29 October 2014
EMA/MB/612373/2014 Adopted
Management Board

Minutes of the 85th meeting of the Management Board

Held in London on 2 October 2014

Sir Kent Woods, chair of the Management Board, opened the meeting by congratulating the Agency and in particular Agneta Brandt, Head of Infrastructure Services, for a smooth and efficient transition to the new premises of the Agency. He informed the Board of his intention to continue to provide updates in the form of a newsletter to members in between meetings. Members will be invited to provide their opinion on how the working methods of the Board could be improved. A proposal will be sent out shortly.

1. Draft agenda for 2 October 2014 meeting

[EMA/MB/354958/2014] The agenda was adopted.

2. Declaration of conflict 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 84th meeting, held on 12 June 2014

[EMA/MB/325638/2014] The Management Board noted the final minutes, adopted by written procedure on 30 July 2014.

A. Points for automatic adoption / endorsement

A.1 Revised implementing rules to the Financial Regulation applicable to the budget of the European Medicines Agency

[EMA/MB/366110/2014; EMA/MB/99010/2014 – rev.01]

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The Management Board adopted the revised Implementing rules to the Financial Regulation applicable to the budget of the European Medicines Agency. The revision was necessary after editorial amendments were made in the model implementing rules developed by an inter-Agency and Commission working group. The European Commission has provided prior consent.

B. Points for discussion

B.1 Highlights from the Executive Director

Appointments

The Executive Director introduced the new Head of the Communication Department, Marie-Agnes Heine, who joined the Agency on 1 September 2014, and Manuel Ortigao, the new Head of the Human Resources Department since 18 August.

Work programmes and budgets 2015 and 2016

As of the 2017 budget year, all agencies will be required to submit both draft and preliminary work programmes and budgets in a single document according to new timelines. The Agency will aim to do so already this year, presenting the draft work programme and budget 2015 and preliminary draft work programme and budget 2016 at the December meeting. Topic coordinators will be kept informed.

Anti-fraud policy

As part of the road map on EU decentralised agencies developed by the inter-institutional group, and as recommended by OLAF to all EU agencies, the Agency is developing an anti-fraud strategy with the aim to submit it to the Management Board for adoption in December.

Roadmap 2020

The current roadmap 2015 will come to an end in December 2015. The Agency is working on a new roadmap to 2020 which will be developed with involvement of the public and the network and should be agreed on by the Management Board at the latest in December 2015. Close collaboration with dedicated or existing topic coordinators would be desirable.

Extension of ADR reports

On 6 October the ADR reports website, which has been live for two years with aggregated data on all centrally authorised products, will be extended to include 1,700 additional substances in nationally approved products. This is in line with the Eudravigilance access policy adopted by the Management Board and in line with the transparency efforts at the Agency.

Ebola

In August, the EMA was asked by the WHO to put together an emergency ad hoc group with relevant expertise composed of scientific committee and working party members and EMA staff. Furthermore, a procedure under Article 5(3) of Regulation (EC) 726/2004[1] was initiated at the September CHMP

[1] At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Human Use shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use. The Committee shall take due account of any requests by Member States for an opinion.

meeting. Interaction is ongoing with the US FDA and Health Canada, in the framework of the regulatory convergence advocated by the International Conference of Drug Regulatory Authorities held in Rio in August.

International Activities

The EMA has established an EU team with NCAs and Commission representation to support the mutual reliance of inspections with the US FDA. An FDA representative observed an audit to an MS inspection system within the framework of the Joint Audit Programme (JAP). The Agency would like to call on the members of the Management Board to support JAP activities to help showcase the European GMP system and support better use of global inspection resources.

Benchmarking of European Medicines Agencies (BEMA) visit

The EMA received a visit from BEMA assessors. It was a positive experience, proving very helpful to staff and management in highlighting strengths and opportunities for improvement for the Agency. The assessors valued particularly the proactive approach to transparency by the Agency, its integrated quality management system and the newly established approach to project management. EMA appreciates the added value that BEMA provides to the network, and supports its continuation for the future.

Some members proposed that the work done on the Road map could be combined with the initiative just started at HMA for the drafting of a Strategy Paper in order to achieve an integrated vision. The Executive Director welcomed the proposal which would be of mutual benefit of all parties involved and help save energy and time.

On the question of providing the Management Board with the Plan for the implementation of improvement actions following the Consultancy engagement on IT Project Management at the EMA by the IAS, this was sent to the members after the meeting in June. The Agency is reviewing and modernising the project delivery approach following the audits and ongoing consultation with the European Chemicals Agency, which has achieved a benchmark status after major restructuring in recent years.

B.2 Report from the European Commission

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

- Expected transfer of Units D5, D6 and B2 of DG SANCO to the new DG Internal Market, Industry, Entrepreneurship and SMEs in the period 1 November 2014 to 1 January 2015
- Adoption of the legislative proposal on revision of the veterinary medicines legislation with discussion to start at the Council on 9 October 2014. The Regulation amending Regulation (EC) 726/2004 will provide for 'Lisbonisation' of the provisions concerning fees payable to the Agency, which will be set by implementing acts, in line with recent findings of the Court of Justice regarding the appropriate legal instrument for fees.
- Progress of EC Antimicrobial Resistance Action Plan with a report expected before end of 2014
- Achievement of first read-through of proposals on medical devices legislation at the Council, with examination of compromise texts ongoing under the Italian Presidency

- Progress with implementing measures for the Falsified Medicines Directive and update on current situation on importation of active substances (no significant shortages).
- Discussion at the Pharmaceutical Committee on timely access of patients to medicines and adaptive licensing. Experience gathered in the EMA pilot project on adaptive licensing will be shared with Member States and relation between the regulatory framework and timely patient access further discussed at the next meeting on 22 October 2014.
- Proposal for a new Joint Action on HTA (from 2016). In the HTA network meeting on 29 October 2014 in Rome discussion will concern adoption of an HTA Network Strategy, EMA report on its HTA relevant activities and possible EMA role in the next Joint Action.
- Update on eHealth network initiatives and timetable and on mutual recognition of prescriptions.
- Status of international developments including ICH, IPRF, ICMRA and TTIP.
- Collaboration on Telematics, where it was stressed that further progress towards enhanced governance of IT projects was needed.
- Adoption of a Commission Staff Working document 'The pharmaceutical industry: a strategic sector for the European economy'. Next steps will include a multi-stakeholder workshop on pharmaceutical industry on 22 October and a meeting of the network of competent authorities responsible for pricing and reimbursement on 23-24 October, both in Rome. The objective is to prepare the strategic agenda for the years to come.

There was some concern, particularly from representatives of civil society, that the transfer of competence for the EMA from DG SANCO to DG ENTR might signify a shift in priorities from patients to markets. The European Commission reassured that the new organisation is in the spirit of a new way of working horizontally and that patients' safety and public health will in any case remain the first priority. Two letters from President-elect Jean-Claude Juncker to NGOs and to the European Parliament, in which the importance of working together for the two DGs was stressed, were circulated to the Board.

Further concerns were expressed on the future setting of fees through implementing acts, and on the splitting of human and veterinary legislation. The representative of the European Commission reminded the Board that discussions in the Council were due shortly. Regarding implementing acts, it was explained that Member States are involved through 'comitology' rules. Concerning the functioning of the Advanced Therapies Medicinal Products legislation, it is important that CAT intensifies cooperation with the tissue and cells authorities. Furthermore, high prices of medicines are at the centre of an intergovernmental debate. After finalisation of discussions in the HTA network, the Board might wish to carry out a reflection on how to better engage on the subject of HTA. Finally, Member States' input in TTIP was deemed relevant on the subject of inspections.

B.3 EMA mid-year report 2014 from the Executive Director (January–June 2014)

[EMA/MB/557450/2014; EMA/444000/2014] The Management Board noted the Agency's mid-year report for 2014. The report provides an overview of the Agency's performance and achievements in implementing the work programme. The overall activities of the Agency are generally on track.

Pre-authorisation activities supporting innovation are increasing. In the first semester a rise in scientific advice reached 16% and orphan designation 30% above the same period in 2013. Paediatric applications followed the same trends, with an increase of 8%. The positive trend concerning rare

diseases was observed also for marketing authorisation applications, while non-orphan medicinal products decreased slightly. The volume of referrals has fallen, due to changes in legislation and a different grouping of products in one procedure, while the actual workload has remained at the previous level.

For veterinary medicinal products activities have returned to regular levels, after a significant increase in 2013. The decrease for scientific advice, MUMS classification and initial application is in line with previous years and can be considered on target.

Inspection activities are stable for GMP, but have decreased by 22% compared to the same period in the previous year for GCP, although in line with preceding years. There is some concern on the availability of inspectors since a number of senior inspectors have left their agencies. Furthermore, EMA fees are considered insufficient in terms of workload/resources involved. EMA fears a possible loss of capacity, which will reduce the inspection coverage of clinical trials included in applications for the centralised procedure, in particular for trials outside of the EU and USA.

IT is undergoing wide-reaching changes to its 15 years old operating model. The future strategy foresees not only managed outsourcing of the IT infrastructure, but also of projects, where this is in the interest of the business and of the network. The future developments should be better integrated already in the design phase with the network systems, rather than undergoing challenging re-integration after their delivery. This will be achieved through a strong focus on a new architecture and a revised procurement strategy. Furthermore, adjustments to the skillsets required will be needed. In June the Board received the Improvement action plan following the IAS consultancy report on IT project management. The Agency has consulted the European Chemicals Agency (ECHA), which enjoys benchmark reputation, and will continue to cooperate with it.

A new project governance and structure and cross-Agency Programme Management Office (PMO) were established on 1 April. A gated project approval ensures resource availability to run a large number of essential programmes and projects alongside core business. Re-prioritisation and redeployment of projects is ongoing to ensure the delivery of foundation projects (such as SPOR) and those with legislative deadlines. Reporting has been harmonised and improved. A model PMO report was shown to the Board.

Among the main new projects, five projects are ongoing or foreseen for the implementation of the clinical trials legislation. A further seven projects are ongoing within the pharmacovigilance legislation programme. A most important programme deals with data integration. Four stages are foreseen to establish a master data management service. A data road map considering existing solutions will be delivered before December.

The Agency clarified that the timelines for delivery of the EU Portal and Database have to be agreed with the Member States and the Commission, in accordance with Article 82 of the Clinical Trial Regulation (EU) No 536/2014. These timelines will have to take into account that the Regulation can apply no earlier than 28 May 2016, but not before the Management Board, on the basis of an audit, has satisfied itself that the systems are functional. The Regulation applies six months after publication of a confirmation by the Commission in the Official Journal that they are satisfied that the system meets the functional specifications agreed. There is therefore a period of about 10 months after the Portal and Database have been fully developed and deployed, but before the Regulation can come into application. A plan is being put in place, taking these constraints into account.

The representative of the European Parliament noted the significant increase in new herbal monographs, and expressed gratitude for the work performed over the years by Dagmar Roth-Behrendt in her role as Contact Person for the European Parliament to the European Medicines Agency.

B.4 Update on compensation of employers of committee chairs

The topic was deferred to a future meeting, given that discussions among DG SANCO and the Agency are still ongoing.

B.5 EMA policy on the publication of and access to clinical trial data

[EMA/MB/557824/2014; EMA/240810/2013; EMA/357536/2014; EMA/541817/2014] The Management Board adopted the EMA policy on publication of clinical data for medicinal products for human use and noted the Q&A document on the policy. The draft policy was discussed at the 12 June Management Board meeting, where the direction of travel was endorsed, as well as the proposal by the Executive Director for a more user-friendly proposal for academic and non-commercial research purposes. After a written procedure on a revised draft was initiated on 20 June and suspended on 7 July following the numerous comments received by members of the Board, a teleconference with interested members and experts was held on 4 July to facilitate discussion at the October meeting. Remaining divergent views concerned two areas: the absence of a legal definition for commercially confidential information (CCI), for which a definition used for years in common HMA/EMA guidance is used; and concern about modalities of redaction of information. It was proposed to adopt the policy, as modified after the teleconference, in full knowledge that the policy is due for revision no later than within 18 months, or at an earlier time point if needed, taking into account experience obtained.

The Board expressed appreciation for the work done at the Agency to address all concerns in a collaborative approach and was ready to unanimously adopt the policy. The Commission representative expressed satisfaction with the collaborative and inclusive consultation process followed by the Agency and conveyed the Commission's understanding that in case of disagreement on redaction of CCI between the EMA and the Applicant/MAH, the Applicant/MAH will be given a defined period prior to the publication to seek an interim injunction from the Court. The Agency will publish the CSR, except for the disputed part(s), until such injunction is lifted or refused by the Court.

Residual issues concerning workload will be addressed at the Agency through internal redeployment of staff. The EMA will explore options for automatisation of certain processes. Member States interested in acquiring experience are invited to second National Experts to the Agency. The Chief Policy Adviser and the chair thanked the Board, the Member States and the multidisciplinary team at the EMA for the work done and for setting a new standard for transparency in public health.

B.6 The role of the EPL and PM in the centralised procedure

[EMA/MB/554771/2014; EMA/537840/2014] The Board discussed and noted the role of EMA Product Lead (EPL) and Procedure Manager (PM) in the centralised procedure. This topic had been discussed in the 19-20 March meeting of the Management Board, as well as on 12 June when it was decided to circulate a document on initial experience to the Board. The new roles are modelled on the description of responsibilities of the Product Team, led by the Product Team Leader, as provided in the Notice to Applicants Volume 2A, Chapter 4. Following the internal Review & Reconnect exercise and the reorganisation at the Agency, the activities have been allocated to the two roles without changing the overall boundaries foreseen in the previous model, in order to better support the work of the committees. The PM's role is to manage multiple procedures facilitating the work of NCA assessment

teams, companies and the EPL, with frequent interaction of a similar nature while working on multiple files. The EPL's function is to support the product across multiple dimensions throughout its lifecycle, working not only with the committees, the (co)rapporteurs and the applicant, but across committees, product classes, spanning the whole product lifecycle and mindful of international regulatory convergence. Resources for the current PM and EPL roles have been entirely drawn from the existing pool of staff performing PTL roles before the reorganisation. A small number of former PTLs could be redeployed to other duties including access to documents, data management, the Chief Policy Adviser's Office and fee management.

Members welcomed the clarifications provided. Practical experience will help to further understand the functioning of the new responsibilities of the EPL and PM and make use of the correct contact points. The Agency is open to suggestions, and Member States were invited to address the committee chairs or the Scientific Coordination Board in any case of perceived confusion.

B.7 Report by the Steering Group on the Management Board data-gathering initiative

[EMA/MB/552867/2014; EMA/MB/552794/2014] The Board heard and noted progress with the data-gathering initiative by the Steering Group since the last meeting. The Steering Group has compiled several documents: a Tabular Abstract of Pharmaceutical Legislation driving EMA activities and associated fee codes, a list of high-level major EMA activity areas — 'non-fee' and 'fee' generating — and three sample process maps concerning complex type-II variations, scientific advice and paediatric investigation plans with identification of involved actors, respective roles and milestone process steps. These will not be used for actual data collection but rather as a reference to explain the complex nature of the processes. Discussion on feasibility of prospective or retrospective data-gathering is ongoing. In the absence of robust and auditable historic data, the Steering Group considers prospective data collection as both a feasible and audit-ready approach which, where needed, could be supplemented with retrospective data. Data collection would be carried out at the level of the process and actor, whereby there should be a distinction between involvement of specialised staff and administrative support.

Some members proposed to carry out a feasibility exercise based on retrospective data. Discussion will continue within the Steering Group.

B.8 Annual report on the performance of the Agency's scientific procedures

[EMA/MB/567962/2014; EMA/538944/2014] The Management Board noted the Annual report on the performance of the Agency's scientific procedures and endorsed the extension of the pilot phase until expiry of the cooperation agreements at the end of 2015. At that time, experience and KPIs will be reviewed in the context of the renewal of the Cooperation Agreement.

B.9 Report on pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2012 to 30 June 2014

[EMA/MB/542875/2014; EMA/285572/2014] The Board noted the report on pharmacovigilance audits carried out in the Agency from 1 July 2012 to 30 June 2014. The Head of Audit reminded the Board of the requirement to perform regular independent audits of the Agency's pharmacovigilance tasks and report the results to its Management Board on a 2-year basis. The report presented is the first of this kind. The audits were performed according to risk criteria and in conformity with a methodology prepared in collaboration with the whole network. The audited processes were signal management and

pharmacovigilance systems and their quality systems. The overall results show that control systems are in place and there is reasonable assurance regarding the achievement of the business objectives. The report includes a detailed list of recommendations issued, which management is implementing.

B.10 Audit strategy and annual audit plan for 2015

[EMA/MB/544312/2014; EMA/427639/2014] The Board noted the audit strategy 2015-2017 and adopted the annual audit plan for 2015. The audit topics were selected on the basis of a risk assessment included in the audit strategy, for which the analysis was conducted through assurance maps. Criteria are based on legal requirements and risk assessment. Of particular interest is the PSUR repository and literature-monitoring audit, for which the Agency will use a Commission framework contract. The fieldwork for the PSUR repository audit is due to take place in February 2015, shortly after the system comes into production.

B.11 Report by the COMP Chair

Bruno Sepodes, Chair of the Committee for Orphan Medicinal Products (COMP) presented his views on the state of play, challenges and opportunities of the Committee. One specificity of the composition of the Committee lies in the fact that it includes three patients' representatives and three members appointed by the European Commission, and that the vice-chair is always a patient representative. Furthermore, the COMP is supported by three observers who have among others the task of finding appropriate patients' representatives for COMP discussions, and informing it of activities at other organisations. The chair pointed out that the cooperation with the representative of the European Commission was excellent. Among the voting members, approx. 53% are from Academia or hospitals, while approx. 38% come from national competent authorities. No alternate members are nominated or considered in the Regulation, and this might lead to problems with the quorum and the voting majority. Furthermore, members do not receive any reimbursement or compensation for assessments. The success of the COMP is demonstrated by high and ever-increasing numbers of applications submitted to it, and of EC designations obtained. Among the orphan marketing authorisations awarded to date, 40% concern oncological products and 20% alimentary tract and metabolism, which includes mostly inborn errors of metabolism. The reduced-fee protocol assistance for products with an orphan designation is carried out by the SAWP with the participation of three COMP members, and is considered of high importance for the success of the development of an orphan drug. The chair felt, though, that more COMP members should be involved, and that an EMA scientific secretariat staff member should be solely dedicated to protocol assistance. Other issues brought to the attention of the Board were the difficulty in assessing significant benefit in the absence of adequate data generated for this purpose and the importance of international collaboration, which requires COMP members to act as 'ambassadors' in different fora. Further emerging topics which the COMP intends to discuss are the concept of an 'orphanage', where orphan drugs could be 'adopted' by sponsors, biomarkers qualification and the intersection between personalised medicine and orphan regulation, and the guideline for trial design for small populations. The chair concluded with a few suggestions to the EMA to enhance its supportive role, for example by increasing the number of scientific support staff, providing an exemption of fees or reduction to academia and SMEs to have free access to protocol assistance, and increase opportunities for interaction with patients.

Several members congratulated the chair on the achievements of the COMP, particularly for the commitment of its members in the absence of any remuneration. There was interest for the idea of instituting an 'orphanage' and for the possibility to revisit designations and significant benefit. The representative of the European Commission asked the COMP chair to comment on the possible

application of the orphan model to support the development of new antibiotics. This was considered interesting, as was a thorough discussion on personalised or precision medicine. The Executive Director thanked the committee and its chair for the valuable work done and assured them of the ongoing support by the Agency.

B.12 Continued activity of the JEG 3Rs

[EMA/MB/541486/2014; EMA/541485/2014] The Management Board endorsed the extension of the lifespan for JEG 3Rs by a further two years. CVMP, CHMP and the EMA Strategy Board supported prolonging the life of the ad hoc expert group, to allow ongoing projects to continue. One member proposed that members of the JEG 3Rs group might wish to have a look at the proposal for a new regulation for veterinary medicines to study in which way the 3Rs are taken into account and feed any comments to their national representative attending the Council Working Group where negotiations on the proposal are taking place.

B.13 Joint annual report on the interaction with patients', consumers' and healthcare professionals' organisations (2013)

[EMA/MB/533940/2014; EMA/103410/2014] The Management Board endorsed the annual report on the EMA's interaction with patients, consumers, healthcare professionals and their organisations (2013). The EMA Healthcare Professionals' Working Party (HCPWP) was established in 2013. The network of eligible healthcare professionals' organisations has expanded to a total of 26, including European learned societies, and joins the network of patients' and consumers' organisations, which had grown to 36 at the end of 2013. Patients are now involved in key milestones of the lifecycle of medicines, and review 100% of product information and safety communications. More and more areas of common interest between patients, consumers and healthcare professionals have been established, leading to several examples of positive and concrete collaboration. Looking ahead, focus will be on the optimisation of limited resources in the organisations, further development of collaboration with healthcare professionals and in particular with GPs, and exploration of ways to recognise individual experts involved in EMA activities.

A.O.B.

C.1 Report on EU Telematics

The Board was informed that some representatives of Member States at the recent IT directors' meeting do not feel they have an adequate overview on the overall Telematics scenario. The chair of the EU TMB informed the Board that a workshop on implementation of the EU Telematics Strategy was discussed at the last meeting. This will take place in two parts, of which the first will be devoted to presenting the strategy to industry stakeholders.

Documents for information

- [EMA/MB/554108/2014; EMA/MB/554068/2014] Report on EU Telematics TMB
- Report from the Heads of Medicines Agencies
- [EMA/MB/406461/2014] Outcome of written procedures during the period 13 May 2014 to 1 September 2014

- [EMA/MB/525840/2014] Summary of the transfers of appropriation 2014
- [EMA/541380/2014; EMA/13787/2009] Veterinary EudraVigilance status report
- [EMA/MB/555039/2014; EMA/458478/2014; Ref. Ares(2014)2449029IAS] Audit on Stakeholders Management and Communication

Written procedures from 13 May 2014 to 1 September 2014

- Consultation no. 05/2014 on the appointment of Hrefna Guðmundsdóttir as CHMP alternate, proposed by Iceland, ended on 3 July 2014. The mandate of the nominee commenced on 4 July 2014.
- Consultation no. 06/2014 on the appointment of Maria Popova-Kiradjieva as CHMP Alternate, proposed by Bulgaria, ended on 29 July 2014. The mandate of the nominee commenced on 30 July 2014.
- Consultation no. 07/2014 on the appointment of Emil Kozhuharov as CVMP member, proposed by Bulgaria, ended on Thursday, 7 August 2014. The mandate of the nominee commenced on 8 August 2014.
- Written procedure for the adoption of the mandate of the data gathering Steering Group ended on 3 July 2014. The mandate was adopted
- Written procedure for the adoption of EMA policy on the publication of clinical data for medicinal products for human use was suspended on 4 July 2014.
- Written procedure for adoption of 84th Management Board meeting minutes ended on 30 July 2014. The minutes were adopted.

List of participants at the 85th meeting of the Management Board, held in London, 2 October 2014

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier de Cuyper	
Bulgaria	*Apology received*	
Czech Republic	Doubravka Kostalova	
Croatia		Viola Macolić Šarinić
Denmark	Else Smith	Matilde Kyst Behrens
Germany	Walter Schwerdtfeger	Klaus Cichutek Karl Broich
Estonia	Kristen Raudsepp	
Ireland		Rita Purcell
Greece	Katerina Fameli	
Spain	Belén Crespo Sánchez-Eznarriaga	Laura Franqueza García
France	Dominique Martin	Jean-Pierre Orand Miguel Bley Jean-Claude Ghislain
Italy	Luca Pani	Pietro Erba
Cyprus	Loizos Panayi	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg		Jacqueline Genoux-Hames
Hungary	Beatrix Horváth	
Malta	John-Joseph Borg	
Netherlands	Hugo Hurts	Birte van Elk
Austria	Christa Wirthumer-Hoche	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Maria Morais
Romania	*Apology received*	
Slovakia	Jan Mazág	
Slovenia		Katarina Štraus David Obranovič
Finland		Pekka Kurki
Sweden		Bengt Wittgren Asa Kumlin Howell
United Kingdom		Ian Hudson Jonathan Mogford
European Parliament	Giuseppe Nisticò *Apology received*	
European Commission		Andrzej Rys (DG SANCO) Salvatore D'Acunto (DG ENTR) Miroslav Griva

	Members	Alternates (and other participants)
Representatives of patients' organisations	W.H.J.M. Wim Wientjens Nikos Dedes	
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	Christophe Hugnet	
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (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 Tony Humphreys Edit Weidlich Emer Cooke Hilde Boone Melanie Carr Nicholas Jarrett Sylvie Benefice Isabelle Moulon Dina Tsiambaou Silvia Fabiani Sophia Albuquerque	