12 February 2014
EMA/MB/723234/2013 Adopted
Management Board

Minutes of the 82nd meeting of the Management Board

Held in London, 11–12 December 2013

Wednesday meeting, held on 11 December 2013

A formal Wednesday meeting session was held at the request of some members for a longer discussion of the Board's role with regard to funding in the European regulatory network, including the impact of the Lisbon treaty.

Session 1: Pharmacovigilance fee regulation — legislative aspects

Sir Kent Woods, Chair of the Management Board of the European Medicines Agency (EMA), introduced the session by reminding the Board of the issues that were identified as requiring further reflection after the last meeting of the Board in October. The Board should clarify its role in ensuring that the centralised system has enough resources, and that they are distributed efficiently and fairly. Furthermore, it needs to discuss how it can carry out this role in circumstances that have greatly changed since the Board was set up 20 years ago. Activities concerning the legislative proposal for a regulation on pharmacovigilance fees have brought to the attention of all the fact that the Lisbon Treaty has brought about changes that could affect the competence of the Board with regard to establishing fees. While discussions on the pharmacovigilance fee regulation are ongoing, it is important that the Board reflects on this experience and determines how it can best contribute to supporting a system that is feasible for Member States, the European Medicines Agency, the European Parliament, the European Commission and stakeholders alike.

The European Commission gave a presentation on the Lisbon Treaty and implementing acts, to clarify its new prerogatives and the role of the Management Board in respect of the EMA fees. Before the Lisbon Treaty, the Commission's and Council's powers were used through secondary legislation, and the Commission's exercise of its powers was controlled through comitology procedures in a rather complex system. In the post-Lisbon framework, the Commission adopts non-legislative acts through 'delegated acts', which supplement or amend non-essential elements of the legislative act, or 'implementing acts', which implement the legislative act.

The role of the Management Board was set out in the EMA Founding Regulation and in the Fees Regulation, giving the Board responsibility over establishing the remuneration for rapporteurs and fixing the rules for repaying part of the fees to the national competent authorities. However, after the

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Lisbon Treaty, any delegation of rule-making power has to be carried out by implementing or delegated acts. A case concerning which of the new non-legislative acts should be used to regulate fee-related matters is currently awaiting a Court ruling, which should provide further clarity in this regard.

In the past, the Court of Auditors and the European Parliament have requested that the remuneration of Member States should be cost-based. At its meeting of March 2013, the Board agreed that the remuneration of the rapporteurs should be considered within the overall revision of the fee legislation, which the Commission intends to start work on as soon as the regulation on pharmacovigilance fees has been adopted, working in close cooperation with the Member States.

One Member State representative reported a statement by his government, which addressed the perceived notion that the Management Board finds itself in a conflict of interests when dealing with issues concerning fees or their repartition. He reminded the Board that the legislation foresees that, in order to ensure close cooperation between the Agency and scientists operating in Member States, the composition of the Management Board should be such as to guarantee that the competent authorities of the Member States are closely involved in the overall management of the Union system for authorising medicinal products. This means that members of the Management Board should take a common interest in the functioning of the whole system, which relies on the contribution by national competent authorities.

The Chair invited the Board to be mindful of the risk of external perception of conflicts of interests in relation to the setting and repartition of fees. This had been explicitly referred to in a special report published by the Court of Auditors in 2012 and discussed at the European Parliament. Regardless of legislative evolutions due to the Lisbon Treaty, the Board's structure and composition continue to place it in a unique position to collect the best-possible evidence and provide trusted information on which the right decisions can be taken. It therefore has an important role to play in making its wide knowledge of the whole system available, and should assert its expert role in advising the legislator and by providing the best-possible evidence. There were therefore positive advantages in separating the expert advisory role from the decision-making role.

Some members expressed some reservations over the limitation of the Board's powers following the Lisbon treaty, but welcomed at the same time the perspective of providing the Commission with data that reflect accurately how the network works, including information on currently unremunerated activities that national competent authorities carry out for the common interest.

The representative of the European Commission reminded the Board that the current legislative proposal on pharmacovigilance fees is already dealing both with the level of fees and with their repartition, and that this would apply to all future legislation concerning fees. The possibility to finance all non-remunerated activities from European contributions in the foreseeable future does not seem realistic. The collection of complete and transparent data would be very welcome, as it would provide a solid and collaborative basis for the next legislative proposal on the overall fee regulation.

Session 2: Considerations on costing

Opening the second session, the Chair presented anonymised sample data for a few national competent authorities, differing greatly in budget size, significance of fees for centralised activities on overall budget, and public vs. fee-based funding models. The complexity of the system must be considered also in an evolving scenario, where over the past 5 years, payments from the EMA to national competent authorities have increased unequally by type of procedure, reflecting shifts in workload. They ranged from modest increases for marketing authorisations to a 90% increase in the area of inspections. While it is true that some of the observable trends might be short-term, it is of fundamental importance to be able to take long-term decisions based on reliable and robust data, also

looking into future developments. Costing might only be a part of the greater picture, as the Board needs to reassure itself of the sustainability of the entire system and network as a whole. A fresh, top-down approach is needed, allowing an overview of the whole system before assessing the cost of single activities. Time spent for work on a procedure might not be the only factor, as great variability has been detected in the past. It was observed that a certain degree of standardisation of activities is necessary, in order to make them comparable and achieve a fair remuneration. There was agreement on the fact that qualitative as well as quantitative information should be taken into account. The representative of the European Commission supported looking first at the best-possible distribution of tasks, and then defining their remuneration. Several members supported the idea of entrusting the Board with the task of gathering data through a dedicated working group, where Member States would be represented at a technical level, with strategic and analytical steer being provided by another, smaller group of members of the Board. Good systems for data collection could be discussed and shared. The Agency presented as an example its activity-based costing system, which combines data from the time-recording system with information on financial resources. Staff members are required to record their daily working time according to activities. These are then costed and form the basis of the activity-based budget, together with overhead costs allocated to the specific activities. Resulting information has been used to forecast the cost of activities in the 2014 work programme of the Agency. As for the possibility of standardising working time, the Executive Director stressed the need to complete the picture by matching the information on cost-based activity with qualitative KPIs and embedding it in improved and streamlined processes.

The Board supported the proposal to develop a programme to gather the evidence needed by the Commission in drafting the future legislative proposal on fees. This should ensure that the system is sustainable and supported by the right level of financial resources. A draft mandate and description of the data-gathering exercise will be presented at the next Board meeting in March, where the Wednesday afternoon session will be dedicated to this topic.

Thursday meeting, held on 12 December 2013

The Chair of the Management Board opened the meeting by welcoming new members Kiril Nenov, representing Bulgaria, and Beatrix Horváth, representing Hungary, as well as John Joseph Borg, representing Malta (in absentia on 12 December).

1. Draft agenda for 12 December 2013 meeting

[EMA/MB/531192/2013]. The agenda was adopted.

2. Declarations of conflicts of interests

The Chair informed members of the Management Board that he had reviewed their 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 conflict of interests was declared.

3. Minutes from the 81st meeting, held on 3 October 2013

[EMA/MB/584118/2013] The Management Board noted the final minutes, adopted by written procedure on 8 November 2013.

A. Points for automatic adoption / endorsement

A.1 Financial compensation for Member States' participation in the linguistic checking of product-related information

[EMA/MB/673504/2013; EMA/673506/2013] The Management Board endorsed the increased flat-hourly rate for 2014.

A.2 Amendment 2 to Annex II of the cooperation agreement relating to linguistic checking

[EMA/MB/688641/2013] The Management Board adopted the amendment increasing the frequency of payments to national competent authorities for financial compensation of linguistic checking from bi-annual to monthly payments.

B. Points for discussion

B.1 Highlights from the Executive Director

Meeting with Commissioner Borg

The meeting took place in Malta on 29 November 2013 and was hosted by Malta's Medicines Authority. A series of bilateral and trilateral meetings were held, involving also the Maltese Minister of Health.

Amsterdam summit 2013

The 8th International Summit of Heads of Medicines Regulatory Agencies was hosted by the Dutch Medicines Board on 3 to 6 December in Amsterdam. In addition to sessions on regulatory science, adaptive licensing, inspections and future perspectives in the global health area, the summit established an interim management committee to take forward a new International Coalition of Medicines Regulatory Authorities (ICMRA). The chair is to be held by Canada, with Ireland and Japan providing joint deputy chairs.

EMA-HTA workshop

The Agency offers parallel scientific advice with health-technology assessment (HTA) bodies in order to reduce the time and cost of medicines' development and facilitate access to medicines. An EMA-HTA workshop on parallel scientific advice in drug development took place on 26 November 2013, bringing together 300 participants in house and an additional 200 online. The workshop built on the experience accumulated with the 25 parallel EMA-HTA scientific-advice procedures conducted in the context of a pilot over the past 3 years. Following the workshop, a report and a procedure will be published for consultation. A significant number of parallel EMA-HTA procedures are in the pipeline for 2014. The Agency will also take part, in 2014, in three early dialogue procedures involving regulators and the HTAs that are part of a consortium funded by the Health Programme of the European Commission. Parallel EMA-HTA scientific advice is also in the 3-year work programme agreed with EUnetHTA.

Improving the efficiency and effectiveness of the Agency's operations

The Review and Reconnect programme is on track, with 12 high-priority projects now under way.

Since the last report to the Management Board, the exercise has delivered three initiatives, now in implementation phase, to improve fee processing, access to documents, and the creation of a central data-management service to support the EU data board, which will agree on common data standards and use of data in the network. A number of processes have been redesigned with the aim of achieving efficiency gains not only for the EMA but also for the EU network of medicines regulatory authorities, whose input, together with that of the Agency's scientific committees, is now sought through a consultation. The separation of technical and administrative roles and responsibilities will be implemented in a staggered approach by clusters of processes.

Update on the Court procedure — outcome of the appeal against interim measures

Early in July 2013, the EMA appealed against the Orders of the President of the General Court (Interim ruling) suspending the decisions to disclose documents contained in the dossiers for marketing authorisation of two medicinal products. The Vice President of the Court of Justice annulled the interim decision, and sent the case back to the General Court for a new assessment and a new decision on the interim relief. Pending the outcome of the new assessment by the President of the General Court, the EMA will not give access to the documents requested in these two cases until the General Court decides otherwise. The Agency will continue to consider all other applications for access to documents on a case-by-case basis, as is currently the case. The main Court cases, currently pending before the General Court, will follow their normal course.

B.2 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 ongoing, with progress being made on the delegated act on post-authorisation efficacy studies, and on the joint action on pharmacovigilance systems. A grant was awarded to the SCOPE project, under UK leadership and with the participation of 25 Member States.
- A Staff Working document on the Use of '-omics' technologies in the development of personalised medicine has been developed by DG SANCO and DG Research.
- A Report on the functioning of the Advanced Therapies Regulation is being finalised and should be published early in 2014.
- A number of implementing measures concerning the Falsified Medicines Directive have been published or are in the consultation phase. The adoption of the delegated act on the unique identifier and its verification is expected in 2014, as are the principles and guidelines of GMP for active substances in the EU, the establishment of a common EU logo for online pharmacies and the guidelines on GMP for API. After entry into force in July without significant shortages of provisions concerning the import of APIs, the Commission is now working on the follow-up of GMP non-compliance of API sites covered by 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), negotiations with the European Parliament are ongoing with a view to adopting the Regulation within the current term. The proposed text now assigns the development and maintenance of the clinical-trial portal and Union database to the Agency.
- The legislative proposal for the revision of the veterinary medicines legislation (including medicated feed and veterinary medicines) should be adopted in Q1 2014.

- A workshop on regulatory options in the fight against antimicrobial resistance was held on 8 November at the EMA and was very well received by stakeholders. A Commission conference on antimicrobial resistance took place on 12 December.
- The legislative proposal on the medical devices legislation is still under discussion at the Council Working Group, and it appears unlikely that it will be adopted within the current term of the European Parliament.
- The implementation of Directive 2011/24/EU on patients' rights in cross-border healthcare is ongoing. Unfortunately, transposition into national legislation is progressing slowly. The HTA network had its first meeting on 16 October, which was attended by all Member States and the EMA. The eHealth network aims at establishing cooperation among the national competent authorities. A first guideline on the electronic sharing of patient data has been adopted and will set a model for exchange of data to be shared across borders. The deadline for the implementation of mutual recognition of prescriptions elapsed on 25 October, but some Member States are still experiencing problems with introducing the model.
- Several international initiatives are in an active phase. Agreement has been reached on the reform of ICH, establishing a new governance model while defining criteria for membership. The International Pharmaceutical Regulators Forum (IPRF) has been set up for exchange of information and regulatory cooperation, as well as the International Coalition of Medicines Regulatory Authorities (ICMRA). EU-US trade negotiations (TTIP) include medicines and are focusing on recognition of GMP inspections.

Some members were concerned about the delays in transposition of legislation, as well as about the protracted legislative process required by some legislation, such as the clinical trials and medical devices regulations. There is a risk that if contradictory national legislation is adopted, some provisions, such as hospital exemption, may generate deregulation instead of control.

B.3 Roles and responsibilities of the Management Board

[EMA/MB/715306/2013; EMA/MB/186362/2007] The Management Board endorsed the revised document on the roles and responsibilities of the Management Board, which needed to be modified to include references to new legislation, improve the terminology used and update the working practices of the Board in order to reflect revisions of the code of conduct, rules of procedure and operating procedures for the Board.

B.4 Draft principles for a revised EMA conflicts-of-interests policy for scientific-committee members and experts

[EMA/MB/734303/2013; EMA/734296/2013] The Management Board endorsed the principles for a revised EMA conflicts-of-interests policy for scientific-committee members and experts. The proposal stemmed from an EMA public workshop on conflicts of interests held on 6 September 2013 that provided an occasion to hear the views of a wide range of stakeholders. It aims at striking the right balance between independence and impartiality of experts, and assuring access to the best-possible scientific expertise. The proposed principles include:

- establishing the nature of the declared interests and their bearing on a specific EMA activity in order to determine an appropriate cooling-off timeframe;
- differentiation of rules for involvement of experts between decision-making and advisory bodies;

- definition of a methodology to identify best expertise, acknowledge and recognise involvement of experts, also by developing a framework for interaction with academia.

The Board supported the proposed approach, which appears to be more proportionate while retaining the necessary stringency in the system. Some members advocated a clearer definition of financial interests concerning participation in educational events, and suggested to conduct an impact analysis of the proposed principles on the composition of the scientific committees and of the scientific advisory groups. A revised policy will be presented to the Board for endorsement at its March 2014 meeting. The need for apt communication about the new rules was also emphasised by many members.

B.5 ~~Revised implementing rules to the Fee Regulation as of 1 January 2014~~

The discussion of this point was deferred.

B.6 Draft principles for implementing rules on publication of and access to clinical-trial data

[EMA/MB/773284/2013; EMA/743046/2013] The Management Board endorsed a set of key principles for implementing rules on publication of and access to clinical-trial data.

During the consultation period on the draft policy, which was concluded on 30 September 2013, an exceptional number of contributions were received from a variety of stakeholders. The comments addressed mainly the areas of protection of patient confidentiality, rules of engagement and legal aspects. Following the review, revised principles were drafted. They principally relate to the scope of the implementing rules, suggesting a stepwise approach to implementation, commencing with the publication of clinical-study reports, redacted as appropriate, and subsequently assessing the issue of individual patient data (IPD) on the basis of discussion with stakeholders.

The principles need to be considered in light of developments in the ongoing court cases concerning access to documents and in conjunction with the provisions that will be contained in the Clinical Trial Regulation. The representative of the European Commission added that other Directorates-General would be affected by the proposed policy of the EMA, and thus need to be consulted.

The policy on publication of and access to clinical-trial data will be discussed at the March 2014 Board meeting.

B.7 Work programme 2014

[EMA/MB/719999/2013; EMA/695772/2013] The Management Board adopted the Agency's work programme 2014. Priorities will concern the delivery of core functions to a high level of quality, enhanced cooperation with the network and international partners, the ongoing implementation of the pharmacovigilance legislation, increased transparency, and facilitation of the early stages of medicines development. These will be supported by enabling priorities, such as improvement of integration and accessibility of data held by the Agency, and a continuous focus on improving operational effectiveness and efficiency at the Agency. A successful move to the Agency's new premises in July 2014 requires continuous attention, but also constitutes an opportunity for changes in culture and way of working.

The overall workload concerning human-medicines evaluation is stable, with a small decrease in initial evaluations, balanced out by a rise in variations. For veterinary-assessment activities, a drop is expected after the unusual surge in 2013, and remains in line with past trends. No significant change is expected concerning inspections and compliance activities.

Members of the Board appreciated the priorities chosen, with particular regard to the support to the network through training initiatives, IT systems delivering value to the network, and facilitating early stages of medicines development as a contribution towards reviving innovation in the EU, in particular supporting smaller companies. It was suggested that a high priority also be set for inspections and compliance activities, which is necessary given the rising numbers in critical findings, and to initiatives on antimicrobial resistance, which remains a serious public-health issue. Linking to the previous day's discussion, the Board also requested that the project on data gathering be included in the work programme. The Agency strives to achieve best distribution by further improving its activity-based costing, and matching it with qualitative KPIs to assess whether the best service is provided. A further analysis of the re-engineered processes will allow the optimal number and skills of staff needed to be assessed. The representative of the Commission pointed out that the Agency fulfils a wide variety of tasks that can only be carried out by an appropriate, centralised structure, and that are necessary to achieve integration and facilitate innovation in Europe through the provision of advice to small start-ups. It was also pointed out that the health ministries of the Member States have requested to streamline the IT systems, as there is a duplication of databases.

B.8.a Draft budget and establishment plan 2014

[EMA/MB/128714/2013; EMA/MB/686942/2013] The Management Board discussed and adopted the Agency's budget and establishment plan for 2014. The budget is in line with the work programme and amounts to EUR 297.2 million, with an increase of EUR 45.7 million (+18.1%) over the 2013 budget. The rise is caused by an increase in fee income due to additional variations, anticipated implementation of pharmacovigilance fees, and estimated inflationary increase of fees by 2.5%. The budget includes additional assigned revenue for the relocation of the Agency. The EU contribution is unchanged at EUR 39.23 million, but is going down in relative terms. In terms of expenditure, staff costs are expected to increase as a consequence of the anticipated exchange rate effect of adjustments required for 2011 and 2012 salaries. IT expenditure will also increase to accommodate rising demand on new IT developments concerning data integration, new pharmacovigilance systems, the eSubmission programme, the intranet and extranet, clinical trials, and the upgrade of datacentre and corporate IT platforms as part of the move to the new premises. Expenditure for activities of the network will increase significantly as well, providing different levels of support according to the needs of national competent authorities, particularly in the area of training and meetings.

The 2014 establishment plan foresees 599 posts, 12 fewer than the 2013 plan. The reduction was necessary due to the decision of the Council for all EU agencies to reduce their establishment plans by 10% (over a period of 5 years).

The topic coordinators Klaus Cichutek, Kristin Raudsepp and Grzegorz Cessak presented their views to the Board concerning the budget supporting the work programme. As the EMA's revenues increase, expenditure for shared fees to the network stays roughly at the same level of 40%. The Agency has reduced the number of posts on its establishment plan, while the total headcount may increase on account of contract agents and national experts. Concerning IT, after a decrease in expenditure in 2013, there is a small rise in 2014, mainly for maintenance and repair. However, the increase is expected to be of a temporary nature. The topic coordinators congratulated the EMA on improvements in the transparency of its budgetary documents, and recommended their adoption. A few points were raised for further discussion. The topic coordinators recognised that a modification of the repartition of fees between the EMA and national competent authorities is not possible at the present moment, and that a general reflection on the overall allocation of resources in the network will be undertaken over the next 12 months, as discussed in the Wednesday session. The Board welcomed the integrated view of the activities and resources used, and in the future would like to see it detailed even further.

The Board thanked the topic coordinators for their constructive contribution. Some members had further questions concerning high costs and headcount in IT. This is due to the fact that systems and databases in an organisation like the EMA are very complex, as they have to be highly integrated, and must furthermore be multilingual. The increased number of contract agents is necessary in order to provide staff substitutions. Additional seconded national experts have been foreseen in the 2014 budget as support to training activities, which will be of benefit to the entire network.

B.8.b Revision of the budget structure and remarks

[EMA/MB/152502/2013] The Management Board noted the revised budget structure, nomenclature and remarks, which are necessary to prepare for the invoicing of fees for pharmacovigilance and to clarify a few budget items.

B.8.c Revision of the establishment plan for 2014

[EMA/MB/700111/2013] The Management Board adopted the revised establishment plan 2014 amending the gradings of posts for 2014 within the parameters defined by the Financial Regulation.

B.9.a Pharmacovigilance legislation: Functional requirements for EudraVigilance to be audited

[EMA/MB/739742/2013; EMA/626168/2013] The Management Board endorsed the EudraVigilance functional requirements to be audited. These will provide a basis for the EMA to develop a detailed plan, including the timeline for implementation and the plan for the conduct of an independent audit. Moreover, detailed business requirements will be developed by the Agency in consultation with Member States, with system delivery including user testing and training. The Pharmacovigilance Risk Assessment Committee (PRAC) will be regularly updated on the project milestones, and its recommendation will be sought for the audit that the functionalities have been delivered as required by legislation. Based on the independent audit report that takes into account the recommendations of the PRAC, the Management Board will confirm and announce when full functionality of the EudraVigilance database has been achieved and the system meets the defined functional specifications.

B.9.b. Functional requirements for the PSUR repository to be audited

[EMA/MB/742130/2013; EMA/681848/2013] The Management Board endorsed the functional requirements for the PSUR repository to be audited. These will provide a basis for the EMA to develop a detailed plan, including the timeline for implementation and the plan for the conduct of an independent audit. Moreover, detailed business requirements will be developed by the Agency in consultation with Member States, with system delivery including user testing and training. The PRAC will be regularly updated on the project milestones and its recommendation will be sought for the audit that the functionalities have been delivered as required by legislation. The Board will confirm and announce when full functionality of the PSUR repository has been achieved, based on the defined functional specifications. This confirmation by the Board will be based on the independent audit report that takes into account the recommendations of the PRAC.

Requirements for the automation of a two-way exchange interface, which is needed by some Member States, have been included, together with a timeframe, in the document 'PSUR repository functionalities to be audited', with a commitment to deliver them in the following post-audit releases.

B.10 Sixth Annual Report on the Interaction with Patients' and Consumers' Organisations (2012)

[EMA/MB/524015/2013; EMA/272219/2013] The Management Board noted the 'Sixth report on the interaction with patients' and consumers' organisations', which includes an assessment of the satisfaction questionnaire. Thirty-four eligible patients' and consumers' organisations work with the Agency. In 2012, the number of interactions continued to grow (307 in 2010, 423 in 2011, 525 in 2012). The increased collaboration mainly relates to participation in scientific-advice/protocol-assistance activities, as well as to scientific advisory groups, committee consultations, workshops and reviews of information intended for the public. Ninety per cent of package leaflets and 100% of EPAR summaries were reviewed in 2012. Patients' and Consumers' Working Party representatives continue to be involved in many EU-wide initiatives, such as Enpr-EMA, ENCePP and the IMI PROTECT consortium. Collaboration is generally perceived to be very good by all sides, as it allows patients to share their real-life experiences, contributing to the quality of Agency outputs. In 2014, a revision of the framework for interaction is envisaged, to take stock of progress made since 2006, and will be presented to the Management Board.

B.11 Publication of agendas and minutes of scientific committees

[EMA/MB745294; EMA/555647/2013] The Management Board endorsed the principles for the publication of agendas and minutes of the EMA scientific committees. The document had been presented at the October meeting of the Board, where some changes and clarification had been requested. A new version has been prepared, taking into account these comments as well as others collected during the course of a written procedure. The Agency will in December 2013 publish the agendas of the CHMP, CVMP and CAT. Minutes of the meetings held in December 2013 will be published in January 2014, once they have been adopted by the relevant committees. This procedure will become standard practice.

A.O.B.

Documents for information

- [EMA/MB/128713/2013; EMA/817331/2012] Multiannual staff policy plan 2014–2016.
- [EMA/MB/711217/2013] Update on telematics from the EU Telematics Management Board (EU TMB).
- Report from the Heads of Medicines Agencies.
- [EMA/MB/622839/2013] Outcome of written procedures during the period from 1 September 2013 to 21 November 2013.
- [EMA/MB/641206/2013] Amending budget, updated on 16 October 2013.
- [EMA/MB/703501/2013] Summary of transfer of appropriations in the budget 2013.
- [EMA/718145/2013; EMA/13787/2009] EudraVigilance report 2013 for veterinary medicinal products.

Tabled documents

- Report from the Heads of Medicines Agencies.

Written procedures during the period 1 September 2013 to 21 November 2013

- Consultation no. 18/2013 on the appointment of Marcel Bruch as CVMP alternate, proposed by Luxembourg, ended on 30 September 2013. The mandate of the nominee commenced on 1 October 2013.
- Consultation no. 19/2013 on the appointment of Aldona Paluchowska as CHMP alternate, proposed by Poland, ended on 24 October 2013. The mandate of the nominee commenced on 25 October 2013.
- Consultation no. 20/2013 on the appointment of Frida Hasslung Wikström as CVMP alternate, proposed by Sweden, ended on 21 November 2013. The mandate of the nominee commenced on 22 November 2013.
- Written procedure for adoption of the 81st Management Board meeting minutes, ended on 8 November 2013. The minutes were adopted.
- Written procedure for endorsement of the document on publication of agendas and minutes of EMA scientific committees, ended on 21 November 2013. The procedure was suspended.

List of participants at the 82nd meeting of the Management Board, held in London, 11–12 December 2013

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Kiril Nenov	Zlatina Gueorguieva
Czech Republic	Doubravka Kostalova	
Croatia	*Apology received*	Viola Macolić Šarinić (Croatia)
Denmark	Else Smith	Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	*Kristen Raudsepp*	
Ireland	*Apology received*	Rita Purcell
Greece	*Apology received*	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	*Apology received*	Jean-Pierre Orand Miguel Bley
Italy	Luca Pani	Pietro Erba
Cyprus	*Apology received*	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	Beatrix Horváth	
Malta	John-Joseph Borg	Gavril Flores
Netherlands	Aginus Kalis	
Austria	*Apology received*	Sylvia Fueszl
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Maria Morais
Romania	Marius Savu	
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	David Obranovic
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Ian Hudson Saira Madden Jonathan Mogford
European Parliament	*Apology received*	
European Commission	Paola Testori-Coggi	Lenita Lindström Sabine Juelicher (on 11 December 2013) Thomas Heynisch
Representatives of patients' organisations	*Apology received* W.H.J.M. Wim Wientjens	
Representative of doctors' organisations	*Apology received*	

	Members	Alternates (and other participants)
Representative of veterinarians' organisations	Christophe Hugnet	
Observers	Rannveig Gunnarsdóttir (Iceland) *Apology received* (Liechtenstein) *Apology received* (Norway)	

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	