5 October 2015
EMA/MB/313663/2015 Adopted
Management Board

Minutes of the 89th meeting of the Management Board

Held in London on 2 October 2015

Sir Kent Woods, Chair of the Management Board of the European Medicines Agency (EMA) opened the meeting welcoming the new members Rita Purcell and Lorraine Nolan, member and alternate for Ireland, and Laurent Mertz, member for Luxembourg. He introduced Guido Rasi, who had been nominated Executive Director at the extraordinary meeting of 1 October 2015. Mr Rasi thanked the Management Board for renewing its confidence and support which will provide great motivation when working towards achieving his commitments towards the Agency and the network.

1. Draft agenda for 2 October 2015 meeting

[EMA/MB/169330/2015] The agenda was adopted with no amendments. Concerning an earlier request for inclusion of a topic on the pilot Scientific Advice concerning non-imposed PASS procedures, this had been deferred to a later meeting as there are at the moment no data available for review. The proposing member informed the board that he will request discussion at the next meeting on issues relating to the procedure followed concerning the pilot.

2. Declaration of conflicts of interest related to current agenda

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 of the 88th meeting, held on 11 June 2015 adopted via written procedure on 24 July 2015

[EMA/MB/313120/2015] The Management Board noted the final minutes, adopted by written procedure on 27 July 2015 and subsequently published.

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B. Points for discussion

B.1 Highlights of the Deputy Executive Director

Meeting with Director General of DG SANTE

A first meeting between Director General Xavier Prats Monné with the Agency's senior management took place on 1 October, followed by an informal all-staff meeting allowing an exchange of views. The agency looks forward to working with Mr. Prats Monné.

Nomination of the Executive Director

After the nomination by the Management Board, Guido Rasi will need to make a statement in front of the ENVI committee of the European Parliament before being formally appointed by the Management Board. For appraisals, the Director General of DG SANTE and the MB vice-chairman Christa Wirthumer-Hoche will act as reporting officers, while the appeal assessor is the chair of the Management Board.

New ad interim Head of Administration

Agneta Brandt has been appointed ad interim Head of Administration with effect from 16 July 2015. Agneta Brandt continues in her role as Head of Infrastructure Services.

Update on public consultation on the Network strategy

Following the publication for consultation of the Strategy for the EU Medicines Network to 2020 on 31 March 2015 inviting comments until 30 June, a total of 37 contributions were received from a wide range of stakeholders. Contributions came also from HMPC and PRAC and from various organizations and association in two face to face meetings. MHRA and EMA have reviewed the comments and have made proposals for amendment of the Strategy which have been discussed by the Steering Group. The Strategy will be presented for adoption at the October HMA and at the December EMA Management Board meetings. In parallel, work on the respective multi-annual work programmes is progressing.

Technical issue with EudraCT

During summer a technical error in the software used by sponsors to upload summaries of results into EudraCT was identified. As a result sponsor accounts and summary results had to be taken from view until they had all been checked and the origin of the problem found and resolved. The Agency is currently working on bug fixing and is cooperating with sponsors to review data with a view to restore full access by the last week of October.

Outsourcing of Pharmacovigilance activities by the Agency

The Agency has received a request for clarification originating from the German government on its measures to avoid corruption in the case of outsourcing of pharmacovigilance activities, including signal detection, to an external company that also provides services for the pharmaceutical industry.

The board was informed that no signal detection activity is outsourced to an external company. These tasks are the responsibility of the Agency and the National Competent Authorities. Two contracts were awarded to the same company after public tender procedures took place: data cleaning and management of duplicates has been outsourced since 2010 with a new tender extending the contract. A further recent tender assigned monitoring of medical literature, which had been done by pharmaceutical enterprises in the past. This is an activity for which the Agency is responsible under

the new legislation and is covered by pharmacovigilance fees. Both activities are very labour intensive and would require large staff increases to be performed in house. The company performing the services was selected after extensive independent tendering procedures. Its performance is closely monitored and audited.

International activities

The first malaria vaccine was approved under the Article 58 procedure (authorisation for use outside the EU) with involvement of non EU regulators. Working arrangements have been signed by DG SANTE and the Agency with Swissmedic and WHO allowing the sharing of confidential information on the quality, safety and efficacy of medicines authorised or under review. A member of the Management Board requested a discussion at a future meeting on a strategic approach to international activities.

EMA resources devoted to EU funded projects

The Agency has been asked by the European Commission to complete a comprehensive overview of its participation in EU funded projects. A report on these will be presented at the December meeting.

B.2 Report from the European Commission

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

- Extended discussions taking place at Council level on the revision of the Veterinary Medicines Legislation, with high activity also at the European Parliament, in the ENVI committee and among MEPs. A vote in ENVI is foreseen on 10 November.
- High priority of antimicrobial resistance (AMR) as an evaluation of the AMR action plan is carried out which will inform further developments in 2016. A meeting took place with EMA, EFSA and ECDC in June to discuss the first Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report. The Commission intends to work closely with the European Medicines Agency.
- Progress with implementing measures for the Falsified Medicines Directive and update on importation of active substances, while Commission, EMA and Member States continue following-up on GMP non-compliance of API sites covered by written confirmations.
- Implementation of Clinical Trials Regulation with a meeting of the ad hoc expert group on clinical trials in September to focus on clarification of legal interpretation and public consultations on three documents launched in August 2015 with closing date 24 November 2015. Collaboration between Member States, the Commission and EMA is important to facilitate progress of the EU portal and database and to streamline the work carried out by the various bodies.
- Update on the Commission Expert Group on STAMP (Safe and Timely Access to Medicines for Patients), which will meet on 20 October to discuss the PRIME (PRIority MEdicine) scheme, conditional marketing authorisation, adaptive pathways and possible cross-cutting issues with HTA and payers.
- Status of international developments, including ICH reform and confidentiality arrangements that have been signed with WHO and Swissmedic.
- State of play in the revision of the EU Medical Devices Legislation. After the vote at the European Parliament on the 1st reading in April the Council has adopted a partial general approach in June. After a full general approach foreseen on 5 October the first trialogue meeting can take place. A possible political agreement is expected by end of 2015 – early 2016.

A concern was raised that the Joint Audit Programme will not support expenses for visits to veterinary only agencies. The European Commission will follow-up on this matter at the October HMA meeting.

B.3 EMA mid-year report 2015 from the Deputy Executive Director (January - June 2015)

[EMA/MB/606869/2015; EMA/506004/2015] The Management Board noted the mid-year report from the Deputy Director. The report provides an overview of the Agency's performance and achievements in implementing the work programme. The overall activities of the Agency are largely in line with the forecast. A notable increase concerns activities supporting innovation, in particular Scientific Advice (+6% on 2014) and Joint advice with HTA (21 vs. 6 in 2014). 77% of Initial marketing applications submitted had previously received Scientific Advice, demonstrating the effectiveness of this procedure. Slight decreases in requests for initial evaluation applications and orphan designations fall within the cyclical fluctuations of the system and are overall at the same level as in 2014. This might also apply to a drop in veterinary applications. Largest movements in procedure numbers have been observed for Variations and GMP inspections. Pharmacovigilance and GCP inspections are stable, with additional 37% of GCP inspections addressed through information exchange with international partners. It is too early to say whether these movements are due to fluctuations or can be confirmed as trends. This applies also for innovation in the veterinary field, where there has been an uptake in MUMS classification (14 vs. 9 in 2014) that has not yet translated into initial applications, currently under the expected forecast. There has been a significant rise in the number of meetings hosted at the Agency and consequently on the numbers of visiting delegates, due to an increase in interaction with stakeholders and to the implementation of Clinical Trials legislation. Access to documents has doubled after a slow-down in the past year due to uncertainty on legal developments. Partner and stakeholder satisfaction with EMA communication is high. There has been good progress with the network strategy and with the efforts to facilitate availability through adaptive pathways, interaction with HTA bodies, better use of existing regulatory tools such as conditional marketing authorisation and accelerated assessment, as well as with the ADVENT (AD hoc group on VEterinary Novel Therapies) initiative on the veterinary side. Main IT projects, such as the PSUR repository and the EU veterinary medicinal products database are on track, and the revenue and expenditure evolution is in line with forecast.

Members were appreciative of the report and discussed whether rising numbers of Scientific Advice applications can be predictive of future numbers of applications for marketing authorisation. The Agency can detect some structural trends within a picture which is nonetheless subject to fluctuations. In the case of Scientific Advice it will provide the board at a future meeting with a report on predictions that take into account the attrition rate, which is still high. Concerning rising numbers of HTA joint advice, it was felt that this is a positive development, but does not yet involve a high number of HTA bodies. Participating companies however feel that the outcome is very useful for their planning. From a regulator's perspective, while reimbursement decisions need to be left to a local level, it might be possible to agree on relative effectiveness. The question was raised on which phase of Clinical Trials requests for scientific advice relate to. In the experience of a member, the trend seems to be shifting from Phase III to Phase Ia and Ib and involves new and promising products. There was interest expressed on how the Agency assesses stakeholder satisfaction concerning communications. This is based on a survey which had a high response rate and delivered information on the wide use of material provided by the Agency in a clear and transparent manner, as well as requests for more engagement in social media. On IT there was concern on the lack of a project for the architecture of veterinary systems. While the outcome of the revision of the veterinary legislation is awaited, systems that support veterinary activities should be at least improved. The Agency is aware of these needs,

but mindful of budgetary constraints and does not wish to invest in possible duplication of systems. A dedicated discussion on this topic will be needed at a future meeting of the Management Board.

B.4 Amending Budget 01-2015

[EMA/MB/50215/2015] The Management Board adopted the amending budget. The adjustment was necessary due to the need to modify staffing composition for a shift of 16 FTE Detached National Experts (END) provisions to Contract Agents; additional cash-revenue from fee related procedures invoiced in 2014 for which the cash was received in 2015; a refund from the landlord for service charges 2014 for the old premises; adjustment for estimated increase in London weighting for exchange rate, due to the variation in the cost of living weighting, and for exchange rate fluctuation for assigned revenue.

The proposed transformation of the provision for ENDs to Contract agents is due to the difficulty in obtaining release from the employers of potential ENDs. For this reason the Agency has to cover some functions by recruiting Contract Agents.

B.5 Amended guiding principles for a revision of the EMA conflicts of interests policy for the Management Board

[EMA/MB/616238/2015; EMA/MB/553180/2015; EMA/615976/2015] The Management Board discussed the amended guiding principles for a revision of the EMA conflicts of interests policy for the Management Board. An update was provided to the board with a view to obtain a steer on the revision of the policy to be presented to the board for adoption in December. Since the discussion at the June meeting, further work on comparison with the handling of CoIs by ECDC, ECHA and EFSA as well as with MHRA has been undertaken. The amended guiding principles were discussed with the chair and the topic coordinators Pekka Kurki and Wolf-Dieter Ludwig. The guiding principles have been further developed, the main revised characteristics being concrete proposals concerning managing personal interests other than in the pharmaceutical industry, making specific arrangements in case of exceptional medicinal product-related discussions at the board, and better categorising board activities with resulting mitigating measures. A new factor in deciding on any restrictions will be the action requested from the board, in particular if the action leads to a decision. The impact of the revised proposals on the current board membership has also been carried out.

The board considered the proposed amendments a further step in the right direction. It was suggested to retain the duty to declare activity as (principal) investigator for the purpose of transparency even though restrictions would not apply. Should financial reward be linked to it, this would need to be declared and would trigger restrictions.

B.6 Implementation of EMA policy on publication of clinical data – Status report

[EMA/MB/614812/2015; EMA/614336/2015] The Management Board noted the status of the implementation of the EMA policy on publication of clinical data. Following the adoption by the Management Board on 2 October 2014, the policy came into effect on 1 January 2015 for any new marketing authorisation application submitted after this date and for extension of indication/ line extension applications submitted after 1 July 2015. Preparation for cost-efficient implementation of this completely new activity is ongoing. A formal opinion by the EU Data Protection Supervisor will be given. Stakeholders are continually involved as the consequences are important for all. Work is

proceeding among five workstreams: data receipt and filing, redaction consultation, publication, presentation and management of the external users. For each workstream one or more business processes have been developed. Three guidance documents (on redaction of commercially confidential information (CCI), on anonymisation, and on the submission of clinical data for publication) have been prepared and are almost finalised. New IT systems will have to be put in place/ existing ones will be customised to provide a user registration system, a publishing system, a workflow and case management system, a digital rights management system, and a watermark system. The Agency will also set up a special help-desk for SMEs to provide assistance. Broad support was expressed by the pharmaceutical industry during meetings held before summer. On 6 July and 7 September face to face meetings were held with all stakeholders, including Member States, to discuss the guidance documents. The guidance on CCI will include information on what is not CCI. Concerning the anonymisation of personal data, the Agency recommendation will be to strive for as much clinical utility of the data whilst ensuring protection of personal data, hence facilitating secondary analysis of the data. Companies will be expected to file an anonymisation report (to be equally published) along with the clinical reports. The EMA will provide updates to the board on the implementation of the policy on a yearly basis.

B.7 Review of Internal Control Standards and Underlying Framework

[EMA/MB/602884/2015; EMA/MB/603324/2015; EMA/MB/555181/2010] The Management Board adopted the revised Internal Control Standards and underlying framework.

The Management Board adopted the ICS for effective management in 2008 and revised them in 2010. This new revision intends to correctly reflect the new organisation's structure and nomenclature. Additionally, the requirements of the standard on Information and communication have been strengthened and the requirements of the standard on Internal Audit Capability have been amended to comply with the new Financial Regulation.

B.8 Draft EMA Framework for interaction with Industry Stakeholders

[EMA/591272/2014; EMA/MB/603766/2015;SANTE.DDG02.03/JV/sc (2015) 4031402] The Management Board adopted the framework for interaction between the Agency and industry stakeholders. The draft framework had been presented to the board at the December 2014 meeting. Written comments had been incorporated before a formal consultation with the European Commission took place following finalisation of the 'Better Regulation Guidelines'. All comments have been included in the draft submitted to the board for adoption. The key principles of the framework address facilitating and streamlining communication, structured interaction, accountability, transparency and a broad representation of the industry. Implementation will include an action plan and monitoring and reporting on the interaction. The comments by the European Commission were overall supportive, and address the emphasis on transparency, a call for multi-stakeholder dialogue and open participation of Commission services. Methods of interaction will be aligned with 'Better Regulation' in order to inform and consult, consult and involve, and co-operate, the last being defined as jointly engaging towards a common technical goal. The action plan foresees establishing criteria for classification of industry associations covered by the framework, updating the Agency's stakeholder database and launching an information webpage, monitoring and reporting annually to the board on interaction with industry associations.

Some members were interested in further information on involvement of Working Groups in classification and in further information on planned and executed industry associations' perception surveys.

B.9 Update on the development of CT Portal and Database

The Management noted and discussed the update on the development of the CT Portal and Database. Timelines for development and delivery plan were presented for information, and will be submitted to the board for endorsement at the December 2015 meeting. An agreement with Member States on timelines will be sought in October and November when auditable requirements and non-mandatory enhancements to be delivered in the immediate post audit iterations will be discussed in detail. The EU Portal and Database will allow a number of stakeholders to complete a wide range of processes on the same system. As such, its development is a complex undertaking whose architecture needs to be integrated with multiple other systems within and outside the Agency. The current timeplan foresees the auditable release to be available in Q3 16, the audit to be carried out November 2016 to February 2017 in order to submit the audit result to the board at the March 2017 meeting. Following a two to three month Commission process, the EC will post a notice in the Official Journal and the Regulation will become applicable six months later, in December 2017. The audit phase has been scheduled to take place before the end of the current IT developer's contract, ensuring continuity and minimising risk. Post go-live releases would further tailor the systems to suit user requirements, based on full user experience, and will be built applying 'agile' methodology, which foresees three monthly iterations, each consisting of four "sprints" and User Acceptance Testing. Constant dialogue with IT Directors and Members States is foreseen in the coming months, also to clarify issues concerning points of interaction with national systems. At the December Management Board meeting the timelines, will be submitted for endorsement.

Reasons for further postponement were questioned by some members, as well as whether remodulating auditable requirements would jeopardise full functionality. The representative of the European Commission stated that in line with the planning, there has to be full commitment by the Agency and the Member States to make it work within the agreed timelines. The Agency intends to commit to realistic planning and a timeline that can be delivered. The system has to be usable, which means reaching beyond the basic requirements of legislation to achieve usability. The previous experience with the development of the PSUR repository has provided a positive experience with the development of post-audit functionality. The plan for it could be included in the auditable requirements, as was done for the PSUR repository. The risk linked to the end of the current contract with the IT developer would be addressed with a Service Level Agreement and a six-month handover period between current and future vendor. This would allow the old vendor to complete the follow-up actions after the audit, in parallel with the handover. There was a question on whether the production version of 2016 could be used before going live. The system would be placed in an environment accessible to industry and National Competent Authorities for testing and training pilots. In conclusion, the chair recommended that the functional specifications, and supporting documents – should be sent to the board well in advance of the December meeting, to allow full understanding and discussion of residual issues.

B.10 Transparency rules for Clinical Trial Regulation

[EMA/MB/585266/2015; EMA/228383/2015] The Management Board endorsed the Appendix on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited". After endorsement by the Management Board in December 2014, a revision of section 6 of the

Functional specifications with a description of the technical features of the EU portal and database to support publication of information from the database was endorsed at the March meeting. As a second step a further revision was prepared in the form of an appendix to describe the rules and criteria setting out what documents and data will be made public, at what stages of the clinical trial or product development. These rules on transparency have been finalised in close collaboration with the Member States and the European Commission, as well as in meetings with stakeholders held between June and September 2015. The EU database should be publicly accessible by default, with exceptions justified on specific grounds. A feasible system should rely on rules and criteria to determine automatically when particular data should be made public, producing a consistent and predictable outcome, so that all parties involved will have clear expectations. The rules will apply to any type of sponsor. Trials are classified in three categories. Sponsors will have the possibility to defer publication of certain data and documents up to a maximum time limit to protect commercially confidential information. The default approach is to make documents public at the first opportunity, and deferrals will be monitored.

There was interest in how the monitoring of clinical trial numbers in the EU will be performed and which structure will be responsible for this. Several members expressed concern over the official interpretation of the Regulation, which does not foresee access from non CMS authorities to application dossiers. Structured information will be visible to all, but other information will need to be exchanged between Member States, possibly through voluntary arrangements. The representative of the European Commission assured the board that it is supportive of such a voluntary arrangement and recalled that there is a Working Group set up by HMA that is looking at the issue, but that automatic sharing might be difficult due to national legislation in some Member States. A member of the board invited the Commission to further explore ways in which the information could be shared without resorting to voluntary arrangements, and to further discuss the issue at the next meeting.

B.11 Report from HMPC Chair

Werner Knöss, chair of the Committee on Herbal Medicinal Products (HMPC), presented his views on achievements and future challenges of the HMPC. The committee is composed of 28 delegates and 5 co-opted members who meet six times a year. HMPC is supported by the Orgam Drafting Group, a Quality Drafting Group and a Working Party for Monographs and List Entries where 20 delegations meet six time yearly for 2.5 days. The Agency provides the secretariat. The HMPC collects the highest scientific and regulatory expertise in the field of herbal medicinal products in Europe and possibly worldwide. Its tasks concern harmonisation of standards, monographs and list entries on herbal substance and scientific opinions. None of the tasks is supported by fees. Since its establishment in 2004 the committee has published 140 monographs and 16 revisions, 11 list entries and 15 public statements. While monographs are recommendations, reference to list entries is binding. Harmonisation is not complete, as it is not always supported by all Member States, but can be considered satisfactory. HMPC provides its expertise to the other committees and working parties when required. Coordinated work with EDQM provides a complete framework of standards to NCAs and the European Medicines Agency, while overlaps and borderline products are considered within their different legal framework in coordination with EFSA. Looking ahead, after having covered about 80% of herbal substances with monographs and public statements, the HMPC is increasingly involved in revisions. The scientific standards established and published by HMPC enjoy worldwide recognition. The committee therefore sees a future role in applying its expertise to the growing presence of non-European traditional medicines in the EU market, also in coordination with EDQM.

Members were appreciative of the work performed at HMPC and interested in further embedding its expertise within network activities. This might take place within the framework of the Strategy 2020

and its implementation in the Multiannual Work plans. The non-binding nature of monographs and the lack of remuneration for work done in the committee was seen by some as a serious problem with no immediate solution.

B.12 Sixth interim report of the Steering Group to the Management Board

[EMA/MB/615242/2015] The Management Board heard and noted progress with the data-gathering initiative by the Steering Group since the June meeting.

A representative of the European Commission described the Commission's plans to launch an evaluation of the EMA fee system in mid-2016. In conformity to the Better Regulation approach, more focus should be on transparency and wide public consultation. An evaluation is therefore carried out in order to decide whether to revise the existing legislation. A roadmap for the evaluation will be published in the coming weeks and submitted to public consultation before the Commission selects an external contractor in Q1 2016. The evaluation will not be limited to EMA fees, but will also look at currently non-remunerated activities. The output of the Management Board data gathering initiative will be considered as input in the evaluation. A provisional timetable foresees the start of the evaluation by mid-2016 to run for 9-12 months with a final report by end of 2017. If it is concluded that the current system is not found to be fit-for-purpose, an impact assessment involving further consultation can be expected to be carried out in 2018, followed by a legislative proposal in 2019.

A 3 cycle pilot exercise was successfully conducted on Scientific Advice procedures between February and July. Compliance from EMA staff and network response rate has been extremely high, with only a slight decrease during the summer months. The pilot has shown that it is possible to collect data with a high granularity, and there is an ambition now to extend this method to the other regulatory procedures. As a further result, it is possible to link the detailed data obtained to the degree of complexity of the procedures. The exercise was not just limited to data on time worked, but also collected average discussion time per Scientific Advice procedure in many Working Parties and committees. An extension of the pilot looked at non product specific activities of the NCAs for the June meeting of SAWP (horizontal scientific overhead), related to time spent at National Competent Authorities in preparation and debriefing by members and scientific and administrative support staff, as well as travelling and plenary attendance time. The veterinary data collection exercise phase I has started, involving 9 agencies working on scientific advice and variation type II procedures. Sufficient data for a meaningful analysis should be available early 2016. Key learnings concern the need for intense co-ordination of the efforts required at national and Agency level. Further analysis is needed on the large variability, both intra and inter delegation. A full report will be provided within October to the board. The Steering Group recommended to continue the per procedure, per delegation collection exercise with key fee generating procedures, a further reflection on collection of horizontal scientific overhead data, and the development of a timetable and methodology plan for 2016 to be presented at the December meeting. It is planned that tying in with the Commission's timetable, the fee generating activities will be examined in first half of 2016 and the non-fee generating in the second half.

It was remarked that at some point in time it will be necessary to convert time data into cost data, taking into account overheads as well. The external contractor will not be limited to the use of the data from the data gathering, but should look at other available data, such as the national fee systems.

B.13 Joint annual report on the interaction with patients', consumers' and healthcare professionals' organisations (2014)

[EMA/MB/604206/2015; EMA/9496/2015] The Management Board endorsed the 2014 Annual report on the EMA interaction with patients, consumers, healthcare professionals and their organisations. In 2014 the main focus was integration of patients' experience and clinical practice into the regulatory activity. New revised eligibility criteria adopted by the Management Board in June 2014 have brought about greater transparency. Interaction levels with patients and consumers have probably reached a plateau. A pilot to involve patients in the benefit-risk evaluation at CHMP started in September 2014 and patients were heard by PRAC for article 31 referrals. Healthcare professionals have been consulted by a variety of committees on several issues, both as professional organisations and as individual experts. While according to a survey satisfaction on general interaction is high, some improvements could take place concerning the potential impact of involvement, for example by capturing patients' values and preferences, incorporating general practitioners' views and feedback in the discussion and measuring impact in EMA activities.

B.14 Enhanced early dialogue to foster development and facilitate accelerated assessment

The Management Board noted and discussed enhanced early dialogue to foster development and facilitate accelerated assessment. As part of the objective to support patient focused innovation and to contribute to a vibrant life science sector in Europe within the Strategy to 2020, the Committees have sponsored a dialogue with the Commission to foster development of medicines with high public health potential, in particular to address unmet medical needs. PRIME (PRIority MEdicines) aims at the early identification of products fulfilling the criteria for accelerated assessment, therefore promoting better use of existing tools and intensifying interactions with developers The concept developed with CHMP sponsors has been presented for discussion and consultation to scientific committees, EC STAMP, HMA, EU Innovation offices network, PCWP/HCPWP. Comments received have been addressed in a revised concept document currently being prepared. While the timely rapporteur appointment is a key feature of the concept, allowing better preparedness of the assessor team and best use of expertise, this might also cause a perception of possible risk concerning objectivity and independence of assessment. Risk mitigation is provided through the presence of multiple actors (e.g. CHMP Co-Rapporteur, peer-reviewer and PRAC rapporteur) not involved at early stages. The impact on resources is estimated at 10 requests per month with an estimated increase of scientific advice due to PRIME of around 10%. Further discussions at the October STAMP meeting are planned, and a public consultation is being considered.

The board supported the initiative. The need for a public consultation was questioned by one member, and a written rather than an oral report to the board was also requested as this would be helpful to better understand the implications for the National Competent Authorities. The representative of the European Commission underlined the need for careful preparation, particularly in the setting of clear criteria for eligibility and on provisions for impartiality. Implications on resources should be discussed in detail. The comments raised at the next STAMP meeting should also be taken on board. He further recommended holding a public consultation according to the Better Regulation approach. The Agency is planning to act transparently and provide a Q and A document after the launch. An annual meeting with the network is planned in which information about the pipeline could be provided. The Agency considers Scientific Advice initiatives at national level compatible with the PRIME initiative, as they can

help preparing early dialogue with the European Medicines Agency once the right maturity level is reached.

List of written procedures during the period from 9 May 2015 to 1 September

- Written procedure for adoption of the Agency's Final Accounts 2014, ended on 29 June 2015. The document was adopted.
- Written procedure for adoption of Revised Implementing rules to the Fee Regulation ended on 14 July 2015. The document was adopted.
- Consultation no. 06/2015 on the appointment of Svetoslav Branchev as CVMP alternate, proposed by the Bulgaria, ended on 23 July 2015. The mandate of the nominee commenced on 24 July 2015.
- Written procedure for adoption of 88th Management Board meeting minutes ended on 24 July 2015. The minutes were adopted.
- Written procedure for endorsement of the EU Telematics strategy and implementation roadmap 2015-2017. The document was endorsed.
- Consultation no. 07/2015 on the appointment of Sinan Bardakci Sarac as CHMP Alternate, proposed by the Denmark, ended on 31 August 2015. The mandate of the nominee commenced on 1 September 2015.

Documents for information

- [EMA/MB/603994/2015;EMA/MB/470927/2015] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/480836/2015] Outcome of written procedures finalised during the period from 9 May 2015 to 1 September 2015
- [EMA/MB/567811/2015; EMA/MB/566902/2015] Results of ex ante and ex post evaluations of programmes and projects Art 29 (5) of the Financial Regulation
- [EMA/MB/567233/2015] Summary of the transfers of appropriation 2015
- EMA/MB/604859/2015; 150709; 150710; Ref. Ares(2015)3292975 - 06/08/2015; EXT/605974/2015;EXT/605975/2015] Confidentiality (administrative) arrangements concluded with Swissmedic and WHO
- [EMA/MB/606173/2015;EMA/13787/2009] Veterinary EudraVigilance status report

List of participants at the 89th meeting of the Management Board, held in London, 2nd October 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	Klaus Cichutek	Karl Broich André Berger
Estonia	Kristin Raudsepp	
Ireland	Rita Purcell	Lorraine Nolan
Greece	Despoina Makridaki	
Spain	Belén Crespo Sánchez-Eznarriaga	Laura Franqueza Garcia
France		Jean-Pierre Orand Miguel Bley
Italy	Luca Pani	Gabriella Conti
Cyprus	Loizos Panayi	
Latvia		
Lithuania	Gintautas Barcys	
Luxembourg	*Apology received*	
Hungary	Beatrix Horváth	
Malta	John J Borg	
Netherlands	Hugo Hurts	Cees de Heer
Austria	Christa Wirthumer-Hoche	
Poland	Grzegorz Cessak	Magdalena Pajewska
Portugal	Hélder Mota-Filipe	Rita Bastos
Romania	*Apology received*	
Slovakia	Ján Mazag	
Slovenia	Katarina Štraus	
Finland		Pekka Kurki
Sweden		Johan Lindberg
United Kingdom		Ian Hudson Andrew Gregory
European Parliament	*Apology received from Giuseppe Nisticò* Björn Lemmer	
European Commission	Carlo Pettinelli (DG GROW)	Lenita Lindstrom (DG SANTE) Chloe Spathari (DG GROW)
Representatives of patients' organisations	W.H.J.M. Wim Wientjens *Apology received from 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) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)	

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