8 November 2013
EMA/MB/584118/2013 Adopted
Management Board

Minutes of the 81st meeting of the Management Board

Held in London on 3 October 2013

Sir Kent Woods, chair of the Management Board of the European Medicines Agency (EMA), opened the meeting by welcoming new members Audun Hågå, representing Norway, and Ian Hudson, the new alternate member for the United Kingdom.

1. Draft agenda for 3 October 2013 meeting

[EMA/MB/197800/2013] The agenda was adopted with the addition of point B.10. 'Role of the Management Board in the discussion on the introduction of pharmacovigilance fees', requested by some members in view of developments in the discussion of the Working Party on Pharmaceuticals and Medical Devices at the Council of the European Union on the proposal for a regulation on the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.

2. Declaration of conflicts of interests

The chair informed members of the Management Board that he had reviewed members' declared interests, together with the secretariat, in accordance with the Board's policy on conflicts of interests. No conflicts relating to today's agenda were identified.

The chair invited members to further declare any specific interests that could not be drawn from their declarations of interests that could be considered prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

3. Minutes from the 80th meeting, held 13 June 2013

[EMA/MB/367978/2013] The Management Board noted the final minutes, adopted by written procedure on 1 August 2013.

A. Points for automatic adoption / endorsement

None.

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B. Points for discussion

B.1 Highlights from the Executive Director

Achieving savings

The reorganisation process 'Review and Reconnect' is proceeding well and it can be expected to start rendering benefits for the Agency soon. In the next few months, the Agency will put together a set of initiatives for the benefit of the whole network, and will submit them to the Board for discussion. They are very likely to concern:

- Additional funding for training. This might take the form of training directly supplied by the EMA, but also of support provided to training initiatives within the network. Currently provided training will be reviewed, along with the progress of the Heads of Medicines Agencies (HMA)/EMA training office. More details on the full programme will be available in December.
- The national experts programme should be expanded, as suggested by the topic coordinators during discussion of previous budgets.
- Support to committee members attending meetings at the Agency should be enhanced, to respond to requests and suggestions collected from one of the regularly conducted surveys on the satisfaction of delegates. Most comments will be taken into account in the planning of the new building the Agency will move into in 2014. Easier access to logistical information relating to meetings, to the documents provided and to databases will be achieved through restructuring of the IT architecture and via the extranet. Small but not unimportant needs, such as free Wi-Fi in hotels, will be satisfied.

Scientific Coordination Board

The Scientific Coordination Board (SciCoBo) met before summer. A pilot on rationalising the use of scientific resources by setting up a single Oncology SAG to support all seven committees was agreed.

Multinational teams

Support for administrative aspects relating to the creation of multinational teams is being tested within existing rules. The initial, limited scope of the trial spans co-rapporteurships for first evaluation.

Publication of clinical-trial data

The consultation on the draft policy was concluded on 30 September. Many comments were received and will now be analysed. A revised policy will be discussed at the December meeting of the Board.

Court cases

The cases concerning access to documents held by the Agency are ongoing. The Agency has been supported by many organisations and Member States, and would like to particularly thank Denmark, Finland, France, Portugal and Slovenia, who have taken an active role in the proceedings.

Workshop on conflicts of interests

A report has been published on the workshop held on 6 September, and a revised policy will be discussed at the December meeting of the Management Board. The workshop focused on the question of how to ensure the impartiality and independence of experts involved in the Agency's work, versus

the need to continually deliver high-quality scientific assessments. Three key elements emerged from the feedback provided by participants:

- The Agency should look at ways to make participation in its work more attractive for experts.
- There is a need for a methodology to identify the best expertise within the European Union.
- When determining a conflict of interests, it is necessary to move away from blanket timeframes, e.g. specific number of years, towards an approach that looks at the nature of the interest.

New Head of Legal Department

The Executive Director introduced the new Head of the Legal Department, Stefano Marino, who started work with the Agency on 16 June 2013.

B.2 Internal reorganisation of the Agency

The Executive Director updated the Board on progress with the internal exercise 'Review and Reconnect', which designed the Agency's new organisational structure, the main components of which were implemented on 16 September 2013. On that occasion, nine new heads of department were appointed. Further transition to the new structure will take place over the coming months, to ensure continuity of service and support to the scientific committees, with a view to complete implementation by July 2014, when the Agency moves to its new premises.

The exercise now moves into a new phase, in which roughly 60 of the Agency's processes will be reviewed and redesigned. Consultation with national competent authorities (NCAs) is crucial in this phase, to ensure the new processes meet all partners' needs. Project teams will identify, for each process, possible interfaces with the NCAs and the people who can provide input into the 'to-be' processes. Heads of NCAs will be consulted and will be provided with clear information on type of input and time requested from their staff. Type-IB and type-II procedures have been chosen as the first pilot processes, and will start in October. Involvement of the scientific committees might be achieved through different processes, such as through the reorganisation of the secretariats. The SciCoBo will assure permanent coordination, and the experts from the NCAs who will be consulted are likely in many cases to be delegates.

B.3 Report from the European Commission

The European Commission reported on EU legislative and policy developments in the public-health area:

- The implementation of the pharmacovigilance legislation is being further completed with the entry into force of the 'Pharmacovigilance II' amendments. The Commission is working on the delegated act on post-authorisation efficacy studies, and has completed the evaluation of projects for the joint action on pharmacovigilance systems.
- The report on experience with the Paediatric Regulation was published, and a full evaluation of the economic and public-health impact is planned for 2017. The report on the functioning of the Advanced Therapies Regulation is planned for the end of 2013.
- A number of implementing measures concerning the Falsified Medicines Directive have been published or are in the consultation phase. Adoption of the delegated acts on the unique identifier and for the establishment of a common EU logo is expected in 2014. No major problems occurred at the start (in July) of application of provisions concerning the import of active pharmaceutical

APIs. Regulators in third countries continue to build up their agencies to sustain written confirmations.

- After the 29 May vote on the Clinical Trials Regulation by the Environment, Public Health and Food Safety Committee (ENVI — the lead committee in the European Parliament), the Presidency is working towards agreeing a common text and starting negotiations with the European Parliament.
- The legislative proposal for the revision of the veterinary medicines legislation is expected to be adopted by the end of 2013, together with the proposal on medicated feed. Policy objectives are: enhancing the level of protection for humans, animals and the environment, and improving access to veterinary medicines by reducing administrative burdens and reducing barriers to free movements of goods.
- Several initiatives are planned on the topic of antimicrobial resistance, in November and December, including the release of results of the Eurobarometer on antibiotic use during the European Antibiotic Awareness day on 15 November.
- Work on the medical devices legislation is progressing at the Council, while the European Parliament will vote in a plenary on 22 October. Trialogues are expected to start in early 2014.
- Preparatory work for the implementation of Directive 2011/24/EU on patients' rights in cross-border healthcare is ongoing. The HTA[1] network will have its kick-off meeting on 16 October, and will be attended by the EMA; a guideline on minimum data sets for the eHealth network is expected to be adopted in November.
- Discussions at the Council on the legislative proposal on fees for pharmacovigilance are ongoing, with difficulties in relation to the annual flat fee, cost estimates for NCAs and reluctance concerning delegated acts.
- The proposal on the transparency directive is under discussion at the Council after having received a positive opinion by the European Parliament.
- The process on corporate responsibility in the field of pharmaceuticals is about to be finalised, at a meeting in Lithuania on 16 October 2013. Further discussion is foreseen as follow-up of progress achieved in each area of the three pillars of the process and how to foster industrial competitiveness in the pharmaceutical sector.

B.4 Mid-year report 2013 from the Executive Director (January–June 2013)

[EMA/MB/503866/2013] The Management Board noted the Agency's mid-year report for 2013. The report provides an overview of the progress on implementation of the work programme through objectives and performance targets. Overall, activities at the Agency are on track and the budgetary situation is stable.

Pre-authorisation procedures are in line with 2012 figures and the 2013 forecast for orphan-designation applications and protocol assistance. Scientific advice is below Q2 2012, but should reach above 2012 volume by the end of the year, while paediatric applications (paediatric investigation plans and waivers) have increased by 16%. Volumes of assessment procedures are stable, with a decrease in generic and biosimilar applications, a reduction in orphan-medicine applications and a decrease by 21% in type-II applications. The main performance indicators have improved from 91% in 2012 to 98% in 2013, with a target of reaching 100%. Production of certificates has increased by 7% over 2012. The increase in number of GMP and GCP inspections is unlikely to continue.

[1] Health-technology assessment.

With regard to advanced-therapy medicinal products, by Q2 one certification and one marketing-authorisation application were received, while scientific-recommendation requests remained at the same level. For herbal medicinal products, activities remained stable overall, with final Community monographs falling from 9 to 4 and monographs released for public consultation increasing to 9 from 6. There were, however, no Community list entries, due to unavailability of genotoxicity data. Referral procedures increased slightly over the Q2 2012 figure (24 over 22) but were fewer than initially estimated (55 for the whole of 2013).

Veterinary applications experienced a rising trend, with an increase in scientific advice, initial applications (11 compared to 3 in Q2 2012) and referrals, with a decrease in type-II applications and a stable number of requests for minor use/minor species (MUMS) classification.

The implementation of the new pharmacovigilance legislation progressed well, with the launch of new business processes, such as post-authorisation safety studies (PASSs), handling of periodic safety-update reports (PSURs) involving both centrally and nationally authorised products, and the creation of a list of products subject to additional monitoring. The activity on data-quality management for EudraVigilance continues.

Transparency and communication are high on the Agency's list of priorities, with work on track towards publication of agendas and minutes of all committees by 2013, a policy on proactive publication of clinical trials in its final drafting stage, and a comprehensive online project looking at internal and external websites and the EU medicines portal. Access-to-document requests increased substantially (242 compared to 109 in Q2 2012), while the number of pages released decreased by 36%. The European Parliament recognised achieved improvements by granting the discharge for the 2011 budget.

The first operational improvement from the Review & Reconnect exercise was achieved with the new organisational structure and the proposals for implementation. A road map for the new architecture of master data has been agreed and work on implementation has begun. Further highlights of the Agency's activities are the reflection on adaptive licensing (now awaiting European Commission review and concrete submissions), the preparation of a dry-run to verify the technical capacity for analysis and improvement of quality data submitted in applications, and a reflection on public hearings.

Satisfaction with the stable financial situation of the Agency in difficult economic times was expressed. The issue of why requests for access to documents are increasing was raised. The Agency is taking concrete action on transparency, but there is a time lag between policies and their implementation. The EMA has acted by creating a centralised task force, which will combine legal and scientific competence. The low uptake of the advanced-therapy legislation continued to cause concerns to some Board members, who wondered about possible measures to improve access to advanced therapies for patients. The increasing number of good-manufacturing-practice (GMP) inspections was interpreted by some as indicating a persistent trend, and not an unusual cluster. Some members also expressed interest for the reflection on adaptive licensing, and for whether and how this concept could develop within current existing legislation. This will be discussed at the March meeting of the Board. The European Commission stressed the importance of complying with the current legislative framework and suggested including in the discussion the subject of HTA.

B.5 Update on the progress of Project 2014

The Management Board noted progress with the planned move to the new premises of the Agency in July 2014, which was considered necessary as the lease in the current location expires at the end of 2014. After a feasibility study conducted in 2011, the option to move to a new site was approved, to allow for efficient and flexible working space in an environmentally efficient building. The EMA will

occupy nine floors, of which two will be devoted to conference space and facilities for delegates. Spaces in the new building are designed according to modern concepts, moving away from enclosed office spaces. The delegates' area will be configured as an open space, facilitating communication and cooperation, while retaining and upgrading technical working facilities provided.

B.6 Amending budget

[EMA/MB/536520/2013] The Management Board adopted the amending budget 01-2013. This was necessary as efficiency gains to the financial processing of the fee application in 2012 had resulted in fee invoices issued for EUR 28.7 million, which remained unpaid at the end of the year. Corresponding revenues were cashed in in early 2013. EUR 20 million will be used to pay the costs of the fitting-out of the new building as they occur.

The European Commission stated that it could agree to this amending budget provided that further explanation is provided by the Agency on the impact of these payments on future payments related to the new building and, in consequence, on futures budgets of the Agency. The European Commission also advised the Agency to inform the European Parliament of this amending budget.

A budget topic coordinator enquired about other expenditure trends discussed at previous meetings, such as the falling percentage of remuneration to NCAs for provision of scientific services. This is due to an increased share of the annual fee on overall fees shared. However, there has been a reversal in 2012, and the NCAs' share is now up to 43%. The Executive Director expressed his intention to continue to look for ways to support the efforts of NCAs working for the EMA by providing improved procedures and enhanced access to EMA-held data and knowledge systems.

B.7 Preparation of a written procedure for adoption of the EMA financial regulation

[EMA/MB/557966/2013; EMA/MB/559920/2013] The Management Board was informed that a new framework Financial Regulation has been prepared by the European Commission and should be adopted within a few weeks. As a result, the EMA financial regulation needs to be amended accordingly and adopted after a favourable opinion from the European Commission. The new EMA financial regulation will not diverge from the framework regulation, other than for references, and will be submitted to the Management Board for adoption by written procedure in October or November 2013. It will enter into force on 1 January 2014, as stipulated in Article 111 of the new framework regulation.

B.8 Report by the PRAC chair: Reflections one year on from the establishment, composition and functioning of the PRAC

June Raine, chair of the Pharmacovigilance Risk Assessment Committee (PRAC), presented her reflections on the functioning of the PRAC and on the challenges that lie ahead. The pharmacovigilance legislation's aim is to reduce societal costs from adverse drug reactions (ADRs), both in terms of lives and costs of care. The PRAC has been running very well from the beginning, cooperating with the other committees, and benefiting from contributions by patient and healthcare-professional representatives in all areas of its work. The work of the PRAC is based on three pillars: proactive safety monitoring, prompt benefit-risk action, and transparency and communication. Proactive pharmacovigilance is attained by means of signal management, which has achieved a shift from reactive firefighting to the rapid handling within the PRAC of validated signals, leading to a clear recommendation on regulatory outcome within a short timeframe. Signal descriptions, listings, recommendations and Q&As are published on the website.

Prompt benefit-risk action is obtained through safety referrals, achieving final outcome generally in a shorter timeframe than in the past. PSUR evaluation has taken on a new role in safety, as PRAC recommendations can lead to urgent binding regulatory action in all Member States. Transparency on PRAC action has reached an unprecedented rhythm, with highlights and recommendations regarding safety referrals being published at the end of the PRAC week, followed by the minutes after their adoption at the following meeting. Significant progress has been achieved towards risk-monitoring throughout the product lifecycle. Stakeholders have been successfully involved through improved communication and consultation.

Efficient management of workload is among the main challenges for the PRAC. After a steady increase in all types of procedures until May 2013, a steady state might have been reached, with workload taken up principally by 15 Member States. The Committee is reflecting on how to improve efficiency, and has recently approved an action plan that will focus, among other things, on scope and optimal use of referrals, currently making up one third of discussion time in meetings. Collaboration initiatives are ongoing, and will also be the object of the Joint Action SCOPE initiative (Strengthening Collaborations to Operate Pharmacovigilance in Europe). During its first year of operation, the PRAC has focused on using the new public-health protection tools, demonstrating a capability for robust scientific decision-making in demanding timeframes. Further goals are strengthening science and achieving clearly demonstrable public-health outcomes.

Several members congratulated the PRAC chair on her presentation and on the achievements of the Committee. Some concern was raised about the 'gap week' between the PRAC and the CHMP week, and it was suggested that a closer sequence would be in best interest of good communication. This issue has been flagged in various fora, and will be further discussed at the upcoming meeting of the Heads of Medicines Agencies. A further issue is the time lapse between decisions and implementation, and how this can be reduced or avoided altogether in certain cases. Outcome of communication is not easy to measure, and some members agreed with the chair that more information is needed on the impact of regulatory measures on behaviour by patients and healthcare professionals. This can only be achieved through collaboration with all stakeholders. The questions of how the PRAC was coping in the absence of pharmacovigilance fees, and whether success of the legislation could be considered risk-proportionate, were raised. The Board was informed that, currently, the PRAC is able to fulfil its duties, but needs to increase its efficiency through long-term rationalisations and clear definitions of roles and responsibilities, to avoid duplication, as well as addressing risk proportionality by minimising recourse to unnecessary and burdensome regulatory procedures, where possible.

B.9 Principles for publication of agendas and minutes of EMA scientific committees

[EMA/MB/555575/2013; EMA/127582/2010; EMA/391939/2013; EMA/434574/2013 Rev. 4 CONFIDENTIAL] The Management Board discussed the principles for the publication of agendas and minutes of the EMA scientific committees and endorsed the implementation plan. Agendas and minutes of the COMP, PDCO and PRAC, as well as pharmacovigilance sections of CMDh meetings, are already published. The Agency intends to also publish agendas and minutes of the CHMP, CAT, HMPC and CVMP according to an agreed set of principles and implementation plan, with a view to publishing all agendas and minutes of the committees by January 2014. The Board welcomed the proposal and expressed general support for the principles. Some amendments concerning equal treatment of personal data of (co-)rapporteurs and EMA staff, as well as further elaboration on some veterinary-specific aspects, were requested. Additional comments will be provided by the European Commission. The Board agreed that a revised text could be circulated by written procedure, and that the publication of agendas and minutes of all committees should proceed according to the implementation plan.

B.10 Role of the Management Board in the discussion on the introduction of pharmacovigilance fees

Some members informed the Board that the legislative proposal for a regulation on the fees payable to the Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use, currently under discussion at the Working Party on Pharmaceuticals and Medical Devices at the Council of the European Union, contains a provision empowering the Commission to adopt delegated acts to amend the fees. Members discussed possible changes that such a provision would have on the role of the Management Board and its prerogatives. The representative of the European Commission explained that, in the post-Lisbon context, an amendment of the amounts set in a basic legal act can only be introduced via delegated acts (or via the full ordinary legislative procedure). The use of delegated acts was therefore chosen by the Commission, to allow for more flexibility and a shorter timeframe. Some members of the Board questioned this position. Furthermore, there have been discussions on the split of the fees between the EMA and the Member States. The Executive Director offered to the Board the possibility of holding a dedicated informal session, if that would help provide advice that could help the discussion in the Council. The Board agreed that the legal forum for the discussion on the draft legislation remains the Council, but that it should be made aware of the discussion at the Board. With abstention by the representatives of the European Commission, the Board agreed the following statement, to be sent to representatives of the Lithuanian Council Presidency, the European Commission and the ENVI committee of the European Parliament:

The Management Board discussed at a high level the draft proposals presently being discussed at the Council working party and Parliament on the introduction of Pharmacovigilance fees. In particular, the members stressed that the final proposal must have regard to the development of the Pharmacovigilance activities of the network comprising the EMA and Member States, provide for adequate remuneration for the work load involved, and be fair, transparent and proportionate. Decisions of the Commission on the setting of fee amounts and the division of remuneration between the EMA and the NCA Rapporteurs and co –Rapporteurs should take due regard to these principles and to the concerns of the Management Board.

A.O.B.

Documents for information

- [EMA/MB/549873/2013, EMA/523568/2013] Update on Telematics from the EU Telematics Management Board (EU TMB).
- Report from the Heads of Medicines Agencies.
- [EMA/MB/378130/2013 V.2] Outcome of written procedures during the period 24 May 2013 to 30 August 2013.
- [EMA/MB/537811/2013] Summary of transfers of appropriations in the budget 2013.

Tabled documents

- Updated draft agenda version 4.

Written procedures during the period 24 May 2013 to 30 August 2013

- Consultation no. 8/2013 on the appointment of Jana Klimsová as CHMP alternate, proposed by Slovakia, ended on 7 March 2013. The mandate of the nominee commenced on 14 June 2013.

- Consultation no. 9/2013 on the appointment of Ljiljana Markuš-Cizelj as CVMP member, proposed by Croatia, ended on 19 June 2013. The mandate of the nominee commenced on 1 July 2013.
- Consultation no. 10/2013 on the appointment of Frane Božić as CVMP alternate, proposed by the Croatia, ended on 19 June 2013. The mandate of the nominee commenced on 1 July 2013.
- Consultation no. 11/2013 on the appointment of Ivana Mikačić as CHMP member, proposed by Croatia, ended on 27 June 2013. The mandate of the nominee commenced on 1 July 2013.
- Consultation no. 12/2013 on the appointment of Ana Dugonjić as CHMP alternate, proposed by Croatia, ended on 27 June 2013. The mandate of the nominee commenced on 1 July 2013.
- Consultation no. 13/2013 on the appointment of Bogdan Aminkov as CVMP alternate, proposed by Bulgaria, ended on 17 July 2013. The mandate of the nominee commenced on 18 July 2013.
- Consultation no. 14/2013 on the appointment of Greg Markey as CHMP member, proposed by the United Kingdom, ended on 27 August 2013. The mandate of the nominee commenced on 28 August 2013.
- Consultation no. 15/2013 on the appointment of Bart Van Der Schueren as CHMP alternate, proposed by Belgium, ended on 27 August 2013. The mandate of the nominee commenced on 28 August 2013.
- Consultation no. 16/2013 on the appointment of Daniel Brasseur as CHMP member, proposed by Belgium, ended on 27 August 2013. The mandate of the nominee commenced on 28 August 2013.
- Consultation no. 17/2013 on the appointment of Hans Hillege as CHMP alternate, proposed by The Netherlands, ended on 30 August 2013. The mandate of the nominee commenced on 30 August 2013.
- Written procedure for adoption of the Agency's final accounts, ended on 27 June 2013. The document was adopted.
- Written procedure for adoption of revised implementing rules to the Fee Regulation ended on 15 July 2013. The document was adopted.
- Consultation procedure on the revised policy for classification and incentives for veterinary medicinal products indicated for minor use, minor species (MUMS)/limited markets ended on 12 July 2013. The document was adopted.
- Written procedure for adoption of the 80th Management Board meeting minutes ended on 1 August 2013. The minutes were adopted.

List of participants at the 81st meeting of the Management Board, held in London, 3 October 2013

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	*Apology received*	
Czech Republic	Doubravka Kostalova	
Croatia		Viola Macolić Šarinić (Croatia)
Denmark	Else Smith	Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	*Apology received*	
Ireland	Pat O'Mahony	Rita Purcell
Greece	*Apology received*	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	Dominique Maraninchi	Miguel Bley
Italy	Luca Pani	Pietro Erba
Cyprus	Arthur Isseyegh	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	Claude A Hemmer	
Hungary	Tamás L Paál	
Malta	*Nomination awaited*	Gavril Flores
Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	
Romania		Simona Badoi
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Ian Hudson Saira Madden
European Parliament	Björn Lemmer Giuseppe Nisticó	
European Commission		Andrzej Rýs Salvatore D'Acunto Miroslav Griva
Representatives of patients' organisations	Nikos Dedes W.H.J.M. Wim Wientjens	
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	Christophe Hugnet	

	Members	Alternates (and other participants)
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway) June Raine (PRAC Chair)	

European Medicines Agency	Guido Rasi Andreas Pott Noël Wathion Agnès Saint Raymond Stefano Marino David Mackay Zaïde Frias Enrica Alteri Alexis Nolte Fergus Sweeney Nerimantas Steikūnas Michael Lenihan Tony Humphreys Peter Arlett Sylvie Benefice Isabelle Moulon Emer Cooke Martin Harvey Allchurch Silvia Fabiani Sophia Albuquerque	