14 November 2012
EMA/MB/653638/2012
Management Board

Minutes of the 77th meeting of the Management Board

Held in London on 4 October 2012

The Chair of the European Medicines Agency's Management Board, Sir Kent Woods, opened the meeting by welcoming the new members: Helder Mota Filipe, representing Portugal; Marious Savu, representing Romania; and Matej Breznik, representing Slovenia.

The mandates of the civil society members of the Board expired on 4 March 2012 and new members have not been appointed yet.

1. Draft agenda for 4 October 2012 meeting

[EMA/MB/397583/2012] The agenda was adopted.

2. Declaration of conflicts of interests

The chair informed members of the Management Board that he has reviewed members' declared conflicts of 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 to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

The chair took the opportunity to remind members who have not done so to send their CVs to the secretariat for publication on the Agency's website.

3. Minutes from the 76th meeting, held on 7 June 2012

[EMA/MB/394635/2012] The Management Board noted the final minutes, adopted by written procedure on 28 July 2012.

4. Election of vice-chair

No nominations for the position of vice-chair were received by the requested deadline of 6 September. The chair was, however, confident that a candidate might come forward in good time for election at the December meeting.

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A. Points for automatic adoption/endorsement

A.1 Revised reimbursement rules for delegates

[EMA/MB/439609/2012] The Management Board discussed the revised document 'Basis for the reimbursement of expenses for delegates and experts attending meetings', and concluded that further data on the rationale for the proposed changes would be desirable.

An updated proposal will be presented for adoption at the December meeting.

A.2 Revised Management Board rules of procedure

[EMA/MB/115339/2004/Rev.4] The Management Board adopted the revised 'Rules of procedure of the Management Board'.

B. Points for discussion

B.1 Highlights from the Executive Director

Discharge for the budget 2010

The European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) and the Committee on Budgetary Control (CONT) have recommended the discharge for the implementation of the Agency's budget for 2010. The vote in the parliamentary plenary is expected at the end of the month. Conditions for the discharge related mainly to the management of conflicts of interests, rather than more traditionally on budget issues. The draft report recognises the significant progress made by the Agency during this period in areas of transparency and conflicts of interests, including the update of conflicts-of-interests policies and rules for scientific committees, for the management board and for staff, the adoption of breach-of-trust procedures, and the publication of curricula vitae (CVs) for Agency managers and shortly for experts. Measures for handling conflicts of interests are now embedded in the routine of the Agency; the Board should, however, be aware of their high cost. As an example of this, the checking of information on eight products, the conflicts of interests relating to one specific product and the verification of declarations of interests in relation to the CVs of over 700 experts has cost the Agency over 700 hours at a total cost of €74,000.

Scientific Coordination Board

The third meeting of the Scientific Coordination Board focused on the objective of achieving greater consistency in the scientific output of the Agency. There was consensus that this can be achieved by enabling access to the same experts across the seven committees of the Agency. In a first pilot, the Scientific Advisory Group on Oncology will be recast and will be consulted by all committees with a view to streamlining and harmonising approaches. Recent experience has shown that the committees can converge and agree on new methodologies to assess benefit beyond the purely statistical approach.

One member called for initiatives concerning unmet medical needs in the geriatric population, including depression.

Raw data analysis

The Agency plans to employ existing in-house scientific capacity, supplemented by external experts, to contribute to the evaluation of the benefit-risk balance of medicinal products, particularly in cases where evaluation of aggregate data alone does not seem sufficient, or where reassurance is considered

of importance for regulatory decision-making. This will add value to the scientific robustness of evaluation and reinforce trust in the system.

New communication strategy in place

A corporate communications strategy and an online communications strategy for 2012-2017 have been adopted. One of the objectives is to improve stakeholder relations within the European medicines network. As part of this, the Communications Sector will shortly approach national competent authorities and delegates to survey needs for improved communication tools. The online communications strategy also covers reviews of the current Agency and telematics websites, and work on establishing the European medicines web portal mandated by the new pharmacovigilance legislation.

Pharmacovigilance fees

Public consultation on the concept paper on pharmacovigilance has been closed, and some criticism is emerging from the ongoing analysis. It has to be taken into account that the initial exercise was started in 2008, based on data available at the time and in a risk-adverse climate leading to expectations that might no longer be realistic. This evolution in environment should be considered in the ongoing work to deliver the legislation on pharmacovigilance fees.

Annual hearing at the European Parliament

This will take place before the ENVI Committee on 10 October 2012. The Agency will have the opportunity to present work carried out and future priorities to the Parliament.

Court of Auditors report

A 2011 report on the handling of conflicts of interests will be released on 11 October 2012. Most recommendations have already been addressed with the measures that led to the proposal for discharge for the 2010 budget.

B.2 Mid-year report 2012 from the Executive Director (January–June 2012)

[EMA/MB/526812/2012] The Management Board noted the Agency's mid-year report 2012. The document provides an overview of the status of the implementation of the work programme 2012 by objectives through performance indicators. The activities of the Agency are substantively on track, with a stable budget situation. An estimated shortfall in revenue of 1% will be offset by savings on expenditure. Reinforcement of the orphan medicinal product fund from the general EU contribution will be requested to make up for consumption above target.

Assessment activities for human products are largely in line with 2011 figures, with substantial increases in the numbers of orphan-designation applications, scientific-advice and protocol-assistance requests, and type-IB variations, while there is a marked decrease in initial applications for generic products. No certification applications for advanced-therapy medicinal products were received.

Veterinary applications are stable compared to 2011, with the exception of a sharp increase in type-II variation applications.

The implementation of the new pharmacovigilance legislation has been among the main objectives of the 2012 workplan and has progressed as planned, supported by the effort of the Heads of Medicines Agencies (HMA) network. Timely input was provided to the European Commission Implementing Measures. A first set of good-pharmacovigilance-practice modules was published, and further ones

were released for consultation. Legal notice was provided to industry on Article 57(2) implementation and a data-entry tool was delivered. The Pharmacovigilance Risk Assessment Committee (PRAC) was launched and has started its activities.

Implementation of the Falsified Medicines Directive is advancing on target as well, with extensive attention devoted to possible challenges deriving from the new import rules for active substances.

The Agency's transparency initiatives have been the subject of much attention, and have progressed well, notably with the publication of agendas and minutes of the Paediatric Committee (PDCO) and the PRAC, as well as of information on therapeutic areas and international non-proprietary names for new marketing authorisations. HMA/Agency guidance on commercially confidential information and personal data that should be protected was published and should help facilitate and harmonise the release of information.

Improvements in the area of managing conflicts were numerous and are ongoing, ranging from revised policies on handling declarations to a new policy on breach of trust, and have addressed the situation for both experts and staff.

Finally, business-continuity provisions during the Olympic Games proved to be effective, although much credit goes to the overall outstanding organisation of the Games itself, and to the national competent authorities who hosted some of the committee meetings during this period. The Agency is thankful for that.

Members expressed concern over the slow uptake of legislation on advanced-therapy medicinal products. Further discussion is needed on the impact of hospital exemptions on the approval process and the resulting availability of these products to patients across Europe. Efforts should be made to bring innovation to patients. This might also be achieved by exploring the possibility of establishing new rules, perhaps in the framework of adaptive licensing. The Board would like to continue this discussion in the future. With respect to risks perceived by patients, members recalled examples in recent authorisation procedures where patients viewed risks posed by medicines differently from regulators. These observations further support the Agency's efforts to bring patient views into the assessment process.

The Board asked for more information on performance relating to timelines for submitting assessment reports. With the launch of the PRAC, these timelines may be put under further stress. The Agency will aim to provide the report for the December meeting.

B.3 Report from the European Commission

The European Commission reported on the following activities relating to the development of EU public-health legislation and policies:

- The new proposals on pharmacovigilance to further strengthen transparency and reporting requirements, adopted by the Commission in February 2012 to be formally adopted by the co-legislators before the end of the year.
- The public consultation on the introduction of fees for pharmacovigilance. The consultation on a concept paper was concluded on 15 September 2012. The Commission is examining the replies, which seem to show little support. As a next step towards the legislative proposal, an impact assessment must be carried out presenting different options. The structure and level of fees in the proposal are not yet known. The ordinary legislative procedure might take 18 to 24 months from the adoption of the proposal by the Commission.

- The implementation of the Falsified Medicines Directive. The main focus is currently on the importation of active substances. The adoption of an implementing act on the requirements for the assessment of the regulatory framework applicable to the manufacturing of active substances from non-EU countries is scheduled for early 2013. A finalised template for the written confirmation for active substances imported into the EU should become available in the next few weeks, following public consultation. Four countries have requested to be listed by the Commission and are undergoing assessment. The Commission is active in awareness-raising on the rules on written confirmation at technical and political levels with third countries; however, good cooperation and exchange of information with the HMA are crucial at this stage.
- The discussion on the proposal for the Clinical Trials Regulation, adopted by the Commission in July 2012, has started in Council at the technical level. ENVI will be the lead committee in the European Parliament.
- A draft proposal on veterinary legislation can be expected in Q2 2013, after the Impact Assessment Board in December 2012.
- Proposals for regulations on medical devices and in vitro diagnostics (IVD) were presented by the Commission on 26 September 2012. The links with the medicinal-products sector are combination products and consultation on companion diagnostics.
- Directive 2011/24/EU on patients' rights in cross-border healthcare entered into force in April 2011 and will be transposed by October 2013. Preparatory work is ongoing on health-technology assessment, e-Health, interoperability for ePrescriptions of pharma databases, mutual recognition of prescriptions, and European references networks.
- The process on corporate responsibility in the field of pharmaceuticals. The work of the Platform on Ethics and Transparency was concluded and a list of guiding principles adopted.
- The evolution of the Transparency Directive. Discussions are ongoing at the Council. The ENVI Committee at the European Parliament is preparing a report.

The Board expressed serious concerns for the implementation of the new pharmacovigilance legislation in the absence of sound financing. A legislative solution appears remote in time. It was suggested that the European Commission and the European Parliament should provide a bridging budget for the implementation of the legislation, pending the delivery and entry into force of the pharmacovigilance-fees legislation. In the meantime, the potential reputational risk to the Agency of public expectations for the effective performance of the new pharmacovigilance provisions exceeding delivery must be addressed, while the European Parliament representative stated that the Parliament cannot be asked for additional budget as there are no funds available, and that alternative sources of financing should be found while making best use of available resources. The Netherlands requested that members of the Board representing the Commission and the Parliament should actively manage expectations within the EU institutions.

Members further considered the proposal for a Clinical Trials Regulation, concluding that further discussions are needed, as it must be made sure that the successful experience of the voluntary harmonisation procedure is taken into account. As for the proposal to develop a dedicated portal, simpler and more cost-effective solutions might be available by integrating existing applications.

B.4 Report from the Heads of Medicines Agencies

The chair of the HMA management group presented an update on the main activities of the network, which included the following:

- The engagement in driving ahead discussion on transparency, particularly practical proposals on handling of data in submissions.
- The Common European Submission Portal (CESP) initiative, joined by 20 Member States and appreciated by stakeholders.
- The implementation of the Falsified Medicines Directive, and the efforts made by Member States to map products that might be affected by new rules for importing active substances into the EU after 1 July 2012.
- The contribution of the HMA to the revision of veterinary legislation.
- The review of HMA working methods.
- The third cycle of the Benchmarking of European Medicines Agencies (BEMA) exercise, with improved methodology.

B.5 Pharmacovigilance Risk Assessment Committee (PRAC)

a) First experience

[EMA/598943/2012] The Management Board noted the update on the first experiences with the PRAC. Three meetings have so far taken place, and the Committee is now fully operational. The July inaugural meeting was dedicated mainly to organisational matters and training, and to the adoption of the PRAC rules of procedure. These were approved with a majority of 25 out of 31 votes, and now need to receive a favourable opinion by the European Medicines Agency and the European Commission.

In its second meeting, in September, the Committee elected its chair and vice-chair. Attention was devoted to the remit and scope of the work of the Committee. The draft agenda was shared with the EU medicines network and published prior to the meeting, along with an explanatory note for the public.

During the October meeting, some possible challenges started to emerge. There are apparent difficulties in identifying rapporteurs who will take on the procedures, due to the strain on resources in the absence of fees. The roles of the Committee for Medicinal Products for Human Use (CHMP) and of the PRAC need to be better clarified, particularly in relation to risk-management plans. Good communication between CHMP and PRAC members within the Member States appears to be crucial. Achievements included the PRAC unanimously adopting a recommendation on the so called 'black symbol' for products, subject to additional monitoring, making up for the still outstanding nomination of representatives of civil society by consulting extensively the Patients' and Consumers' Working Party on the matter. Meeting minutes will be published shortly and, in order to promote better understanding, will include data to help put decisions in a benefit-risk context.

The Board members expressed appreciation for the successful launch of the Committee and stressed the importance of monitoring its operation very closely, as careful management of resources vis-à-vis the workload is necessary, and because the system may sometimes have to operate in strained circumstances.

b) Rules of procedure

[EMA/MB/592761/2012; EMA/PRAC/488608/2012]. The Management Board discussed the outcome of the written consultation to obtain favourable opinion on the rules of procedure of the PRAC, which was suspended on 30 August 2012 following comments by members. In particular, the position expressed jointly by the two German national competent authorities on 22 August and their joint proposal of 27

September on a different wording for Art. 6.1 brought up the need for further discussion on the practical and legal implications of the text in the current rules of procedure, adopted by the PRAC on 20 July 2012. These do not allow for rapporteurships to be assigned to experts nominated by the European Commission or to the representatives and alternates of civil society.

The view of the members who put forward the alternative proposal was that there is no legal basis for depriving nominated experts from taking part in all activities of the PRAC, rapporteurships included. Their exclusion might have an impact on the work of other committees, where co-opted members are awarded rapporteurships. The six additional experts are nominated by the European Commission for their specific experience that is needed within the composition of the PRAC. For this reason, the delegation proposed to include them among the members who can be awarded rapporteurships, and concluded by inviting the Board to postpone the vote on the rules of procedure, while exploring the possibility of a different agreement between the PRAC, the European Commission and the Management Board.

The representative of the European Commission (SANCO) pointed out that, due to the late submission of the alternative proposal, there was a formal/procedural problem, as, according to the rules of procedure for the Management Board, documents are to be submitted at least two weeks in advance of meetings.

The Commission was of the view that the six experts appointed by the European Commission cannot act as rapporteurs notably due to the following:

- The role of the six experts is different from the role of the other members, as was also clear in the initial legislative proposal from the Commission, which foresaw only independent experts.
- There is a risk of shifting power in the PRAC if some Member States can count on an additional expert to act as rapporteur.
- The Commission disagrees with the German analysis that excluding independent scientific experts would have an impact on other committees.
- Finally, there is a rising concern about the tendency of over-regulating through rules of procedure topics already covered by legislation, leading to different interpretations and limiting flexibility.

In the discussion, members expressed the following positions:

- The issues raised in the German proposal were considered very valid, and it was suggested that their precise implications for other committees might not have been clear at the time of the vote for adoption at the PRAC, and hence this might be further discussed.
- The choice of rapporteur should be primarily based on expertise and ability to mobilise resources within an expert team free of conflicts of interest, as well as the capacity to take up responsibility over the whole lifecycle of a product.
- The discussion on rapporteurships in PRAC should not be carried out in conjunction with the discussion on fees for pharmacovigilance activities, but should concentrate on scientific and legal aspects.

The Board decided not to bring the issue to a vote at the current meeting and appointed a small subgroup comprising Germany (PEI), Ireland, the Netherlands, France and the European Parliament representative Prof. Lemmer, with support from the European Medicines Agency, to explore in dialogue with the European Commission and the PRAC the possibility of aligning positions on a legally sound solution which may be acceptable to all. The European Commission expressed willingness to legally assess the German proposal. Consideration must be given to the need not to delay significantly the

endorsement of the PRAC rules of procedure. If the PRAC were to adopt an amended version of the rules, these could than undergo consultation for favourable opinion by the Management Board and the European Commission by written procedure.

B.6 Proposal to progress on costing evaluation activities

[EMA/MB/522525/2012] The Management Board discussed a proposal by the Agency to progress on costing of evaluation activities by contracting a study to a consulting company. The need to make the current systems of remuneration to the Member State national competent authorities (NCAs) cost-related (for their evaluation activities) has previously been raised by the Court of Auditors, and also more recently by the European Parliament in their discussion on the 2010 discharge.

The Management Board agreed with the principle of employing a third party to support the costing of evaluation activities. The Board recalled that the costing exercise had been carried out by a working group established by the Board in the past. However, these efforts did not lead to introducing an alternative remuneration system. Members, however, expressed concern at the scope and the objectives of the proposed study, not wishing to confuse the issue of remuneration to the NCAs with the analysis necessary for the overall discussion on an appropriate fee structure and levels. It was also suggested that the earlier proposal of remuneration, which takes into account purchasing-power coefficients, should be considered. The European Commission representative pointed out that information about the costing of evaluation activities is also needed for the preparation of the impact assessment that precedes the legal proposal on fees. The proposal will be amended and circulated to all members for comments before being discussed at the December meeting.

B.7 Nomination to the Management Board Telematics Committee (MBTC)

Two positions are to be filled by the Management Board within the MBTC, of which one is reserved for the patients' representatives of the Board, who have not yet been nominated. Members were invited to express their interest for one nomination.

B.8 Status update on the information and communications technology (ICT) strategy exercise

The Management Board noted the progress with the definition of the new ICT strategy. A new vision has been developed in line with three priorities set out by the Agency's executive director: increase collaboration with the network, align systems with European Commission technology choices, and integrate systems with a view to reducing costs. In the immediate future, priority will be given to operations rather than development, in order to guarantee stable and robust support to upcoming challenges. The strategy is guided by high-level principles, such as investing in people to improve performance, aligning with established technology choices, minimising the procurement done by the Agency by making use of tenders run by the European Commission, using well-proven technology, and stopping running long projects. The strategy aims at moving towards an integrated data vision. The end-to-end vision of data management also includes the final publication of a portal. The ICT vision will be validated in Q1 2013 and transposed into a new architecture. A road map detailing all activities will be drafted. It is expected that improvements to the whole system will extend over a period of 2-3 years.

The Board supported the outline of the new strategy, which will need to be complemented by new ICT governance. Proposals from the MBTC are expected soon.

B.9 Annual report on interaction with patients and consumers

[EMA/MB/605792/2012; EMA/597517/2012] The Management Board noted the 'Fifth report on the interaction with patients' and consumers' organisations', which includes a comparison to preceding years, as requested by the Management Board. The year 2011 saw extensive collaboration, with growing numbers of interactions (307 in 2010 to 423 in 2011). Growth is mainly due to increased involvement in benefit-risk evaluation in scientific advisory groups and the reviewing of safety communications and package leaflets. It is expected that a plateau might be reached in 2014, although new activities in cooperation with the PRAC might bring a further increase. Collaboration is generally perceived to be very good by all sides. Administrative procedures for the review of eligibility of organisations have been strengthened, as have mechanisms to achieve greater transparency on funding of patients' organisations. The 2012 report will contain the results and analysis of a survey on patients' and consumers' satisfaction with their interactions with the Agency.

B.10 Reflection paper on product supply and feedback on the product-supply workshop

[EMA/598676/2012; EMA/590745/2012] The Management Board endorsed the 'Reflection paper on medicinal product supply shortages caused by manufacturing/GMP-compliance problems'. The document was previously presented to the Board on 15 December 2011, and was subsequently amended, following comments by members and by the European Commission. The current version was endorsed by the HMA on 21 September 2012.

On 10 September 2012, a workshop with the European Commission and the Member States was held at the Agency, focusing on the reflection paper and implementation plan, as well as on discussing the implementation of Article 46 of the Falsified Medicines Directive. Additional actions identified for inclusion in the reflection paper/implementation plan included development of the concept of 'essential' medicine and development of a decision tree to identify shortages to be handled at EU level. Reflection on interaction at national and EU levels on communicating shortages, revision of the quality-defect procedure to avoid unnecessary information overload and a survey on initiatives taken by the NCAs were also included in the implementation plan. The link to the EU incident-management plan and the role of the Incident Review Network were supported.

At the workshop, the Commission provided information on current and upcoming initiatives concerning the smooth implementation of Article 46. The Agency presented the methodology for risk analysis for centrally authorised products; this is needed to identify possible risks of shortages due to Art. 46 application, and for evaluating alternative products in case certain products become unavailable. NCAs welcomed the methodology but anticipated that its application to nationally authorised products might identify thousands of products at risk. It was decided to raise awareness with the marketing-authorisation holders, while continuing to explore possible contingency measures.

Some Board members shared their experiences with national measures put in place to deal with shortages. The Board stressed the importance of 'essential medicines', which should also be protected from shortages deriving from economic factors. The issue of stockpiling 'essential medicines' will be raised in a workshop with industry in Q1 2013, along with other measures to secure supply.

List of written procedures during the period from 18 May 2012 to 19 September 2012

- No. 08/2012 on the appointment of Bruno Sepodes as CHMP member; ended with endorsement on 13 August 2012.
- No. 09/2012 on the appointment of Dinah Duarte as CHMP alternate; ended with endorsement on 13 August 2012.
- No. 10/2012 on the appointment of Leona Nepajchalova as CVMP alternate; ended with endorsement on 29 August 2012.
- No. 11/2012 on the appointment of Stanislav Primožič as CHMP member; ended with endorsement on 10 September 2012.
- No. 12/2012 on the appointment of Hans Kristian Ostensen as CVMP member; ended with endorsement on 13 September 2012.
- No. 13/2012 on the appointment of Stephen Spiteri as CVMP member; ended with endorsement on 14 September 2012.
- Written procedure for the Agency's final accounts; ended with adoption on 26 June 2012.
- Written procedure for the 76th Management Board meeting minutes; ended with adoption on 27 July 2012.
- Written procedure for Fee Regulation implementing rules; ended with adoption on 23 August 2012.
- Consultation procedure on Pharmacovigilance Risk Assessment Committee (PRAC) rules of procedure; ended with suspension on 24 August 2012. The topic was presented for discussion and endorsement at this Management Board meeting.

Documents for information

- [EMA/613881/2012] EU Telematics Operations Report.
- [EMA/612414/2012] EU Telematics Projects Report.
- [EMA/600775/2012] Minutes of the Management Board Telematics Committee (MBTC) from 18 July 2012 meeting.
- [EMA/MB/607587/2012] Outcome of written procedures during the period from 18 May 2012 to 19 September 2012.
- [EMA/MB/582825/2012] Summary of transfers of appropriations in the budget 2012.
- [EMA/609678/2012] Advisory Committee on Procurements and Contracts (ACPC):

  a) [EMA/269255/2012] Decision on setting up ACPC.

  b) [EMA/576425/2012] Composition of ACPC.

  c) [EMA/269247/2012] Rules of procedure of ACPC.

Tabled documents

- Presentation from the European Commission.

- Amended B.10 — Reflection paper on product supply and implementation plan.

List of participants at the 77th meeting of the Management Board, held in London, 4 October 2012

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Apologies received	
Czech Republic		Jiří Bureš
Denmark	Else Smith	Tina S Engraff
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland	Pat O'Mahony	Rita Purcell
Greece		Aikaterini Moraiti
Spain		Laura Franqueza García
France	Dominique Maraninchi	Jean-Pierre Orand Jean-Baptiste Brunet Miguel Bley
Italy	Luca Pani	Paolo Siviero Daniela Salvia
Cyprus	Arthur Isseyegh	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	Claude A Hemmer	
Hungary	Tamás L Paál	
Malta	Apologies received	
The Netherlands	Aginus Kalis	
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	
Portugal	Helder Mota-Filipe	
Romania	Marius Savu	
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Jonathan Mogford
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission		Andrzej Rýs Salvatore D'Acunto Lenita Lindstrom
Representatives of patients' organisations	Nominations awaited	
Representative of doctors' organisations	Nomination awaited	

	Members	Alternates (and other participants)
Representative of veterinarians' organisations	Nomination awaited	
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway) Lisette Tiddens-Engwirda (Former representative of doctors' organisations)	Viola Macolić Šarinić (Croatia)

European Medicines Agency	Guido Rasi Patrick Le Courtois David Mackay Andreas Pott Luc Verhelst Noël Wathion Sylvie Bénéfice Isabelle Moulon Frances Nuttall Emer Cooke Silvia Fabiani Zuzana O'Callaghan Nerimantas Steikūnas	