15 December 2017
EMA/MB/701078/2017 Adopted
Management Board

Minutes of the 98th meeting of the Management Board

Held in London on 13-14 December 2017

The chair opened the meeting welcoming Ekaterini Antoniou, new member for Greece, and Nando Minella, new alternate member for Italy.

1. Draft agenda for 13-14 December 2017 meeting

[EMA/MB/611419/2017] 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.3 Programming; Programming 2018-2020, including 2018 work programme, budget, establishment plan; Draft programming 2019-2021 and B.7 Information Management Strategy 2018-2020 and Information Management Strategic Plan 2018-2020".* The Secretariat informed the board 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.

3. Minutes from the 97th meeting, held on 5 October 2017 adopted via written procedure

[EMA/MB/660406/2017] The Management Board noted the final minutes, adopted by written procedure on 27 November 2017.

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4. Outline of the offer made by the Netherlands to host the EMA in Amsterdam including EMA impact assessment

The Deputy Executive Director reported to the board on the offer presented by the Dutch government to host the EMA in Amsterdam, focussing on the most relevant aspects for the Management Board and including some additional information made available by the Dutch authorities following the decision on the seat. Following the decision taken on 20 November 2017, the EMA will be permanently situated in a building to be constructed in Amsterdam Zuidas. The Agency will lease the building from the Central Government Real Estate Agency (CGREA), which will also maintain the building. Since the building will not be completed when the EMA needs to relocate by end of March 2019, the Agency will need to settle in temporary premises, which will be made available from 1 January 2019, or earlier, if required by EMA. Two temporary premises were proposed in the confidential part of the bid to house the Agency, and following reservations expressed by EMA during a site visit because of observed important weaknesses two further temporary premises have subsequently been offered by the Dutch authorities. Whilst the different buildings offered for the temporary premises are being examined, it already seems advisable to choose an option allowing to house the meeting room facilities in the same building as the temporary offices in the year before moving to the final building. The Agency, therefore, has decided on a single step approach to the relocation from the temporary to the final building, and will only move into the permanent premises once both office space and conference facilities are complete and fully operational by 15 November 2019. The Dutch offer foresees an all-encompassing and personalised expatriation programme with support provided to EMA staff and families throughout the entire trajectory of the relocation. EMA will work with the city of Amsterdam to facilitate staff relocation, and will budget for logistic costs and costs related to staff retention support measures not provided in the Dutch offer. The costs relating to the temporary premises will be carried by the Dutch government, while for the permanent premises EMA will pay a lease for the building and land costs, maintenance and insurance costs and any other costs, such as additional fitting out costs to take into account EMA's additional requirements. A one-off financial incentive of €18 million is foreseen to cover the first instalments of the lease of the Vivaldi building or as a contribution to cover a part of the fitting cost, or even to reduce the annual rent for the entire duration of the agreement. Furthermore, the Dutch government will cover the costs related to the removal from the temporary premises to the permanent premises and the re-installation into the permanent building. EMA is still assuming that the costs for the relocation of the EMA from London to Amsterdam would have to be borne by the UK government. A preliminary impact assessment for the permanent premises, highlights the work to be done to prepare for the launch of the building approval process according to Art. 88 of the Financial Regulation. The preliminary impact assessment for temporary premises have highlighted the need for a dedicated relocation Business Continuity Plan (BCP).

The representative of the UK reminded the board that in the Communication from the Commission to the European Council on the state of progress of the negotiations with the United Kingdom under Article 50 of 8 December 2017, the Commission had welcomed the United Kingdom Government's offer to discuss with Union Agencies located in London how the United Kingdom might facilitate their relocation, in particular as regards reducing the withdrawal costs.

4.1 Authority to the Executive Director to accept one of the options offered by the Dutch Government for the EMA temporary premises in Amsterdam

[EMA/MB/827245/2017; EMA/827795/2017] The Management Board adopted an authority to the Executive Director to accept one of the options offered by the Dutch government for the EMA temporary premises in Amsterdam. The Executive Director specified that this authority only extends to

accepting a temporary free of cost building which may not have been included in the original offer by the Dutch government, but that he would not accept to take any decision that may have budgetary consequences.

5.1 Presentation from the Netherlands including how it will meet EMA requirements

A delegation of the Dutch government composed of Maurice Galla, Project leader of the Dutch Government's Candidacy European Medicines Agency (EMA), Aginus A. W. Kalis, Project Director for the Relocation of the EMA and Marcel van Raaij, Director of Medicines & Medical Technology at Ministry of Health, Welfare and Sport, presented the commitment by their government to provide the EMA with full support for its headquarters, provide individual tailor-made expat programme for its staff, propose a seat agreement and provide financial incentives for new premises. It was stressed that the Dutch authorities and the building project team intend to work closely with the Agency to make the best use of the limited timeframe. A memorandum of understanding and a Joint Governance with EMA will ensure a seamless transition for the Agency. The final building, purpose built on EMA specifications, will be fully functional by 15 November 2019. In the option contained in the Dutch bid it had been envisaged to complete and provide the conference facilities in the Vivaldi building by April 2019, and offer temporary office space to EMA in an accessible nearby location until the building is finished. Currently EMA's orientation favours a second option whereby the temporary building can provide also the conference facilities, and no interim delivery of partial final premises is necessary. As part of its offer, the Netherlands has stressed commitment to regulatory cooperation within the EU network. Its investment of €8 million has been met with interest by a number of Member States and will be used in close cooperation with the EU Network Training Centre. It is foreseen that the final draft for a seat agreement is submitted to the Management Board in March, and that it may be approved by the Dutch government before summer. An extensive relocation programme relies on partnership with Amsterdam In Business, the INAmsterdam Expat Centre and the central government. A helpdesk has been set up in the EMA London premises and will provide information sessions as well as individual relocation support to EMA staff. A support team in the Netherlands will provide help with settling in and with access to international schools.

Several members of the board expressed optimism over the conditions provided, allowing business continuity for EMA, and asked for further details on the Memorandum of Understanding and on a high level roadmap. Both will be provided to the board as soon as available. Concerning a question on the possibility for the EMA to remain in London until completion of the permanent premises in Amsterdam, the representative of the European Commission reminded the board that the EMA needs to leave by the time the UK leaves the EU, i.e. by 29 March 2019. Now that a clear decision, based on a clear offer, has been taken, there are no reasons not to follow through with it.

6. EMA Preparedness on Brexit

6.1 Update on EMA preparedness

At its meeting in October the Management Board was informed of the need to launch phase 2 of the BCP as of 1 January 2018 on the basis of the already agreed principles and methodology. In order to free-up additional resources for EMA preparedness in 2018, while safeguarding the resources necessary to carry out EMA activities with the highest priority is was proposed to maintain for 2018 the 2017 already temporarily suspended/scaled back activities, further reduce category 3 (lowest priority) activities and temporarily suspend/reduce some category 2 (medium priority) activities. The proposed temporary suspensions/reductions should be sufficient to free up the ca. 80 FTE needed for Brexit

preparedness in 2018, although this may not be sufficient should there be an important staff loss as a result of the relocation to Amsterdam. It was therefore proposed not to introduce at his stage further cuts to EMA activities, but to monitor carefully and inform the board if further action was needed. The consequences of the BCP have been elaborated in the 2018 EMA Work Programme and will need to be reflected in the 2018 Work Programmes of the scientific committees and working parties.

Some concern was raised in the board on how staff reduction might affect IT, particularly maintenance of systems, and have lasting consequences. The Executive Director shared this concern, and warned the board that disruptions might be possible as a consequence of the need to cut 40 FTEs as demanded by EU institutions, of the current possible difficulty in replacing staff loss through recruitment, as well as of the possible need in the upcoming year to cover two locations. One way in which Member States could support EMA would be by seconding experts to the Agency. Further details about the impact of the BCP on activities can be found in the Work Programme.

6.2 Collaboration framework between the Netherlands and EMA

A collaboration framework between the Netherlands and the EMA is necessary to ensure that all necessary arrangements are put in place for EMA to be operational in its new location at the latest at the end of March 2019. The close collaboration should involve all governmental levels and ensure EMA's continuity of operations also longer term, beyond a successful relocation. A joint governance structure between the Netherlands and EMA has been set up and comprises a Steering Committee, a Task Force and the number of work streams necessary to cover the various tasks. Each body within the governance structure is co-chaired by the Netherlands and EMA, with the exception of the work-streams relating to the buildings which are chaired by the Netherlands. The principles and the approach for collaboration will be incorporated in a legally non-binding Memorandum of Understanding.

6.3 High-level roadmap for relocating EMA to Amsterdam

A high-level roadmap will be prepared jointly with the Netherlands once more information about the temporary premises of the Agency in Amsterdam becomes available, and will set out also the involvement by the Management Board. It is planned to publish a dashboard where progress with the relocation can be monitored and followed.

6.4 Building requirements in the context of the building approval process

– Preparation for written procedure of building approval process

The board noted the building requirements and the preparation for a written procedure for the building approval process. Before the Agency enters into contractual obligations for its premises, a positive opinion from the Council and European Parliament according to Art. 88 of the Agency's Financial Regulation is needed. Following indication by the European Commission that the approval procedure should be launched as soon as possible, a draft notification will be sent to the European Commission and to the Management Board for endorsement by written procedure on 5 January 2018 with a deadline of 12 January 2018. On 15 January the notification will be sent to the Council and European Parliament who will issue an opinion on the building notification by late February 2018. The dossier, which will be prepared in close collaboration with the Dutch authorities, who are supplying part of the information needed, will contain information on the final building and its location, key dates, technical

features of the building, main conditions of the contract, market analysis and estimated costs and financing.

To facilitate the involvement of the Management Board in this time critical procedure, the board nominated Audun Hågå (Norway) and Karl Broich (Germany) as Topic Coordinators.

6.5 Working groups on committees' operational preparedness for human and veterinary medicines

6.5.1 Feedback from the working group meetings and the 15 November 2017 EU27 Information meeting

Since the October meeting of the Management Board the working groups have held a combined human and veterinary meeting. On 15 November a second information meeting in a EU27 setting with Management Board members and Heads of Agencies (both human and veterinary) who are not members of the board, took place. The meeting was attended also by chairs or vice-chairs of the CHMP, PDCO and PRAC. At the meeting it was agreed to run a second survey of the NCAs for the mapping exercise in collaboration with the HMA Brexit Task Force. It should take place at the end of Q1 2018 in order to take into account information on the Agency's operational capacity available as of February 2018, as well as information on the NCAs' preliminary draft 2019 budgets. The second survey should also address NCAs' training needs, including targeted training for NCAs recently involved in assessment work. The outcome from the working groups on UK participation in pre-authorisation procedures and proposals for the redistribution of the UK portfolio were also supported. There are still a number of issues that need further discussion at the Working Groups. The potential impact of Brexit on supply of medicines once the UK becomes a 3rd country was discussed, and might require further action once a survey with Marketing Authorisation Holders of Centralised Procedures provides precise information.

6.5.2 Outcome from the working groups

[EMA/MB/824752/2017; EMA/MB/816950/2017] The Management Board noted the outcome from the working groups relating to the UK participation in pre-authorisation procedures and endorsed the recommendations relating to the redistribution of the UK product portfolio. The Working Groups have finalised discussion in these two areas, applying the working scenario that UK membership of the EU will end on 29 March 2019 and that on that date the UK will become a 3rd country and no longer be able to engage in centralised procedures expected to be finalised after that date. For pre-authorisation human and veterinary procedures, the principle of best and available expertise will be applied to the appointment of (Co)-Rapporteurs and Coordinators, whereby in the context of Brexit, "available" is to be understood as still available after 29 March 2019. Concerning UK participation in pre-authorisation procedures in a role other than (Co)-Rapporteurs and Coordinators, some further clarification from the European Commission is needed on UK experts' use beyond March 2019. In any case the non-UK (Co)-Rapporteur will need to sign a letter of undertaking to take on full responsibility for the part of the assessment done by the UK up to the stage relating to the Opinion. The proposals for the redistribution to the network of the UK portfolio for CHMP, CVMP and PRAC (Co)-Rapporteurships, are built on a risk based approach. They take into consideration the results of the survey of the NCAs, the expertise within the network and the workload of the medicinal products. The proposals ensure an optimised and robust allocation of the workload among NCAs and guarantee efficiency within the network. It is envisaged that the implementation will take place stepwise, whereby the UK product portfolio will be allocated by the end of Q1 2018, followed by communication with the Marketing

Authorisation Holders. In an unchanged scenario with the UK leaving the Union on 29 March 2019, the actual implementation of the redistribution will not take place before September 2018.

The representative of the UK invited the board to keep an open mind on the possible outcome of the negotiations between the UK and the EU. He reminded that until the UK leaves the EU, it retains full membership and has continued to offer full support. He recognised the need for the network to plan, but invited all to await the discussions to take place early in 2018 on a transition period.

The representative of EC cautioned against putting on hold any action because of a possible transition period, and invited the board to continue to focus on 30 March 2019 for relocation and other consequences of the UK leaving the EU. The representative of veterinarians' organisations warned of the risk of shortages of medicines due to delays by pharmaceutical companies in taking necessary regulatory actions. The Executive Director concluded that the working groups have tackled issues within the EMA's remit only, and that it will be necessary to converge their activities with those of the HMA Brexit Task Force as all procedures rely on a single shared pool of expertise.

6.6 Staff Retention Support Measures

The Agency is working on the measures to be taken during a transitional period to facilitate the relocation for staff. These consist in changes to EMA practices and implemented rules, which complement support measures offered by the new host Member State, as well as the entitlements and allowances foreseen in the Staff Regulations. Extraordinary measures will be put in place only in case of a critical situation, depending on budget and subject to Commission approval.

6.6.a Overview of Staff Retention Support Package

Tele-working rules based on the ex ante agreement will be presented to the board in March and arrangements for part-time work for staff will be organised through existing rules. Language training will be provided to staff and their families following discussion with the host Member State representatives. The Amsterdam office was established at EMA on 11 December and will provide information sessions on living in the Netherlands, housing, schooling and the job market for household members. Practical information and support on housing and schooling will be offered in a second phase.

6.6.b Executive Decision on Relocation visits

[EMA/MB/772574/2017; EMA/744063/2017] The Management Board endorsed the Decision of the Executive Director on relocation visits to the new Host Member State. As of 1 December the Agency is offering to staff the opportunity to familiarise themselves with the new location, including housing, schooling and other conditions, through relocation visits for the purpose of orientation. A separate decision on a second relocation visit with a clear definition of eligible staff will be submitted separately at a later stage.

6.6.c Update on rules on Teleworking

It had been envisaged to request a derogation from the final ex-ante agreement from the Commission on teleworking, which was received on 27 July 2017, and successively adopt EMA's own amended implementing rules based on the Commission's model rules. An additional paragraph (Article 4.7) would include a defined transitional period (until 31 July 2020) in which teleworking would be applied with added and defined flexibility. During this transitional period staff would also be allowed to telework for an uninterrupted period from any location in the European Union, European Economic

Area or the United Kingdom. Following discussion with the Commission's DG HR, the approach has been changed as it was recognised that the Agency is in a special situation and exceptions can be granted based on existing rules. No derogation from rules is therefore necessary, as the added need for flexibility can be covered by Art.4.3 and 4.5 of the model rules. The model rules for teleworking will be submitted to the board for adoption in March.

6.7 Communication activities

Following the decision of the UK to withdraw from the EU, EMA has been the object of wide-spread public interest. In the run-up to the decision of the future seat of the Agency a number of documents and press releases focussing on the relocation of EMA and the necessary business continuity arrangements were published, as well as more generic material to inform about the EMA's work and its policies. The Agency is now working closely with the Dutch authorities to communicate the progress of the relocation project. In addition, stakeholders are informed about the regulatory/procedural implications of Brexit and the need to take action in due time. A 2nd batch of information for companies to prepare for the UK's withdrawal has recently been published together with procedural guidance.

A. Points for automatic adoption / endorsement

A.1 Financial compensation and workload estimation of the revised EMA organisation of translations of product related information

[EMA/MB/731638/2017; EMA/732995/2017] The Management Board endorsed the fixed flat hourly rate for 2018, unchanged from 2017.

B. Points for discussion

B.1 Highlights of the Executive Director

EU activities

The annual 'exchange of view' with the ENVI Committee of the European Parliament took place on 7 December. MEPs were informed of the achievements by the Agency in 2017, which were attained despite the need to reprioritise certain activities in view of the preparation for the relocation to Amsterdam. Topics raised in the discussion included AMR, vaccine campaigns, the clinical trial portal and database and EMA interaction with HTA bodies.

International activities

The regular EMA-FDA bilateral took place on 7-8 November and focussed on reinforcing collaboration on ATMPs, PRIME and Breakthrough products and on analysing the functioning and outcomes of the 14 existing EMA-FDA clusters. A visit of an EMA staff member to the MHLW/PMDA to look at respective assessment practices took place end of November in the framework of a reduced fellowship programme.

EMA coordinated crisis simulation

The Pharmacovigilance and Epidemiology Department in October coordinated a crisis situation exercise to test the EU-Incident Management Plan. The exercise involved members of the Incident Review

Network, EU-Executive Task Force, the European Commission and National Competent Authorities. The exercise was considered very useful and will enable EMA to further streamline relevant procedures.

Change in Telematics Governance

Due to his heavy involvement in EMA's Brexit preparedness activities, Noël Wathion has been replaced by Enrica Alteri as an EMA representative to the EU Telematics Management Board.

Interactions with the European Ombudsman (EO)

Interactions concerning the strategic enquiry into pre-submission activities of the Agency are continuing in a collaborative and constructive atmosphere. Some preliminary elements have been clarified and the time constraints at the Agency have been acknowledged. The EO is aware of the support by the Management Board, for which the Agency is grateful. On 13 October the EO issued a decision in the enquiry concerning allegations of maladministration in the HPV referral procedure stating that EMA conduct was correct and in line with EU law. The EO confirmed with a final decision in another enquiry, that the Executive Director had not failed to declare any direct or indirect financial interest when he joined the Agency in 2011 and that there was no maladministration by the EMA. Finally, the EO dismissed the latest complaint put forward by an individual who on several occasions had addressed Management Board members as well.

Court of Auditors

The recently published Court of Auditors report on annual accounts for the financial year 2016 contains recommendations which the Agency will address by introducing changes in its practices. In addition to the normal annual audit, the Court carried out a pilot on the use of consulting services. It highlighted the issue that while the EMA is assigned new tasks and its budget increases, at the same time its establishment plan is being reduced, and the Agency is forced to resort to contractors. These are however comments which the Agency will work to implement within resource constraints as far as possible. Concerning the Agency's accounts 2016, these were audited by the Court of Auditors and by external financial auditors. It was concluded that the accounts present fairly the financial position of the Agency, and that the revenue and payment transactions are legal and regular in all material aspects. The Court is visiting the Agency to discuss preparations for Brexit and how related aspects will have to be addressed in the 2017 accounts.

Call for Seconded National Experts (ENDs)

EMA has always relied on a high number of ENDs nominated by the NCAs to bring a fresh perspective combined with experience and competence. Over the next two years the nomination of ENDs will be particularly appreciated as EMA focuses on operational tasks due to the BCP.

B.2 Report from the European Commission

Brexit

One week after the decision on the relocation of EMA the European Commission has introduced a proposal for a change to the founding regulation of the EMA to reflect the new location, to be adopted by the European Parliament and the Council. The Commission will work closely with the Agency to ensure a smooth transition.

Vaccinations

A major initiative on vaccination in spring has been announced following the State of the Union address by President Juncker. It will pursue collaboration on hesitancy, improvement in development,

exchange of information and collaboration between Member States and will involve healthcare professionals, EFSA, EMA and the Commission.

Paediatric report

The report from the Commission to the European Parliament and the Council on the Paediatric Regulation published in October 2017 has concluded that the legislation has achieved the authorisation of medicines for children which would not have been available otherwise. As next steps a roadmap for the evaluation of the Paediatric and Orphan Regulations was published in December for a 4 week consultation. An additional study on orphan medicines has been commissioned and a joint evaluation of the orphan and paediatric legislations where policy options will be presented will be concluded in 2019.

External study supporting the evaluation of the EMA fee system

A draft interim study report is under review by the interservice group of the Commission. The next step will be a 3 month open public consultation. A final report is expected by June 2018. Possible further steps might lead to launching an impact assessment setting out policy options for a legal proposal to be put forward by the Commission in 2020. Such impact assessment would require a separate public consultation.

Initiative on strengthening EU cooperation on HTA beyond 2020

Work is progressing on a proposal to be presented by end of January 2018 which will address the synergies between regulatory work and HTA issues. The Commission welcomes the current initiatives in the work plan by EMA and EUnetHTA for 2017/2020.

Implementation of the falsified medicines Directive

Safety features will become mandatory as of February 2019, but there are concerns on the readiness by hospitals and on delays in setting up the necessary IT infrastructures. Member States are invited to take an active part in the implementation of the legislation.

Implementation of the EU-US MRA

After the recognition by the FDA on 1 November of 8 Member States, the Commission and EMA will continue to facilitate the recognition of the remaining Member States in the coming months until the deadline of July 2019.

Veterinary Databases

As the new veterinary legislation is making good progress, with the agreement of the contract on EVVET3 it will be possible to fulfil VICH obligations and ensure that the IT component for veterinary pharmacovigilance will be ready on time. The Commission remains committed to support putting in place the new veterinary legislation as soon as possible.

The EMA pointed out that while human IT systems are funded through fee revenues, it is at the moment not clear how IT systems for veterinary legislation are going to be financed.

B.3 Programming

a) Programming 2018-2020, including 2018 work programme, budget, establishment plan

b) Draft programming 2019-2021

[EMA/MB/770050/2017; EMA/417705/2017; EMA/MB/799068/2017; EMA/800271/2017] The Management Board adopted the 2018-2020 Programming document and the budget 2018. The Programming document 2018-2021 is presented as a single document and is made up of the Programming 2018-2020, which includes the final 2018 work programme, budget and establishment plan, and of the Draft programming 2019-2021. After adoption by the board, the Agency will include any comments received, update the final 2017 figures and divide the documents presented into two separate ones, which will be circulated to the board before being mailed to the European Commission and other institutions by 31 January 2017. In order to facilitate the discussion of the Programming Document, the presentation to the board was structured according to the different components of the package: Work programme overview, draft budget 2018 and 2019-2021 overview, IT budget and projects. The Topic Coordinators Grzegorz Cessak, Catarina Andersson Forsman and Lorraine Nolan had performed the key role of scrutinising the evolving documents on behalf of the Board over three months and with the exception of Catarina Andersson Forsman, who could not be present, took part in the presentation.

Work on this year's Programming documents was particularly challenging, as the critical aspects related to Brexit, such as the decision on the future location of the Agency, only became known very recently and a number of factors, such as the final numbers of staff prepared to relocate, are not yet known at the present time. Therefore the documents could be finalised and circulated to the board only a few days before the meeting, but a draft version had been sent before to the board for familiarisation.

The work programme is based on the framework of the Network strategy through 2018-2021 multiannual work programme themes and activities for its 'Business as Usual' aspects. In addition to this, however, additional Brexit-derived activities and assumptions had to be considered, and are based on the scenario where EMA retains 80% of its staff and is able to deliver on its core operations. In the perspective that the Agency continues to operate as usual for as long as possible, changes concerning innovation and development trends point to a substantial increase in the areas of ATMP classification, human scientific advice and orphan designation. Trends for authorisation and maintenance workloads appear to be stable, with increase foreseen for initial applications for human medicines. Forecast for inspections shows a continued decrease of GMP inspections as a result of the recent MRA agreement with the US FDA, and an increased focus on GCP inspections. A further factor of impact for the 2018 and 2019 Work Programmes will be the temporary suspension or reduced output for category 3 and 2b activities decided according to the business continuity (BCP) plan. On top of the activities concerned in 2017 which will continue to be affected, other activities will be temporarily suspended or scaled back in 2018 and 2019. The need to allocate resources to preparing and implementing the relocation, and mitigating negative implications of it, translates in terms of resources needed to 86 FTE for 2018 and 62 FTE in 2019. The 'best case' scenario which is considered, foresees the risk that 20% of staff leaves the Agency in the next two years, and that they can be replaced through an intensive recruitment programme and by hiring additional Brexit Contract Agents (CA) (20 FTE in 2018, rising to 40 FTE in 2019). For 2018 EMA will have to cut further 5 fee-financed Temporary Agent (TA) posts but will request additional 11 posts in 2019 to cope with the 'business as usual' growing fee-financed workload. The budgetary authority did not support the

request for additional TA in 2018 endorsed by the board in 2016, but approved instead an equivalent number of CA. The Agency is further requesting a minor shift between END and CA posts, as well as requesting further 20 CA to support the Brexit preparedness for 2018 and to mitigate staff attrition through early knowledge transfer through the relocation transition period. As an outcome of a job mapping exercise carried out in 2017 as a foundation of the development of the competency and career development framework, it emerged that 74 positions in the establishment plan should be amended from assistant to administrator to reflect evolution and complexity of the job. This was later confirmed by an establishment plan benchmarking exercise carried out across EU agencies. A final decision would form part of the 2019 budget and work programme and would be implemented over a number of years, but would allow to hire new staff at the correct grading when managing the large turnover due to Brexit. The 2018 draft budget (DB) and the preliminary 2019 budget (PDB) are both balanced. The 2018 budget includes €14.8 million expected Brexit-related costs rising to €43.5 million in 2019. Under current assumptions, the budget is expected to grow by 2.0% in 2018, driven up primarily by an estimated 6.8% increase in fee-financed activities, and by 5% in 2019. A detailed analysis of the evolution of the IT budget was provided, together with the reasons for requesting non-automatic carry-forwards from 2017 to 2018 for certain projects which were costed and included in the budget and the Work Programme 2017 but for which the Agency will not be in a position to conclude specific contracts with the respective service/goods provider before the end of the year (see Agenda point B.9). Concerning the procurement plan for 2018, it is foreseen that a number of tender procedures will need to be launched to meet on-going business needs in respect of contracts which will expire naturally or which, due to Brexit, will not be portable to the Agency's new location as the services are specific to EMA's current location in London.

A discussion on the Work Programme followed. Further details on forecast were requested, in particular how the growing complexity of procedures and their impact on workload and staffing is forecast, and what degree of precision is envisaged. Complementary to this was a request on information on how the transfer from London to Amsterdam might affect the budget due to the switch from GBP to Euro and on how salaries are being calculated. It was explained that one way of assessing the complexity of procedures at EMA is based on continuously improving and analysing the time recording system and application pipelines. This captures the evolution of work and supports decisions on outsourcing or automatising certain tasks, while reserving staff increases for complex work. The switch from GBP to Euro will greatly simplify budgeting, as a substantial part of the current expenses are in GBP. Now that the future location is known, there are no more uncertainties concerning the weighting of salaries, which for 2019 were calculated with London coefficients from January to March, and with the coefficient for the Netherlands from April onwards. Concerning a question on desirable levels of GMP inspections, the GMP MRA with the FDA will allow for the future to apply a risk based approach, addressing resources for example towards API sites and the so-called mega-sites. Proposals for amendments of the veterinary part of the Work Programme had been provided in writing, and will be accommodated following the meeting. Assurance was provided that the gap and impact analysis of the new legislation that was last updated in 2016 will be updated in 2018. Further consideration will be necessary, now that new responsibilities and requirements arising from the legislative veterinary proposal are becoming more clear. The issue of whether the functioning of the network as a whole is adequately described in the Work Programme was raised. Taking this into account a request was made to include the role of the NCAs and their experts in the scientific committees of the EMA in the introductory text of the Programming document. It was explained that the Programming document is not conceived for communication but is a legal document of the EMA which describes how the Agency intends to implement its programme to the budgetary authorities and to the board, who have to evaluate if the programme is achievable, and if the budget is consistent. Consideration to scaling down of training and capacity building activities for non EU regulators under the BCP was suggested. EMA has already decreased such activities. With the upcoming survey to the

NCAs it will be possible to ascertain which NCAs can take on the increasing demand for training outside the EU, while EMA will continue to make sure that the training needs of newer Member States are provided for. It was also requested that initiatives related to the common network strategy are organised jointly. The Executive Director made the distinction between activities which are common, and NCAs are involved, and initiatives which are driven by the Committees, and are handled by EMA in a long established way. Specific cases are handled on a case by case base, and joint initiatives might be considered where EMA is short on resources or workforce. A reduction of meetings in general is expected in the next few years. The representative of the European Commission welcomed the programming of IT related spending orientated at deliverables in 2018. He observed that it should be for the future made more explicit that some indicators for f. ex. number of procedures are to be understood as output estimates rather than KPIs, and concluded by stating that the budget proposal and the increase of the establishment plan for 2018 by 20 CA are acceptable. Both will need to be closely monitored, and developments due to Brexit reported to the board.

B.4 Audit Strategy and Annual Audit Plan 2018

[EMA/MB/768580/2017; EMA/716214/2017] The Management Board adopted the Audit Strategy 2018 – 2020 and Annual Audit Plan for 2018. The strategy was prepared on the bases of the analysis of the Agency's risk register, with special consideration given to Brexit, and to the applicable legal requirements. The number of planned audits for 2018 is lower than in 2017 due to the prioritisation of activities laid down in the Brexit BCP submitted to the board on 5 October 2017. The planning relies on the assumption that current staffing levels of the Audit Function will remain unchanged in 2018. Any change that may lead to re-adjusting the plan will be presented to the board in due time. The Audit Strategy 2018 – 2020 and Annual Audit Plan for 2018 foresee a total of 10 audits to be conducted at the EMA in 2018, of which three to be carried out by the Agency's Audit Function.

A member asked whether it would be possible in the future to invite representatives of the IAS of the European Commission and of ECA to attend a meeting of the Management Board and report directly. A visit by ECA or the IAS should be possible, but would depend on their workload and availability.

B.5.a) Report to the Management Board on the implementation of the clinical trial Regulation (EU) No. 536/2014, in particular on the development of the clinical trial EU Portal and Database and related projects (EudraCT legacy and Safety Reporting)

[EMA/MB/689288/2017; EMA/687143/2017] The board noted the report on the implementation of the clinical trial EU Portal and Database and related projects.

B.5.b) Report on the state of play, as of 1 December 2017, of the progress and revised planning for further development of the EU Portal and Database

[EMA/MB/692978/2017; EMA/692972/2017] The board noted the report and discussed the state of play of the progress and revised planning of the EU Portal and Database. At the meeting of the Management Board in December 2015 it had been agreed that all MUST (auditable and non-auditable) requirements for the development of the EU Portal and Database (EUPD) would be included in the auditable version of the system. In April 2017 the API version 1 was deferred from release 0.7 to release 0.8 after the audit, but it has now been returned to the scope of release 0.7 (the auditable release) and will therefore be part of the functionality included in the audit from its start. The EU portal and Database is designed to support a large and very complex system with multiple

stakeholders. As such release 0.7 will provide Member States with the agreed MUST functionality needed to support their operations.

The report on the state of play, as of 1 December 2017, provides a status update on the progress and revised planning for the further development of the EUPD and safety reporting functionality, a high level assessment of key risks that could impact on the successful delivery of the system, including risks related to the developer, as well as a preliminary summary of UAT findings. Since re-planning and remedial actions are currently being undertaken with the developers, no timeframe is proposed for endorsement at the present meeting of the board. Since 24 November the developer has mobilised additional project management capacity and quality assurance resources in a planning taskforce involving senior staff from their consortium and EMA IT. The mission of the planning task force is to elaborate a robust and credible plan to support the board in confirming a timeframe at its March 2018 meeting for the Regulation to come into application. Concerning risks related to the relocation of the EMA, these are linked to the possibility that during the relocation period some physical and human resources may become less available, and that some key team members may leave the Agency. These risks are addressed in the BCP, which has classified the EUPD as category 1 (high priority). In evaluating the outcome of UAT 0.6, which took place in November, it is important to consider that release 0.6 is not a complete system and only 0.7 will provide full overview over the whole system. However, a high number of blocking, critical and major bugs (BCMs) in release 0.6 were not resolved prior to UAT, and hampered the user evaluation. For 0.7 the UAT will not commence until BCMs are fixed and the system has met the SAT (Site Acceptance Testing) criteria. At the closing meeting of the on-site UAT conducted at the Agency, it was agreed to invite a small group of clinical trial users who have tested the system to clarify what changes are needed and which will give greatest benefit, in a top down business defined approach. The EMA will evaluate feasibility of each change and indicate in which release from 0.8 to 1.0 or post go-live, additional functionality may be accommodated, and validate the outcome and its prioritisation with all MSs and with sponsors for sponsor functionality. The analysis and design of the safety reporting functionality is ongoing. Its development will be merged with the EUPD functionality as part of release 0.9 of the EUPD project. Between release 0.7 for audit and the go live of the system there is a period of 11-13 months during which the focus will be on the safety system and on prioritised improvements for Member States and sponsors.

In the discussion, a number of members welcomed the establishment of the planning task force and the closer involvement of key experienced users from the Member States, but voiced some doubts on whether this contribution could constitute an oversight to the project that could guarantee the expected results. They suggested the involvement of a 3rd party, tasked with providing an independent perspective on matters such as adequacy of governance, organisation, planning and monitoring of the system, in order to allow the Management Board to form an informed opinion on whether the project is viable or not. Others considered that the creation of the Task Force provides an opportunity to channel user experience into a close cooperation with the developer, who needs to provide evidence of having a robust risk management system in place. Under these conditions the project should be considered as delayed, but still repairable as the functionality is present. The Executive Director expressed scepticism about the involvement of 3rd party experts, who would add an additional layer of complexity to the governance of the project. Furthermore, it might be difficult to identify a legal basis on which to operate a tender, and on which to provide the 3rd party with a clear mandate. He suggested instead that the presence of 2 or 3 experienced ENDs from the Member States would provide a qualified external contribution. He further pledged closer personal involvement, now that a particularly demanding phase of the preparations for the relocation of the Agency had closed. The representative of the European Commission recognised the magnitude of the project and of the effort provided by all. He reminded the board that after the audit there is more than a year to continue with the development. While understanding the rationale for engaging a 3rd party, he reminded all that this may duplicate partially the audit, which is also a 3rd party, adding additional

complexity. He welcomed the stepping up of the user group. The Commission is intent on having July 2019 as the date from which the regulation applies. The Agency will hold workshops with core Member State and then also sponsor users who have been testing the system in order to clearly identify what is already included in release 0.7, what are bugs that will be fixed and then see which change requests are of greatest value to users so that these can be prioritised with Member States and evaluated for priority and cost of implementation so they can be allocated in future releases in an agreed sequence. Concerning the involvement of 3rd party experts, the board would keep an open mind, and would await results from the Task Force, hopefully strengthened by the secondment of experts from the Member States.

The Agency also thanked Spain and Ireland for their support in providing ENDs with clinical trial assessment expertise and indicated that an additional END with clinical trial assessment/management expertise at NCA level would be very useful over the coming year.

B.6 EudraVigilance Auditable Requirements project update

[EMA/MB/792430/2017; EMA/779748/2017] The board noted a report on the EudraVigilance auditable requirements project. Following the confirmation and announcement in May 2017 by the Management Board that the EudraVigilance database had achieved full functionality, a new and improved version went successfully live on 22 November 2017.

B.7 Information Management (IM) Strategy 2018-2020 and Information Management Strategic Plan 2018-2020

[EMA/MB/711126/2017; EMA/232224/2017; EMA/302624/2017] The Management Board endorsed the Information Management Strategy 2018-2020 and the Information Management Strategic Plan 2018-2020. The IT operating model was redesigned to deliver three core objectives of the IM strategy in the context of the relocation and beyond: deliver solutions required by EU law, share information on medicines and establish and improve the Agency's information services. The Agency aims to gradually replace standalone applications with enterprise platforms, continue building a close working relationship with the network on Telematics, continue to support master data management through the SPOR programme, using fixed price contracts to stabilise costs and spread risk more evenly while continuing the integration of standard IT management frameworks. Brexit related risks are being considered and concern mainly potential loss of staff and key contractors. Prioritisation and ring-fencing of IT projects and activities for relocation will be needed, while application maintenance (including for Telematics projects) will be reduced to the essential activities in 2018. As the current Telematics strategy nears its end, reflection is ongoing to prepare a new Telematics strategy to 2025 which will provide an input into the EMA IM strategy and plan. Once adopted, the IM strategy and strategic plan will be reviewed annually to align with the EMA's planning cycle and the objectives of the new Telematics strategy to 2025.

There was support expressed for the focus on strategic risks as well as on key priorities. EMA stressed the need to make investments for internal systems which underpin operational effectiveness at the Agency. The criticality of IT systems in the upcoming veterinary legislation was stressed by some members. Legislative changes will make veterinary regulators more reliant on IT systems, for example for pharmacovigilance, and it is important that the necessary tools will be available at the time of the implementation. As the remarks by the ECA on the annual accounts for the financial year 2016 point out, tasks attributed to the Agency on IT systems have not been accompanied by corresponding resources in the past. In EMA's view, budgets are not the only important factor, but systems should be integrated, and built on platforms that can serve more than one purpose, whether for human or

veterinary purpose. Concerning possible staff loss, there was interest in how knowledge and competence in the National Competent Authorities could provide support. The Executive Director welcomed the offer. Once precise information on EMA requirements is known in Q1 2018, the EMA will know what support can be provided by National Competent Authorities, of which availability of ENDs is an important element.

B.8 Revision of the Anti-fraud Strategy (AFS) and new action plan 2018-2020

[EMA/MB/811979/2017; EMA/812072/2017] The board adopted the Anti-fraud Strategy and new action plan 2018-2020. The revision follows a 3-year cycle and is the first after the strategy was adopted in December 2014. The four objectives in the AFS gave rise to an action plan with 12 actions scheduled for 2015-2016, to which four additional actions were added in December 2016. All actions were successfully implemented within the assigned deadlines. The current revision of the strategy takes into account the lessons learnt in the course of the implementation over the last 3 years and proposes four objectives to be reached through 14 actions planned over the next three years. The Anti-fraud office at EMA will continue to act as coordinator for the implementation of the AFS and as reference point for OLAF and EMA staff members in relation to fraud matters. No additional resources have been budgeted to implement the action plan for 2018-2020. The next revision of the strategy will be submitted to the board for adoption in December 2020.

B.9 Preparation for written procedure on non-automatic carry-over of appropriations from 2017 to 2018 for various IT projects

[EMA/MB/800148/2017] The Management Board was informed that a written procedure will be launched in January 2018 for the adoption of a decision on non-automatic carry-forwards of budget allocations from 2017 to 2018 for various IT projects which are experiencing delays which could not have been anticipated and are outside the Agency's control. Detailed information will be provided as part of the written procedure.

List of written procedures finalised during the period from 13 September 2017 to 20 November 2017

- Consultation no 20/2017 on the appointment of Maria Orfanou as CHMP alternate, proposed by Greece ended on 14 November 2017. The mandate of the nominee commenced on 15 November 2017.
- Written procedure for adoption of the 97th Management Board meeting minutes, ended on 27 November 2017. The minutes were adopted.

Documents for information

- [EMA/MB/781734/2017; EMA/706184/2017] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/771195/2017] Outcome of written procedures finalised during the period from 13 September 2017 to 20 November 2017
- [EMA/MB/794050/2017] Summary of the transfers of appropriation 2017
- [EMA/MB/775352/2017; CH4089422EN05 dated 19.09.2017; EXT/51775/2017] Report on the annual accounts of the European Medicines Agency for the financial year 2016

List of participants at the 98th meeting of the Management Board, held in London, 13-14 December 2017

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper *(member)*
Bulgaria	Assena Stoimenova *(member)*
Czech Republic	*Apology received from Zdenek Blahuta*
Croatia	*Apology received from Siniša Tomić*
Denmark	Thomas Senderovitz *(member)*[1] Mette Aaboe Hansen *(alternate)* Tina Engraff *(observer)*
Germany	Karl Broich *(member)* Birgit Naase *(alternate)* Wiebke Loebker *(observer)*
Estonia	Kristin Raudsepp *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)* Deirdre Hanson *(observer) (partial attendance)*
Greece	Despina Makridaki *(member)*
Spain	César Hernández *(alternate*)
France	Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Nando Minnella *(alternate)* Gabriela Conti *(observer)*
Cyprus	Loizos Panayi *(member)*
Latvia	Svens Henkuzens *(member)*
Lithuania	Gintautas Barcys *(member)*
Luxembourg	Laurent Mertz *(member)*
Hungary	Csilla Pozsgay (member)[1] Beatrix Horvath *(alternate)*
Malta	Gavril Flores *(alternate)*
Netherlands	Hugo Hurts *(member)* Michiel Hendrix *(observer) (partial attendance)* Birte van Elk *(observer) (partial attendance)*
Austria	Sylvia Fuezl *(alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska *(observer)*
Portugal	Rui Santos Ivo *(member)* Maria Joao Morais *(observer)*
Romania	Nicolae Fotin *(member)*
Slovakia	Zuzana Baťová *(member)*
Slovenia	Andreja Čufar *(member)*[1]
Finland	Esa Heinonen *(alternate)*

1 Competing interest declared resulting in no participation in decision with respect to agenda points B.3 and B.7.

	Participants
Sweden	Sara Rosenmuller *(alternate)* Annika Wennberg *(observer)*
United Kingdom	Ian Hudson *(member)* Jonathan Mogford *(alternate)*
European Parliament	Björn Lemmer Tonio Borg
European Commission	Xavier Prats-Monné (DG SANTE) Carlo Pettinelli *(DG GROW)* Jerome Boehm DG Sante *(observer)* Chloe Spathari (DG GROW) *(observer) (partial attendance)* Agnes Mathieu-Mendes (DG GROW) *(observer) (partial attendance)*
Representatives of patients' organisations	Ilaria Passarani Yann le Cam
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland) Brigitte Batliner (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Guido Rasi Noël Wathion Stefano Marino Fergus Sweeney Nerimantas Steikūnas Melanie Carr Alexis Nolte Anthony Humphreys Zaide Frias Agnes Saint-Raymond Enrica Alteri Fia Westerholm Edit Weidlich Michael Lenihan Anabela Marcal Wim Nuyts Monica Dias Marie-Agnes Heine Hilde Boone Silvia Fabiani Sophia Albuquerque

Dutch delegation present during point 5.1 Presentation from the Netherlands including how it will meet EMA requirements:	Maurice Galla *(observer) (partial attendance)* Aginus A. W Kalis *(observer) (partial attendance)* Marcel van Raaij *(observer) (partial attendance)*