7 October 2016
EMA/MB/489158/2016 Adopted
Management Board

Minutes of the 93rd meeting of the Management Board

Held in London on 6 October 2016

The Management Board observed a one minutes silence in memory of Dr Wim Wientjens, who died on 28 July. Dr Wientjens had served on the board as a committed representative of patients' organisations from March 2013 to March 2016.

1. Draft agenda for 6 October 2016 meeting

[EMA/MB/440637/2016] The agenda was adopted with no amendments.

2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics *B.4 Amendment to the Procurement Plan (Annex 5) of the Work Programme 2016, B.5 Amending budget 01-2016, B.7 Annual review of the EMA independence policies and ensuing actions, EMA policy on the handling of declarations of interests of scientific committees' members and experts (Policy 0044), EMA policy on the handling of competing interests of Management Board members (Policy 0058) and B.11 Reflection paper on the development of the European Medicines web portal.* The Secretariat informed the board of the restrictions arising from the current policy in force and that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

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

3. Minutes from the 92nd meeting, held on 16 June 2016 adopted via written procedure on 27 July 2016

[EMA/MB/421228/2016] The Management Board noted the final minutes, adopted by written procedure on 27 July 2016.

4. Election of the Vice-Chair of the Management Board (in camera)

Following the election of Christa Wirthumer-Hoche as chair of the Management Board on 17 March 2016 the position of vice-chair became vacant and elections for the position were announced at the meeting of 16 June.

In accordance with the election procedure the chair announced that no proxies had been received and the board appointed Brigitte Batliner, observer from Liechtenstein, to act as teller. The vote took place by secret ballot.

The Management Board elected Grzegorz Cessak, representing Poland, as the vice-chair.

A. Points for automatic adoption / endorsement

A.1 European Commission part-time rules

[EMA/MB/566944/2016; C(2015) 9720; EMA/MB/463031/2016] The Management Board adopted the decision to implement the European Commission rules on part time work. The rules shall come into effect as of 1 November 2016 at the European Medicines Agency.

A.2 Revised rules on working time

[EMA/MB/566910/2016; EMA/MB/562311/2016] The Management Board adopted the revised Rules on working time, to align the provisions on minimum lunch break with the European Commission's rules on part time.

B. Points for discussion

B.1 Highlights of the Executive Director

Organisational changes

To respond to changed processes following the streamlining of operations, further fine-tuning of the organisation in the operational Divisions for human medicines was needed. Divisions have been reduced from four to three, comprising three fewer Departments. A new entity for Scientific Committees Regulatory Science was created in order to respond to the need for leadership in this area. Further organisational changes have taken place in the Administration area, which has been reshaped to better apply an integrated approach to strategic planning and monitoring at the Agency. As a result the structure now counts five fewer Departments than a year ago.

Preparedness for Brexit

The UK Prime Minister has announced that a notification according to Article 50 to withdraw from the European Union will be launched before the end of March 2017. The Agency continues to run its business as usual, while performing the necessary work on preparedness, as advised by the Court of Auditors. An internal Task Force is working on financial preparation and on impact analyses of the possible consequences of relocation and of loss of expertise for the Agency's activities. Facts and figures on the Agency's operations and logistic features are being prepared to respond to the numerous requests by cities and governments expressing an interest in hosting the Agency in the future. In the meantime the Agency continues to stay in close contact with the European Commission and relevant institutions.

EU activities

The Agency together with the PDCO has provided a significant contribution to the Commission's 10 year report on the experience gained with the Paediatric Regulation. The European Parliament has voted positively on the Agency's draft 2017 budget. The annual Exchange of views between the Executive Director and the ENVI Committee is scheduled for 8 November.

Publication of first Clinical Trials data under Policy 70

The policy was published in October 2014 and since then the Agency has been working on its implementation. The publication of the first clinical data sets is scheduled for 20 October 2016 and will concern two products.

Workshop on Adaptive Pathways

As suggested by the European Commission the Agency has organised a full day meeting on Adaptive Pathways on the 8 December. The workshop will aim at clarifying the Adaptive Pathways approach to support the development of medicines that promise to address unmet medical needs.

Workshop on Big Data

As a consequence of significant interest expressed by NCAs and others, the Agency has managed to move the workshop on 14-15 November to a larger external venue enabling an invitation to be extended to all Heads of medicines agencies. The aim of the workshop is to gather information on the latest developments in big data in order to inform thinking on how to realise its potential in supporting medicinal decision making and identify what resources will be needed in the future.

Framework for interaction with academia

After a survey and a workshop with academia, the Agency has prepared a framework for interaction to be reviewed by the European Commission ahead of its submission to the board in December.

International activities

The European Commission and the Agency met on 1-2 September at the EMA with the Japanese PMDA and the US FDA to discuss a more global approach to developing new antibacterial medicines. The conclusions of the meeting were presented at the G7 Health Ministers meeting in Japan on 11-12 September 2016. EMA and FDA have worked together on paediatric medicines for over a decade, and have met on 28 September for a strategic bilateral on the future of global development of medicines for children. Important staffing changes will take place in mid-November, when Emer Cooke will leave the Agency to take up her new role as Head of Regulation of Medicines and other Health Technologies in the Essential Medicines and Health Products Department at the WHO. Her key role at the Agency will be filled ad interim by an experienced colleague, Agnès Saint-Raymond.

A representative of the European Parliament supported preparedness for a relocation by the Agency, as disruption of operations will need to be avoided. The representative of the UK assured the board of the UK's full commitment until future arrangements are made and it will leave the EU. A representative of Patients' organisation welcomed the workshop on Adaptive Pathways as an occasion for public discussion to clarify and dispel preoccupations. The board was informed that initiatives on Big Data are ongoing also at HMA, and that a mandate for a Working Group will be discussed in November. The Agency was complimented for the performance of the PSUR repository, which was judged to fully respond to NCAs' needs.

B.2 Report from the European Commission

The representative of DG SANTE stated his satisfaction with the excellent level of collaboration between EMA and the European Commission and referred to the highlights of the Executive Director as initiatives of strategic importance. A presentation on written updates from the European Commission had been circulated to the board, which was invited to consider a few main topics:

Brexit

As a decision by the British people has been made to leave the EU, the European Commission must await that their government triggers the Article 50 provisions. In the meantime the European Commission set up a Task Force led by Michel Barnier as Chief Negotiator for the preparation and conduct of the negotiations with the United Kingdom; with a single contact point for DG SANTE to deal with these issues. Given that the location of the Agency is agreed at the level of the Heads of Government, the decision is not formally connected to the negotiations relating to the Article 50 procedure. The Court of Auditors has informed the Agency that the Court will examine how the Agency prepares contingency plans to ensure business continuity. The European Commission is very aware of the condition of uncertainty for the Agency's staff and will do its utmost to alleviate it.

Antimicrobial Resistance (AMR)

A staff working document on the AMR Action Plan is in preparation; however it appears certain that a new Action Plan will be proposed for the coming five years. At the UN General Assembly in September for only the fourth time in history a healthcare issue was taken up and a resolution issued. The Commission will encourage EMA, ECDC and EFSA to cooperate even closer on this issue.

Council conclusions on access to medicines, June 2016

The Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States highlight the need to maintain the MSs' prerogative on pricing, while working towards the defragmentation of market access and strengthening dialogue between regulators, HTA bodies and payers. The European Commission has been mandated to conduct a number of studies on the impacts of the current legal framework of intellectual property rights and a study on the economic impact of the Paediatric Regulation.

HTA

Work on HTA will continue in the coming year to involve EMA, both within the EMA-HTA network and the EUnetHTA Joint Action 3. An Inception Impact Assessment on Strengthening of the EU cooperation on Health Technology Assessment, providing 5 policy options, was published on 14 September and will explore how more than 50 national and regional HTA bodies can increase cooperation. Stakeholders, including MSs, are invited to contribute to the consultation. The Commission is confident that the Agency will play an important role in the years to come.

Slovak presidency initiative on shortage of medicines

With pricing and provisioning fully under the responsibility of Member States, the European Commission recognises that shortages can lead to critical situations and fully supports and encourages the work of the joint EMA/HMA task force on availability. It furthermore encourages Member States to closer cooperation and to the use of tools such as joint procurement of medicines or vaccines.

Vaccination

The Commission considers vaccination a most effective instrument of healthcare, and supports greater cooperation in order to increase vaccine acceptance and uptake in the EU, strengthen sustainability of vaccination programmes and ensure vaccine supply.

TTIP negotiations

At the current round of negotiations both sides are focussing on achieving tangible outcomes by the end of the year. Some interim agreements may be made before the conclusions of the TTIP negotiations, such as the mutual recognition of GMP inspections, which could be concluded by December 2016 on condition of good progress of the HMA Joint Audit Program.

EU medical Devices Regulation

The European Commission DG GROW representative updated the board on the new EU Medical Devices Regulations. Following political agreement by the Council and the European Parliament on Medical Devices and In Vitro Diagnostic Medical Device Regulations in June earlier this year, a final vote and publication can be expected in early 2017. The legislation addresses an enormous field with over 500,000 medical and in vitro diagnostic devices on the market, and over 500,000 people employed in about 25,000 companies. The new legislation will replace the current three Directives with two Regulations, which will become applicable without need to be transposed into national legislation. As next steps the adoption by the Council is expected by end of 2016 at the earliest and by the European Parliament in early 2017. Some further time for language check of the over 700 pages long technical documents will be needed before publication. The main transition period will extend over several years into 2022. Priorities for implementation are the essential role of notified bodies, common specification on devices without a medical purpose and reprocessing of single-use devices, introduction of Unique Identifiers and the EUDAMED database, setting up of the Medical Device Coordination Group (MDCG) and expert panels to provide governance.

The board welcomed the Commission initiatives on vaccines, as several Member States are experiencing drops in vaccination rates, and even hesitancy by the medical professionals themselves. Although vaccination programmes are national, the Commission would like to have a discussion with all stakeholders to consider providing tools such as fact-sheets, joint procurement on a voluntary bases and synchronised campaigns. There was some request for further focus on veterinary vaccination, and more in general for future updates on animal health.

Concerning AMR more information on timelines for adoption of a new action plan was requested. As the Commission reflects on the results of the evaluation of the 2011-2016 Action plan, three key priorities have been identified: making the EU a 'best practice' region, promoting research and innovation and strengthening the role of the EU in the global agenda.

Members who expressed themselves supported closer cooperation and regular communication between the EMA, the Commission, payers and HTA bodies, as well as with NCAs. A request was made for the circulation of the Terms of Reference for the evaluation of the fee system of the Agency. This will be taken into account in line with the Commission rules.

B.3 EMA mid-year report 2016 from the Executive Director (January - June 2016)

[EMA/MB/614902/2016; EMA/469742/2016] The Management Board noted the mid-year report from the Executive Director. The report provides an overview of the Agency's performance and achievements in implementing the work programme 2016. It is based on data available at the end of June and provides a comparison to the forecast for 2016 presented as a "traffic light system". Adjustments of workload forecasts are indicated. Among the key developments and achievements of the first half of 2016 the following are to be noted: the launch of the PRIME procedure in March, followed by ca. 120 applications; implementation of a revised process for accelerated assessment; agreement of a conceptual framework of the Agency's interactions with EUnetHTA; successful delivery of the PSUR repository; in the veterinary area the publication of three problem statements by the ADVENT group and the development of the EU network action plan to promote availability of veterinary vaccines. Concerning interactions with stakeholders the Agency created an expert group of general practitioners, conducted a dry run on public hearings and opened training opportunities of the EU NTC to non EU regulators in developing countries. The Agency was very active also in the time-data collection for fee generating and non–fee generating activities which is part of the data gathering initiative, and revised and implemented the policy on competing interests for the Management Board Members. Regarding workload trends, applications concerning innovation and SMEs appear stable, as are Scientific Advice applications seen at the time of the midyear report, but followed by renewed increase in September. For human medicines applications some qualitative change from applications for generics to innovative products was noticed, while changes in average clock-stop figures seem to reflect the greater complexity of the products to be assessed. A very steep increase was noticed in initial applications for veterinary products, adjusting the yearly forecast from 10 in 2015 to 28 in 2016. MUMS applications appear to have reached a plateau. The number of GMP and GCP inspections continues to increase and lead to an annual forecast adjustment, while pharmacovigilance inspections were slightly lower than in 2014 and 2015. Additional 8% of routine GMP re-inspections and 31% of GCP inspections were addressed through information exchange.

The board congratulated the Agency on the report. Some members enquired on progress and investment into veterinary projects, in particular EVVET, to which the Executive Director confirmed that a strategic review is foreseen and a detailed update will be provided at the next meeting of the Management Board. It was suggested that the report on telematics projects could be included in the

overall report next year, and that more information on AMR activities is provided, possibly as a dedicated future agenda topic.

B.4 Amendment to the Procurement Plan (Annex 5) of the Work Programme 2016

[EMA/MB/629515/2016; Annex 5 of EMA/92499/2016] The Management Board adopted an amendment to the Work Programme 2016. The start of a procurement procedure, initially planned for 2017 and included in the preliminary procurement plan of the programming document, was moved forward to the last months of 2016. This was necessary due to the early consumption of the current financial envelope and concerns a high-level business consultancy Framework Contract extending over four years, which provides a variety of services to projects at the Agency. The Agency agreed to provide further details on how the framework contract is used to support specific projects. The final tender amount will be determined following detailed analysis of needs arising from the implementation of the multi-annual work programme.

B.5 Amending budget 01-2016

[EMA/MB/572210/2015] The Management Board adopted the amending budget. The adjustment was necessary due to the need to take into account the significant decrease in the Pound value against the Euro following the outcome of the UK referendum. Expenditure for staff, meeting costs, maintenance and utilities, and in a lesser degree for rental of the building, which takes into account assigned revenue, has sensibly decreased. On the revenue side, the decreased expenditure is offset by an estimated 2% reduction in application revenue compared to the initial forecast, although fee revenue is still higher than in 2015, and by a reduction of the general balancing EU and EEA contribution.

B.6 Revision of budget structure from financial year 2017

[EMA/MB/572210/2015] The Management Board endorsed the revised budget structure. The new budget structure reflects the European Commission's template and will come into effect as of the financial year 2017.

B.7 Annual review of the EMA independence policies and ensuing actions

- **EMA policy on the handling of declarations of interests of scientific committees' members and experts (Policy 0044)**
- **EMA policy on the handling of competing interests of Management Board members (Policy 0058)**

[EMA/MB/608752/2016; EMA/175527/2016; EMA/626261/2014, Rev. 1; EMA/MB/655150/2016; EMA/MB/715362/2015, Rev. 1] The board noted the first Annual review of the EMA independence policies and adopted the revised EMA Policy on the handling of declarations of interests of scientific committees' members and experts and the revised EMA policy on the handling of competing interests of Management Board members. The annual review was requested in January 2015 by the European Commission and will be presented to the Management Board every year. In this first report the status

of all independence policies and their implementation, including controls, was reviewed. Concerning the scientific committees' members and experts, no breach of trust procedure was formally launched in 2015, and ex ante and ex post controls did not identify any major issues. Overall transparency was achieved through appropriate publication of declaration of interests, CVs and minutes including restrictions applicable to meeting participation. For the members of the Management Board the findings were similar, although ex ante and ex post controls were not planned for 2015 and hence no controls were undertaken. For EMA staff 28 applications to engage in an occupation within two years of leaving EMA were received and examined, resulting in authorisation with restrictions in 5 cases. Future initiatives include further work on handling of competing interests for suppliers and contractors and for other experts, and conducting systematic ex ante and ex post controls. As a result of the review, inconsistencies in the alignment of policy 0044 and 0058 were detected, and have been addressed in the revisions submitted to the board. In particular provisions on handling grants in 0058 were aligned with 0044, and provisions on close family member in 0044 aligned with 0058.

The representative of the European Commission welcomed the review of independence which will contribute to the important task for the Agency to monitor and improve its policies.

The adopted revised policies will be implemented as of 1 December 2016.

B.8 Decision on rules concerning the handling of declared interests of EMA staff

[EMA/MB/608567/2016; EMA/259494/2016] The Management Board adopted the Decision on rules concerning the handling of declared interests of EMA staff. The guiding principles for the revision of the Decision had been presented and endorsed by the board at the March 2016 meeting.

It was pointed out that for staff members who have indicated that they will leave the Agency, provisions concerning restrictions on existing activities taking into account the intended post-employment occupational activities until they leave the Agency are not fully aligned with similar provisions in the policy for scientific committees' members and experts. This is due to the different work performed by staff members and experts, with a limited scope for staff members to influence regulatory outcomes. Furthermore, provisions concerning staff members need to be compatible with the Staff Regulations, and as such the present decision will need to be approved by the Commission's DG HR and is therefore adopted on an interim basis. Its implementation is foreseen from 1 January 2017.

B.9 Report on changes to GCP inspections fees as of 1 August 2015

[EMA/MB/365399/2016; EMA/INS/GCP/264055/2016] The board noted the report on changes to GCP inspection fees. On 1 August 2015 the board adopted by written procedure Implementing Rules to the Fee Regulation that revised the definition of a 'distinct' GCP inspection to reflect the effort involved in inspecting distinct activities. As a result, the number of chargeable fees and therefore the remuneration to the NCAs was increased. The present report was requested by the board and by the Commission and covers the first year of experience. The outcomes show an increase in fees charged, resulting in increased remuneration for NCAs, increase by 11% of inspected GCP sites, as well as additional actual or planned recruitment of GCP inspectors in NCAs. A further follow-up report will be provided to the Management Board in October 2017.

B.10 Pharmacovigilance Programme: Update on the EudraVigilance Auditable Requirements Project

[EMA/MB/587863/2016; EMA/452911/2015; EMA/325783/2016; EMA/835422/2016] The board noted the update on the EudraVigilance Auditable Requirements Project. At the meeting in June 2016, the board had approved an updated schedule for the implementation of the new EudraVigilance (EV) system due to the need to further strengthen the performance of the new system prior to its go-live. As a result, some key project milestones were impacted and the new timeline now foresees that the audit takes place in February 2017 with an adoption by the board of the final audit outcome in May 2017 and a final delivery of the system in November 2017. The EudraVigilance Auditable Requirements Project is currently on track and activities are ongoing in system testing and development of a curriculum of online training. An updated EV Stakeholder Change Management Plan was published on 5 August 2016. In the framework of the transition to a new IT supplier, a new specific contract for the PV-ADR project is being processed. A phased handover of IT deliverables from the current to new supplier is expected by end of February 2017. At the December meeting of the board further details will be provided on enhanced NCA access to Article 57 reports via the EV data warehouse.

B.11 Reflection paper on the development of the European medicines web portal

[EMA/MB/607095/2016; EMA/MB/654700/2016; EMA/585981/2016] The Management Board adopted a reflection paper on the development of the European medicines web portal. After endorsement at the June HMA meeting of a vision, extended as proposed by the EU TMB, the Management Board had confirmed this approach and endorsed the principal elements for a vision on developing a European medicines web portal at the meeting of 16 June 2016. The finalised reflection paper provides a high level outline of vision, ownership, roles and responsibilities, as well as content and source of data for nationally authorised products. The reflection paper has been presented on several occasions in 2016 to the EU TMB and the Telematics Forum, and has been commented on by IT Directors and EU TMB. It was endorsed in its final version by HMA on 6 September 2016. The European Commission has asked for a strengthened statement concerning support to the European eHealth action plan 2012-2020, including the development on the cross-border exchange of ePrescription as part of the eHealth Digital Service Infrastructure. Following the adoption, EMA will develop a high-level project plan, allocate financial and human resources, develop a multi-annual delivery plan and propose a governance model describing NCA and Telematics representation.

The representative of the European Commission expressed its support for this project. Some members considered that the web portal will be successful only if it maintains links to trusted data on national websites and provide access to information currently not available at a single level, such as on availability of medicines or prices. Resources will need to be looked into carefully, as the project is very ambitious. The Agency intends to tackle the project with a stepwise approach, keeping the board always updated.

B.12 Report on dry-run of Public Hearings

The board heard a report on the dry-run of public hearings which took place at the Agency on 5 July. Approximately 75 EMA staff members took part, volunteering to act as speakers or observers in the discussion of a fictitious medicine. The EMA Public Hearing Task Force, which included the PRAC secretariat, referral team, meetings management, audio-visual/multimedia, security and facility

management and the press office, prepared the dry run in close cooperation with the PRAC. In the discussion of the feedback no major issue was identified, but some fine-tuning was found to be necessary. An auditorium providing better visibility and inclusion of observers is also needed. Some further issues to be considered concern personal data protection, which will need to be discussed with the EU Data Protection Supervisor, and specific training requested by the PRAC. Starting in September PRAC has now the possibility to hold public hearing if required.

A representative of the Patients' organisation welcomed the approach, in particular the possibility to stream the hearings.

B.13 Clinical Trial EU Portal and Database

The board noted a status update on the development of the EU Portal and Database. The project has reached its 4th iteration and the 3rd User Acceptance Testing (UAT) has been performed. As the switch to a new service provider in Q1 2017 approaches, framework contracts have been signed at the end of July and a specific contract for the development of the auditable version has been signed with the new contractor and handover between the old and the new contractor has been initiated. Engagement in UAT remains high both in terms of participating organisations and testers. The number of 'bugs' requiring further work appears to be falling, as the last release focused on delivering software as free as possible from outstanding issues in preparation for the handover. Preparation and planning for the audit continue according to plan. Following a request by the board, members and alternates have now been provided with access to view information published on the project microsite, and are now able to access documents and reports. Between September 2016 and January 2017 four workshops will be held with a group of Member States to discuss application programming interface (API) and coordination functionality within the Portal and database workspace, followed by a workshop with IT directors to present the API specification which will focus first on those aspects which are auditable requirements. Concerning access to clinical trial dossiers and assessments for non-MSC (Member State concerned) a proposal by the CTFG was agreed at the HMA on 6 September. Some issues remain to be clarified, while four Member States need to confirm that they can accept the proposal after having reviewed all national legal aspects. It is agreed that access to Part 1 of the dossier will be enabled in a first instance. In addition it is proposed that all Member States agree on sharing their assessments of the Clinical Trial application dossiers and related data in a document to be agreed by all. Once an agreement is reached, the Agency will perform a technical evaluation and prepare a proposed solution for implementation which will be presented to Member States and to the board for endorsement during 2017. The functionality will be developed after the audit as part of one of the subsequent iterations.

The representative of the European Commission acknowledged the agreement to start implementing access to Part 1 once all Members States have removed all legal hurdles. He reminded the board of the high priority of keeping agreed timelines and warned that additional non legislative requirements might slow down this process. Some members were aware of a letter by industry stakeholders requesting greater flexibility of the system for user management and access. The Agency is working with these stakeholders, but must consider any functional request in the context of the legislative pillar of single submission, and the priority to first implement the auditable and must requirements. Concerning the API, the Agency is working with experts from NCAs to define specifications as part of the clinical trial project. Following a request for closer oversight by the board of the Clinical Trial EU Portal and Database project, it was decided that written updates will be provided to the board and that three members, Karl Broich, Ian Hudson and Xavier De Cuyper, will join the Clinical Trial Regulation Coordination Group.

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

[EMA/MB/630665/2016; EMA/655001/2016] the board noted the 10th interim report of the Steering Group and an update on pharmacovigilance report. Data collection has now been launched for all fee and non-fee generating human procedure types, and will be completed at the end of October in order to allow the drafting of a report by the end of the year, to be finalised in March. The volume of activities examined is such that will generate healthy samples if compliance by all participants to the exercise is high. Should there be weaknesses in reporting rates, data about less frequent procedures might not achieve the necessary robustness. Some slowing down of submission of data was noticeable after summer, but it is to be hoped that there will be a recovery during the last weeks of the exercise. Distribution across Member States has been very good, leading to a representative sample. Collection of so called horizontal data shows a lower compliance than for data relating to procedures. For veterinary procedures data collection has largely been completed. Due to the low numbers for some procedures, it may be necessary to rely to some degree on comparison and extrapolation from human procedure data. A final report will be completed by end of Q1 2017.

Data collected for pharmacovigilance procedures was presented separately, as it is required by a specific legal basis which foresees an annual provision of information on hours worked on certain procedures. For 2016, data have been collected quarterly with a prospective approach, which was expected to determine better ease of execution and therefore compliance than the retrospective approach used in 2015. Currently available data however still show incomplete compliance, with data by some NCAs not available. Currently emerging data presents high variability, but together with the 2015 data can be considered robust enough to complete the data gathering exercise for the pharmacovigilance procedures.

Following a request by the board, the Steering Group will circulate records on data emerging from the data gathering exercise in a post mailing.

B.15 Multinational assessment team concept – The next phase – Broadening the concept to the post-authorisation phase

[EMA/MB/619857/2016; EMA/619544/2016] The board noted a proposal to extend the Multinational Assessment Team concept (MNAT) to the post authorisation phase. The concept was launched initially in November 2012 by a Baltic Sea Consortium and was limited in a pilot phase to initial Co-Rapporteur involvement. Following its uptake, extending also to Rapporteurs, Veterinary and Scientific Advice procedures, all but five Member States have been involved in a MNAT in some capacity. Following a request made by some CHMP delegates for a broadening to the post-authorisation phase, the Agency has analysed the request and set out some ground rules. These aim at allowing utmost flexibility whilst achieving a sustainable solution, ensuring knowledge transfer and an efficient and transparent post-authorisation process. The implementation is meant to take place with a stepwise approach, in a first phase limited to line extensions and extensions of indications (and addition of non-food target species in veterinary medicines), progressing to further phases once lessons learned become available. In a teleconference with CHMP members on 3 October, CHMP members were generally supportive, and provided some feedback which will be taken into account in the proposal which will be presented at the November HMA meeting and the December Management Board meeting for agreement.

List of written procedures finalised during the period from 12 May 2016 to 6 September 2016

- Consultation no. 05/2016 on the appointment of Noemi Garcia del Blanco as CVMP Alternate, proposed by the United Kingdom, ended on 18 May 2016. The mandate of the nominee commenced on 19 May 2016.
- Consultation no. 06/2016 on the appointment of Paolo Pasquali as CVMP member, proposed by Italy, ended on 6 June 2016 2016. The mandate of the nominee commenced on 7 June 2016.
- Consultation no. 07/2016 on the appointment of Antonio Battisti as CVMP member, proposed by Italy, ended on 13 June 2016. The mandate of the nominee commenced on 14 June 2016.
- Consultation no.08/2016 on the appointment of Hanne Lomholt Larsen as CHMP alternate, proposed by Denmark, ended on 7 July 2016. The mandate of the nominee commenced on 8 July 2016.
- Consultation no 09/2016 on the appointment Paula Boudewina van Hennik as CHMP alternate, proposed by the Netherlands, ended on 11 August 2016. The mandate of the nominee commenced on 12 August 2016.
- Written procedure for adoption of the 92nd Management Board meeting minutes, ended on 27 July 2016. The minutes were adopted.
- Written procedure for adoption of Agency's final accounts 2015, ended on 27 June 2016. The Opinion of the Final Accounts 2015 was adopted.

Documents for information

[EMA/MB/600489/2016; EMA/MB/588736/2016] Report on EU Telematics Feedback from the Heads of Medicines Agencies
[EMA/MB/607820/2016] Outcome of written procedures during the period 12 May 2016 to 6 September 2016

[EMA/MB/577322/2016] Summary of transfer of appropriations in the budget 2016

[EMA/MB/600445/2016; EMA/13787/2009] EudraVigilance Veterinary / Signal Detection and on-going related Veterinary-IT projects
[EMA/MB/490849/2016; EMA/490850/2016] Report on ex ante and ex post evaluations (January - June 2016)

Tabled documents

- [EMA/MB/655150/2016] Annual review of the EMA independence policies and ensuing actions
- [EMA/MB/654700/2016; EMA/585981/2016] Reflection paper on the development of the European medicines web portal

List of participants at the 93rd meeting of the Management Board, held in London, 6 October 2016

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Assena Stoimenova *(member)*
Czech Republic	Zdenek Blahuta *(member)*
Croatia	Delfa Radic-Kristo *(member)*
	Siniša Tomić *(alternate)*
Denmark	Thomas Senderovitz *(member)*
	Mette Aaboe Hansen *(observer)*
Germany	Karl Broich *(member)*
	Klaus Cichutek *(alternate)*
	Ansgar Schulte *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)*
	Rita Purcell *(alternate)*
Greece	Despina Makridaki *(member)*
Spain	Belén Crespo Sánchez- Eznarriaga *(member)*
	Laura Franqueza *(alternate)*
France	Jean Pierre Orand *(alternate)*
	Miguel Bley *(observer)*
Italy	Luca Pani *(member)*
	Gabriella Conti *(alternate)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Csilla Pozsgay *(member)*
Malta	Gavril Flores *(alternate)*
Netherlands	Hugo Hurts *(member)*
	Birte van Elk *(observer)*
Austria	Sylvia Fuezl (alternate)
Poland	Grzegorz Cessak *(member)*
	Magdalena Pajewska *(observer)*
Portugal	Rui Santos Ivo *(member)*
	Maria Joao Morais *(observer)*
Romania	Nicolae Fotin *(member)*
Slovakia	Valeria Pernišová *(alternate)*
Slovenia	Andreja Čufar *(member)*
Finland	Pekka Kurki *(alternate)*
Sweden	Catarina Forsman *(member)*
	Asa Kumlin Howell *(observer)*

United Kingdom	Ian Hudson *(member)*
	Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer *(member)*
	Tonio Borg *(member)*
European Commission	Xavier Prats-Monné (DG SANTE, *member*) Carlo Pettinelli (DG GROW, *member*) Jerome Boehm (DG SANTE, *observer)* Chloe Spathari (DG GROW, *observer)*
Representatives of patients' organisations	Ilaria Passarani *(member)*
	Yann le Cam *(member)*
Representative of doctors' organisations	Wolf Dieter Ludwig*(member)*
Representative of veterinarians' organisations	Nancy de Briyne *(member)*
EEA-EFTA states observers	*Apology received for Iceland* Brigitte Batliner (Liechtenstein) *Apology received for Norway*

European Medicines Agency	Guido Rasi Noël Wathion Stefano Marino Nerimantas Steikūnas Fergus Sweeney Enrica Alteri Anthony Humphreys Alexis Nolte Melanie Carr Jos Olaerts Emer Cooke Marie-Agnes Heine Isabelle Moulon Edit Weidlich Silvia Fabiani Sophia Albuquerque