21 February 2013
EMA/MB/810387/2012 Adopted
Management Board

Minutes of the 78th meeting of the Management Board

Held in London on 13 December 2012

The Chair of the European Medicines Agency's Management Board, Sir Kent Woods, opened the meeting by welcoming the new member: Evelin Yakov Blagoev, representing Bulgaria.

The mandates of the civil society members of the Board expired on 4 March 2012 and new members have not been appointed yet. The Board was informed that the 'Coreper' (the Committee of Permanent Representatives) will vote on 14 December 2012 and, shortly thereafter, the Council will formally appoint the new members.

1. Draft agenda for 13 December 2012 meeting

[EMA/MB/659251/2012] 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 and alternates who have not done so to send their CVs to the secretariat for publication on the Agency's website.

3. Minutes from the 77th meeting, held on 3 October 2012

[EMA/MB/653638/2012] The Management Board noted the final minutes, adopted by written procedure on 13 November 2012.

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4. Election of vice-chair

The Management Board unanimously elected Walter Schwerdtfeger, representing Germany, 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:

- Claude Hemmer (Luxembourg) to Aginus Kalis (Netherlands)

The Board appointed Brigitte Batliner and Gro Ramsten Wesenberg, 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
35	29	29	0	0	6[1]

The vote took place by secret ballot.

The newly elected vice-chair thanked the Board and expressed his anticipation at cooperating with the chair.

A. Points for automatic adoption / endorsement

A.1 Revised Management Board Telematics Committee (MBTC) terms of reference

[EMA/729062/2012] The Management Board adopted the revised MBTC terms of reference, which allowed for membership of the MBTC by representatives of doctors and veterinarians.

A.2 Financial compensation for Member States' participation in the linguistic checking of product-related information

[EMA/MB/742965/2012] The Management Board endorsed the increased flat hourly rate cost for 2013.

B. Points for discussion

B.1 Highlights from the Executive Director

The highlights provided an occasion for the Executive Director to reflect upon his first year in office. The experience has been overall very positive, thanks to the high level of commitment and competence of the staff, which manages to cope with the ever-increasing demands on its resources. Strengthening relations with the network is also necessary, to help provide mutual help and support in activities such as training and sharing of product data. The visits by the Executive Director to the national competent authorities (NCAs) — 5 carried out in 2012, more planned for 2013 — and the creation of a dedicated NCA desk are proving to be valuable tools for this purpose.

Implementation of anti-falsification legislation

Work is progressing in support of the European Commission and the Member States in preparation for the implementation of the falsified-medicines legislation. The Agency has developed a risk methodology to analyse the potential for shortages of medicinal products, thus helping to streamline capacity in the inspection of the supply chain. This good example of European Union (EU) integration

[1] Two members sent their apologies for the meeting; four mandates representing civil societies are currently vacant.

has received attention from other world regions in international fora, such as ICCDRA and the recent global meeting in Manaus, Brazil.

The Agency has worked closely with the European Commission in the discussion with third countries about their intentions regarding the certification of active pharmaceutical ingredients. The number of countries requesting listing by the European Commission is growing, also thanks to recent interest by the US, and reluctance by other exporting countries is being gradually overcome as they agree to the provision of written confirmations. Nonetheless, much work still needs to be done, and this issue stays at the forefront of priorities and concerns in the network.

Review of core processes

The issue of how to manage conflicts of interests has been successfully tackled with the collaboration of the European Commission and the network, and is now the object of routine activities. The attention of the Agency must now be turned pre-eminently to achieving efficiency gains and managing resources effectively. Budget constraints are becoming more severe, while the internal workload is soaring beyond routine capacity and approaching breaking point. Reassurance on high performance is provided by the high expertise of staff, but a deep review of underlying processes is now needed to face upcoming challenges. The Agency is therefore undertaking a major review of its core processes, guided by the same methodology and principles it is applying to the review of its ICT processes. Attention will focus on support provided to the committees in delivering the best quality and consistency of opinions. Their input into process design will be very valuable to achieve greater integration and consistency of scientific output. The exercise should be completed in March and implemented by September. Advice and good ideas from Board members are highly welcome. Initiatives are reflected in the Agency's work programme.

Access to clinical-trials data

The discussion started many years ago but has now reached a point of maturity, encouraging acceleration of concrete initiatives. A very successful workshop was held at the Agency on 22 November 2012, and received much media attention, as well as public support from the UK's prime minister. The proposal to take forward the release of clinical-trial data was met with divergent positions. Policies will need to be established in close dialogue with all stakeholders. Calls for expressions of interest have been opened until 21 December, to allow interested persons or parties to participate in advisory groups.

IAS report

The Agency has received the draft follow-up audit report by the Internal Audit Service of the European Commission (IAS). Most issues identified in the past have been closed, notably concerning the handling of conflicts of interests, in line with the conclusions of the 2010 discharge procedure.

Web portal

A survey has highlighted stakeholder dissatisfaction with the existing 17 Agency-managed websites. There is a need for rationalisation, which could also contribute to the reduction of costs in the long term. The European Heads of Medicines Agencies will be consulted with a view to developing a joint European medicines web portal.

3Rs — entry into force of legislation

As the coming into force of '3Rs' (replacement, reduction and refinement in the testing of medicines) approaches, a task force on implementation will be set up.

European Surveillance of Veterinary Antimicrobial Consumption

The second annual ESVAC report on sales of antimicrobials was published in October. The next report will contain still more detailed information.

The Management Board expressed its appreciation for Guido Rasi's work in his first year as the Executive Director of the Agency. There was approval for the way in which challenges such as the increasingly difficult economic situation and the handling of experts' conflicts of interests were handled through the strengthening of transparency and efficiency. Member States liked initiatives such as the visits to the national competent authorities, designed to improve cooperation in the network, and stressed the importance of continuously fostering close collaboration between all parties involved. Some members stressed the need to focus on improving efficiency, together with the network. The European Commission representative spoke of the need to respond to the demands of the legislator while at the same time reducing administrative burdens and making cost savings, as resources are likely to decrease in the years to come. The Board agreed to hold a more exhaustive discussion at the March meeting.

B.2.a Work programme 2013

[EMA/MB/945561/2011] The Management Board adopted the Agency's work programme for 2013. This is based on the preliminary work programme 2013 adopted by the Management Board in March 2012, and reflects the objectives set out in the 'Road map to 2015'. This was supported by the Commission representative, provided that reference is made in the work programme to the need for greater efficiency and reduction of administrative burden. The main drivers of the work programme are the effective operation of core business and the delivery of the strategy.

Workload has been increasing annually, owing mainly to the growing complexity of scientific work and to the implementation of new legislation, which adds to the pressure on resources. At the same time, there has been a shift over the years to non-fee-paying activities. Increased demand for transparency has brought the workload connected to access to documents to new heights, with millions of pages to be released every year. This trend subtracts highly skilled resources from scientific work. Implementation of new legislation is progressing, though the absence of fees for pharmacovigilance poses major concerns.

Continuous technological development provides new challenges. With the approval of the first gene therapy, new ground has been successfully broken. This experience has shown the need for an easier and more linear path.

Assessment activities are foreseen to remain stable in 2013, with some growth in orphan-medicines applications, small fluctuations in paediatrics medicines and a significant drop in variations. One of the financial impacts of the pharmacovigilance regulation is a reduction of all variations, amounting to approximately EUR 10 million, which means a decrease of revenues for the network of approximately EUR 4 million. Parallel scientific advice work with health-technology-assessment bodies remains stable in numbers, but benefits from greater experience and interest from stakeholders. The Agency intends to progress with the stepwise publication of the agendas and minutes of all its committees.

Members remarked that in the current difficult economic climate the work programme might appear very ambitious, and proposed that the structure be modified in future years to better highlight

priorities with a clearer emphasis on core business. The contribution and capacity of NCAs should also be taken into consideration, and emphasis made on the work to achieve greater efficiency.

B.2.b Budget and establishment plan 2013

[EMA/MB/978095/2011] The Management Board discussed and adopted the Agency's budget and establishment plan for 2013. The budget is in line with the work programme and amounts to EUR 231.6 million, with an increase of EUR 9.07 million (+4.1%) over the 2012 budget and a decrease of EUR 7.5 million (-3.1%) compared to the 2013 preliminary draft budget (PDB). This increase is offset in real terms by a loss in value in 2012 of 5.5% of the euro towards the pound sterling (GBP), in which approx. 60% of the expenditure has to be paid. The estimated fee income is increased by EUR 6.6 million (+3.85%) compared to 2012, which is EUR 445,000 (-0.2%) less than was estimated in the PDB 2013. The increase must be considered in the light of an assumed 3.0% inflationary rate. The EU contribution requested in the PDB has been decreased by EUR 7.8 million (-16.6%) as there has been a delay in the requirement for the Agency to pay for the pension contributions of staff, and amounts now to EUR 39.2 million, which represents an increase of EUR 389,000 (+1.0%) compared to the 2012 contribution.

On the expenditure side, savings have been achieved concerning allocations for business travel and training of staff, as well as on meeting expenses, which have been kept under the 2012 level, despite the accession of Croatia and the creation of a seventh scientific committee. A reduction of EUR 3.7 million (-13%) was possible following an ICT cost-optimisation exercise.

The 2013 establishment plan foresees 611 posts, of which 21 are new posts for temporary agents as requested by the Management Board with the 2013 PDB. The budgetary authority has agreed to these posts. However, given the reduction in budget as compared to the March PDB, the Agency might need to reduce the number of contract agents employed.

The topic coordinators Klaus Cichutek, Kristin Raudsepp and Grzegorz Cessak have had a strong input into the preparation of the work programme and budget. As part of their report to the Management Board, supporting the adoption of the 2013 budget, they put forward a number of views on further improvements to the budgeting approach. They advised to put more effort into providing detailed explanations on how resource constraints are met and managed. While they acknowledged an effort to reduce mission and meeting costs, these are unfortunately only a minor part of the overall costs. Staff costs are increasing, due mainly to unfavourable currency exchange rates, and a careful reflection on the repartition of personnel is needed to make sure that the Agency remains effective. Amounts paid to national authorities for scientific services have grown in absolute terms but decreased in relative terms, due to a shift to procedure types with lower remuneration: while in 2009 they made up a share of 47.1% of fees collected by the Agency, in 2013 they have decreased to 43.0%.

The representative of the European Commission agreed that an effort to change the structure and processes is needed to improve the Agency's ability to face further deteriorations of the financial situation. The ICT budget appears to be an area where further significant savings can be brought about. An objection was also raised by the European Commission against the inclusion of a grading in the establishment plan contained in the multiannual staff-policy plan of the Agency.

The Board decided to vote on the budget and establishment plan 2013 as proposed. The chair announced one proxy:

- Claude Hemmer (Luxembourg), to Aginus Kalis (Netherlands).

The Board requires 24 votes in favour to adopt a decision. The outcome of the vote was as follows:

Total no. votes	Votes cast	Votes in favour	Votes against	Abstained	Not present
35	29	25	4	0	6

The vote took place electronically and openly, in full view of all present. The full details of votes by delegation and proxies can be found in Annex 1.

Post-meeting note: following subsequent clarification with the representatives of the European Commission concerning the 2013 establishment plan in the multiannual staff-policy plan and its resulting correction (Annex 2), the vote results were amended as follows:

Total no. votes	Votes cast	Votes in favour	Votes against	Abstained	Not present
35	29	27	2	0	6

Reasons for the votes against the adoption of the budget were not provided.

The Board thanked the topic coordinators and agreed to entrust a subgroup with preparing a discussion, to be held at the next meeting of the Board, on how to ensure that not just operations at the Agency, but within the whole system (the Agency, NCAs and EC) remain sustainable in the years to come, in the light of ever-increasing pressure on resources. Five members of the Board — Klaus Cichutek, Aginus Kalis, Jonathan Mogford, Marcus Müllner and Paola Testori Coggi — expressed an interest in participating.

B.2.c Implementation of the pharmacovigilance legislation — activities to be undertaken in 2013

[EMA/MB/768373/2012] The Management Board discussed pharmacovigilance activities for 2013 as part of the work programme 2013 and endorsed them. Reassurance was provided on a number of topics raised by members. The European Commission representative advised that work is ongoing on the preparation of the impact assessment on fees for pharmacovigilance, which will include different options for the charging of the fees. If the Impact Assessment Board approves the impact assessment at its first meeting, the legal proposal could be adopted in spring 2013. Given that the legislation entered into force only on 1 July 2012, there is still little experience with the interactions between the Pharmacovigilance Risk Assessment Committee (PRAC) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh), but business processes have been developed and should be implemented smoothly. Patient reporting and medication errors are new activities in the network, and common guidance will be developed in 2013, in collaboration with the Member States. A workshop on medication errors is scheduled to take place in January. Some pharmacovigilance activities at Member State level are heavily dependent on the quality of the data in EudraVigilance. It was decided in 2011 to perform the audit of EudraVigilance once the delivery of enhanced functionalities has been completed (Q4 2015).

B.2.d ICT budget and projects 2013

[EMA/734900/2012] The Management Board discussed and endorsed the ICT budget and projects for 2013. The development of the ICT budget is strongly oriented towards lowering costs. The savings of EUR 3.7 million (-13%) compared to 2012 were achieved by reducing running costs and new project development purchase/replacement costs. Part of the savings could be redirected to necessary investments in hardware and software. It is expected that greater integration of systems (such as the current 17 websites) and stabilisation of the number of transactions performed will reduce the stress on the systems. Progress with standardisation and avoidance of duplication will provide further savings in the ICT budgets of the years to come. The Agency is aligning its strategies on DIGIT and making use

of its tenders. As a standalone organisation, however, it does not benefit from access to the horizontal systems of the European Commission, which would allow for very substantial savings.

Members acknowledged the efforts to rationalise ICT systems and management undertaken at the Agency in 2012, and also recommended integration and avoidance of duplication with IT applications developed in the Heads of Medicines Agencies network. What constitutes a sound ratio of ICT expenditure in an IT-intensive environment was the subject of some discussion, with some members considering the current 11% of total Agency expenditure as sustainable, given its role in developing pan-European ICT systems for medicines regulation. The European Commission representative reminded the Board that the ICT systems must fulfil institutional expectations, such as the call recently expressed by the eHealth network for a single European database.

B.2.e Revised reimbursement rules for delegates

[EMA/724164/2012] The Management Board discussed and adopted the revised reimbursement rules for delegates. The new provisions, concerning minor amendments to flexibility of travel arrangements and to requirements for the granting of daily allowances, will allow for an estimated yearly saving of EUR 30,000–40,000.

B.3 Pharmacovigilance Risk Assessment Committee (PRAC) rules of procedure

[EMA/MB/729027/2012] The Management Board endorsed the PRAC rules of procedure adopted by the PRAC on 29 November 2012. Following a favourable opinion from the European Commission, the rules of procedure will enter into force. The chair thanked the European Commission and the Board for the good cooperation that has provided a common ground on which to give the PRAC a strong basis.

B.4 Revised proposal to progress on costing evaluation activities

[EMA/MB/733324/2012] The Management Board discussed the revised proposal to progress on costing of evaluation activities. Members expressed scepticism over the possibility that an external consultant could have greater knowledge and access to data on costing in the NCAs than what the Member States have been able to collect and discuss over many years of Agency-sponsored costing exercises. The need for a cost-based remuneration system is recognised by all, having been raised by the Court of Auditors and, more recently, by the European Parliament. Progress will need to be reported by May 2013, and it seems unlikely that a comprehensive study and proposal can be put together by then. This would also need to address currently non-remunerated activities, and take into consideration the need to continue to provide both the Agency and the NCAs with a stable and sustainable system.

It was considered that cost-accounting does not necessarily have to be based on hourly fees, which have shown to lead to unreliable time-accounting and micromanagement, but can be achieved also through fixed fees. For this reason, the Board decided to take into consideration an earlier proposal on remuneration, based on the purchasing-power coefficient in the Member States. This would introduce a cost-based element and could be implemented in a short time frame. The Agency agreed to submit the data on EUROSTAT purchasing-power coefficients at the next meeting of the Board, together with a simulation of repercussions on the system based on remuneration of NCAs in the past years, as well as various scenarios of application in the future. The European Commission representative emphasised that the legal proposal on pharmacovigilance fees needs to be cost-based (which also explains the duration of this exercise). The Court of Auditors and the European Parliament have repeatedly requested to make the reimbursement system cost-based, and the Commission representative raised doubts that simply adding a coefficient based on purchasing power to the current amounts paid to the Member States would be sufficient.

B.5 European Directorate for the Quality of Medicines and HealthCare (EDQM)

[EMA/MB/740545/2012] The Management Board endorsed the request by the EDQM for participation in meetings of the Committee for Advanced Therapies (CAT).

B.6 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 civil societies' representatives of the Board, who have not yet been nominated. The Chair, as the Acting Chair of the MBTC, informed the Board of the proposed establishment of the new EU telematics governance model, and of the timeline for this proposal. Members will be provided with draft information regarding the proposed changes to the MBTC well in advance of the March Management Board meeting.

B.7 Report from the European Commission

The European Commission reported on the following activities relating to EU legislative and policy developments in public health:

- The new legislation on pharmacovigilance was adopted on 25 October 2012 by the European Parliament and the Council. The Directive will become applicable on 28 October 2013 and the Regulation on 5 June 2013. Public consultations on phasing-in requirements on the black symbol and on situations for requirements of post-authorisation efficacy studies are ongoing.
- A summary of replies to the public consultation on the concept paper on the introduction of fees for pharmacovigilance was published and an impact assessment is being prepared before putting forward a legal proposal, expected in spring 2013. The impact assessment will include different options, such as flat fees and fees differentiated by procedures.
- In 2013, the Commission has to present to the European Parliament and the Council a general report on experience acquired as a result of the application of the Paediatric Regulation. In preparation for this, the Commission has released and submitted for consultation until November 2012 a document based on a report prepared by the Agency and its Paediatric Committee.
- The implementation of the Falsified Medicines Directive is proceeding well, with several implementing measures being drafted or in consultation. Concerning importation of active substances, Switzerland has been included in the list of third countries with standards in the manufacture of active pharmaceutical ingredients equivalent to those of the EU. Assessments of Australia, Israel and Singapore are ongoing. Japan and Brazil will shortly submit documentation. The adoption of an implementing act on the assessment of good manufacturing practice for active substances from non-EU countries is expected in early 2013.
- The proposal for the Clinical Trials Regulation is being discussed in Council at the technical level. The Environment, Public Health and Food Safety (ENVI) Committee will be the lead committee in the European Parliament. Reception of the proposal has been very positive, especially in academia.
- There has been good progress on the proposed reform of the International Conference on Harmonisation (ICH); new governance has been agreed and criteria for membership are being defined.
- The Impact Assessment Board will meet shortly on the impact assessment relating to the revision of veterinary medicines legislation, and a draft legislative package comprehending medicated feed and veterinary medicines is expected to be adopted Q2 2013.

- The European Parliament report on antimicrobial resistance was adopted, and there are now calls on the European Commission for an integrated road map and a progress report on the implementation by the end of 2013.
- Directive 2011/24/EU on patients' rights in cross-border healthcare entered into force in April 2011 and should be transposed by October 2013. Preparatory work on the implementation of the Directive is ongoing on health-technology assessment, e-Health (including interoperability of pharma databases and possible synergies with ePrescriptions), mutual recognition of prescriptions, and European references networks.
- The process on corporate responsibility in the field of pharmaceuticals should be completed by mid 2013, and will identify areas for further cooperation, including cooperation in relation to the work of the Platform on Ethics and Transparency, with the final approval of a document containing a List of Guiding Principles in this area.
- The Transparency Directive is being discussed at both the Council and the European Parliament, where the work is being carried out on compromise amendments.

Members of the Board expressed concern at the situation regarding importation of APIs at the moment of entry into force of the legislation in July 2013. It is important to receive confirmation that proposed practices are indeed going to be acceptable, as the option of conducting risk-based inspections would be affected by capacity problems, particularly if the whole market were to be affected.

B.8 Report from the Heads of Medicines Agencies (HMA)

The chair of the HMA Management Group presented an update on the main activities of the network, specifically concerning the extraordinary Strategic Reflection Day hosted by the Norwegian Medicines Agency to progress with the work undertaken by the HMA Reflection Task Force.

Main topics discussed:

- The governance and funding model of the Common European Submission Platform (CESP).
- IT development in the network, in particular IT strategy; better sharing of resources and avoidance of duplication of systems; funding in areas of common interest with the Agency.
- The functioning of the network, particularly with regard to the inclusion of representatives of competent authorities for medical devices, and a possible review of the mission and scope of the HMA. The number and effectiveness of HMA working groups will be further reviewed.
- Professionalisation of support structures to HMA currently provided by agencies on a voluntary bases. In order to build a permanent structure, funding and a legal basis are needed, and not supported by the legal provisions in many Member States. A stepwise approach, starting with a single dedicated officer and keeping the permanent secretariat 'virtual' seems to be the way forward.
- Funding is a closely connected issue, and may not have a solution for the time being, although the network has to find a way to finance single projects or initiatives that bring benefits or savings to the supporting agencies.

B.9 Interim report on the performance of the Agency's scientific procedures (selected key performance indicators (KPIs) for medicinal products during the period from January to September 2012)

[EMA/732911/2012] The Management Board discussed an interim report on performance for selected KPIs, which showed a stable performance in comparison with 2011 data. Some members reported that the perception in their NCA is that the system may be strained, particularly since the close sequence of Committee for Medicinal Products for Human Use (CHMP) and PRAC deadlines puts assessors under increased pressure. The Agency is aware of this, and will ask its Scientific Board to discuss how to better support Member States. The representative of the European Commission recommended involving a greater number of Member States in evaluation work, rather than relying on a few agencies.

B.10 EudraVigilance report 2012 — Veterinary medicinal products

[EMA/MB/732279/2012] The Management Board noted the report. The prerequisite for EudraVigilance to be effective is the availability of a common veterinary database. This is an agreed objective between the HMA and the Management Board, and will have to be delivered in a short time, also as it is likely to be a component of the new legislation proposal. In summary, the work currently delivered is based on an existing database, where signal detection can be performed on centrally authorised products and on data of nationally authorised products supplied by the NCAs.

A.O.B.

A letter concerning an Agency personnel matter was sent by its author to all members of the Management Board. A draft answer to it will be circulated to the Board before being mailed to the recipient.

Documents for information

- [EMA/777362/2012] EU telematics operations report.
- [EMA/777358/2012] EU telematics projects report.
- [EMA/MB/736880/2012] Minutes of the MBTC from 11 September 2012 meeting.
- [EMA/MB/729025/2012] Outcome of written procedures during the period from 20 September 2012 to 21 November 2012.
- [EMA/MB/724367/2012] Summary of transfers of appropriations in the budget 2012.
- [EMA/573841/2012] Report from the Olympics 2012 task force.
- [EXT/745532/2012] Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies.
- [EMA/MB/723380/2012] Overview of Staff Regulation implementing rules signed by the Management Board Chair during the period from 7 October 2011 to 15 November 2012.
- [P7_TA-PROV(2012)0366] European Parliament Discharge 2010 to the EMA.

Tabled documents

- Presentations from the European Commission.
- Presentation relating to point B.6 Nomination to the MBTC.

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

- No. 14/2012 on the appointment of Ondrej Slanar as CHMP member; ended with endorsement on 12 October 2012.
- No. 15/2012 on the appointment of Marc Schmit as CVMP member; ended with endorsement on 20 November 2012.
- Written procedure for the 77th Management Board meeting minutes; ended with adoption on 13 November 2012.

List of participants at the 78th meeting of the Management Board, held in London, 13 December 2012

Chair: Sir Kent Woods

	Members	**Alternates (and other participants)**
Belgium	Xavier De Cuyper	
Bulgaria	Evelin Blagoev	Meri Paycheva
Czech Republic	Petr Čapek	
Denmark	Else Smith	Tina S Engraff
Germany	Walter Schwerdtfeger	Klaus Cichutek
Estonia	Kristin Raudsepp	
Ireland		Rita Purcell
Greece	Ioannis Tountas	Aikaterini Moraiti
Spain	Belén Crespo Sánchez-Eznarriaga	Laura Franqueza García
France		Jean-Pierre Orand Jean-Baptiste Brunet Miguel Bley
Italy	Luca Pani	Daniela Salvia
Cyprus	Arthur Isseyegh	
Latvia	Inguna Adoviča	
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	*Apology received*[2]	
Malta	Patricia Vella Bonanno	
Netherlands	Aginus Kalis	Birte Van Elk
Austria	Marcus Müllner	
Poland	Grzegorz Cessak	Tomasz Kaldus
Portugal	Helder Mota-Filipe	Eurico Castro Alves
Romania	*Apology received*	
Slovakia	Jan Mazág	
Slovenia	Matej Breznik	
Finland		Pekka Kurki
Sweden		Bengt Wittgren
United Kingdom		Jonathan Mogford Nassim Parvizi Sarah Speedie
European Parliament	Giuseppe Nisticó Björn Lemmer	
European Commission	Paola Testori Coggi	Salvatore D'Acunto Lenita Lindstrom
Representatives of patients' organisations	Nominations awaited	

[2] Absence was due to fight cancellation because of severe weather conditions.

	Members	Alternates (and other participants)
Representative of doctors' organisations	Nomination awaited	
Representative of veterinarians' organisations	Nomination awaited	
Observers	Rannveig Gunnarsdóttir (Iceland) Brigitte Batliner (Liechtenstein) Gro Ramsten Wesenberg (Norway) *Apologies received* (Croatia)	

European Medicines Agency	Guido Rasi Patrick Le Courtois David Mackay Andreas Pott Luc Verhelst Noël Wathion Peter Arlett Emer Cooke Martin Harvey Allchurch Tomasz Jablonski Michael Lenihan Frances Nuttall Agnes Saint Raymond Maria Alves Sophia Albuquerque Silvia Fabiani Zuzana O'Callaghan Nerimantas Steikūnas	

Annex 1

Vote on the adoption of agenda item B.2.b – Budget and establishment plan 2013

Proxies announced by the Chair

1. Claude Hemmer (Luxembourg) gives his vote by proxy to Aginus Kalis (Netherlands).

	In favour	Against	Abstained	Not represented
1	European Commission - DG Sanco	Germany		Hungary
2	European Commission - DG Enterprise	Slovenia		Romania
3	European Parliament - Giuseppe Nistico			Patients' organisations' representative[3]
4	European Parliament - Bjorn Lemmer			Patients' organisations' representative[2]
5	Austria			Doctors' organisations' representative[2]
6	Belgium			Veterinarians' organisations' representative[2]
7	Bulgaria			
8	Cyprus			
9	Czech Republic			
10	Denmark			
11	Estonia			
12	Finland			
13	France			
14	Greece			
15	Ireland			
16	Italy			
17	Latvia			
18	Lithuania			
19	Luxembourg by proxy			
20	Malta			
21	Netherlands			
22	Poland			
23	Portugal			
24	Slovakia			
25	Spain			
26	Sweden			
27	United Kingdom			

[3] Mandate vacant; nomination awaited.

Annex 2

B.02.b_Annex IV_REVISED_Multianr