18 June 2015
EMA/MB/313120/2015 Adopted
Management Board

# Minutes of the 88th meeting of the Management Board

Held in London, 11 June 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 Carlo Pettinelli, member for DG GROW, Zdeněk Blahuta, member for the Czech Republic, Mette Aaboe Hansen, member for Denmark, Despoina Makridaki, member for Greece, and Johan Lindberg, alternate member for Sweden.

## 1. Draft agenda for 11 June 2015 meeting

[EMA/MB/170636/2015] The agenda was adopted with minor amendments. Point B.5 *Update on the Implementing rules to the Fee Regulation*, was cancelled from the agenda as, based on EMA request and information, DG SANTE had launched a consultation of the relevant Commission services on two proposed amendments, which is now at the final stages. In case of a favourable opinion, the amendments to the Implementing rule to the Fee Regulation will be submitted to the Management Board for adoption by written procedure.

## 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 conflict 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 87th meeting, held on 19 March 2015

[EMA/MB/178925/2015] The Management Board noted the final minutes, adopted by written procedure on 4 May 2015 and subsequently published.

Concerning a Q&A document that had been circulated for information after the last meeting, it was considered that the document had provided the board with comprehensive and clear information on a pilot Scientific Advice concerning non-imposed PASS procedures. There was a broad support to the

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pilot, on request by some members however, the topic will be included in the agenda of the October meeting, to be discussed also in the light of further data on volume of activity.

# A. Points for automatic adoption / endorsement

## A.1 Management Board meeting dates 2015-2016

[EMA/MB/239247/2015] The Management Board adopted the following meeting dates

for 2015:

- Thursday, 1 October[1];
- Wednesday, 16 December and Thursday, 17 December;
- for 2016:
- Thursday, 17 March;
- Thursday, 16 June;
- Thursday, 6 October;
- Wednesday, 14 December and Thursday, 15 December;

The Board also noted the following proposed meeting dates

for 2017

- Thursday, 16 March;
- Thursday, 15 June;
- Thursday, 5 October;
- Wednesday, 13 December and Thursday, 14 December;

for 2018

- Thursday, 15 March;
- Thursday, 7 June;
- Thursday, 4 October;
- Wednesday, 12 December and Thursday, 13 December;

The chair informed the board that the process for the selection of the Executive Director is progressing and that it can be expected that a shortlist of candidates will be available by mid-September. This would allow circulation of all relevant documents to the board ahead of an extraordinary meeting of the Management Board, to be held on 1 October with participation restricted to members or their alternates, but not both, observers from EEA countries, the EMA Management Board Secretariat and limited EMA staff. In this case the scheduled meeting would take place on 2 October to conduct the routine business.

The chair also reminded the board of all the steps that need to follow the designation by the board, which includes the Executive Director-Designate making a statement to the European Parliament and

[1] Meeting may take place on 1 and 2 October 2015 in case of need for an extraordinary meeting.

answering questions by its Members before being officially appointed by the board and offered an employment contract. In order to keep the process as short as possible, at the extraordinary meeting the chair will ask the board for authorisation to sign the offer of employment once the procedure at the European Parliament is completed.

In preparation for the extraordinary meeting the European Medicines Agency will prepare detailed guidance for the proceedings, which will be sent to the board along with the Curricula Vitae and motivation letters of the candidates. Members were invited to volunteer to prepare the questions by the board in the interviews of the candidates.

# B. Points for discussion

## B.1 Highlights of the Deputy Executive Director

**Working language of the EMA**

Although English has been used as working language at the agency from the very start of its activities, this choice was never formalised and some formal activities, such as the publication of selection procedures, were carried out in all languages. The European Medicines Agency has now joined other European agencies in formally adopting English as its working language as of 1 June 2015. This will allow some savings as most selection procedures will not have to be published in all languages of the Union. The new language regime does not affect the rights of EU citizens to write to the Agency in any official language and to receive a reply in that language. Staff will still be required to speak at least two European languages.

**Update on the discharge 2013 procedure**

The Agency received the European Parliament discharge for its 2013 accounts. All observations from the Parliament concerning budget or financial management were positive and no further action is required.

**Opinion on the Agency annual accounts for the financial year 2014**

The preliminary 2014 annual accounts have been audited by the Court of Auditors and by an independent external auditor. The Agency is currently corresponding with the auditors on various preliminary observations. The final accounts are under preparation and will be submitted to the Management Board for adoption by written procedure in the coming weeks.

**Launch of the Medical Literature Monitoring Service of the Agency**

The Agency's medical literature monitoring service for suspected adverse reactions will be launched in July. Based on the 2010 pharmacovigilance legislation, the EMA is responsible for monitoring medical literature for a number of substances to identify suspected adverse reactions with medicines authorised in the EU, and for entering the relevant information into EudraVigilance. Following the completion of the tender, a contractor has been appointed to support the Agency in these activities. The service will start on 1 July with 50 substances and is expected to reach full operational levels for 400 substances by September 2015. This is part of the activities supported by the annual pharmacovigilance fees.

**Pathfinder initiative**[2]

2 Please note the name 'Pathfinder' is no longer being used to refer to this scheme

In line with the Network strategy and keeping the European Commission informed, scientific committee members supported by EMA have developed a proposal for additional supportive measures that may provide incentives to support beneficial innovation.

The proposed scheme, currently known as Pathfinder, builds on existing regulatory tools and processes and National initiatives and aims at

- reinforcing scientific and regulatory support to optimise development and
- enabling accelerated assessment of new medicines addressing major public health needs.

The initiative aims at enhancing the scientific quality and flexibility of evolution of the procedures. It will be presented and discussed with HMA as well with EU innovation offices network with a view to launch the scheme in Q3 2015.

The representative of the European Commission considered the pathfinder initiative interesting under the perspective of boosting innovation and facilitating access to innovative medicinal products. The Commission stressed the need to carefully plan the initiative and provide full clarity on eligibility criteria, transparency, impartiality,fair treatment and legal certainty. The financial impact on all actors needs to be considered and success of the initiative would be desirable. A holistic approach should be applied to favour the impact of the initiative, and should consider integration with regulatory tools such as conditional approval.

**2016 Budget procedure**

The Agency is concerned about additional 5% staffing cuts that the European Commission is requesting and is discussing with the European institutions options to be able to maintain flexibility in hiring staff for activities financed from fee income.

**International activities**

The Agency has taken part in joint delegations with the European Commission which recently visited India and the BMFG to discuss respectively closer engagement, particularly in the areas of GMP, GCP and biosimilars, and strategic use, role and vision of the 'Article 58' scientific opinion procedure. A further delegation will meet the US FDA later in the month as part of the annual bilateral meeting. A confidentiality arrangement with the Swiss authorities has been finalised together with the European Commission and will be signed shortly.

**Online survey of committee and working party members**

The Agency is conducting its biannual online survey of delegates of committee and working party members which will also cover participation in virtual meetings. The survey aims at gauging the satisfaction of delegates with the services and support provided.

**5th Inter-Agencies Football Tournament**

To celebrate its 20th anniversary, the EMA hosted 'London 2015' – 5th EU Inter-Agencies football tournament on 23-24 May. More than 450 players enrolled in 24 male teams and 9 mixed teams represented 25 EU Agencies over two days. The whole event went very smoothly thanks to the commitment of more than 50 volunteers from EMA and EBA. For the first time ever, one of the two EMA male teams won.

## B.2 Report from the European Commission

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

- Status of discussion at the Council and at the European Parliament of the revision of veterinary medicines legislation;
- Action at various levels on antimicrobial resistance is gaining top priority with the creation of a Task Force for horizontal coordination at the European Commission;
- Update on Falsified Medicines Directive with last implementing measures to be delivered by Q3. Assessment of 3rd countries for importation of active substances ongoing, Commission, EMA and Member States continue following-up on GMP non-compliance of API sites covered by written confirmations;
- Progress with the implementation phase of the Clinical Trial Regulation with work on clarification of legal interpretation and collaboration with EMA and Member States to define rules on transparency of the EU portal and database; monthly meetings by the coordination group to follow progress and avoid duplication;
- The College has not yet taken a decision whether to review the ATMP Regulation; in the meantime steps to improve the regulatory environment are being taken by the Commission;
- Progress of initiatives on timely access of patients to medicines ('STAMP' Commission expert group with experts from Member States and the EMA), with concrete proposals for optimising the use of the conditional marketing authorisation and of the accelerated assessment procedure and possible early identification of promising innovative products (pathfinder); Mandate of STAMP limited to pre-marketing regulatory aspects, but at EU level work ongoing on establishing links with existing groups on HTA and pricing and reimbursement;
- Launch of a study on off-label use that will last 14 months with a comprehensive mandate to consult all stakeholders in a stock-taking perspective. The Commission will evaluate later if coordination at EU level is necessary;
- Status of initiatives on pricing and access to medicines, with the Health Programme 2014-2020 funding two projects linked to the Commissioner's Health Priorities 2015-2019;
- Progress of implementation of mutual recognition of prescriptions;
- Feedback on the implementation of the Cross-border healthcare Directive and need for clarification of some aspects at Member State level;
- Update on International activities and a working arrangement between DG SANTE and the European Medicines Agency according to the Common approach on decentralised agencies; the Commission and the EMA services are currently working together to find the most appropriate way for the Agency to continue cooperation with other public bodies in the interest of public health;
- Update on Commission appointments of experts to the PRAC and COMP;
- Information on commemorating 50 years of EU pharma legislation;
- Provisional timeline on the selection procedure of the Executive Director of the European Medicines Agency leading up to the meeting of the Management Board in October 2015 where the Board is

expected to identify amongst the candidates proposed by the Commission the candidate to be appointed as Executive Director.

Some members underlined the importance of the study on off-label use, which should be considered not only from the regulatory point of view, but also with a focus on clinical practice and pharmacovigilance. On antimicrobial resistance there was an invitation to consider repositioning and revamping of old antibiotics, which according to recent data could be used in difficult situations. Interest was also expressed in the discussion on the definition of promising innovative products, and the recent European Parliament study : "Towards a harmonised EU assessment of the Added Therapeutic Value of medicines". ..

## B.3 Amendment to Work programme 2015-2016 Annex 4: Operational procurement decisions

[EMA/MB/297623/2015] The Management Board adopted an amendment to the Work Programme 2015-2016. The proposed amendment concerned the inclusion of a procurement procedure for 'Provision of software development, integration services, solutions and IT Security and Network consultancy'. This tender replaced another which was included in the 2014 Work Programme and needed to be re-launched to include more technical specification, as well as other minor contracts. These were consolidated into the procurement procedure with a view to decrease the chance of overlap between the contracts and to cover all aspects of IT consultancy that the Agency might need.

## B.4 Assessment of the Executive Director's Annual Activity Report (AAR) 2014

[EMA/MB/333954/2015; EMA/95858/2015; EMA/277613/2015] The Management Board noted the 'Annual activity report' and adopted the document 'Analysis and assessment of the Deputy Executive Director's annual activity report 2014', which had been drafted by the topic coordinators Christa Wirthumer-Hoche and Hugo Hurts.

The topic coordinators were pleased with the results presented in the annual activity report and the considerable work programme delivered in 2014, as well as the description of the roles that National Competent Authorities and the Agency both play in the functioning of the EU Medicines Network. They also noted the Agency's effort to support early access to medicines through the adaptive pathways project, the implementation of the EU Telematics governance structure, the creation of the EU-Network training centre, the establishment of the Management Board steering group on data gathering, the successful move of the Agency to its new premises, the good functioning of the internal-control systems and the reliability of the 2013 accounts confirmed by the European Court of Auditors, as well as the actions taken by the Executive Director to review and improve the management and control systems related to IT project management. Concern was expressed on the consequences of the Decision of the Civil Service Tribunal to annul, on formal grounds, the 2011 decision of the Agency's Management Board to appoint Guido Rasi as the Executive Director of the Agency and on the length of the procedure leading to a new appointment. The European Commission representative explained that the normal procedure has been followed and that it is difficult to further shorten it.

## B.5 Update on the Implementing rules to the Fee Regulation

Item deferred.

## B.6 Draft guiding principles for a revision of the EMA CoI policy for the Management Board

[EMA/MB/332272/2015; EMA/332353/2015] The Management Board endorsed, without prejudice to further reflection and development, the draft guiding principles for a revision of the EMA CoI policy for the Management Board. Following the adoption last year by the Management Board of a revised 'European Medicines Agency policy on the handling of declarations of interests of scientific committee's members and experts' (Policy 0044) the current policy for the members of the Management Board and later for the Agency's staff need to be reviewed. The legal basis is the same for members of scientific committees/experts and for board members, however the board has a different role and its policy must be aligned, where relevant, to policy 0044. Draft guiding principles were proposed to achieve a better balance in managing declarations of interests of Management Board members versus the specific role and responsibilities of the board, maintaining the high level of independence in the work to be performed. The objective would be met by maintaining alignment with policy 0044 where relevant, and by taking into account the specific role and responsibilities of the board. Alignment with policy 0044 would be maintained in the areas of revision of key definitions and concepts in both policies, looking first at the nature of the declared interests before determining length of time of restrictions, and by addressing the perception issue. Specific focus on the Management Board roles and responsibilities would be achieved through improved categorisation of the board activities with resulting mitigating measures, further elaboration of possible interests with non-pharmaceutical companies and specific arrangements in the exceptional case of discussions on product related matters at the board. As next steps the board would be invited to appoint two topic coordinators to contribute to the drafting of a revised policy and revised breach of trust procedure for adoption by the Management Board in Q4 2015.

In the discussion that followed some further issues emerged, concerning among other the definition of organisation/institution, funding of patients' organisations, matters of perception of bias, categorisation and length of interests, specificities of roles in the Management Board as well as occasions in which scientific or product related issues might be discussed by the board. The representative of the European Commission invited the board to take stock from the experience from other EU agencies. The representative further suggested with respect to exceptional product-related discussions, that the specific cases in which this can happen should be clarified and that consequent specific arrangements should be made. Some of the matters raised by the board might be addressed through fine-tuning or risk mitigation when drafting the policy, other might impact on the principles themselves. In order to provide the Agency with some steer, it was decided to endorse the principles without prejudice to further reflection and development, and to appoint Wolf-Dieter Ludwig and Pekka Kurki as topic coordinators.

## B.7 Update on the EU Telematics Strategy and Implementation Roadmap 2015-2017

[EMA/MB/334709/2015; EMA/322556/2015] The board noted the EU Telematics Strategy roadmap v.2.0. The document aims to provide a concrete description of how to put into action the Strategy and is based on the planning directives originated in a workshop held on 26-27 February 2015 involving IT and business representatives from all NCAs and subsequent consultation of Industry associations. The draft Roadmap was released for consultation with NCAs and industry with deadline for comments until 21 June. The document provides an indication of the implementation of EU Telematics projects from 2015 to 2017 and should be used for reference as the timelines provided are subject to change as further developments mature. It will be updated at the end of the consultation period but also

periodically as projects evolve. The current timelines foresee an adoption by the EU Telematics Management Board on 30 June and an endorsement by the Management Board in July by written procedure after discussion and endorsement by the HMA in its early July meeting.

The representative of the European Commission welcomed the decision by EU TMB to adopt CESP as the single submission portal. IT services at the Commission agree that it should be used for all authorisation procedures. For the European Medicines Agency some technical implications and CESP's development plan need to be clarified in order to achieve integration with existing systems developed at the Agency. The Agency shares the ambition to avoid redundancies and is committed to start with initial Marketing applications.

Reference was made to the proposal to be discussed at HMA to create a new structure related to the Telematics governance. For the Agency the approach to the Telematics governance should be holistic and aim at avoiding redundancy of structures which might lead to unclear communication and diminished transparency. A brainstorming of the IT Directors Executive Committee on improving the Telematics governance is planned for 1 July.

Some members were interested in further information on Art. 57 implementation and on its impact on NCAs. The Agency has conducted a pilot with some Member States on data quality in Art. 57, and a study will be available soon. A paper on how quality control is performed will be made available. Furthermore, the ISO IDMP Implementation Task Force is looking at how to achieve transition from Art. 57 to ISO IDMP.

Concerning the issue of tight timelines for approval of the Roadmap after the end of the consultation period, it will be the task of the EU TMB to decide whether the comments received warrant a delay in the adoption. In that case discussion at the Management Board would be taken up at the October meeting.

## B.8 Response to outcome of the public consultation on public hearings at the PRAC

June Raine, Chair of the PRAC, joined the board for the discussion of points B.8, B.9 and B.10.

[EMA/MB/332804/2015; EMA/332813/2015] The board discussed and noted the Response to outcome of the public consultation on public hearings at the PRAC. Draft Rules of Procedure (RoP) on the organisation and conduct of public hearings were submitted to a public consultation which ended on 15 October 2014. Feedback was overall very positive; 200 comments from 25 organisations had to be reviewed and responses prepared, which were discussed by PRAC at its May meeting. PRAC overall expressed support on the EMA proposed responses whilst making some further comments. HMA was consulted at its May meeting, and broadly supported the amendments by the PRAC providing further comments. Next steps foresee consultation of the Scientific Coordination Board (SciCoBo) in June before amending the draft RoP in view of finalisation. The Agency is preparing additional material, such as an impact assessment, a guidance document, a training plan and a communication plan. Adoption of the revised RoP is envisaged at the PRAC in Q4 2015, following the favourable opinion by the European Commission and subsequent endorsement by the Management Board.

The board welcomed the approach and assured June Raine of its trust in her stewardship of this new and complex activity. Some members however were concerned by the lack of support from PRAC to the presence of members of other Committees to the public hearing. The Chair of PRAC reassured that this is part of a prudent stepwise approach. The Agency informed that discussion on the participation of members of other committees will take place at the SciCoBo where all Committees are represented.

The representative of the European Commission stressed that public hearings can provide value in well selected cases and recommended to start with a pilot phase. The representative of the Commission asked the Agency to provide the board with an assessment on the impact on the tasks of PRAC and on resources and cost of the exercise. The Agency will present it along with the final RoP. Concerning possible risks of side-lining of the hearings raised by other members of the board, the Agency is confident that by setting clear expectations and timeframes if will be possible to achieve specific objectives.

## B.9 PSUR Repository

[EMA/MB/290716/2015; EMA/321731/2015; EMA/PRAC/233445/2015; EMA/312973/2015; EMA/681848/2013; EMA/313926/2015; EMA/MB/303824/2015] The Management Board noted the outcome of the audit and PRAC recommendation, noted the Plan for further functionality and adopted and announced the Confirmation of functionality of the PSUR repository establishing its mandatory use as of 13 June 2016.

On 12 December 2013 the Management Board had endorsed the 'PSUR Repository functionalities to be audited' which included a project plan for the delivery of additional functionality, including an automated two-way exchange of documents between NCA systems and the PSUR repository. The PSUR repository was released as a pilot on 26 January 2015 and underwent an independent audit which was finalised on 20 March 2015. Following the audit, the PRAC adopted a positive recommendation on 10 April 2015 concluding that the PSUR repository meets the functional requirements. As next steps the Agency plans to focus on the further project development plan with delivery target before December 2015.

The board congratulated the Agency for the outstanding work done and thanked for the excellent collaboration.

## B.10 Management Board liaison process for PRAC composition – Liaison after the first 3 years of PRAC in 2015

[EMA/MB/330972/2015; EMA/324491/2015; EMA/525507/2014; EMA/330665/2015] The board discussed and noted the 'Briefing note on competence and expertise of CHMP and PRAC members and alternates' and recommended the PRAC composition and 'Expertise of PRAC members'. The most recent status of the PRAC composition showed 15% new members and alternates in 2015, however over the last three years turnover has been of ca. 45%. This does not seem to have impacted substantially on the expertise represented at the PRAC, which continues to be very broad and covers all areas of core expertise as well as complementary expertise. A Briefing note has been prepared in collaboration with CHMP and PRAC for consideration by Member States for future nominations. Criteria for experience and expertise are set out, however no minimum period for post graduate experience has been defined although nomination of recently graduated experts is not recommended.

June Raine assured the board that competence and expertise of the PRAC have successfully delivered against a broad range of tasks and heavy workload, which probably accounts for some of the turnover. The PRAC has profited from the outreach into academia provided by the six members nominated by the European Commission and from the contribution from Patients' and Healthcare Professionals' representatives. While continuity in the Committee is important, looking at the future some disciplines will become more valuable. The Patients' representative stressed that proposal by the Agency to set down expectations on the role of Patients' and Healthcare Professionals' representatives should be taken up.

## B.11 Update on the development of CT Portal and Database

[EMA/MB/331420/2015] The board noted an update on the development of the CT Portal and Database. At its meeting of March 2015 the Management Board adopted a revision of section 6 of the 'Functional Specifications for the EU Portal and Database to be audited'. Since then work has continued on disclosure rules incorporating comments received during public consultation. Several meetings with partners and stakeholders are planned before a final draft will be presented to the Management Board at the October meeting. The design work is making good progress and should be completed by September 2015. It is expected that the project will be in the build/development phase by Q4 2015. The Agency will provide a communication on timelines in mid-2015.

The question was raised whether non-CMS would have access to applications in the Portal and Database in application of the relevant legislation. The representative of the European Commission referred the matter to the level of the relevant working group where the Commission is represented.

## B.12 IAS Mission Charter

[EMA/MB/271124/2015; Ares(2014)3984092] The Management Board adopted the IAS Mission Charter. As the Agency's internal auditor the IAS provide their revised Mission Charter to be agreed and signed by the Agency's representative and by the Chair of the Management Board. The Charter describes how it intends to work under the board's authority. The last Charter was issued in 2010

## B.13 2014 annual reports of Audit Activities at the Agency

[EMA/MB/281256/2015; EMA/668428/2014] The board noted the annual reports of Audit Activities. The 2014 Internal Audit Report was not issued by the Internal Audit Service of the EC (IAS) due to the fact that there were no open critical or long overdue very important recommendations. The Annual Report of the Internal Audit of EMA 2014 provided information about audit activities, main audit findings and on the monitoring of main audit recommendations. Of these no critical recommendations are open and for all other recommendations improvement actions are being implemented according to agreed deadlines.

The representatives of the European Commission suggested to provide in the annual report information on time and resources spent on each audit and on whether an action plan had been prepared by EMA. Furthermore, a summary on type and number of findings for each audit was considered to be helpful, as well as information on the results from external audits. The representative of the European Commission suggested adopting the Commission document management rules, in view of some of the findings.

The Audit Advisory Function's Audit Strategy already includes the information about the resources. The annual report includes information about the implementation of the action plans and also on consultancy and other activities of the Audit Function.

The requested detailed information on type and number of findings for each audit will be provided in future annual reports.

## B.14 Amendment of audit strategy 2015-2017 and annual audit plan 2015

[EMA/MB/281376/2015; EMA/427639/2014] The Management Board noted the audit strategy 2015-2017 and adopted the amended audit plan 2015. The audit plan was amended to avoid duplication after the IAS informed that they would perform in 2015 an audit on Paediatric Medicines which was also included in the EMA plan.

## B.15 Report by the Steering Group on the Management Board data gathering initiative

[EMA/MB/344426/2015] The board noted the 5th Interim Report by the Steering Group of the data gathering initiative. The pilot exercise on scientific advice procedures is well under way and data from the 1st of three cycles of collection have become available. Data from the 2nd cycle is awaited on 12 June, in parallel with an extension of the pilot that looks at collecting data on the so-called Scientific overheads (non procedure specific product-related time collection). After a first slow start the provision of time recording data has suddenly improved as reports were received by all 15 delegations, covering 90% of procedures. These results are impressive also given that the exercise is very resource-intensive, also for the Agency. A first look at complete submissions of data show high variability, particularly in the contribution of NCA scientific staff. Whether this variability reflects different procedural and scientific complexity or is the result of network diversity will become clearer as more data become available. Further reflection will also be needed as to the appropriate level of detail of the collection.

## B.16 Annual report on the performance of the Agency's scientific procedures

[EMA/MB/320899/2015; EMA/268699/2015] The Management Board noted the Annual report on the performance of the Agency's scientific procedures and endorsed the extension of the pilot phase within the renewal of the Cooperation Agreement.

## A.O.B.

The representative of the European Commission pointed out that a year-on-year fixed reporting format for all EMA IT projects (master plan) is needed, including budgets, priorities and major release cycles, so that the management board can have an overview and a reasonable assurance regarding IT expenditure.

## Documents for information

- [EMA/MB/320899/2015; EMA/268699/2015] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/233602/2015] Outcome of written procedures finalised during the period from 19 February 2015 to 8 May 2015
- [EMA/MB/279870/2015] Summary of transfer of appropriations in the budget 2015
- [EMA/MB/281871/2015; Ares(2015)1769698] IAS Strategic Internal Audit Plan 2016-2018

- [EMA/MB/322505/2015] Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2014

## List of written procedures during the period from 19 February 2015 to 8 May 2015:

- Consultation no. 03/2015 on the appointment of Tuomo Lapveteläinen as CHMP alternate, proposed by Finland, ended on 9 March 2015. The mandate of the nominee commenced on 10 March 2015.
- Consultation no. 04/2015 on the appointment of Sigitas Siriukaitis as CVMP alternate, proposed by Lithuania, was extended on 13 May 2015.
- Consultation no. 05/2015 on the appointment of Viola Macolić Šarinić as CHMP member, proposed by Croatia, ended on 30 April 2015. The mandate of the nominee commenced on 1 May 2015.
- Written procedure for adoption of 87th Management Board meeting minutes ended on 28 April 2014. The minutes were adopted.

## Tabled documents

- [EMA/MB/322505/2015] Status Report on EMA Staffing
- [EMA/MB/273417/2015] Report on EU Telematics

List of participants at the 88th meeting of the Management Board, held in London, 11 June 2015

Chair: Sir Kent Woods

| | **Members** | **Alternates (and other participants)** |
|---|---|---|
| **Belgium** | Xavier De Cuyper | |
| **Bulgaria** | Assena Stoimenova | |
| **Czech Republic** | Zdenek Blahuta | |
| **Croatia** | | Viola Macolić Šarinić |
| **Denmark** | Mette Aaboe Hansen | Matilde Kyst Behrens |
| **Germany** | | Karl Broich<br>André Berger |
| **Estonia** | Kristen Raudsepp | |
| **Ireland** | | Rita Purcell |
| **Greece** | Despoina Makridaki | |
| **Spain** | Belén Crespo Sánchez-Eznarriaga | Laura Franqueza Garcia |
| **France** | | Jean-Pierre Orand<br>Miguel Bley |
| **Italy** | Luca Pani | Gabriella Conti |
| **Cyprus** | Loizos Panayi | |
| **Latvia** | | Dace Kikute |
| **Lithuania** | Gintautas Barcys | |
| **Luxembourg** | | Jacqueline Genoux-Hames |
| **Hungary** | Beatrix Horváth | |
| **Malta** | John J Borg | |
| **Netherlands** | Hugo Hurts | |
| **Austria** | Christa Wirthumer-Hoche | |
| **Poland** | Grzegorz Cessak | Magdalena Pajewska |
| **Portugal** | Hélder Mota-Filipe | Maria Morais |
| **Romania** | *Apology received* | |
| **Slovakia** | *Apology received* | |
| **Slovenia** | Katarina Štraus | David Obranovič |
| **Finland** | | Pekka Kurki |
| **Sweden** | | Johan Lindberg |
| **United Kingdom** | | Ian Hudson<br>Jonathan Mogford |
| **European Parliament** | *Apology received*<br>Björn Lemmer | |
| **European Commission** | Ladislav Miko (DG SANTE)<br>Carlo Pettinelli (DG GROW) | Miroslav Griva (DG SANTE) |
| **Representatives of patients' organisations** | W.H.J.M. Wim Wientjens<br>Nikos Dedes | |

| | Members | Alternates (and other participants) |
|---|---|---|
| **Representative of doctors' organisations** | Wolf-Dieter Ludwig | |
| **Representative of veterinarians' organisations** | Christophe Hugnet | |
| **Observers** | Runa Hauksdottir Hvannberg (Iceland)<br>Brigitte Batliner (Liechtenstein)<br>Augun Haga (Norway) | |

| | | |
|---|---|---|
| **European Medicines Agency** | Andreas Pott<br>Noël Wathion<br>Agnès Saint Raymond<br>Stefano Marino<br>Enrica Alteri<br>Tony Humphreys<br>Alexis Nolte<br>Luc Vanheel<br>Jordi Llinares<br>Nerimantas Steikūnas<br>Kornelia Grein<br>Anabela Marcal<br>Isabelle Moulon<br>Edit Weidlich<br>Hilde Boone<br>Monica Dias<br>Martin Harvey Allchurch<br>Dina Tsiambaou<br>Silvia Fabiani<br>Sophia Albuquerque | |