14 February 2022
EMA/MB/761948/2021 - Adopted
Management Board

Minutes of the 114th meeting of the Management Board

Held virtually on 15-16 December 2021

The Chair of the Management Board opened the meeting which was held fully in form of a videoconference due to the extraordinary circumstances of the COVID-19 outbreak. The Chair asked for confirmation of the number of participants and of the quorum and received this assurance from the Management Board secretariat. The Chair confirmed the validity of the meeting and welcomed the new members: Siniša Tomić, formerly alternate, is now the member for Croatia; Katrin Kiisk is the new member from Estonia. Yannis Natsis notified the board he will leave the European Public Health Alliance at the end of 2021 and hence also the EMA Management Board; the Chair and EMA thanked him for his contributions as civil society representative in the Board. His position will remain vacant at the March meeting until a new member is appointed by the Council in May 2022.

1. Draft agenda for 15-16 December 2021 meeting

[EMA/MB/761948/2021] The agenda was adopted without amendments.

2. Declaration of competing interests 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.3Programming 2022-2025 a) Technical amendment to procurement plan of programming document 2021-2023, b) Final programming document 2022-2024, c) Preliminary programming document 2023-2025; B.9 EMA Cloud Strategy 2022; B.10 Update on preparation for implementation of Veterinary Medicinal Products Regulation Expiry of the MUMS policy, Draft mandate of the future VMP-Reg systems improvement advisory group (VSIAG), Revised rules of procedure of CVMP; B.11 Joint Controllership Agreement under the Veterinary Medicinal Products Regulation; B.12 Update on Big Data, Data Standardisation Strategy; B.13 Risk Management Plan (RMP) publication.* The Secretariat informed the Board

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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 and that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

3. Minutes from the 113th meeting, held on 7 October 2021 adopted via written procedure

[EMA/MB/571618/2021] The Management Board noted the final minutes, adopted by written procedure.

4. COVID-19

• EMA Status Report

The Board noted a verbal update from the EMA's Executive Director on COVID-19 developments since the previous Board meeting and a progress update on lessons learned exercise.

Omicron was designated as a variant of concern in Europe and globally, based on high number of mutations. At this stage there is insufficient evidence to indicate the need for possible vaccine strain update, which is considered a public health decision that is still being discussed at WHO and EU level. There is also a potential impact of the new variant on the antiviral therapeutics (in particular monoclonal antibodies) which have been authorised and more are under evaluation. Regulators are prepared to authorise the changes if necessary and since February 2020 guidelines have been published for industry as to what trials are expected for these situations. There is strong need for international alignment and EMA is already involved in discussions with the International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO.

With regards to the most recent product-related outcomes, EMA has concluded on the variations for a booster dose for Spikevax and Janssen vaccine. A joint EMA/ECDC communication on 'mix and match' of vaccines in primary series and for boosting was published and concluded that this is safe and produces a good level of immunogenicity. Further evidence determined that booster dose can be used after three months of primary series. Extension of Comirnaty for children aged 5 to 11 was authorised with a new formulation (using a third of adult dose) to ensure effectiveness and supply of this new formulation is being rolled out across Europe. Regular safety update reports are being monitored and published for all authorised vaccines. There has been high focus on the risk of myocarditis and pericarditis with mRNA vaccines. The conclusions by the PRAC highlight that while these are very rare events for both vaccines, there is an increased incidence of myocarditis for Spikevax in young male adults. In addition, EMA continues to work on several variations to increase supply capacity, including to extend shelf life of the authorised vaccines. For ongoing activities, an ad-hoc CHMP meeting is being organised to finalise the marketing authorisation application for the vaccine from Novavax. Other rolling reviews for

Sanofi Pasteur, Gamaleya (Sputnik), Sinovac and Valneva are ongoing and conclusions are not expected before end of the year. Further work is ongoing on the Spikevax for children aged 6-11. An upcoming procedure is expected to allow a revision of product information to include use in pregnant women following positive results from a number of studies.

There have been some positive advances in COVID-19 therapeutics. Two monoclonal antibody therapies were recently approved (Regkirona and Ronapreve) and extended indications for two existing immunomodulators (RoActemra and Kineret) are under evaluation. The Art. 5.3 opinion to support possible early use at national level of Lagevrio (molnupiravir) was finalised. A marketing authorisation application for Xevudy is currently under review and a few extensions of indications are in progress (Veklury and Olumiant). The outcome of the Art. 5.3 procedure for Paxlovid is expected soon.

EMA provided a progress update on the upcoming European Medicines Regulatory Network workshops as part of the ongoing work on the COVID-19 lessons learned review. The Agency has been working with the Heads of Medicines Agencies (HMA) and identified two themes for the upcoming workshops from the top 10 key learning areas identified as part of the lessons learned exercise. The first workshop on sustainability and resourcing of the network and optimisation of processes is planned on 21 January 2022 and the second workshop on 1 February 2022 will focus on cooperation and communication with institutions and stakeholders outside the network. The workshops will involve around 20 participants from HMA, NCA, relevant scientific groups (CHMP, PRAC, ETF, SAWP), European Commission (SANTE B5) and EMA Secretariat. The European Medicines Regulatory Network meetings continue on a biweekly basis and the regular press briefings are also organised between committee meetings. The Agency has suspended face-to-face meetings and these may resume in Q1/Q2-2022. EMA continues to engage with international regulators through the ICMRA and WHO and through bilaterals with other regulators, including MHRA and FDA. Support to NCAs in dealing with the backlog of individual case safety reports is being provided by EMA.

A. Points for automatic adoption/endorsement

A.1 Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2022

[EMA/MB/94384/2021] The Board adopted the annual update of the financial compensation to National Competent Authorities (NCAs) for their participation in the linguistic checking of product related information in their respective national languages. As per the EMA-NCA Cooperation Agreement, the fixed flat hourly rate is revised annually considering the official inflation. For 2022, taking into account the inflation, the compensation rate will increase from 46€ to 47€ per page. The financial compensation/remuneration is then calculated based on the forecasted workload as stated in the Agency's Work Programme of 2022.

A.2 Revision of budget remarks for budget 2022

[EMA/MB/254845/2021] The board adopted an update of budget nomenclature for 2022 in line with the Agency's Financial Regulation.

The update includes two amendments. The first one is splitting the expenditure on business consultancy from audit services into different budget items for greater transparency. The second amendment is related to the new extended mandate in crisis preparedness and response which will require the use of remunerated external experts on medical devices and in vitro diagnostic medical devices. It is considered that this expenditure does not fall within the scope of any of the already existing budget items and, consequently, it is proposed to create budget item 3032 to ensure appropriate management of this expenditure. Both amendments are designed to achieve more transparency and they do not change the budget for 2022.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update covering EMA's activities with EU institutions and agencies, international cooperation, temporary pause of face to face committee meetings, sustainability of the network, updated EMA Engagement Framework with patients, consumers and their organisations and information on contact details of Management Board members on the EMA's website. The Deputy Executive Director also provided an update on cyber security at the EMA.

The Executive Director attended her first annual exchange of views with the European Parliament's ENVI Committee on 30 November. The Agency was invited to provide an update on COVID-19 vaccines and therapeutics at an Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting on 7 December 2021. EMA is involved in a number of activities related to European Commission's Pharmaceutical Strategy for Europe, including interviews for an external study supporting the Evaluation and Impact Assessment of the general pharmaceutical legislation. Preparatory activities for the implementation of EMA's extended mandate are ongoing in the areas of shortages of medicines, Emergency Task Force and medical devices expert panels. Implementation activities for shortages of medical devices will start later in 2022, in line with the implementation deadline of 2023 as set in the final legal text. The European Shortages Monitoring Platform (ESMP) will be the most challenging article to implement. The Platform will collect information on shortages for the medicines on the critical lists, as well as marketing status information for all human medicines. In order to implement it, the Agency, in collaboration with the Medicines Shortages Steering Group, will have to: develop the technical and functional specifications of the platform; develop standardised reporting terminology and guidance; draw up an implementation plan until 2025. At international level, EMA continues with DG SANTE to assist the European Commission DG International Partnerships (DG INTPA, ex-DG DEV) on their proposal to support the establishment of an African Medicines Agency. ICMRA had its annual combined summit and plenary meeting on 1 and 2 December. At the EU- Latin America and the Caribbean Leaders' summit on 2 December, EU Leaders discussed with

Latin American Heads of State proposals on possible support for regulatory systems strengthening work as part of ongoing Pan American Health Organization (PAHO) programmes.

On 29 October, EMA decided to temporarily pause the resumption of face to face Committee meetings due to quickly evolving COVID-19 epidemiological situation across Europe. The March 2022 MB meeting is currently planned as a hybrid meeting in the EMA building. The SAWP continues to face problems in identifying scientific advice Co-ordinators when the number of monthly submissions exceeds 75-80 requests. Mitigation measures have been put in place to address these measures and workshops with SAWP members were conducted to identify further solutions, which will be communicated to the Scientific Coordination Board in early 2022. The framework of EMA interaction with patients' and consumers' organisations has been further revised since its last revision in December 2014. A written procedure to adopt the updated framework document will be launched following this MB meeting.

The Deputy Executive Director provided an update on incident management activities after the cyberattack in December 2020. EMA has structurally strengthened its cybersecurity capacity and has established an Information Security Management Steering Committee (ISSC) to provide an agency-wide oversight, ownership and direction to the implementation of its information security strategy. The Agency has also drafted a new Information Security Strategy and has secured substantial budget in 2022 for Information Security activities.

The representative of the European Parliament asked how the move from London has impacted on the availability of IT security staff at the Agency and if there are plans to increase staff in this area. A member inquired on what recovery plans are in place in case of further data breaches or losses and if a separate back up data centre is available. EMA explained that the relocation did not particularly affect resources for IT security. An additional staff member working on this will join in February 2022. However, due to lack of available posts on the EMA establishment plan for cybersecurity, the Agency had to significantly outsource its IT security operations. EMA has a physically separate back-up Data Centre and a Disaster Recovery Plan which allows it to restore all data within 24 hours; an audit of this plan is foreseen in 2022. Questions were asked about the role of EMA in the setup of the African Medicines Agency and in managing the medical device expert panels under the extended mandate regulation. EMA explained it has engaged for years with African regulators to explain how it performs its activities with the EU network. The Agency can further support with trainings, including meetings on site, in the areas of its competence and by providing lessons learned based on its activities in Europe. Although the political go ahead for the African Medicines Agency has been secured, more time is need for African countries to define in detail what the new Agency will do. As regards the medical device expert panels, EMA has been working closely with DG JRC in Ispra to understand what the new tasks will involve and has focussed on putting in place all necessary contracts to manage and convene the panels. Preparations are on target for the official implementation deadline of 1 March 2022.

B.2 Report from the European Commission

The Board noted an oral update from the representative from DG SANTE on: Pharmaceutical Strategy, revision of orphan and paediatric legislation, HTA proposal, regulation for a

reinforced role for the EMA, future EU joint actions in the domain of pharmaceuticals, titanium dioxide, international collaboration activities and other legislative initiatives to be published in 2022. These include the Implementing Regulation on the cooperation in safety assessment of clinical trials, which will become applicable on 31 January 2022 at the same time as the applicability of the Clinical Trials Regulation, the European Health Data Space legal proposal and the legal proposal for the revision of the blood, tissues and cells directives.

Under the Pharmaceutical Strategy, the European Commission is preparing a package of legislative changes to be published by the end of 2022, including a revision of the basic pharmaceutical legislation and of the regulations on orphan and paediatric medicines. A number of studies for the impact assessment of these legal proposals are ongoing, with several representatives of the European regulatory network currently being interviewed. The Impact Assessment for the proposals on orphan and paediatric medicines is on target. For the basic legislation, a number of workshops have been conducted and will be further organised in 2022 in the Pharmaceutical Committee, while 13 concept papers proposing technical changes to the current legislation have been requested from the Heads of Medicines Agencies (HMA) and the EMA. The HTA regulation was adopted by the European Parliament on 13 December and is to be published in the EU Official Journal soon. It will enter into force in January 2022 and, amongst other things, will formalise the ongoing cooperation between EMA and HTA bodies. Joint work between HTA bodies will start in January 2025 and the Commission is currently setting up projects for preparatory work and to continue cooperation between HTA bodies and EMA over the next two years. The EU4Health Programme will also include projects for HTA cooperation in the coming years. As regards the EMA's extended mandate, the legislative process should be finalised by end January after legal linguistic review and the regulation will apply from 1 March 2022 including for the medical device expert panels. Cooperation between EMA and the Joint Research Centre for the transfer the expert panels is progressing well. The delay of one year for the chapter on shortages of medical devices also reflects earlier discussions with Member States at EMA's Board. The Commission also decided to postpone the application of the In Vitro Diagnostic Medical Devices regulation, which becomes applicable in May 2022 but will be implemented with some delays for certain lower risk devices: the legislative procedure for this deferred application is expected to conclude by the end of 2021. Several Member States have signed up for joint actions under the EU4health programme and a workshop explaining the planned activities was organised by the European Health and Digital Executive Agency (HaDEA) on 8 November. The Delegated Regulation banning titanium dioxide as food additive is expected to be adopted in January 2022 and foresees a period of three years for the Commission to re-assess the use of titanium dioxide in medicinal products, based on a report to be prepared by EMA by April 2024. During this period, the pharmaceutical industry is strongly invited to develop alternatives and engage with EMA and NCAs for the safe replacement of titanium dioxide with other substances. As regards international cooperation, the Commission is working with EMA to establish a Coordination Group on International Matters with all NCAs. It aims to increase coordination of EU positions and to advance EU interests on strategic and important topics in international fora, with a focus on the International Coalition of Medicines Regulatory Authorities (ICMRA) and covering other international aspects, as needed.

Further details were requested about the Coordination Group on International Matters, including whether it would include veterinary NCAs. The representative of DG SANTE and the EMA explained that a Terms of Reference for this group will be prepared by the end of Q1 2022 and an update can be provided at the next Management Board meeting. Once a Terms of Reference has been agreed, all NCAs will be asked to nominate representatives.

The representative of DG Research and Innovation informed the board about the launch on 1 December 2021 of two new EU Joint Undertakings: the Innovative Health Initiative and the Global Health EDCTP3 partnership (also known as 3rd European and Developing Countries Clinical Trials Partnership). The Innovative Health Initiative is a pre-competitive public-private partnership with different health industries, including medical devices and imaging. Regulators will be invited to provide input into the activities of IHI via the Science and Innovation Panel whose task, among others, will be to advise on the scientific priorities, including the content of calls for proposals. EDCTP3 is a partnership with African countries to address infectious diseases with high burden in Africa. It will also focus on AMR and on capacity building for clinical trials and regulatory procedures. It is an enabler for setting up the African Medicines Agency. First activities for both Joint Undertakings will take place in the first half of 2022. A collaborative research project, EU-SolidAct, has also been launched and it aims to create a pan-European platform for pandemic research and preparedness by helping to set up adaptive platform clinical trials, which can study multiple interventions simultaneously, including for COVID-19 therapeutics; it will run until 2025.

B.3 Programming 2022-2025

a) Technical amendment to procurement plan of programming document 2021-2023

[EMA/MB/707273/2021] The Management Board adopted the technical amendment to procurement plan of programming document 2021-2023

EMA explained that as per the Financial Regulation, the final Programming Document 2021-2023 (EMA/53919/2021) includes in Annex XIII the Procurement Plan constituting the financing decisions for operational expenditure. The DARWIN EU procurement started in 2021 and will finish in 2022. The financial envelope for this tender has been increased and the type of contract and procedure changed compared to those initially planned. Therefore, a technical amendment to the procurement plan is introduced in order to align it with the multi-annual programming 2022-2025 where updated information is already included.

b) Final programming document 2022-2024

c) Preliminary programming document 2023-2025

[EMA/MB/713342/2021; EMA/MB/591134/2021; EMA/MB/678773/2021; EMA/546314/2021] The Management Board adopted the 2022-2025 Programming document, including the 2022 budget.

The Programming document 2022-2025 is presented as a single document and is made up of the Programming 2022-2024, which includes the final 2022 work programme, budget and establishment plan, and the Draft programming 2023-2025. After adoption by the board, the Agency will include any comments received, update the final figures and divide the presented documents into two separate ones, which will be circulated to the board and submitted to the European Commission and other institutions by 31 January 2022. The Board's Topic Coordinators Grzegorz Cessak, Rui Santos Ivo, Nancy De Briyne and Lorraine Nolan, together with the Chair, had examined the evolving documents on behalf of the board over the past three months and presented the findings of their review after an introductory presentation from EMA.

2022 is expected to be a year of delivery with the go-live of the Clinical Trials Information System, the launch of the new Accelerating Clinical Trials in the EU initiative (ACT EU), implementation of the new veterinary legislation and application of the proposed EMA mandate extension. These activities are combined with other priorities related to the implementation of new Agile telematics and programme governance, enhancing EMA's IT security systems, execution of public health strategies EMANS and RSS to 2025, communication to maximise the transparency, international activities, integration of digital technologies and delivery of DARWIN EU. Inevitably in 2022, the Agency will continue to face a significant level of workload that could be further exacerbated by unforeseeable developments of the pandemic.

EMA noted the 2022 budget will include increased revenues due to a higher number of scientific applications and workload (not only COVID-19 related) and a higher EU contribution linked to the mandate extension. The net increase for staffing in 2022 will be minimal with only 2 FTEs, as the staff addition linked to the new mandate (+5 TAs and +2 CAs) is offset by the reduction of the Brexit Contract Agents. Significant IT budget allocation in relation to IT projects is expected to ensure delivery of legislative responsibilities and to support digitalisation effort for the benefit of the Network. EMA building cost and other operational costs are stabilising and in line with forecast for normal activities. The subtenant is orderly paying rent for 30 Churchill Place and EMA has received payment for Q1-2022 in compliance with the lease, which will trigger payment of inducements. 2022 will be a volatile year with regards to the uncertainties linked to the pandemic and thus the 2022 budget will continue to be subject to intensified monitoring.

On the income side, fee revenues are expected to increase by 5.5% to €357.7 million, with workload for NCAs and EMA also increasing by approximately 4%. For 2023, it is foreseen a further 4.5% growth in fee revenue in relation to the increase in workload. Concerning the expenditure side, staff-related costs have remained stable with a minimal increase from €132 million to €135 million linked to the few staff for the extended mandate. Infrastructure and administrative costs have grown from €55 million to €58 million due to the higher IT operational and maintenance costs. Operational costs are likely to significantly increase from €192 million to €224 million to cover the payments to NCAs follow the increasing application trends and workload, IT projects and also the reimbursement for delegates as face-to-face meetings may restart.

During 2022 and 2023, the number of TAs and CAs will decrease by 20 full time equivalents CA positions in 2022, and a further loss of 40 COVID-19 related posts TA posts in 2023. This

will represent a reduction of a total 60 positions. EMA's request for TA posts for 2022 to manage workload which grew significantly over the last years was not accepted by the Commission. As EMA workload continues to grow steeply in proportion to the increased portfolio of products, safety assessments, transparency measures, access to document requests, international collaboration and new legislation, this remains a major issue for the Agency. EMA will need to reinstate the request for 20 TA posts to partially cover the increasing workload and also ask to extend the 40 time-bound TAs to cope with COVID-19 related work, which will continue in the coming years, for a further 3 years.

Concerning the Work Programme, Topic Coordinator Grzegorz Cessak introduced the multiannual EMA programming document 2022-2025 which has been developed by clustering the activities around 3 main pillars: product-related activities, public health activities and strategies and programmes and projects. The EMA Multiannual Work Programme has been developed under the wider umbrella of the EU Pharmaceutical Strategy to 2025, with the European Medicine Agencies Network Strategy (EMANS) to 2025 and Regulatory Science Strategy to 2025 continuing to provide the Agency with a strategic direction. EMA is managing to absorb some of the growing activities, both fee-related and legislation-related, through efficiency gains and effective staff reallocation, but also through increased reliance on short-term staffing contracts, Contract Agents and contractors. This is not sustainable in the longer term and is not in the best interest of enabling the Agency to contribute to a robust and sustainable European Health Union. Already, because of staff capacity constraints, the Agency is unable to fully carry out the required scope of its objectives, therefore some activities linked to the objectives had to be deprioritised.

According to the Topic Coordinator Rui Santos Ivo, the 2022 budget is balanced and robust taking into account the foreseen activities, including the extended mandate and the ongoing EMA and HMA work on progressing the EMANS, and the impact of the COVID-19 constraints. The 2022 budget and its related level of revenues and expenditures will be subject to constant monitoring to reflect changes of these activities. The impact of the establishment of European Health Emergency Preparedness and Response Authority (DG HERA) will be considered and the new Authority will have to ensure good cooperation with EMA and NCAs.

The Topic Coordinator Nancy De Briyne confirmed the budget 2022 is sufficiently robust to ensure that EMA can deal with the issues related to COVID-related work, new mandate, Churchill Place etc. With regards to the programming document, she agreed with the main priorities identified and noted the introduction of negative priorities, which is necessary in light of the high workload and insufficient staffing. In addition, she supported the request for additional staff for 2023, in particular the extension of contracts for COVID-19 posts. The Board thanked Nancy De Bryne for her last contribution as topic coordinator on behalf of the EMA Management Board.

EMA presented the IT budget and product portfolio. 2022 will have the largest IT programme in EMA's history with plans to deliver major legislative initiatives, such as CTIS and Union Pharmacovigilance and Product databases, which in turn boosts IT demand. IT delivery is challenging in the current environment due to a complex stakeholder landscape with diverse needs which creates challenges in prioritisation. The transition period for the Agile transformation and the digital business transformation is ongoing. Regulatory business optimisation (previously known as IRIS) has also advanced with many processes already

being implemented on a modern cloud-enabled platform. IRIS and SPOR will be scaled up in 2022. A large focus will be on technology debt and legacy systems as large majority of software is reaching end-of-life and this will be highlighted in the portfolio. Information security continues to be a top priority and EMA will continue to explore how to improve the maturity of the Agency's security operations. COVID-19 continues to impact IT delivery, for example the onboarding of new technology partners and smooth transfer within teams. A snapshot of the 2022 portfolio was presented using the Kanban method to visualise the ongoing and future activities by different theme areas ("swim lanes").

Budget Topic Coordinator Lorraine Nolan provided her analysis of the IT Budget evolution and carry-overs, and the budget outlook for 2023. For 2021 to 2022 ICT operations carry-over is estimated at 35% and for ICT projects and platforms the carry-over for services to be provided in 2022 is 42%. For 2022 the IT budget is €71.2 million and there has been an increase of €11.6 million in areas of operations and project and platform maintenance. In 2022, the key investment areas which make up 80% of IT budget will be: VMP Reg; delivery of CTIS and its continued development over 2022; a large increase in the Regulatory Business Optimisation programme (incl. IRIS, SPOR, New Mandate); continued implementation of PMS; operational investments and implementation of IT security programme; legacy maintenance; data centre; licences. Looking at 2023, the total IT budget (€66 million) is lower compared to 2022 taking into account that IT funding for New Mandate is foreseen for the 2022 budget year. However, activities related to the New Mandate are expected to span in 2022-2023 timelines and therefore this is likely to result in some carry-over. There is a need for continued investment to continue to deliver on strategic priorities and to address technology debt. In 2023, CTIS and VMP Reg projects will move into maintenance and the implementation of Agile transformation will be completed. The migration of applications to the Cloud will also be finalised.

A question was raised with regards to the carry-over of the appropriations for ongoing IT contracts which was thought to accrue instead of carry over. EMA confirmed that the Agency produces not only financial accounts but also budgetary accounts, as required by its financial regulation. Therefore, it accounts its expenditure as accruals according to the international accounting standards, and as carry-overs according to budgetary accounts. Questions were raised on the EMA's plans for implementing the chapter on medical devices in the extended mandate and the exact references in the Programming Document were highlighted by EMA.

The Chair noted EMA's request for additional 20 TAs to cover the increasing workload and extension of 40 time-bound TAs to cope with COVID-19 related work, which will continue in the coming years, for a further three years. The Board supported the request to increase the EMA's establishment plan as soon as possible in 2022, either via an Amending Letter to the Budget 2022, and only if this is not achievable, via the Draft EU Budget 2023. The representative of DG SANTE abstained and expressed reservations on the possibility of an Amending Letter to the recently adopted 2022 EU budget.

B.4 a) Amendment to audit plan 2021

[EMA/MB/385281/2021; EMA/MB/434298/2020] The board adopted an amendment to the EMA's audit plan 2021.

The amendment foresees that, taking into consideration the current context of ongoing COVID-19 pandemic and Business Continuity prioritisation, the 2021 audit engagement "Review of agency operational procedures and measures taken in response to COVID 19" is to be carried out in 2022 and its scope is to be extended to include another audit post-Brexit transition originally foreseen for 2022. The resulting audit engagement is included in the Audit Plan 2022 with the title "Organisation and impact of transitional operational measures taken in the BCP period".

b) Audit strategy 2022-2024 and audit plan 2022

[EMA/MB/385166/2021] The board adopted the Audit strategy 2022-2024 and audit plan 2022.

The Strategy outlines the audit activities proposed to be undertaken at EMA in 2022-24. The proposal is based on: priorities laid down in EMA and EU network strategies and multiannual work programme, the Agency's Annual Activity Report, COVID-19 Business Continuity Plan, analysis of the EMA's risk registers, applicable legal requirements, audits to be performed by the European Court of Auditors / Internal Audit Service (IAS) of the Commission, and is complemented by dedicated discussion with EMA's management.

The Plan includes 12 audits in 2022, four of which will be performed by the EMA's internal audit function. In 2022 the Internal Audit Service (IAS) will do an audit on Human resources and ethics, while the audit by IAS on Management of meetings for EMA's committees, working parties and other groups is yet to be confirmed. An audit on IT security is also planned by IAS or, depending on the capacity of IAS, by external auditors. The EMA's internal audit function will coordinate all audit activities at the Agency and with the IAS, the follow up on all audit recommendations, and manage audit related planning, reporting and communication activities, including targeted audit related Network trainings.

B.5 Review of activities of the Working Parties of the EMA

Update from the Implementation Task Force

The Board noted an oral update from the Implementation Task Force for the Review of the Activities of the Working Parties of the EMA.

The Chair acknowledged that a letter was sent by a member to the entire Board on 19 November expressing concerns on the future composition of BWP and QWP and noted this would be addressed in the EMA's presentation. EMA reported on the progress made by the Project Implementation Task Force that has been activated in September 2021 to deliver the High-level Implementation plan endorsed by the EMA Management Board in March 2021. EMA reminded the Board of the new agreed Working Party structure consisting of five Domains (quality, non-clinical safety, methodology, clinical and veterinary) which would report to CHMP and CVMP. The Domains are new strategic oversight bodies to govern the Working Parties and European Specialised Expert Communities (ESECs) which will report the Domains. As part of the implementation of the new Veterinary Regulation, the veterinary domain has already re-organised its 5 Working Parties (WPs) in Q4-2020 based on expertise. ESECs have not yet started as the Veterinary Domain and EMA Secretariat are awaiting the lessons learned from implementation of the human domains. A transitional governance for

the four Human Domains was established in September 2021 and has met regularly. The new Working Party model is being implemented in a step-wise approach as different Domains are being activated based on workload and operational activities are taking precedence in order not to disrupt ongoing core activities. A prioritisation of the workplans and activities for each Domain has been undertaken. The Quality Domain has prioritised the creation of the Quality Innovation Group which brings together expertise on manufacturing and innovation. The Quality Domain has launched a survey aimed at interested parties in December 2020 (i.e. stakeholders, academia, learned societies). The scope of the survey is to better understand the challenges this group will need to face, and the areas of expertise required for the future. The following activities are planned by the Implementation Task Force in Q1-2022: transmit call for nominations; match demand and available secretariat support; nominate members / experts for each Working Party. Following the nomination process, the Working Parties will be constituted, and elections of the new chairs and vice-chairs will take place. The plan foresees that the new operating models for the clinical, non-clinical and methodology Domains will be implemented in a phased approach starting in May-June 2022. The work on Quality Domain is only planned later in the year as QWP and BWP are heavily impacted by COVID-19 workload. A pilot project for the new ESEC structures will be run in parallel to gain an understanding of how they will operate. Phase two of the plan will focus on further developing the model and will gather lessons learned and experience with the newly established structures of WPs and ESECs. Using the knowledge gained from this experience, the implementation of the new Quality Domain will take place in September 2022.

EMA addressed points raised by Management Board members in advance of the meeting and concerns about loss of knowledge transfer across the Network. On the contrary, the aim of the review is to strengthen expertise and facilitate knowledge management within the Network. The review will also not lead to exclusion of any CHMP/CAT/PRAC delegates leading as rapporteur or participating in the evaluation of medicines. As next step, a new 3-year rolling workplan at the Domain level is being introduced, with a 1-year operational plan for 2022 to be published when WPs are operational. The phase 1 of the implementation plan will start in January 2022 for Clinical, Non-Clinical and Methodology Domains with a call for nominations at the CHMP PROM. Further updates will be provided at the next Board meeting.

The presentation was followed by a number of interventions from Board members. A call for continuing full representation of Member States in BWP was raised, taking into consideration the systematic contribution of BWP to CHMP for quality dossier assessments. Concern was also raised that an expertise-based model might penalise small Member States, who cannot afford to have experts in all fields. The revision of the legislation as part of the European Commission Pharmaceutical Strategy was seen as an opportunity to address these issues and to propose more streamlining of regulatory procedures. Innovative approaches could be explored to improve coordination and increase productivity of the Working Parties whilst addressing the training needs and capability development through modern online collaboration tools and settings.

The Topic Coordinators of the Management Board Review Group acknowledged once again the concerns raised by several board members and reassured that these have been considered in the review process and various mitigating measures introduced. They highlighted the main benefits of the new model which are the potential to deliver strategic

priorities, be adaptable to future needs and introduce efficiency by redistributing expertise in more agile structures. Time should be given to implement the agreed model now in order to gain the necessary experience to adjust the next implementation phases as necessary. The veterinary Domain, which has already implemented the new model, has shown the success of the new structures and working methods. The implementation plan, which is driven by efficiency gains and better use of resources, was already adapted in March 2021 to integrate similar concerns that were raised at the 2020 December Management Board meeting as regards the composition of QWP and BWP. The EMA's proposal to implement the Quality Domain after a mid-term review and lessons learned can be considered an acknowledgement that these concerns will be taken into account.

The Chair recalled that the reform has been supported by the Management Board to increase efficiency and allow for best use of resources in the network. In addressing the concerns, the Chair asked the Board to allow phase 1 of the implementation plan focusing on Clinical, Non-Clinical and Methodology Domains to start as planned. The MB Review Group will be continuously updated on progress and, before entering phase 2, a review of phase 1, including examples of new structures and relevant lessons learned, will be presented at a future board meeting.The Board supported this way forward.

B.6 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/589223/2021] The board noted updates from EMA and from the EU Clinical Trials Regulation Coordination Group on the implementation of the Clinical Trials Information System (CTIS) project and an update by EMA on the Go Live communication plan endorsed by Coordination Group in November 2021.

a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation

[EMA/MB/589226/2021] EMA explained that the current focus of the CTIS project is on delivering a stable system for Go Live meeting stakeholders' expectations. The functionalities agreed with the Management Board have been delivered and intensive testing is ongoing to ensure no blocker bugs are present. Final testing results will be communicated to the EU CTR Coordination Group in early January 2022, including information on issues that may be outstanding at the time of Go Live. All nominated MS Administrators are registered in the EMA Account Management System. Organisations that will use CTIS, as provided by MS via survey, have also been registered. Training and communication activities are on track. Extensive training materials for Member States and for sponsors have been published. A revised Sponsor handbook was published on 2 December 2021. Access to Sandbox was granted to Member State Master Trainers in October 2021, with access to Sponsor Master Trainers in November 2021. A dedicated User Support Service is in place. In October 2021 EMA and Member States started configuring different organisation models in the Sandbox to help get ready for Go Live. Dedicated training sessions with NCAs and Ethics Committee representatives have taken place in December 2021 and will be repeated in January 2022 prior to Go Live. A CTIS communication package is in development to assist Member States.

A network CTIS Launch Communication plan for Go Live use was endorsed by the EU CTR Coordination Group at end of November. The Implementing Regulation on safety aspects is pending adoption at the Standing Committee; both its IT-related and business-related activities are on track. The CTIS Data Protection Notice, annexed to the CTIS Joint Controllership Arrangement (JCA), has been subject to a minor update to align with the new Safety Implementing Regulation and to delete a reference to personal data of trial participants that was contradictory to a preceding paragraph. Principles for a Joint EU Query Management process have been agreed and a working group comprising Member States, European Commission and EMA colleagues has been established in order to pilot the joint query management process. The implementation of technical items is progressing as planned and the CTIS production environment is being set up and tested for performance.

In 2022, the three main objectives are to ensure a smooth Go Live of CTIS, to assist Sponsors and Member States with CTIS processes (including communication, training and operations) and to strengthen and further develop CTIS. Key activities include: i) a 6 months hyper-care and stabilisation period focussing on incident management and technical deliveries; ii) support activities such as harmonised query management process, provision of CTIS trainings and revision and finalisation of guidelines and procedures related to CTIS processes; iii) analysis of feedback and setting priorities for further CTIS functionality development. A high-level overview of deliverables to be implemented in each quarter of 2022 for authorities, sponsors and the public was provided.

b) EU CTR Coordination Group Report following EU CTR meeting

[EXT/MB/712003/2021] The Chair of the EU Clinical Trial Regulation Coordination Group reported on the situation at 46 days until the new Clinical Trial Regulation enters into force on 31 January 2022. Extensive training and support material is now easily available, dedicated User Support Service is gaining experience and knowledge for Go Live, and additional training sessions for Member States can be organised by EMA as required. The Coordination Group is confident the EU CTR will Go Live on 31 January as planned. As this was the final board discussion on CTIS before Go Live, he thanked EMA, the European Commission and all MSs for the significant work accomplished together over the past few years.

c) Communication plan endorsed by EU CTR Coordination Group

[EMA/708143/2021] The Go Live communication plan describes how EMA plans to raise awareness about the changes and benefits brought about by the EU CTR and CTIS. It identifies tailored key messages for Sponsors, Member States (NCAs, ethics committees), public (patients, healthcare professionals, other) and the media in order to explain the benefits of CTIS, the rules during the transition period towards the CTR and the level of transparency and functionalities for public search in CTIS, which will build over time as more clinical data is entered in the new system. The plan also includes an operational part

describing the main communication activities until the end of the transition period in January 2025.

B.7 Accelerating Clinical Trials in the EU (ACT EU), formerly known as Clinical Trials Transformation Initiative

[EMA/MB/714555/2021; EMA/715525/2021] The Management Board endorsed the paper that sets out proposals for the initial set up of ACT EU.

As background, EC stressed that the current EU environment for clinical trials is challenging and this has been demonstrated also during the pandemic where a relative absence of impactful multi-state trials organised in the EU for COVID-19 medicines has been visible. The different regulatory requirements between Member States complicates the submission of multi-state trial applications which might in part explain the reduction of clinical trials in Europe compared to other regions. However, Europe has a long history of conducting clinical trials and a strong academic base, suggesting the right ingredients are available to foster innovation. Both the European Medicines Regulatory Network Strategy to 2025 and the European Commission's Pharmaceutical Strategy include recommendations to foster innovation for clinical trials in Europe. Together with the coming into effect of the clinical trial regulation on 31 January 2022 and the go-live of its accompanying IT solution, the Clinical Trials Information System, there is a unique opportunity to strengthen the environment for clinical trials in Europe.

The representative of DG SANTE explained that, following the discussions on clinical trial transformation at the previous Management Board and HMA meetings, the Commission convened a Clinical Trial Working Group consisting of representatives of EC, HMA and EMA. The paper finalised by the group sets out proposals for the initial set up of ACT EU initiative and includes high-level objectives, governance, organisation, priority actions for 2022-2023, and resourcing. The paper was endorsed at HMA on 24 November. Following endorsement of the proposal, a revised mandate for the Clinical Trials Regulation Coordination Group will be drafted (as the steering group of ACT EU) and a written procedure would be launched after the meeting in order to adopt it. The priority actions will be organised into domains and an implementation plan will be presented at the next Management Board.

The Board fully supported the proposal and next steps. A joint EMA/EC/HMA communication on the paper will be published in early January 2022 following endorsement by the Board.

B.8 Agile transformation progress report

[EMA/MB/720214/2021] The Board noted a progress update on the implementation of the new Agile framework for the IT Portfolio.

EMA has been steadily introducing a new way of Agile working for the delivery of Information Management projects since the EMA Management Board endorsed a plan for implementation at its June 2021 meeting. It has been a steep learning curve and the Agile Pilot is progressing well. The ePI project will join the Pilot during the first quarter of 2022. The new governance bodies are still adapting to the new management approach and ceremonies are starting to take place. The EMA Executive Board is currently discussing the Agile transformation activities for 2022 and the operationalisation of the value streams. NCA

representatives and Industry have been regularly informed of developments of the pilot. In 2022, EMA will focus on identifying the right experts to join the pilot product teams.

The Network Portfolio Advisory Group (NPAG), Network ICT Advisory Committee (NICTAC) and a new Enterprise Architecture Board (EAB) have been established and have already had their first meetings. In terms of agile ceremonies, the first EMA Programme Increment (PI) Planning event took place on 19 October 2021 with a focus on DADI and Product Management System (PMS). The ceremony was a success and provided an understanding between each team's priorities and aligned the backlog to optimise delivery and business outcomes. A meeting with SPOR task force on Agile Governance was organised on 28 October. The NICTAC had their inaugural meeting on 14 October. On 9 November, a PB-Industry meeting on Agile Governance took place. In December, two ceremonies took place: System Demo and Quarterly Portfolio Sync. Both ceremonies were well received, particularly with System Demo which had 35 participants with the NCA product owners running the demo session. A second NICTAC meeting was organised together with EAB on 8 December where the discussions were focused on the Cloud Strategy and changes to the common repository. The first big ceremony on 11 November was the Strategic Portfolio Review and was attended by the NPAG, NICTAC and Portfolio Board. During this ceremony, participants reviewed the 2022 Portfolio plan, ensured strategic alignment and portfolio focus and received necessary guidance to effectively respond to new and changing priorities. Participants appreciated having a full understanding of the entire portfolio rather than focus on certain areas. To conclude, EMA is fully committed to delivering the Agile transformation and has set it as a strategic objective in the 2022 EMA work programme. The pilot has provided EMA with good insights and a sandbox to learn from. In order to see the full benefits, the pilot needs to be rolled out for the entire portfolio. Thus, a phased approach with an intensive coaching and training programme is planned for 2022. Agile is a holistic approach and is not limited to how business and IT work together. All parties must be involved and hence Member States and industry will need to evolve in line with the Agile principles. Ultimately a lot of work remains and 2022 will be a critical year to transition to an Agile way of working. A suggestion was made by a Board member to circulate for information to Management Board and HMA members a recording or summary of the Strategic Portfolio Review ceremony, if available.

B.9 EMA Cloud Strategy 2022

[EMA/MB/714597/2021; EMA/686675/2021] The Management Board endorsed the EMA Cloud Strategy 2022-2025 to enable strategic goals around digital business transformation and the Agile operating model.

In 2017, the Management Board endorsed EMA's first cloud strategy which promoted the opportunistic adoption of Software as a Service (SaaS) and had a long-term perspective of "transitioning application and infrastructure platform services to a cloud-based provisioning model". Five years later, Cloud services have become an essential part of EMA's system landscape and operating environment. The new strategy builds and expands upon that initial effort and acts as a guideline for EMA's cloud adoption in the coming years, providing the Agency with the principles and approach to fully adopt and benefit from the potential of cloud-based technologies. The new Strategy contains a built-in focus on security, data

protection and compliance, which will be embedded in both existing and new solutions by design and can be elevated to new levels with the help of state-of-the-art solutions powered by the cloud. Driven by the need for accelerated digital transformation and increasing IT demand, the new strategy was developed to serve as a key enabler for the successful delivery of the IT portfolio and to directly support the Network strategy to 2025 and the agency's annual work programme/multi-annual programming document. Cloud will give the Agency access to the ready-made tools and capabilities to expand its current services and accelerate and scale up its ability to deliver innovative services to European citizens and organisations. Furthermore, increased cost-efficiency would be achieved through pay-as-you-go payment models, infrastructure optimisation and transition to cloud-native services compared to expensive software licenses.

Over the last 12 months, EMA conducted, with consultancy support, a thorough benchmarking exercise across EU agencies and several highly regulated organisations from the banking and health care industry to develop the updated cloud strategy. EMA also liaised regularly with EMA Data Protection Officer to pursue data protection by design and overall compliance with the EU Data Protection regulation. The benchmarking showed that the Agency's ambitions with regard to cloud adoption are in line with its peer group and that many other organisations are looking at the full adoption of cloud technologies within the next five years. Two thirds of the organisations saw improved cost efficiency with the cloud technologies.

Cloud will be a key enabler for the 2022 portfolio as there is hardly a single project that will not require Cloud capabilities. This can be seen with expanded use of cloud-based application development platforms for the modernisation of all core regulatory processes and the implementation of the new extended mandate. Similarly, a New Expert Management System is planned to be delivered through Software as a Service and the New Document Management solution will be enabled through SharePoint online. Furthermore, CTIS will be secured through cloud-based data loss prevention capabilities. Cloud was also used for data exchange services in the Agile Pilot including DADI, PMS and ePI. Consultation has been undertaken with NPAG and NICTAC before the endorsement by Management Board at its December meeting. Positive feedback was expressed by several Board members.

B.10 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The board noted an oral report by the representative of DG SANTE and EMA on the preparation for implementation of the Veterinary Medicinal Products Regulation.

The representative of DG SANTE provided an update on the latest adopted Implementing and Delegated Acts which need to be in force before or by 28 January 2022. Eleven of them have been adopted and published in the EU Official Journal so far. The Implementing Act on the format for the data collection of antimicrobials is currently under the feedback mechanism at the European Commission and will be sent to the Veterinary Standing Committee in January 2022. The Delegated Act on detailed rules on imports of animals and products of animal origin is still being drafted and will be submitted to Member States for discussion at the beginning of 2022. The Feasibility study requested under Article 156 for an active-substance-based review system ('monographs') for the environmental risk

assessment of veterinary medicinal products and possible alternatives was published in November 2021. Its conclusion is that a monograph system will be resource intensive at first, but in the long term it will have important benefits. For the European Commission this approach is very important for the implementation of the European Green Deal and the EU Strategic Approach to pharmaceuticals in the environment. By end January, the Commission will publish a report to the European Parliament and Council based on the feasibility study and to be accompanied, if appropriate, by a legislative proposal.

The EMA provided the board with a status update on the implementation of the Veterinary Medicinal Products Regulation (VMP-Reg) programme. The work on two scientific advices for AMR is ongoing. Both were dependent on finalisation of the Delegated Act on criteria for reserving antimicrobials for human use which has been revised subject to an attempted objection procedure in the European Parliament. The advice on the list of antimicrobials to be reserved for human use will be submitted to the European Commission in February and the one on the list of substances not to be used or used subject to certain conditions under the so called 'cascade' in March 2022. For 2022 no further scientific advices are expected to be requested by the European Commission. As regards the development of the four union databases under the VMP-reg programme, the focus at 43 days until go live is on dealing with bugs so that a robust Minimum Viable Product can be delivered. The Union Product Database repository has been implemented and is currently being populated with legacy data by Member States. The Union Product Database, the Union Pharmacovigilance Database and the Manufacturers and Wholesalers Database will go live on 28 January 2022. Submission of legacy data into UPD has been subject to some bottlenecks in late 2021 but after some bugs have been resolved recently a significantly higher number of products has been created in UPD production. Work on the database for the collection of sales and use data for antimicrobials has also started in 2021 and the system will go live at the end of 2022. All IT projects are supported by an extensive change management programme to train all users. User Interface coaching sessions providing individual support to Member States choosing to enter products manually and weekly meetings to support on the Application Programming Interface usage are ongoing. As regards the change management programme, the priorities are supporting NCAs in their UPD legacy data upload and in the operation of the new pharmacovigilance system. Many webinars have been organised for both NCAs and MAHs and have been published on the EU Network Training Centre catalogue and on the EMA website. In addition, six VMP-Reg newsletters have been published this year.

• Expiry of the MUMS policy

[EMA/MB/603352/2021; EMA/308411/2014-Rev.2] The board endorsed an extension of the current EMA "Policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market" (policy 0075), which was originally set to expire on 1 January 2022, to remain valid until 27 January 2022.

The Policy 0075 extension is required in order to ensure fairness to applicants holding a valid MUMS classification or submitting late applications under the old legislation. The amended MUMS policy will be published on the external website and withdrawn on 28 January 2022 because Article 23 of Regulation (EU) 2019/6 provides for a new legal basis with reduced

data requirements for Limited Markets marketing authorisation applications and will delete Article 79 of Regulation (EU) 726/2004 which is sustaining the current MUMS policy.

- **Draft mandate of the future VMP-Reg systems improvement advisory group (VSIAG)**

[EMA/MB/654769/2021; EMA/555001/2021] The Board adopted the mandate of the Advisory Group for prioritisation of the Veterinary Medicinal Product Regulation's System Improvements (VSIAG).

EMA explained that the mandate for Advisory Group had already been shared for information with the HMA-Veterinary in November and a draft had been agreed by the VMP-Reg Coordination Group on 2 December. The VSIAG is being proposed to discuss prioritisation of development activities for all IT systems under the VMP Reg programme after mid-2022. It will have representatives of NCAs, industry, and veterinarians. The Group will be created with a call for nominations in January 2022 and hold its first meeting in February/March 2022.

- **Revised rules of procedure of CVMP**

[EMA/MB/698644/2021; EMA/CVMP/422/04] The board adopted a favourable opinion for the amendments to the existing Rules of Procedure of the Committee for Veterinary Medicinal Products (CVMP) in accordance with Article 61(8) of Regulation (EC) No 726/2004.

The revision aims to introduce a set of technical adaptations to align the Rules of Procedure to the new provisions of Regulation (EU) 2019/6, for example by deleting references to type II variations and extensions and adding references to variations requiring assessment, adding articles on observers and on joint reporting with EFSA and ECDC on the sales and use of antimicrobials. The revised rules had been adopted by CVMP on 8 September 2021 and have received a favourable opinion by the European Commission on 19 November 2021. They will enter into force on 28 January 2022.

B.11 Joint Controllership Agreement under the Veterinary Medicinal Products Regulation

[EMA/MB/715837/2021; EMA/366104/2021] The board noted the proposal of EMA to launch a written procedure in January for the Management Board to endorse the Joint Controllership Agreement for the Union Product Database, following a final opinion from the European Data Protection Supervisor (EDPS).

EMA explained that the Joint Controllership Agreement is required by the EU Data Protection Regulation as the Union Product Database contains and processes personal data for the Qualified Persons for Pharmacovigilance. The Agreement between UPD joint personal data controllers was drafted based on the CTIS Joint Controllership Arrangement endorsed by the board in October 2021 and has been subject to some further adaptations. A draft was shared for comments with the HMA Task Force for the implementation of the New Veterinary Regulation in October and agreed without objections on 26 November 2021 by the data protection representatives appointed by NCAs. As the role of the European Commission as one of the UPD joint controllers is still being discussed with the EDPS, references to the European Commission are currently shaded in grey colour in case they might have to be

removed. As the Agreement needs to be adopted and published before the date of application of the Veterinary Medicinal Products Regulation, the Agency proposed an adoption by written procedure in January.

The representative of DG SANTE explained that discussions with the EDPS are still ongoing as the matter is complex and so he supported adopting by written procedure after the final EDPS opinion. The representative of veterinarians' organisations welcomed the positive progress and asked if a Communication Plan for the Go Live of the New Veterinary Regulation is also being envisaged in order to communicate about the new databases and to make stakeholders aware that more data on veterinary medicinal products will become available. EMA confirmed that such a plan is under preparation and will be structured in a similar way to the one for the CTIS.

B.12 Update on Big Data

- ## Big Data Steering Group progress report

[EMA/MB/555173/2021] The Board noted a progress update from EMA co-chair of the Big Data Steering Group (BDSG) on their workplan implementation since the last board meeting, with a focus on the use of Real World Evidence in regulatory decision, DARWIN EU, the Learning Initiative workshop, big data stakeholder forum and the Cluster of Excellence initiative.

The Big Data Steering Group (BDSG) is on track with all the different workstreams included in the BDSG workplan 2021-2023 published in August 2021. Since the last reporting period, BDSG has selected and signed a contract with an academic and service provider consortium to deliver a draft EU data quality and framework in 2022. In addition, the data holders of Pharmacoepidemiology Community have been consulted on real-world metadata. A crucial CHMP pilot is planned in 2022 for clinical raw data analysis of marketing authorisation applications. On 30 November 2021, a successful Learning Initiative workshop was organised. The main objectives of the workshop were to learn from current experience of using real-world data for regulatory purposes and discuss important challenges related to optimal use of real-world data, including training needs. It also aimed to discuss with stakeholders how to support effective collaboration and share learnings which could feedback into processes, stakeholder consultations and ultimately advice on individual product submission and development of guidelines. A Big Data Multi-Stakeholder Forum took place on 7 December 2021 to inform stakeholders on the delivery of the data pillar of the Network Strategy 2025 which is being delivered through the HMA-EMA BDSG workplan. Other aims of the forum meeting were to listen to stakeholders' views and discuss areas for collaboration. A summary report of the meeting will be published in early 2022 and several recommendations will be included in the BDSG workplan, such as guidelines for RWE and a more central role for patients. The tender for the DARWIN EU Coordinating Centre is in progress and the award decision will take place in January 2022. A 3rd DARWIN EU Advisory Board meeting was organised and included an overarching communication strategy and a first exploratory discussion on HTA use cases for DARWIN EU, which will be further elaborated by EUnetHTA21 consortium. A constructive meeting with Industry Stakeholder was held on 27 October 2021 and BDSG committed to continued collaboration on the next steps of DARWIN EU. The pilots with committees have progressed in preparation for the

future operating model of DARWIN EU which will become the principal tool to deliver RWE analysis to the Committees in 2022. PRAC has the most advanced pilot and the use of RWE will become a routine support in 2022. Proofs of concepts have been delivered for SAWP, COMP, PDCO and CAT during the pilot phase in 2021 and will be further expanded in 2022. For CHMP, pilots have been included in the 2022 workplan, including to support the geriatrics strategy. A presentation and a discussion will take place in December 2021 on the pilot phases for CMDh, in particular on safety issues in different MSs. The French Data Hub is organising the European Health Data Space for secondary use (EHDS2) pilot and EMA will participate to test how DARWIN EU can perform in the context of the future EHDS. The Danish Medicines Agency is leading Clusters of Excellence (CoE) initiative to bring together learnings from national approaches on data analytics and to share recommendations and good practices within the EU regulatory network. The recommendations will be drafted into a paper to identify the key building blocks to establish an analytics CoE. In early 2022, the BDSG will engage with Joint Action Towards the European Health Data Space (TEHDAS) to initiate work on the EU Data quality framework and agree on real-world metadata to build a catalogue of RWD sources. For EU Network skills, procurements for external academic service providers will be launched to deliver big data training curricula. A workshop will be organised in Q2-2022 with International regulators on real-world evidence collaboration.

- **Data Standardisation Strategy**

[EMA/447502/2021] The Board endorsed the European Medicines Regulatory Network Data Standardisation Strategy.

The Big Data Taskforce Report identified the need for a data standardisation strategy, as without data standards the collection, processing and management of large volumes of healthcare and medicinal product data can be inefficient and costly. The Data Standardisation Strategy (DSS) is an important deliverable of the Big Data Steering Group workplan and will be maintained overtime to reflect changes in priorities and additions of new requirements. The strategy has been adopted by the BDSG, the EU Network Data Board (EUNDB) and the HMA in November 2021. The creation of a strategy will enable the reduction of effort and enable a quicker approach to adopt and implement data standards. Use of data standards will also drive-up data quality and enable data linkage and data analysis. This strategy sets out the principles used to guide data standardisation efforts and the adoption of data standards by the European Medicines Regulatory Network. It is also intended to support the work to create internationally applicable data standards and to help deliver the Network strategy to 2025.

The process to develop the Strategy was initiated in December 2020 with stakeholder assessment of existing standards and interviewing standard development organisations, which led to creating 330 potential use cases for data standards. A public workshop and survey were organised with 97 participants and 49 organisations responding to the survey in order to finalise the Data Standardisation Strategy. The recommendations in the strategy fall into the four domains of: medicinal product, healthcare and study data, safety and risk management and submissions. The implementation of specific standards needs to follow a stepwise approach in order to support NCAs, network systems and have effective change management.

The BDSG and the EUNDB are jointly responsible for maintaining the data standardisation strategy document. In 2022, they will make proposals for what actions are needed in order to implement the recommendations and veterinary requirements will be added to the strategy. The mandates of the BDSG and EUNDB will also be reviewed with a view to rationalisation. In addition to supporting collaboration and coordination within the EU regulatory network, this strategy will support working with international regulators on common requirements by clearly setting out EU needs and direction at international fora such as ICH. Following endorsement by EMA Management Board, the document will be published.

Several board members welcomed the progress of the BDSG and the development of the Data Standardisation Strategy. The representative from DG Research and Innovation drew attention to an EU project that started in February 2021 with regards to new methods for clinical trials including use of RWE. In addition, the European Commission published a call for proposals for Horizon Europe funding for "new methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment". The representative from DG SANTE asked how the BDSG and EMA plan to develop capabilities and increase capacity of data scientists in the EU Network. A few members of Board asked if the CHMP pilot of clinical raw data analysis might impact on the Methodology domain, due to the limited availability of biostatisticians within the Network and since the same pool of experts are being used for standard marketing authorisation and scientific advice procedures.

EMA explained that the work of clusters of excellence will be key to build capability and capacity through sharing of best practices amongst NCAs. A specific Big Data training curriculum made up of three different areas (biostatistics, pharmacoepidemiology, data science) will be made available through the EU-NTC by Q3-2022. In the workplan of BDSG, there is the ambition to establish in collaboration with EU-NTC Steering Group a Digital Academy to invest in skills in the digital and data areas. EMA offered to have a detailed presentation on the CHMP pilot on raw data analysis at the March Management Board meeting to focus on the implications and lesson learned after the pilot. EMA confirmed it has the biostatistics capacity in house to assist with the 10 product cases during the pilot phase. However, questions remain on how to best increase capacity after the pilot phase. The Board agreed with the proposal to have a comprehensive presentation in March and a discussion on the resources.

B.13 Risk Management Plan (RMP) publication

[EMA/MB/227679/2021] The board endorsed the proposal for the publication of the full Risk Management Plans (RMPs) of centrally authorised products, in line with Article 80 of Regulation (EC) No 726/2004 on the availability to the public of regulatory, scientific or technical information concerning medicinal products.

EMA explained that under this new transparency measure it will start publishing non-confidential parts of the body, Annex 4 (Specific adverse drug reaction follow-up forms) and Annex 6 (Details of proposed additional risk minimisation activities) of Risk Management Plans. This initiative expands the exceptional transparency measures currently in place for

COVID-19 medicines, whereby the full RMP and not just the summary is published. The measure aims to further increase transparency of safety information for the public and to decrease the number of access-to-documents (ATD) requests for RMPs, which constitute a heavy administrative burden for EMA. As the RMP body already contains the RMP summary, a separate RMP summary will no longer be required and published. The guidances for the RMP template will also be updated to minimise the need for redactions of personal data and commercially confidential information by pharmaceutical companies. The publication will be implemented by EMA with a phased approach starting with newly approved medicinal products containing new active substances and for the most requested products via ATD (about 6 products) as well as for all new ATD requests. The RMP publication will follow the release to an individual requester. In a subsequent phase, EMA will continue with other centrally authorised products, including generics, which are newly authorised and older products reaching the expiry of their data protection period. In a third phase, the full RMP publication will be extended to all remaining CAPs at the time of a major update to the RMP where the marketing authorisation holder would normally have been requested to provide an RMP summary. An announcement will be published on the EMA's website to inform about the planned phased implementation of full RMP publication.

B.14 OPEN Pilot: one-year review and proposal for follow-up

The Board noted preliminary findings from the one-year review of the Opening Procedures at EMA to Non-EU authorities (OPEN) pilot.

EMA reminded that the pilot was endorsed by the board at its December 2020 meeting for COVID-19 vaccines and therapeutics. This pilot allows non-EU regulators (TGA Australia, Health Canada, MHLW/PMDA Japan, Swissmedic, WHO) to be invited to attend and contribute to ETF and CHMP evaluation meetings for COVID-19 vaccines and therapeutics. Hitherto, these non-EU regulators have been involved in the assessment of 8 vaccines and therapeutics against COVID-19 and 10 more products are currently under review under the OPEN pilot. After a year of operation, EMA surveyed OPEN stakeholder by sending questionnaires to four categories of stakeholders: CHMP/ETF rapporteurs and assessors, OPEN Non-EU Regulators, applicants and MAHs, EMA Product Leads and CHMP/ETF Secretariats. A good response rate has been received and the contributions obtained are an essential first step towards a better understanding of the operating model and impact of OPEN. Surveys have highlighted the benefits of the pilot, which has facilitated discussions and exchanges with non-EU regulators and enabled global assessment of the same data. This has in turn accelerated decisions for non-EU regulators and contributed to reliance pathways. The OPEN pilot has been an excellent opportunity to highlight and promote the EU leadership in areas where global collaboration is essential. A key example of this has been the involvement of the WHO Prequalification team, which used the CHMP assessments to facilitate the WHO Emergency Use Listing (EUL) of Vaxzevria at the end of January 2021. This led to the finalisation of WHO EUL procedure within two weeks, which was then used by 101 low- and middle-income countries to take their own national decisions to approve the vaccine. The project maximised the efficiency of the Agency's assessment by pooling and increasing scientific resources and it could be expanded to other non-COVID regulatory procedures. Areas for improvement have been identified, such as defining ground rules to strengthen collective assessments and align timetables for submissions and decisions.

Communication and promotion of the pilot project by EMA and non-EU regulators also need to be further enhanced. Overall, international collaboration in the context of COVID-19 was considered key by all current respondents and there is consensus on transitioning the pilot to a more permanent way of working for specific disease areas and products. Nevertheless, expanding the pilot will require a new set of ground rules. EMA will continue to collect and review responses from the surveys to see how to better use the pilot. EMA will further engage with CHMP to find the best solution for the Committee with regards to contributions and share the findings with non-EU regulators. A proposal for the next steps for OPEN as an operating model for other disease areas will be presented at the next MB meeting in March.

A question was raised by the representative of DG SANTE on whether other international partners have initiated similar projects. EMA explained that FDA has a similar project for oncology products called ORBIS. ACCESS is another example of collaborative work-sharing schemes that operates between international regulators from Australia, Canada, Switzerland and UK. The Board agreed to discuss the detailed findings and future plans for the OPEN pilot at the next meeting.

B.15 Annual report on the implementation of the EMA's Anti-Fraud Strategy

The board noted an oral report from the EMA on the implementation of the EMA's Anti-Fraud Strategy.

The EMA's Anti-Fraud Strategy and related action plan for 2021-2023 were revised by the board in March 2021. According to the action plan, the following five actions were to be performed on an annual basis and they have been regularly implemented in 2021: maintain regular communication to staff on anti-fraud matters, targeted awareness raising sessions on anti-fraud and ethics matters, information on the implementation of the Anti-Fraud Strategy in the Annual Activity Report and other strategic documents, assessing the adequacy and effectiveness of the controls in place and designing and implementing additional controls if needed, conducting fraud-specific risk assessments. Furthermore in 2021 EMA updated the compulsory anti-fraud e-learning training course for new staff, taking into account new fraud trends and the new organisational entity of the European Public Prosecutor Office (EPPO), and worked closely with IT security and other internal functions in managing the consequences and follow up actions of the cyberattack of December 2020. For 2021, no additional action was deemed necessary and no administrative enquiry was launched in relation to fraud aspects. The European Anti-Fraud Office (OLAF) also opened no investigation involving EMA in 2021. EMA continued its engagement with OLAF to clarify the terms of Union institutions' and Agencies' collaboration with the Office, further to the creation in late 2020 of the EPPO, which can also receive notifications of cases of suspected fraudulent behaviour. In November 2021 OLAF confirmed that such cases can be notified only to one of the two EU bodies and therefore EMA will continue to notify them only to OLAF, in order to avoid duplication. As regards plans for 2022, EMA might continue leading the Anti-Fraud Working Group of the Inter-agency Legal Network for the drafting of an Agencies' model cooperation agreement with the EPPO. New anti-fraud trainings would be performed on recommendations from colleagues and internal collaboration with IT security will be intensified in order to upgrade the internal controls and defence systems as per the new cybersecurity article in the recently agreed EMA's extended mandate regulation.

B.16 Report on the implementation by EMA of the EU Data Protection Regulation

The board noted an oral report on the implementation by EMA of the EU Data Protection Regulation.

Compliance activities by EMA have been intense throughout the year and have focussed on: reformulation and periodic update of 90 data protection notices of personal data processing operations conducted at the Agency; scrutiny of records, data protection notices, data protection impact assessments, joint controllership arrangements; response to data subject complaints and EDPS queries and investigations; creation of video and written training courses on key elements for data protection compliance for all staff and contractors; provision of tailor made presentations given by the acting Data Protection Officer and DP Coordinators to several internal divisions. Main achievements by the acting DPO included: the co-drafting and finalisation of two Joint Controllership Agreements (CTIS, UPD) and of a Data Protection Impact Assessment for CTIS; contribution to the development of the revised EMA Cloud Strategy, of the tender for the DARWIN EU platform; input in internal reflections on the use of artificial intelligence and RWE in regulatory decisions; and compliance activities with the EU DPR for COVID-19 entry requirements for visitors. Ongoing activities include: the preparation of a Data Protection Impact Assessment (DPIA) for the use of Microsoft Office 365; providing initial reflections for DPIAs for EudraVigilance and for the use of raw data for regulatory purposes; and supporting the EDPS negotiation team for ensuring compliance by Cisco WebEx with the data protection legislation. Following the EDPS Enforcement Order of 5 October 2020 after the Schrems II Judgment, EMA had to complete a vast mapping exercise of all its international data transfers, which was submitted to the EDPS in November 2020. The latest position of the EDPS is that all international transfers, including to other public authorities, need to comply strictly with Chapter V of the EUDPR, i.e. using adequacy decisions or other safeguards adopted via administrative arrangements. In line with this approach, the EDPS authorised the Administrative Arrangement with Health Canada but with many conditions, some of which were refused by Health Canada and this development will require EMA to continue negotiations in 2022. In 2021 EMA continued to pay a lot of attention to the handling and review of personal data breaches in cooperation with the internal data protection coordinators and data controllers: out of thousands of processing operations, 21 cases were annotated on the EMA's central registry and no notifications have been sent to the EDPS as no risk for the data subjects was detected. Human error remains the main root cause for personal data breaches, which is common to all EU institutions, agencies and bodies, so special emphasis has been given to this aspect in all DPO/DP coordinators trainings. Two remote audits on EMA were carried out by EDPS in 2021: the first one, which is still ongoing, regards the use of cookies in EMA newsletters; the second one concerns the Executive Director's decision on the so-called Article 25 restrictions, which recently concluded with the outcome that EMA is compliant. EMA continues to be actively involved in discussions regarding the interplay between data protection rules and scientific research, advocating for a progressive interpretation of the GDPR provisions in order to allow robust scientific research. The board was informed that as of 15 January 2022 Sabine Brosch will become the new EMA Data Protection Officer. The Chair congratulated Dr Brosch for her new role and thanked Stefano Marino, acting DPO, for the intense and good work on data protection in the last three years.

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The Chair announced that the next board meeting on 17 March will be her last one as her mandate as Chair expires on 20 March 2022. She will also cease to be a board member as she will retire in May 2022. A communication will be sent to the board in January to explain the process for the election of the new MB Chair and to open a call for nominations. The vote session will be in camera using a remote IT system, for which dedicated training sessions will be organised in advance of the March meeting.

List of written procedures finalised during the period from 14 September 2021 to 24 November 2021

During the period from 14 September 2021 to 24 November 2021, the Board was consulted seven times via written procedure, as listed below:

- Consultation no 05/2021 on the appointment of Silvijus Abramavicius as CHMP alternate as proposed by Lithuania ended on 24 September 2021. The mandate of the nominee commenced on 25 September 2021.

- Consultation no 06/2021 on the appointment of Kristina Nadrah as CHMP member as proposed by Slovenia ended on 14 October 2021. The mandate of the nominee commenced on 15 October 2021.

- Consultation no 07/2021 on the appointment of Jan Sjöberg as CHMP alternate as proposed by Iceland ended on 14 October 2021. The mandate of the nominee commenced on 15 October 2021.

- Consultation no 08/2021 on the appointment of Anastasia Mountaki as CHMP alternate as proposed by Greece ended on 28 October 2021. The mandate of the nominee commenced on 29 October 2021.

- Consultation no 09/2021 on the appointment of Elena Maria Vella as CVMP alternate proposed by Malta ended on 3 November 2021. The mandate of the nominee commenced on 25 November 2021.

- Consultation no 10/2021 on the appointment of Vlasta Zavadova as CHMP member as proposed by Liechtenstein ended on 3 November 2021. The mandate of the nominee commenced on 4 November 2021.

- Consultation no 11/2021 on the appointment of Thalia Marie Estrup Blicher as CHMP alternate as proposed by Denmark ended on 11 November 2021. The mandate of the nominee commenced on 12 November 2021.

Documents for information

- [EMA/MB/649865/2021;EMA/649909/2021] Updated Engagement framework: European Medicines Agency and patients, consumers and their organisations
- [EMA/MB/709844/2021; EMA/693976/2021] Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- [EMA/MB/717729/2021] Outcome of written procedures finalised during the period from 14 September 2021 to 24 November 2021
- [EMA/MB/613491/2021] Summary of transfers of appropriations 2021
  [EMA/MB/617640/2021] Summary report on implementation of assigned revenue
- [EMA/MB/632403/2021; EMA/92059/2021; EMA/586800/2020; EMA/446490/2020] Ex-post evaluations to the building notifications and update on 30 Churchill Place

List of participants at the 114th meeting of the Management Board, held virtually on 15-16 December 2021

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Lars Bo Nielsen *(member)* Mette Aaboe Hansen *(alternate)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)* Deirdre Hanson *(observer)*
Greece	Eleftherios Pallis *(member)*
Spain	César Hernández *(alternate)* Sonia García Pérez *(observer)*
France	Christelle Ratignier-Carbonneil *(member)* Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta *(alternate)* Agnese Cangini *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Apology received from Jānis Zvejnieks *(alternate)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Mátyás Szentiványi *(member)* [1]

	Participants
	Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)*
Netherlands	Tina Leguijt *(alternate)* Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak *(member)*
Portugal	Rui Santos Ivo *(member)* Maria João Morais *(observer)*
Romania	Apologies received from Romica Andrei Baciu *(alternate)*
Slovakia	Zuzana Batova *(member)*
Slovenia	Momir Radulovic *(member)*
Finland	Eija Pelkonen *(member)*
Sweden	Björn Eriksson *(member)* Åsa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points*

European Parliament	Mattias Groote Tonio Borg
European Commission	Andrzej Rys (DG SANTE) *(alternate)* Barbara Kerstiens on behalf of Irene Norstedt (DG RTD) *(alternate)* Kristof Bonnarens (DG SANTE) (*observer*) Gudrun Gallhoff (DG SANTE) *(observer)* Fergal Donnelly (DG RTD) (*observer*)
Representatives of patients' organisations	Ioannis Natsis Marco Greco
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (Iceland)

	Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Emer Cooke Ivo Claassen Fergus Sweeney Nerimantas Steikūnas Melanie Carr Anthony Humphreys Hilmar Hamann Alexis Nolte Peter Arlett Pierre Pradal Stefano Marino Martin Harvey Maria Alves Hilde Boone Riccardo Mezzasalma Marie-Agnes Heine Rebecca Harding Apolline Lambert Sophia Albuquerque Olga Oliver-Díaz