20 March 2015
EMA/MB/178925/2015 Adopted
Management Board

Minutes of the 87th meeting of the Management Board

Held in London, 19 March 2015

Sir Kent Woods, Chair of the Management Board of the European Medicines Agency (EMA), opened the meeting and welcomed the participants, in particular the new members Ladislav Miko, member for DG SANTE, Katarina Štraus, member for Slovenia and Runa Hauksdottir Hvannberg as observer for Iceland.

Draft agenda for 19 March 2015 meeting

[EMA/MB/551/2015] The agenda was adopted with no amendments.

Declarations of conflicts of interests

The chair informed members of the Management Board that he had reviewed members' declared interests, together with the secretariat, in accordance with the Board's policy on conflicts of interests. No conflicts relating to today's agenda were identified. He informed the board that principles for a revised policy for conflict of interest of its members will be presented in June.

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.

Minutes from the 86th meeting, held 17-18 December 2014

[EMA/MB/791352/2014] The Management Board adopted the minutes of the 86th meeting. The minutes had been circulated for adoption by written procedure on 30 January. A number of comments were received and the adoption was deferred to the March meeting. The adopted minutes include an Annex 4 with the verbatim contribution of Cyprus to agenda item B.1 – Follow up of the Extraordinary meeting of the Management Board of 27 November 2014. The inclusion of this statement was agreed to by the chair in view of the exceptional nature of the subject discussed. The board was reminded that much of topic B.1, the table in Annex 1 as well as the Annex 4 will be redacted in the publication until the appointment of the next Executive Director of the agency. The name of the person who gave the legal advice on behalf of the Legal service of the Commission will be permanently redacted.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Election of the Vice-Chair of the Management Board

The Management Board elected Christa Wirthumer-Hoche, representing Austria, as their Vice-Chair. In accordance with the election procedure noted by the Board in advance of the meeting, the chair announced votes by proxy:

- Denmark gave their vote by proxy for agenda point B.4 to the Netherlands.
- Nikos Dedes (Representative of patients' organisations) gave his vote by proxy to Wolf-Dieter Ludwig (Representative of doctors' organisations)

The Board appointed Brigitte Batliner and Audun Hågå, observers from Liechtenstein and Norway, to act as tellers.

The Board requires 24 votes in favour to reach a decision. The results of the vote were as follow:

Total no. votes	Votes cast	Votes in favour	Votes against	Abstained	Not present
	[redacted]				

The vote took place by secret ballot.

The newly elected Vice-Chair thanked the Management Board and looked forward to working with the board and the Chair in this new capacity.

A. Points for automatic adoption / endorsement

A.1 Revised charter of (financial) tasks and responsibilities of the Executive Director as of 1 April 2015

[EMA/MB/767187/2014; EMA/MB/56129/2015] The Management Board adopted the revised charter of (financial) tasks and responsibilities of the Executive Director.

A.2 Revised charter of (financial) tasks and responsibilities of the accounting officer as of 1 April 2015

[EMA/MB/56041/2015; EMA/MB/655670/2014] The Management Board adopted the revised charter of (financial) tasks and responsibilities of the accounting officer.

B. Points for discussion

B.1 Highlights from the Deputy Executive Director

20th anniversary celebrations

The Deputy Executive Director informed the board on the celebrations surrounding the European Medicines Agency's 20th anniversary in 2015. The year began with the official inauguration of the new premises for staff on 26 January. The scientific conference 'Science, Medicines, Health: Patients at the heart of future innovation' marked the anniversary by convening a large number of persons who had collaborated with the agency over the years to explore along with stakeholders how best to deliver the agency's role in the future. On this occasion a 20th anniversary book was produced, commemorating two decades of achievements and describing how the agency intends to successfully address future public and animal health challenges.

Visit by Commissioner Vytenis Andriukaitis

The Commissioner for Health & Food Safety, Mr. Vytenis Andriukaitis, visited the agency for the first time on 17 March. He expressed appreciation for the work of the agency in the course of various meetings, and assured increasing engagement.

Visit by the ENVI Committee of the European Parliament

A delegation from the ENVI committee, led by MEP Matthias Groote, the new contact point for the EMA, visited the agency on 16-18 February. The MEPs were extremely positive on the work and interested in the future plans of the agency, particularly on adaptive pathways and antimicrobial resistance.

Update on the Discharge 2013 procedure

The discharge procedure is currently at the European Parliament. The report by the Court of Auditors has been extremely favourable, however the agency must wait for the voting at the Parliament to take place.

B.2 Report from the European Commission

The European Commission introduced its report on EU legislative and policy development in the public health area by informing the board on its new working approach under the new Commission, demanding horizontal collaboration between the DGs under the responsibility of the Vice-Presidents. The Commission's priorities for the health area have been finalised and will be published shortly.

- Progress of revision of veterinary medicines legislation with extended discussions taking place at Council level and reading started at the European Parliament;
- Action on antimicrobial resistance under a horizontal approach seeking common ground also through international collaboration. EMA advice and joint report of ECDC/EFSA/EMA have been published and guidelines on prudent use of antimicrobials prepared by DG SANTE;
- Update on Falsified Medicines Directive implementing measures with establishment of a common EU logo for online retailers of medicines applicable as of June 2015. Ongoing assessments of 3rd countries for importation of active substances progressing without risk of shortages;
- Progress in the implementation phase of the Clinical Trials Regulation in close collaboration with EMA and Member States to define rules relating to the transparency of EU portal and database, with the coordination group following progress to avoid duplication of work;
- Review of ATMP regulation still under consideration by the college of Commissioners, work ongoing in the meantime to improve the regulatory environment with the support of CAT and Inspectors Working Group;
- Update on STAMP Commission Expert Group (Safe and Timely Access to Medicines for Patients), with first meeting held in January;
- Progress on implementation of the HTA strategy adopted in October 2014 through the EUnetHTA Joint Action 3, with focus on exploring synergies with bodies that have developed know-how. A specific key objective of setting up long term provisions for HTA cooperation includes reflection on the role of EMA;
- Status of measures to facilitate mutual recognition of prescriptions;

- No major international development since the last Management Board meeting;
- Follow-up on the Commission Staff Working Document on pharmaceutical industry with a multi-stakeholder workshop to be held 15 April in Riga;
- The College of Commissioners reviewed several pending legislative proposals and among others Directive 89/105/EEC (the so called Transparency Directive) was formally withdrawn following a line of political discontinuity. The Commission will reflect on alternative ways of achieving the proposal's objectives and ensure the implementation of the existing Directive.
- Progress on the revision of the medical devices legislation with intention to open trialogues within Q2 2015. Presidency intensifies efforts to reach a political agreement at Council.

Some members expressed concern that SMEs and academia may experience difficulties with the new regulation on clinical trials and with the ATMP legislation, which some consider too complex for smaller players. The European Commission is aware of this issue and is looking into the matter. The board was interested to be updated on progress with the selection procedure for the Executive Director. The European Commission reassured the board that the process is ongoing and is proceeding as fast as possible. Hugo Hurts, observer for the Management Board, confirmed that work on the pre-selection of candidates has begun.

Post meeting note: Christa Wirthumer-Hoche, Hugo Hurts and Katerina Fameli will act as topic coordinators for the Assessment of the Annual Activity Report (AAR) 2014 to be presented in June.

B.3 Annual Report 2014

[EMA/MB/62472/2015; EMA/65445/2015] The Management Board adopted the Annual Report 2014 after some editorial amendments. The report shows a stable level of activities in most areas for 2014, with the exceptions of a significant increase in request for scientific advice and orphan medicinal products designation (respectively 16% and 63% increase over 2013). The report also highlights the major achievements of the agency, such as the adoption of a policy on the publication of clinical data, the launch of the adaptive pathways pilot project, strengthened collaboration with HTA bodies, as well as initiatives to facilitate the development of Ebola medicines and to limit antimicrobial resistance.

The report had been circulated to the board and resulting comments incorporated. In the course of the discussion at the meeting some members further requested a more complete description of the role of NCAs in the introduction, as well as information on Working Groups and type of products authorised to be included in the report.

B.4 Report from CAT Chair

Paula Salmikangas, Chair of the Committee for Advanced Therapies (CAT) presented to the board an overview of the achievements of the committee as well as the challenges that lie ahead. The CAT can rely on an extremely broad expertise of its members, which is needed, given the complexity and diversity of the products examined. Five Advanced Therapy Medicinal Products (ATMP) have been approved since the beginning of operations of CAT in 2009 and four products are under evaluation. The pipeline appears strong, with 123 adopted recommendations on advanced therapy classification, 216 Scientific Advice/Protocol Assistance discussed and 195 Phase I/II and 39 phase III clinical trials authorised in Europe. This should lead to a rising number of applications for marketing authorisations, possibly including breakthrough therapies. Typically ATMP clinical trials are conducted by small entities, who might encounter several challenges in the development of products, particularly as they

often concern orphan products with small populations. Further challenges are of a regulatory nature, as ATMP seem to be subject to a high number of variations, and companies struggle to cope with post-marketing obligations. ATMPs are impacted by complex layers of other legislation, such as GMP, Clinical Trials, Tissues and Cells and Medical Devices, while the ATMP legislation itself might be subject to review. The European Commission has started to work on issues that can be improved without need to change legislation, and CAT is collaborating by providing input. Support to translation of research into medicines could be achieved by streamlining requirements to obtain marketing authorisation, clarification of legal boundaries and extension of incentives to academia. In its work plan 2015-2016 CAT is dedicating the majority of its time to core tasks, but will also be contributing to adaptive pathways and will continue to work on publications and guidelines.

Member of the board were very appreciative of the work done by the Committee and of the information provided by Dr. Salmikangas. Further questions concerned cooperation with the CHMP, views on how to encourage development by smaller companies, and ability of the system to cope with rapid changes in science. Dr. Salmikangas was happy about cooperation with the CHMP, which shares five members with the CAT, and was confident about basic research being able to move smoothly to development. Once promising clinical trials are completed, a high number of applications for ATMP should be expected. Consolidation of the sector is not apparent, as products are typically developed by SMEs and academia, but may later be taken on by larger companies. Science may indeed move at such a speed as to cause obsolescence of products very fast, and regulators should reflect on appropriateness and timing of data required.

B.5 Strategy for EU Medicines Network to 2020 – working together to improve health

[EMA/MB/125751/2015; EMA/MB/151414/2015] The board endorsed the EU Medicines Agencies Network Strategy to 2020 for public consultation. Noël Wathion and Ian Hudson presented together the strategy which will be published for a 3-month consultation. The document had been drafted by a joint EMA/HMA Strategy Group and discussed at a dedicated strategic session at the HMA meeting in Riga in February. Following that meeting input had been invited from the European Commission and the EMA Scientific Coordination Board and input received had been incorporated in the current draft. In parallel, agreement to the launch of the public consultation by the HMA had been given through written procedure. Following endorsement by the Management Board of the version commented on by HMA, the strategy will be published on both HMA and EMA websites and comments collected on a dedicated email address. Following a review of the comments made, a consolidated version will be prepared by the Strategy Group and discussed in the meetings of July (HMA) and October (Management Board), with a view to adopt the final document before the end of 2015. Aspects of less strategic nature, as well as detailed implementation, will be handled through separate multi-annual work programmes.

The board congratulated the Strategy Group on an impressive achievement over only three months. The document provides a good reference for the road ahead. Some concepts will gain further clarity and operational force once included in the multi-annual work programme. The European Commission explained that there had been discussions on the document and reminded the board of the importance of aligning EMA and HMA initiatives to EU objectives and priorities, as well as to avoid initiatives which may require legislative changes.

B.6 Revised implementing rules to the Fee Regulation as of 1 April 2015

[EMA/MB/530041/2014 Rev.1; EMA/MB/530034/2014] The board adopted the revised implementing rules to the Fee Regulation as of 1 April 2015. In accordance with legal provisions on adjustments to inflation, all fees decrease by 0.1%, rounded off to the nearest EUR 100, or EUR 10 for administrative charges. Further amendments concern remuneration of multi-national assessment teams, a total waiver of fees for certain post-authorisation activities concerning vaccines against certain epizootic diseases for veterinary medicinal products and clarifications and updated definitions. These changes had all been given favourable opinion by the European Commission, while other amendments, concerning introduction of a new definition for 'distinct' GCP inspections, which would have caused an increase in payments to the NCAs, and the introduction of a new total waiver for pharmacovigilance related Type IA variations for veterinary medicinal products, had not been accepted.

Several members suggested that the European Commission gives further consideration to the two rejected amendments, as it was felt that one is needed as a matter of urgency to support NCA's work in carrying out GCP inspections, while the other would align veterinary to human practice. The European Commission clarified that it will need a more detailed justification and analysis of the impact and once received, it will review the outstanding issues in collaboration with the Agency.

B.7 Framework for interaction between the European Medicines Agency and industry stakeholders

[EMA/MB/151500/2015; EMA/591272/2014] The board noted progress with the framework for interaction between the European Medicines Agency and industry stakeholders. The framework document is a high level document in line with existing frameworks for Patients' and Healthcare Professionals' organisations. After discussion at the December meeting of the Management Board it was sent for comments via written procedure. The comments received have been incorporated and the document is now with the European Commission for internal consultation and agreement. The European Commission informed that there is a need to await the adoption of the Commission's Communication on better regulation and stakeholder consultation before the inter-service consultation is launched. It is hoped that the process might be completed by the June meeting.

B.8 Reflection paper on the use of individual patient data in electronic format for the evaluation of benefit-risk of human medicines

The board noted an update concerning the Reflection paper on the use of individual patient data which was discussed at the board's December meeting and endorsed subject to clarification by written procedure. The paper had been updated taking into account the discussion at the board, also concerning the creation of a working group, and then circulated to the board for comments by written procedure. A high number of comments were received, and on account of this, further reflection is needed at the agency. Further discussion is deferred to a future meeting when a mandate with clear boundaries for the work to be carried out by the Working Group will be proposed to the board.

B.9 EMA policy on the handling of DoIs of scientific committees' members and experts – Update on implementation

[EMA/MB/117456/2015; EMA/118531/2015; EMA/154320/2012, Rev.1] The Management Board noted the impact assessment on the implementation of the revised EMA policy on the handling of declarations of interests of scientific committees' members and experts and endorsed the revised European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts in line with the request by the European Commission of regular discussion on independence at the Management Board. Following the endorsement at the March 2014 meeting of the Management Board, the revised EMA policy for committees and experts entered into force on 30 January 2015. . The guiding principles in the revision of the policy were to better look at the nature of the interest declared before determining the length of restriction, better balancing of cooling-off period versus maintaining the expert's knowledge, and better differentiation between decision-making and advisory bodies. Overall the impact assessment shows that the approach is balanced, with comparable numbers of committee members/alternates undergoing more restrictions as those undergoing fewer restrictions in comparison with the 2012 policy. As a consequence of the impact assessment further clarifications are needed concerning previous employment in an executive role in pharmaceutical companies and more detailed guidance in case of intention by a member to become an employee in a pharmaceutical company. The Breach of Trust procedure has been amended to take into account the revised policy and the experience since 2012. The board endorsed the breach of trust procedure after requesting some modifications concerning the length of the clarification phase and notification to the relevant National Competent Authority of the result of the clarification.

B.10 Management Board liaison process for PRAC composition

[EMA/MB/40714/2015; EMA/43845/2015] The board adopted the Management Board liaison process for PRAC composition – Liaison after the first 3 years of PRAC. The Management Board was first consulted on the final composition of the PRAC in 2012 in accordance to legislation. A liaison process was foreseen at a 3 year interval. As the first 3 year mandate of most members of the PRAC is about to expire, National Competent Authorities have been invited to prolong the mandate of their members or nominate new ones. A renewal of the mandate will be possible in the future, once a prolongation has been already made. In parallel, the European Commission has also been addressed seeking prolongation or new nominations of the six independent scientific experts on the Committee. The results of these two strands of requests will be provided to members at the June meeting, when the board will be asked to discuss the current composition and identify gaps in expertise, and provide an opinion on whether the expertise at PRAC is to be considered sufficient. Recommendations will also be provided on gaps which should be made known to the European Commission and the National Competent Authorities when nominating their members. The chair of PRAC will be invited to present to the board the experience after the first 3 years of the committee and discuss best use of its expertise at the June meeting.

Following request for clarification by some members, a paper describing the procedure for non-imposed PASS will be circulated to the board for information.

B.11 EU Portal and EU database

B.11.a Draft revision of section 6 of the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" setting out features to support making information public

[EMA/MB/29326/2015/Rev. 2; EMA/129363/2015 REV.2; EMA/42176/2014] The board endorsed the Draft revision of section 6 of the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" setting out features to support making information public, and noted the Functional specifications for the EU portal and EU database to be audited.

At the December meeting the Management Board endorsed the functional specifications and noted that further specifications concerning transparency would be submitted as an addendum at the March meeting. A public consultation on the addendum was held until 18 February and a two step approach agreed with Member States and with the European Commission. As a first step the addendum for endorsement describes the technical features of the EU portal and database which support publication of information from the database. The second step will set out the rules and criteria of what documents and data and at what time will be published. Following further cooperation with Member States and the European Commission and taking into account the responses to the public consultation, an appendix to the functional specifications will be presented to the Management Board at the October meeting.

Members expressed concern that the wording of the legislation seems to deny access to information in the database to Member States which are not RMS or CMS in a procedure. The European Medicines Agency is exploring whether from a legal point of view, information could be shared on a voluntary basis within the workspace. Any solution would need to be found within existing legislation.

B.11.b Update on development of CT Portal and Database

The board was informed that preparations are moving ahead, with use cases being finalised and the development team starting to come on board in May. Final choices on technical platform will be made in the coming months, and in mid-year a clear picture of delivery time will be available. The board was reminded that after satisfactory audit of the completed systems 6 months need to elapse from publication of the favourable announcement in the Official Journal before the legislation comes into application. Therefore during circa 10 months no new development is possible. During this period however testing and training can take place. An announcement on timelines will be provided in mid-2015, as stakeholders and Member States need to know the technical specifications and timelines to build their own systems.

B.12 Update on PSUR repository

[EMA/MB/45976/2015] The board noted the status of the PSUR Repository project. The first release of the PSUR repository with functionalities approved by the Management Board in December 2013 went live on the 26th of January 2015. An independent audit was performed, and the audit report should be circulated to the PRAC with a view for a recommendation to be issued no later than May. At the June meeting the Management Board could confirm and announce the full functionality of the repository. The PSUR repository advisory group (PRAG) is further working on the requirements to enhance the search and retrieval for non-EU single assessments procedures. A proposal may be ready

by the June meeting of the board. A phased implementation has begun with a pilot on centrally authorised products, expanding then to a selection of nationally authorised products as of May 2015. A 'switch-on' will be planned in agreement with the Member States, once the pilot is completed and ahead of the mandatory use of the repository, which will be applicable 12 months after the announcement of the full functionality of the repository. The agency is working on the post-audit functionalities, with particular attention to the automated two-way exchange which is planned to be delivered within a release in November.

There was appreciation for the way the agency has cooperated with Member States in the last few months. Member States would like to be reassured that connectivity will be fully operational before moving into the mandatory phase. The agency invited all parties to express possible concerns ahead of the June meeting, so that issues can be resolved before adopting the recommendation.

B.13 Renewal of the Cooperation Agreement between the NCAs and the EMA

[EMA/MB/99041/2015] The board noted the proposal to renew the Cooperation Agreement between the NCAs and the EMA. The Cooperation Agreement came into force on 1 January 2011 and has been updated four times in order to incorporate new legislation. It is due to expire on 31 December 2015. In view of the upcoming substantial changes in legislation on veterinary medicines it is to be expected that there will be considerable impact on the content of the Cooperation Agreement, as well as on the Fee Regulation. For this reason the agency is proposing to renew the Cooperation Agreement in its current form, and to review its content later. The proposal was presented at the February meeting of HMA in Riga where it was supported. The Management Board agreed to the proposal as well.

B.14 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/114870/2015; EMA/MB/114869/2015; EMA/MB/49037/2014 v.1] The board noted the 4th interim report of the Steering Group of the data gathering initiative and adopted a revised mandate. The first cycle of the pilot on Scientific Advice procedures has started in February and the second in March. A third cycle is envisaged only if the previous data do not provide sufficient robustness. 100% of ongoing procedures should be captured from the side of the NCAs and of the EMA. The Steering Group will also start working on veterinary procedures and has revised its mandate to include two veterinary only members, one from the board and one from the agency. Veterinary data collection will build on the ongoing human pilot and will include initially procedures which are not affected by the revision of the legislation. The Steering Group will further extend the exercise to other fee-generating activities, where major revenue generating procedures are going to be analysed first. Data collection for procedures will be carried out in parallel, with longer procedures broken up in phases. Retrospective data collection will be considered where prospective is not deemed to be feasible. Discussion on non-remunerated activities and time overheads is ongoing. It is expected that data gathered during the pilot will be analysed in July and a report prepared in August 2015. The Steering Group aims at starting all procedures in Q3 2015 with a view to completing them mid-2016.

B.15 5th Annual Report Veterinary MUMS/limited market

[EMA/MB/82817/2015; EMA/47723/2015] The board endorsed the 5th Annual report Veterinary MUMS/limited market. The Policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market was implemented in 2009 and has since

been updated twice. The board is informed via annual reports on the performance of the policy. In 2014 28 requests for classification were submitted, of which two were awarded financial incentives for food producing species. Classified products have received marketing authorisations, with two further full applications submitted through the centralised procedure in 2014. Applicants have also the choice to use the decentralised procedure. The effect of the restriction of incentives to food producing animals is being monitored but does not seem to have reduced general interest in the classification. Restrictions have had no impact on the number of very diverse applications received. For 2015 further work is planned on updating the Guidelines for data requirements for MUMS. Changes to the veterinary legislation will also be monitored on impact on the policy.

1. A.O.B.

Documents for information

- Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- Outcome of written procedures finalised during the period from 13 November 2014 to 18 February 2015
- Summary of transfer of appropriations in the budget 2014 and 2015
- 2014 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission (Reporting period: 1 January-31 December 2014)
- Overview of Staff Regulation implementing rules signed by the MB Chair during the period from 27 February 2014 to 13 February 2015

Written procedures from 13 November 2014 to 18 February 2015

- Consultation no. 01/2015 on the appointment of Martti Nevalainen as CVMP alternate member, proposed by Finland, ended on 20 January 2015. The mandate of the nominee commenced on 1 February 2015.
- Written procedure for comments to the Framework for interaction between the European Medicines Agency and industry stakeholders ended on 31 January 2015.
- Written procedure for adoption of the Reflection paper on the use of individual patient data in electronic format for the evaluation of benefit-risk of human medicines was suspended on 31 January 2015.
- Written procedure for adoption of 86th Management Board meeting minutes ended on 13 February 2015. The minutes were adopted.
- Consultation no. 02/2015 on the appointment of Ivana Pankuchová as CHMP alternate, proposed by Slovakia, ended on 17 February 2015. The mandate of the nominee commenced on 18 February 2015.

List of participants at the 87th meeting of the Management Board, held in London, 19 March 2015

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Assena Stoimenova	
Czech Republic	Doubravka Kostalova	Zdenek Blahuta
Croatia		Viola Macolić Šarinić
Denmark		Matilde Kyst Behrens
Germany	Klaus Cichutek	Karl Broich André Berger
Estonia	Kristen Raudsepp	
Ireland	Pat O'Mahony	Rita Purcell
Greece	Katerina Fameli	
Spain	Belén Crespo Sánchez-Eznarriaga	
France	Dominique Martin	Jean-Pierre Orand Miguel Bley
Italy	Gabriella Conti	Pietro Erba
Cyprus	Loizos Panayi	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg		Jacqueline Genoux-Hames
Hungary	Beatrix Horváth	
Malta	John J Borg	
Netherlands	Hugo Hurts	Birte van Elk
Austria	Christa Wirthumer-Hoche	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Maria Morais
Romania	Marius Savu	
Slovakia	Jan Mazág	
Slovenia	Katarina Štraus	David Obranovič
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Ian Hudson Jonathan Mogford
European Parliament	Giuseppe Nisticò Björn Lemmer	
European Commission	Ladislav Miko (DG SANTE) Gwenole Cozigou (DG GROW)	Lenita Lindstrom (DG SANTE) Chloe Spathari (DG GROW)
Representatives of patients' organisations	W.H.J.M. Wim Wientjens *Apology received*	
Representative of doctors' organisations	Wolf-Dieter Ludwig	
Representative of veterinarians' organisations	Christophe Hugnet	

	Members	Alternates (and other participants)
Observers	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Augun Haga (Norway)	

European Medicines Agency	Andreas Pott Noël Wathion Agnès Saint Raymond Stefano Marino David Mackay Enrica Alteri Alexis Nolte Fergus Sweeney Luc Vanheel Nerimantas Steikūnas Jordi Llinares Marie-Agnes Heine Tony Humphreys Emer Cooke Hilde Boone Melanie Carr Ulrike Nagl Edit Weidlich Karen Quigley Silvia Fabiani Sophia Albuquerque	