among the experts who had acted as peer-reviewers in the pre-authorisation phase. It was suggested that for already authorised products and ongoing procedures, the system of the rapporteur in the pre-authorisation stage being appointed as the PRAC rapporteur could be applied. After entry into force of the new legislation, the system of the peer-reviewer becoming a PRAC rapporteur could be applied for procedures starting after 2 July 2012.

Members also discussed that a clear distinction of responsibilities between the CHMP and the PRAC is needed with regard to benefit-risk assessment and risk management. The Commission representatives reiterated the importance of providing clear explanations in the case of divergent opinions, as this will also facilitate the task of the Commission in the decision-making phase. The PRAC is an independent committee and, moreover, considering that the rapporteurships in the initial evaluation stage are not evenly spread out among the Member States, the Commission took the view that the PRAC rapporteur should be from a different Member State than the rapporteur in the pre-authorisation phase.

The participants stressed that the pharmacovigilance system should be supported by fees, which are foreseen in the legislation but will not come into force until after a few years. Rapporteurship arrangements could be reviewed after that time.

# Session 3:
# Adaptive licensing: a useful approach for drug licensing in the EU?

In this session, the Board reflected on the concept of 'staggered' approval (also known as adaptive or progressive licensing). The concept is being debated among regulators worldwide, and is referred to in the Agency's strategy document on the subject, which states that a key issue for regulators will be whether a more staggered approval concept should be envisaged for situations not covered by conditional marketing authorisations. The Agency wishes to launch a debate with all stakeholders on the appropriateness of introducing such a concept in the European Union (EU), including a consideration of appropriate incentives to support the development of new medicines.

Adaptive licensing can be defined as a prospectively planned, adaptive approach to regulation of drugs through iterative phases of evidence-gathering, followed by regulatory evaluation and license adaptation. Adaptive licensing seeks to maximise the positive impact of new drugs on public health by balancing timely access for patients with the need to provide adequate evolving information on benefits and harms.

The Board welcomed the presentation by Hans-Georg Eichler, the Agency's Senior Medical Officer, and provided supportive feedback about the concept and issues raised. The meeting discussed that the concept as such is not completely new in the regulatory world. There are a number of precursors to adaptive licensing – such as conditional marketing authorisation, new pharmacovigilance legislation, risk-management plans, periodic safety update reports, etc.

However, members also saw challenges that need to be overcome for this marketing-authorisation route to succeed. These include, among others, the possible difficulty of enrolling patients for placebo-controlled clinical trials after the product has been authorised, assuring the support of payers who decide on reimbursement for such products, and addressing concerns of the industry. Regarding the collection and use of evidence, participants were of the opinion that the use of data from electronic

registries would become easier in future, which would significantly facilitate the application of the concept.

The meeting concluded that this debate needs to continue and pilots should proceed as planned for in the 2012 work programme. A broader constellation of stakeholders has to participate, including the clinical community, healthcare providers, patients, payers and industry. This would allow the alignment of interests and would pave the way for applying this concept in future regulatory decisions.

# Thursday meeting, held on 22 March 2012

This was the last meeting for those civil-society representatives who attended as observers today. The Board thanked them for their active involvement and valuable contributions in numerous capacities — as members, topic coordinators and as a vice-chair — to the successful work of the Board. The Board also extended its invitation to the observers from civil society to participate at the next meeting, in June, if the nomination process for new representatives is not completed in time for the meeting.

# 1. Draft agenda for 22 March 2012 meeting

[EMA/MB/47692/2012] The agenda was adopted.

# 2. Declaration of conflicts of interests related to current agenda

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 74th meeting, held on 15 December 2011

[EMA/MB/33634/2012] The Management Board noted the final minutes, adopted by written procedure on 9 February 2012. The document had been redacted and published on the Agency's website.

# 4. Organisation of Management Board meetings

[EMA/MB/131620/2012] The Board discussed whether the current practice of holding one-day meetings is the most efficient arrangement. Due to travel arrangements, some members are obliged to leave before the meeting finishes. This may pose difficulties, as situations may occur when the Board is not in a position to take decisions at the end of the meeting, due to it not having a quorum. Identifying different arrangements that would address this concern and that would also enable the Board to discuss documents, amend them and resubmit them for adoption at the same meeting would add to the effective conduct of business.

A number of alternative meeting formats are possible, including holding meetings over two half-days (where more complex items could be discussed on the first day, allowing for any follow-up on the

second), starting meetings earlier, arranging meeting agendas differently (to ensure the quorum for items requiring adoption), using teleconferencing, or a combination of these measures.

A group has been set up to propose alternatives at the June meeting. The members of the group are: Marcus Müllner, Luca Pani, Kristin Raudsepp, Andrzej Rys, Gro Wesenberg and Kent Woods.

# 5. Highlights from the Executive Director

**New appointments**

The Board was informed that Luc Verhelst took office as the Head of the Agency's Information and Communications Technology Unit.

**Visit of Commissioner John Dalli**

John Dalli, Commissioner for Health, visited the Agency on 6 February 2012. Ways to ensure efficient and timely communication between the Agency and the European Commission, and the need for adequate financing of legislative initiatives, were among the topics discussed during the visit. The Commissioner addressed the staff of the Agency and responded to questions.

**Bilateral with the FDA**

The annual bilateral between the European Commission/the Agency and the US Food and Drug Administration (FDA) took place from 5 to 7 March. The EU team met with a high-level team from the FDA's leadership, and discussed, among other topics: the FDA's pathway to global product safety and quality; regulatory science; biosimilars; a global approach to clinical studies; and inspection-related matters.

**Cooperation with the Mexican authorities**

COFEPRIS[1] Mexico plans to recognise unilaterally EU centralised authorisations. A delegation from the authority will visit the Agency to compare regulatory requirements in June.

**Cooperation with EFSA**

The Agency and a delegation from the European Food Safety Authority (EFSA) met on 27 January to exchange views on areas of common interest in both scientific and governance fields. The agencies then signed a memorandum of understanding setting out their commitment to fostering cooperation.

**Discharge for the budget 2010**

The European Parliament rapporteur for the discharge of EU agencies visited the Agency on 10 February. The rapporteur questioned the Agency's management team on a number of issues, including procurement and contract management, procedures for managing conflicts of interests, assessment procedures, and review of the system of payments to Member States.

The rapporteur was of the opinion that the Agency has to do more in the area of conflicts of interests. The Board was informed that, to date, the Agency has introduced a revised policy on managing conflicts of interests of experts, adopted rules on managing conflicts of interests of staff, discussed the Management Board policy and presented it for adoption at this meeting, drafted the breach of trust procedure, is introducing ex post controls, has published risk ratings for committee members, and has

[1] The Federal Commission for the Protection against Sanitary Risk

published professional profiles of the Agency's managers, committee members and Management Board members.

During the visit, the rapporteur informed the Agency that the draft discharge report had already been finalised and any comments made by the Agency during the meeting could not be reflected in the report. This raised concern about the possible outcome of the discharge procedure even though considerable improvements had been made. The rapporteur did not indicate whether or not she would recommend granting the discharge for the Agency.

The meeting was informed that the Agency had received a European Court of Auditors draft audit report on conflicts of interests conducted in 2011. The draft report highlights a number of issues which the Agency believes are addressed through the developments mentioned earlier. Replies to the Court are being prepared.

**Evaluation of the Agency**

The Management Board was informed of the ongoing evaluation of the European Medicines Agency and the European Aviation Safety Agency (EASA). The evaluation was requested by the European Parliament, and focuses on the impact on the EU and national budgets of a transfer of responsibilities form the national to the European level following the creation of EU agencies. A number of national competent authorities will be visited as part of the study.

**European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)**

The Executive Director stressed the Agency's commitment to contributing to combating antimicrobial resistance. As part of that work, the Agency had launched the ESVAC project in September 2009. The pilot project was begun as the result of a request from the European Commission to develop a harmonised approach for the collection and reporting of data from the Member States on the use of antimicrobial agents in animals. The Agency's financing of the pilot phase will amount to over EUR 350,000 in 2012.

**Organisational changes**

The Agency is stepping up its communications activities. To achieve its strategic objectives in this area, the Agency established the Communications Sector, which will aim to further strengthen consistency and coordination of communication activities, in cooperation with the medicines regulatory network and the EU institutions.

In addition, a new sector for international and European cooperation has been established, to respond to the growing levels of interaction and activities in this area. As part of the strategy to ensure effective liaison with the national competent authorities, and following discussions with the Heads of Medicines Agencies, the Agency has also appointed an HMA liaison officer.

# 6. Annual report 2011

[EMA/MB/977044/2011] The Management Board adopted the Agency's annual report 2011. The report reveals that, despite a challenging environment, the Agency was able to deliver a growing volume of core business in 2011. There was a 10% increase in the number of applications for initial-marketing authorisation for medicines for human use, with 100 applications received in 2011. This included 62 applications for new medicines, an increase of 35% as compared to 2010.

There was also a strong increase (over 20%) in post-authorisation activities, and a major rise in the number of referral procedures (77 compared to 55 in 2010). The number of applications received for initial-marketing authorisation for veterinary medicines declined slightly. However, the rise seen in the number of requests for veterinary scientific advice shows that interest remains high in bringing innovative veterinary medicines to the market through the centralised procedure. Significant progress was made in other areas, including the launch of the EU clinical-trials register and the new online database of European experts.

Members reiterated their concern at the consistently low number of entries to the list of herbal substances, due to the unavailability of genotoxicity data. The Board will meet the Chair of the Committee on Herbal Medicinal Products (HMPC) in June to discuss topics relating to herbal medicines.

The Board also noted the steep increase in the number of pages released under the access-to-documents legislation: from 8,000 in 2010 to over a million in 2011.

# 7. Work programme and preliminary draft budget 2013

### a.) Preliminary draft work programme 2013

[EMA/MB/945561/2011] The Management Board adopted the Agency's preliminary draft work programme 2013. The work programme sets the following priorities for 2013: continued implementation of the legislation on pharmacovigilance and on falsified medicines; further development of the communication activities, with increased transparency and better explanation of how the Agency arrives at decisions; ensuring efficient interactions between the scientific committees; and increasing the efficiency of the Agency's operations. Initiatives to set up the system for the review of raw clinical-trial data will be undertaken. It is also planned to set up a team of scientific writers to deliver high-quality scientific articles for publication in scientific journals.

With regard to assessment activities, the Agency is largely at cruising speed. Overall, the number of applications is stable, with 112 applications for marketing authorisations for medicines for human use and 13 for veterinary use forecast. The Board noted the budgetary uncertainties and their impact on the work programme, as described below.

The Board also noted the changed structure of the work programme, which now follows the three strategic areas of the Agency's five-year strategy document.

### b.) Preliminary draft budget and establishment plan 2013

[EMA/MB/121516/2012] The Board adopted the Agency's preliminary draft budget and the draft establishment plan for 2013. The budget for 2013 is €239.1 million (2012: € 222.5 million), of which the forecast fee revenue is €181.9 million. The EU contribution remains at the 2012 level of €38.8 million. The Agency also requested 21 additional posts, which will be financed from the fee revenue, and plans to reduce the number of contract agents by 7 full-time equivalents (FTEs). This would increase the overall headcount by 14 FTEs. The number of national experts would remain unchanged, with 15 FTEs expected. The additional posts reflect the increase in workload in the period 2010 to 2012. The final budget will be adopted once the level of the EU contribution has been decided by the European Parliament and the Council.

The Board discussed significant constraints affecting the 2013 budget. These include: implementation of the pharmacovigilance legislation without the bridging budget or pharmacovigilance fees, and without the possibility of remunerating national competent authorities; no additional financial

resources for the implementation of the falsified medicines legislation; the need to finance the move to new premises; and a likely requirement to finance the employer's part of the pension contribution.

Due to the number of budgetary uncertainties for 2013, the decision about which information and communications technology (ICT) projects will be planned for development in 2013 is pending, and the implementation activities for the pharmacovigilance legislation are subject to change. The Management Board requested details of which ICT projects will be taken forward in 2013 to be provided for the next meeting.

With regard to the lack of budget to fully implement the pharmacovigilance legislation, the Board stressed the importance of managing expectations of stakeholders as to what can and cannot be achieved. The Board also expressed continuing concern that the EU legislation was adopted without adequate consideration being given to the costs required to implement the legislation. This puts significant strain on the Agency and the national competent authorities. The Dutch member asked the European Commission and the Parliament representatives to bring these concerns to the attention of the EU Parliament, and to make the Parliament aware that full implementation of the pharmacovigilance legislation in July will not be possible.

The Commission representative stressed the importance of the Agency concentrating on its core tasks, especially because 2013 will be financially a critical year, and discussions are still ongoing in the Commission concerning the EU contribution.

**Language regime of the Management Board meetings**

The Board adopted the decision to hold its meetings in English only. Interpretation will be discontinued, starting from the June 2012 meeting, resulting in savings of around EUR 25,000 per year.

**Topic coordinators**

The Board set up a new group of topic coordinators with responsibility for the Agency's work programme and budget. Its members are Klaus Cichutek, Kristin Raudsepp and Grzegorz Cessak.

The Board also set up a group for the analysis and assessment of the Executive Director's annual activity report 2011, with the following members: Xavier De Cuyper, Martina Cvelbar and Gro Wesenberg.

Other members and alternates wishing to participate in these groups were invited to do so.

**c.) Information and communications technology**

[EMA/MB/82882/2012] The Management Board noted the document outlining the preliminary budget for ICT project development and systems maintenance in 2013. A further discussion on ICT projects is planned for the June meeting.

**d.) Project 2014**

[EMA/MB/955795/2012] The Management Board noted the document outlining the high-level budgetary requirements for 'Project 2014' (the move of the Agency to its new premises).

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

[EMA/MB/13210/2012] The Management Board adopted the amended rules, adjusting the fees payable to the Agency by 3.1%, for inflation. The revised rules will enter into force on 1 April 2012, pending the publication of the Commission Regulation adjusting the aforementioned fees. The document will be published on the Agency's website.

# 9. Amending budget 01-2012 for changes to entry grade for a post

[MB/EMA/155755/2012] The Management Board adopted the change to the entry grade from AST 3 to AD 6 for the post of Section Head for Financial Support services. The change reflects the increased responsibilities – staff management, authorising and reporting officers – attached to the post. The decision takes affect on 22 March 2012.

# 10. Policies on conflicts of interests

### a.) Second update on implementation

[EMA/154547/2012] The Board noted the analysis on the implementation of the revised conflicts of interests policy for Committee members and experts. The analysis concluded that further amendments to the policy are warranted (as described in the next section). The analysis also proposed the establishment of a breach of trust procedure and a system of *ex-post* checks of information provided in declarations of interests (DoIs). The Agency will also publish CVs of all experts in the European experts database, and a project to enable the receipt of electronic CVs and their automated publication was agreed.

The Agency also plans to carry out *ex-post* checks on risk-mitigating actions and *ex-ante* controls to ensure that interests are included in correct parts of DoI forms. This is important to ensure that correct risk levels are generated by the system.

### b.) Revised conflicts of interests policy for experts

[EMA/513078/2010] The Management Board endorsed the amendments to the revised conflicts of interests policy for Committee members and experts. The amendments concern:

- the definitions of ownership of a patent and (principal) investigator;
- introduction of restrictions in case of a pharmaceutical company giving a grant or other funding;
- the definition of an institution in the context of receiving grants or other funding;
- introduction of restrictions in case current direct interests of one or more household members have been declared;
- clarification on the involvement in academic trials and in publicly funded research/development initiatives;
- clarification on the membership of an ethics committee;
- clarification on the follow-up to be taken in case a member intends to be engaged in occupational activities with a pharmaceutical company;

- inclusion of a reference to a system of *ex-post* checks, as well as the development of a breach of trust procedure.

When adopting these changes, members voiced their concern that increased tightening of conflicts of interests policies threatens to deny the Agency access to the full range of scientific expertise that is necessary for the highest-quality assessment of medicines. A specific comment was made by the Netherlands' representative in relation to the restrictions that will apply in situations where the member's/ expert's institution receives a grant or other funding from a pharmaceutical company for research work and the individual receives no personal gain. The representative, supported by other Board members, expressed concerns about the impact of such restrictions on the availability of members/experts from academia. It was proposed to limit this impact by introducing the notion of 'department of an academic institution'. This was agreed upon by the Board. [Post-meeting note: the Agency secretariat, when further reflecting on the amendment made, and taking into account additional feedback from CHMP members, will specify in a Q&A document (which will be published on the Agency's website, as well as being provided to all members/experts when completing their DoI) that a 'department' needs to be understood as 'the immediate organisational entity in which the member/expert operates'.] On a general note, the Agency agreed to continuously monitor whether the amended rules restrict access to the necessary expertise.

Members also recalled a discussion at the HMA meeting, where the HMA felt that a harmonised system to manage conflicts of interests throughout the network cannot be enforced. Instead, policies adopted by the Agency should be used as a reference when developing national policies in this domain.

**c.) Breach of trust policy**

[EMA/154320/2012] The Management Board endorsed the breach of trust procedure on conflicts of interests for scientific-committee members and experts. The procedure concerns any incomplete and/or incorrect declarations of interests. In this context, the Board discussed in more detail the conditions for the suspension of an expert from his or her activities pending the outcome of the review. The final wording will be verified with the Legal Service of the Agency. The adopted procedure also puts in place a framework for checking the integrity of the scientific review.

The Management Board will develop a similar procedure applicable to its members.

**d.) Revised Management Board conflicts of interests policy**

[EMA/MB/64234/2012] The Management Board adopted the revised policy on managing conflicts of interests of its members. The policy takes into account comments made at the previous meeting and those received by correspondence. Before publishing it, the amendments clarifying the receipt of grants by an institution and membership in ethics committees will be introduced. The final policy will be sent to the Board, together with a request for its members to complete a new declaration of interests.

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

The Board was informed that, following the receipt of the Commission Decision of 23 January 2012 confirming agreement on the Agency's rules under Article 110 of the Staff Regulations, the Chair signed the 'Decision on rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency', on 1 February 2012. These rules are applicable to temporary agents and contract agents, and are fully in place. The implementation plan has been completed, including the assignment of risk levels, the implementation of mitigation procedures and the provision of training. Some outstanding work will be finalised by mid

May 2012. The Board also noted that declarations of interests and professional profiles of all managers have been published on the external website.

# 11. Pharmacovigilance Risk Assessment Committee

**a.) Consultation procedure on final composition**

[EMA/MB/139702/2012] The Management Board adopted the procedure for consultation on final composition of the Pharmacovigilance Risk Assessment Committee (PRAC). According to the procedure, the Board will issue its recommendations on whether any of the areas of PRAC expertise need strengthening. This step will be completed at the June Management Board meeting, once nominations from all Member States and the European Commission have been received.

**b.) Overview of nominations received**

[EMA/MB/146762/2012] The Management Board noted the nominations to the PRAC provided by Member States to date. The formal process of reviewing nominations and identifying areas requiring reinforcement will take place at the June meeting.

During this interim discussion, members noted that more expertise may be needed in the areas of pregnancy and lactation. Although recognising that it is not possible to cover all clinical areas within the committee, members considered that more clinical experts would be welcome, to ensure that PRAC recommendations take due account of the benefits of medicinal products.

Patient representatives expressed concern that the legislation provides that only one member (and an alternate) representing patients shall be nominated to the PRAC, while for other committees there are two or more members. Patient representatives requested a possibility for both a member and an alternate to attend all PRAC meetings. The Agency will consider the request and will respond to the proposal. At the same time, the Agency will nominate a contact who will provide permanent support to patient representatives, to facilitate their participation in the work of the Committee.

The European Commission representative made the remark that the Commission does not generally receive many applications for such posts from European organisations representing patients and healthcare professionals.

The Board also discussed that, when re-nominating members after the expiry of the three-year mandate, Member States may wish to reflect whether to limit the number of continuous terms to ensure the turnover of experts.

# 12. Appointment of Michael Lenihan as the Agency's accounting officer

[EMA/MB/124276/2012] The Management Board appointed Michael Lenihan, Head of the Finance and Budget Sector, as the Agency's accounting officer, replacing Gerard O'Malley. The decision comes into effect on 1 April 2012.

# 13. Report from the European Commission

The European Commission provided an update on legislative and policy developments, including the following:

- The implementing measures of the pharmacovigilance legislation (planned adoption in Q2 2012).

- The appointment by the Commission of six experts and patients' and healthcare professionals' representatives for the Pharmacovigilance Risk Assessment Committee (to be finalised in Q2 2012).
- The implementing measures for the falsified medicines legislation (public consultations on unique identifier finishes 27 April 2012, on GMP for active substances from non-EU countries finishes 23 March 2012, on principles and guidelines of GMP for active substances finished 20 April 2012).
- The split of the amended proposal into two proposals: 'information to patients' and 'pharmacovigilance'. The adoption of the pharmacovigilance proposal is expected soon.
- The legislative proposals for clinical trials and medical devices planned for 2012.
- The proposal on the revision of the veterinary medicines legislation planned for 2013.
- The action plan and road map to tackle antimicrobial resistance.
- The EU proposal to reform ICH as regards its governance, global outreach and greater transparency.
- The international initiative on generics (the debate about whether to make this a standalone initiative or to include it within the ICH).
- The finalisation of the eHealth Network with good representation from national authorities. The first meeting of the network is planned for May 2012.
- The proposal for the transparency directive, which, among many measures, clarifies the scope, reduces the time limits for pricing and reimbursement decisions, and addresses the grouping of medicines for reimbursement purposes.
- The renewed EU strategy 2011-14 for social corporate responsibility.

In the context of the social corporate responsibility, the meeting considered it appropriate that the pharmaceutical industry should be asked to publish names of experts with whom it cooperates. This information would be important for regulators and for society at large in further ensuring that interests of experts contributing to the regulatory assessment of medicines are known. This action would strengthen the credibility of the system, would facilitate the work of regulators and increase the transparency of the pharmaceutical industry.

# 14. Report from the Heads of Medicines Agencies

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

- The endorsement of the reflection paper on ethical and GCP aspects of clinical trials in third countries.
- The HMA's agreement to publish information on the authorisation of clinical trials in the EU as part of the impact assessment of the revision of the Clinical Trials directive.
- The CMD(v)'s work to prioritise the veterinary medicinal products for which summaries of product characteristics (SmPCs) should be harmonised and to propose an approach to SmPC harmonisation.
- The DIA EuroMeeting, where two sessions will be dedicated to the European medicines regulatory network.

## 15. Report on performance of national competent authorities against newly established key performance indicators (KPIs)

[EMA/112052/2012] The Management Board noted the report on a sample of key performance indicators included in contractual arrangements with national competent authorities. The report concluded that, in general, performance was stable over the last two years. The report does not aim to provide the reasons for delays in submitting assessment reports by rapporteurs and co-rapporteurs. This should be analysed separately. The meeting also discussed that indicators measuring the quality of reports have to be developed over time, while recognising the difficulty in establishing and monitoring such indicators.

The Management Board decided to extend the pilot phase for one further year.

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

- Consultation no. 13/2011 on the appointment of Merete Blixenkrone-Moller as CVMP alternate, proposed by Denmark, ended on 8 December 2011. The mandate of the nominee commenced on 9 December 2011.
- Consultation no. 14/2011 on the appointment of Ugne Zymantaite as CVMP alternate, proposed by Lithuania, ended on 19 December 2011. The mandate of the nominee commenced on 20 December 2011.
- Consultation no. 15/2011 on the appointment of Esther Werner as CVMP alternate, proposed by Germany, ended, with observations from Members raised in respect of the candidate's expertise, on 3 January 2012. The mandate of the nominee commenced on 4 January 2012.
- Consultation no. 01/2012 on the appointment of Ingunn Hagen Westgaard as CHMP alternate, proposed by Norway, ended on 26 January 2012. The mandate of the nominee commenced on 27 January 2012.
- Consultation no. 02/2012 on the appointment of Outi Maki-Ikola as CHMP member, proposed by Finland, ended on 26 January 2012. The mandate of the nominee commenced on 27 January 2012.
- Consultation no. 03/2012 on the appointment of Martti Nevalainen as CVMP member, proposed by Finland ended on 2 February 2012 with Members' observations, raised in respect of the candidate's level of conflict of interests and supported by the CVMP Chair, sent to the nominating authority on 13 February 2012. The nominating authority confirmed the withdrawal of the nomination in a letter addressed to the MB Chair, received on 24 February 2012.
- Written procedure for adoption of non-automatic carry-over of appropriations from 2011-2012 closed on 30 January 2012. The document was adopted.
- Written procedure for adoption of the 74th Management Board meeting minutes closed on 9 February 2011. The minutes were adopted.

## Documents for information

- EMA/135591/2012 Annual report 2011 of the Agency's Audit Advisory Committee.
- EMA/135587/2012 Annual report 2011 of the Agency's Internal Audit.

- EMA/MB/157253/2012 Performance of the Agency's scientific procedures: Survey 2011 for medicinal products for human use.
- [EMA/185199/2012] EU telematics projects report; [EMA/189200/2012] EU telematics operations report; [EMA/177625/2012] Minutes from the Management Board Telematics Committee meeting held on 14 February 2012.
- [EMA/MB/2671/2012] Outcome of written procedures during the period 25 November 2010 to 29 February 2012.
- [EMA/MB/115063/2012] Summary of transfers of appropriations in the budget 2012.
- [EMA/MB/137391/2012] Overview of implementing rules to Staff Regulations signed by the MB Chair during the period from 7 October 2011 to 29 February 2012.

# Tabled documents

- Revised draft agenda version 4.0.
- Presentation on public hearings.
- Presentation on public hearings in Europe.
- Presentation on implementation of the pharmacovigilance legislation.
- Presentation on PRAC rapporteurs: Proposed principles for appointment and roles/responsibilities of PRAC rappoerteurs.
- Presentation on overview of PRAC expertise so far.
- Presentation on conflicts of interests policy for scientific-committee members and experts.
- Presentation on EU legislative and policy developments in the public-health area.
- Presentation on proposal for a directive of the European Parliament and the Council relating to the transparency measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.
- Presentation on annual report 2011.
- Report of performance with respect to a limited subset of quantitative KPIs 2011.
- [EMA/177625/2012 Rev.1] Minutes from the Management Board Telematics Committee meeting held on 14 February 2012.
- [EMA/888135/2011] MBTC-2012-02-002 Management Board Telematics Committee meeting held on 9 November 2011[2].

[2] Circulated to the Board by e-mail on 17 January 2012; recorded in the minutes of the next meeting, as relevant.

# List of participants at the 75th meeting of the Management Board, held in London, 21-22 March 2012

**Chair: Sir Kent Woods**

| | **Members** | **Alternates (and other participants)** |
|---|---|---|
| **Belgium** | Xavier De Cuyper | |
| **Bulgaria** | | Meri Peycheva |
| **Czech Republic** | Jiří Deml | |
| **Denmark** | Jytte Lyngvig | |
| **Germany** | | Klaus Cichutek |
| **Estonia** | Kristin Raudsepp | |
| **Ireland** | Pat O'Mahony[3] | |
| **Greece** | | Katerina Moraiti |
| **Spain** | Belén Crespo Sánchez-Eznarriaga | |
| **France** | Dominique Maraninchi | Jean-Pierre Orand<br>Miguel Bley<br>Jean Baptiste Brunet |
| **Italy** | Luca Pani | Daniela Salvia |
| **Cyprus** | Arthur Isseyegh | |
| **Latvia** | Inguna Adoviča | |
| **Lithuania** | Gintautas Barcys | |
| **Luxembourg** | Claude A Hemmer | |
| **Hungary** | Tamás L Paál | |
| **Malta** | Patricia Vella Bonanno | |
| **The Netherlands** | Aginus Kalis | Birte Van Elk |
| **Austria** | Marcus Müllner | |
| **Poland** | Grzegorz Cessak | |
| **Portugal** | | Nuno Simoes |
| **Romania** | Petru Domocos | |
| **Slovakia** | Jan Mazág | |
| **Slovenia** | Martina Cvelbar | |
| **Finland** | | Pekka Kurki |
| **Sweden** | Christina Åkerman | Bengt Wittgren |
| **United Kingdom** | Kent Woods | Jonathan Mogford<br>Sandor Beukers |
| **European Parliament** | Giuseppe Nisticó<br>Björn Lemmer | |
| **European Commission** | Andrzej Rys<br>Pedro Ortum Silvan | Lenita Lindström<br>Salvatore D'acunto[4] |
| **Representatives of patients' organisations** | | Mary Baker[5]<br>Mike O'Donovan |

[3] Pat O'Mahony participated on Thursday, 22 March 2012
[4] Salvatore D'acunto participated on Thursday, 22 March 2012
[5] Mary Geraldine Baker participated as an observer on Wednesday, 21 March 2012

| | Members | Alternates (and other participants) |
|---|---|---|
| **Representative of doctors' organisations** | | Lisette Tiddens-Engwirda |
| **Representative of veterinarians' organisations** | | |
| **Observers** | Rannveig Gunnarsdóttir (Iceland)<br>Brigitte Batliner (Liechtenstein)<br>Gro Wesenberg (Norway) | Viola Macolić Šarinić (Croatia) |

| | | |
|---|---|---|
| **European Medicines Agency** | Guido Rasi<br>Andreas Pott<br>Patrick Le Courtois<br>David Mackay<br>Luc Verhelst<br>Noël Wathion<br>Martin Harvey Allchurch<br>Emer Cooke<br>Tomasz Jablonski<br>Michael Lenihan<br>Isabelle Moulon<br>Frances Nuttall<br>Zuzana O'Callaghan<br>Nerimantas Steikūnas | |