06 October 2022
EMA/MB/592684/2022
Management Board – Adopted

Minutes of the 116th meeting of the Management Board

Held in person/virtually on 15-16 June 2022

The Chair of the Management Board opened the meeting which was held as a face-to-face meeting, with a few Members joining via videoconference, as per the revised Rules of Procedure. The Chair confirmed the quorum and welcomed the new members: Dimitrios Filippou, member of Greece, Maria Gazouli, alternate of Greece and Răzvan Mihai Prisada, member of Romania.

The Chair welcomed the recently appointed civil society representatives to the board, in particular the new representative of patients' organisations, Virginie Hivert, representative of doctors' organisations, Denis Lacombe and representative of veterinarians' organisations, Despoina Iatridou. Marco Greco, one of the previous representatives of patients' organisations, had been confirmed for a second 3-year mandate. The Chair also welcomed the new European Parliament representative as of June, Karin Kadenbach and noted that Anthony Borg was re-appointed for another term.

The Chair also informed that a representatives of Internal Audit Service at the European Commission would be virtually observing the part of the Board meeting on the audit activities and present under agenda item 10.

The Chair noted that the election of the new MB vice-Chair would take place on 15 June and that, according to the Rules of Procedure, applications for Chair could be submitted in writing to the EMA secretariat "no later than the start of the Management Board meeting at which the election is to take place", namely until that day at 15:00. [redacted]

1. Draft agenda for 15-16 June 2022meeting

[EMA/MB/94596/2022] 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.7 HMA/EMA Task Force on availability of medicines (TF AAM) progress report.* The Secretariat informed the Board that all

concerned member(s) 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 115th meeting, held on 16-17 March 2022 adopted via written procedure

[EMA/MB/169135/2022] The Management Board noted the final minutes, adopted by written procedure on 14 June 2022 with no comments.

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

The election of the Vice-Chair was held in camera and was attended only by members or their alternates, the observers from EEA countries and a limited number of EMA staff. The nomination process was launched on 2 May 2022.

In accordance with the election procedure the Chair announced votes by proxy as follows:

- Paula Loekemeijer (The Netherlands) proxy to Lars Bo Nielsen (Denmark)
- Marco Greco (Representatives of patients' organisations) proxy to Virginie Hivert (Representatives of patients' organisations)

[redacted]

The Board appointed observers from Iceland, Liechtenstein and Norway, Runa Hauksdottir Hvannberg, Vlasta Zavadova and Audun Hågå, to act as tellers. The vote took place by secret electronic ballot.

[redacted]

The Management Board elected Christelle Ratignier-Carbonneil, representing France, as the Vice-Chair for the next three years. The newly elected Vice-Chair thanked the Management Board.

5. COVID-19

EMA Status Report

The Management Board noted a status update from EMA on COVID-19 related activities.

The work in preparing for the update of the composition of the currently authorised vaccines before the possible roll out in autumn vaccination campaigns is of high focus and relates to mRNA vaccines only. The current programmes are based on omicron BA.1 with investigation for both mono and bi valent (omicron + Wuhan) options. As agreed with ICMRA, EMA is currently requiring clinical immunogenicity data in comparison to current vaccine. An ICMRA workshop is planned on 30 June to align with the international approach. The required clinical data will become available over the summer months, and regulatory approval of modified mRNA vaccines is expected in September.

Since the last Board meeting, the most recent product-related outcomes were relate to boosters with variations being finalised for the heterologous booster dose for Comirnaty and use of Vaxzervria booster dose in adults. Variations to support manufacturing scale up and extension of shelf life continue to be reviewed. Recently EMA have worked with ECDC to provide advice on the use of a second booster for mRNA vaccines. The rolling review of the HIPRA vaccine is on-going, as are the marketing authorisation (MAA) reviews of vaccines from Valneva and Sanofi Pasteur, with promising data emerging on the use of a beta variant version of the Sanofi vaccine as a heterologous booster. A number of variations have been submitted to extend use to children for Spikevax (6 months to 5 years of age) and Nuvaxovid (from 12 years of age) and their booster doses in adolescents. An application to further extend the use of Comirnaty for below 5 years of age is expected to be received soon. Regarding COVID-19 therapeutics, a marketing authorisation for an antiviral monoclonal antibody therapy Evusheld(tixagevimab/ cilgavimab) was granted end of March and in early April the product information for Regkirona (regdanvimab) was updated with an increase in its approved shelf life. The marketing authorisation procedures for Lagervio (molnupiravir) and the extension of indication of the immuno-modulator Olumiant (baricitinib) for use in COVID-19 remain under review. There is an ongoing review at the level of ETF on emerging evidence on activity of different therapeutics against various SARS CoV 2 variants and sublineages. EMA also continues to have meetings with developers for several additional therapeutics and vaccines, with a potential start for a review later in 2022.

As part of the ongoing work on COVID-19 lessons learned review, EMA provided an update on the first meeting of HMA/EMA Tactical Group on resourcing which took place on 18 May 2022. HMA and EMA participants reviewed the current initiatives for tackling the current resourcing issues and agreed on the scope of activities, objectives, expected outcomes and work organisation. Leads from HMA and EMA have been nominated for various areas of action identified and regular meetings will be organised for the tactical group with the next meeting taking place on 16 June 2022. Furthermore, EMA continues to organise its regular press briefings with two planned in July. Through ICMRA, the Agency engages with international regulatory partners on COVID-19. Publication of clinical data for COVID-19 products from initial MAA and also post-authorisation phases. It has been agreed to extend the scientific advice fee waiver for COVID-19 products until the end of the Public Health Emergency of international concern.

A. Points for automatic adoption/endorsement

A.1 Management Board meeting dates 2022-2023

[EMA/MB/94597/2022] The board adopted the proposed meeting dates for 2023 and noted the meeting dates for 2024.

A.2 Model decision on the Conduct of administrative inquiries and disciplinary proceedings

[EMA/MB/169781/2022] The board adopted by analogy, and in line with Article 110(2) of the Staff Regulations, the Model Decision of the European Commission of 12 June 2019 on the Conduct of administrative inquiries and disciplinary proceedings, C(2019) 4231 final.

A.3 Commission decision on payment of education allowance provided for in Article 15 of Annex X Staff Regulations

[EMA/MB/237105/2022] The board adopted a MB Decision, which adopted by analogy the Commission decision, C(2021) 8179 final, laying down implementing provisions regarding payment of education allowance to staff members in temporary assignments in third countries, as provided for in Article 15 of Annex X to the Staff Regulations. Even if EMA does not currently have staff on temporary assignments while serving in a third country, the new rules will allow the Agency to cover education costs for staff in that situation, should this situation occur in future.

A.4 Rules for reimbursement of expenses for delegates attending meetings

[EMA/MB/279597/2018] The board adopted revised Rules for reimbursement of expenses for delegates attending meetings. The revision updates the existing rules in line with the Regulation EU 2022/123 and introduces changes in hotel accommodation for experts living less than 80 kilometers from the Agency and new procedures to notify medical conditions to the EMA travel agents.

Questions were raised in relation to the reimbursement rates, the cancellation policy in case of unexpected sick leave due to COVID-19, the daily allowances for Member States' experts, and the provisions for experts with mobility limitations. EMA explained that the reimbursement rates and daily allowances are derived from the EC rules, unexpected cancellations can always be referred to the EMA meeting managers, experts with mobility impairments will be facilitated by the revised rules allowing reimbursement at shorter distances.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update covering the regulatory and coordinating actions arising from the war in Ukraine and update on Monkeypox, EMA's activities with EU institutions and agencies, international cooperation, reactivation of face-to-face meetings and updated organisational changes.

At the beginning of March, EMA set up a small internal EMA leadership group to closely follow the situation in Ukraine. One of the main areas of concern is potential medicine shortages, which the Agency continues to closely monitor through its network of Single Points Of Contacts from National Competent Authorities (NCA SPOC Working Party) and no critical shortages have been identified so far. The European Medicines Regulatory Network (EMRN) and now also the newly established Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) have been kept regularly informed. The MSSG has also set up a focus group of the SPOC Working Party composed of neighbouring countries to Ukraine and other Member States, to also look at the impact of the war in Ukraine on the availability of medicinal products. EMA has reviewed the lists of essential medicines for Ukraine and there are no major groups of medicines identified that would not be known to the EU

regulatory system. NCAs are encouraged to use national exemptions to address the needs of refugees for non-EU or non-available products, where needed (e.g. paediatric TB medicines). The war has also significantly affected clinical trials and to help address this impact a guidance on methodological aspects of ongoing clinical trials was published on 13 April. EMA is closely engaging and cooperating closely with the Heads of Medicines Agencies (HMA), European Commission, including DG SANTE and HERA (Health Emergency Preparedness and Response Authority) and European Centre for Disease Prevention and Control (ECDC) to share information and identify critical issues.

With regards to the monkeypox outbreak, EMA has been monitoring the situation since it was first reported and is in close contact with ECDC and the European Commission. EMA is actively discussing the treatments and vaccines available and the EMA Emergency Task Force (ETF) is already activated to discuss this outbreak and possible countermeasures. MSSG is also being kept informed in the context of shortages. Two medicines with potential to be used against monkeypox are already authorised in the EU (Tecovirimat and Imvanex) for use to treat or protect against smallpox. A promising antiviral is also in the pipeline (Brincidofovir). ETF is continuing to engage with the MAHs to prepare for the submission of data for Imvanex that could support an extension of indication to include prevention of monkeypox based on already available evidence. The WHO and International community are in discussion with EMA on the on the possibility of conducting additional clinical research that could provide more guidance on how to use efficiently the current medicines/therapeutics available.

On 4 May 2022, the European Parliament granted a very positive discharge on EMA's accounts for the financial year 2020 and acknowledged the Agency's resourcing constraints due to new tasks and increased workload. EMA and ECDC have been invited to two EPSOC meeting (on 29 March and 14 June) to contribute to the discussions on the EU's response to the crisis in Ukraine and preparedness for authorizing adapted COVID-19 vaccines. In addition, EMA and ECDC have agreed on the key principles of cooperation for the development of the new EU Vaccines Monitoring Platform (VMP). The Board was also informed that a Memorandum of Understanding (MoU) between HERA and EMA is also currently under-development. At the international level, the first meeting of International Cooperation Platform, consisting of NCA international relations teams, DG SANTE and EMA, took place on 30 May. The main focus of the platform is for information sharing, common positions in multilateral forums and alignment on EU bilateral priorities. The International Coalition of Medicines Regulatory Authorities (ICMRA) are planning two workshops: one workshop on Real World Evidence taking place on 29-30 June and COVID-19 Variant Workshop on 30 June.

With regards to reactivation of face-to-face meetings at EMA, the pilot to resume face-to face Committee meetings from May to July 2022 has been launched and there is now a need to decide on an approach for other types of meetings. Since April, EMA staff are required to present in the EMA building for 40% of their working time and COVID-19 restrictions are being lifted, such as the suspension of mandatory masks. The Board acknowledged the organisational leadership changes within the Agency and welcomed the appointment of Steffen Thirstrup as the Chief Medical Officer.

B.2 Report from the European Commission

The representative of DG SANTE provided the board with an update on the implementation of the Pharmaceutical Strategy for Europe, the Joint Action on Capacity building of EU Medicine Regulatory Network and on the legal proposal for the European Health Data Space. The revision of the general pharmaceutical legislation will be proposed in December 2022 together with a legal proposal for the revision of the regulations on orphan and pediatric medicines and an overarching Communication explaining the approach taken in the legal proposals. The key objectives of the revision are to promote innovation, access, affordability, address shortages, reduce the environmental footprint of medicines and reduce the regulatory burden. Main blocks of interventions will be on: incentives for innovation, in

particular to address unmet medical needs; AMR; future proofing legislation to deal with emerging science; access to medicines; security of supply; free competition for generics and biosimilars; quality and manufacturing; environment; regulatory simplification; crisis preparedness and resilience; digitalisation of regulatory procedures. The Joint Action on Capacity Building will start at the end of 2023 with a budget of €8 million and last for three years. Interested National Competent Authorities (NCAs) should nominate the relevant organisations by 1 September 2022 and submit their detailed proposals by January 2023. There European Health Data Space aims to create a "Schengen space" for health data and will be implemented in full respect of data protection rights of EU patients.

The representative of DG RTD presented on the two Horizon Europe Joint Undertakings on health, namely the Innovative Health Initiative and the Global Health European and Developing Countries Clinical Trials Partnership (EDCTP3). The Science and Innovation Panel of the Innovative Health Initiative has been set up recently and it includes Anna Chioti as Chair and Ralf Herold as Vice-Chair. The Panel is tasked with providing the Governing Board of this Joint Undertaking with science-based advice on a range of matters, including their work programmes, and will help steer IHI investments in the most needed areas in the future. The first call for projects has been launched and the Governing Board will adopt their first annual work programme in June. The EDCTP3 Joint Undertaking is a partnership with a total budget of €1.6 billion with sub-Saharan countries to accelerate the clinical development of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases, including (re-)emerging diseases. Its Scientific Committee includes experts from Europe, Canada and Africa. The first call for projects was published with a deadline in August. Recruitment of the staff, including of a permanent Executive Director, for this Joint Undertaking has now started. On monkeypox, DG RTD has not released any research funding yet, but discussions with HERA, EMA and ECDC are ongoing and the Commission is ready to mobilise its resources for public health emergencies if needed.

The representative of doctors' organisations stressed the need for the EU Pharmaceutical Strategy to focus on access to medicines and to promote non-commercial research on the optimal use of authorised medicines. Comments were made to support actions on access to medicines, including for small markets, via repurposing and via greater generic competition, and on EU global competitiveness in terms of regulatory simplification, while avoiding a race to the bottom on evidence requirements for authorisation. On AMR a suggestion was made to focus on pull incentives linked to pricing and reimbursement, rather than for data exclusivity vouchers. Questions were asked about the publication of the legal proposals on EMA fees and on the deadlines to apply for the Joint Action on Capacity Building. The representative of DG SANTE confirmed that patients' rights, including the right to equal access to medicines, will be the main priority of the European Commission. A race to the bottom on evidence requirements is not the direction of travel, but efficiency gains in the governance and procedures of the regulatory network will be explored. The EMA fees regulation will be published inthe next few weeks. Applications for the Joint Action should be sent by 1 September and do not need to contain full-fledged proposals but only the name of the organisations that will represent each Member State; at least four Member States are required to submit nominations for the Joint Action to go ahead as planned. The representative of DG RTD commented that, in the past, EU projects on repurposing of off-patent medicines have often failed due to the difficulty for clinical trials sponsors to get access to compounds at GMP grade.

B.3 Assessment of the Executive Director's Annual Activity Report (AAR) 2021

[EMA/218218/2022; EMA/MB/558786/2022; EMA/75685/2022] The board noted the Executive Director's Annual Activity Report (AAR) 2021 and adopted the Assessment of the Executive Director's

AAR 2021 which had been prepared by the topic coordinators María Jesús Lamas Diaz, Gytis Andrulionis and Lars Bo Nielsen. As part of the review the Topic Coordinators have discussed the Agency's accounts with the Accounting Officer.

EMA presented the AAR which provides information on the management and control systems of EMA and on the work programme implementation. It is prepared in accordance to article 48 of the EU financial regulation and forms part of the next discharge process. The consolidated annual activity report (AAR) is submitted to the Management Board for assessment and by no later than 1 July the consolidated AAR together with its assessment shall be sent by the Management Board to the Court of Auditors, the Commission, the European Parliament and the Council.

The AAR highlights EMA's contribution to tackle the COVID-19 pandemic and the Agency's adjustments to a new working environment. A comprehensive data is provided on the EMA's 2021 budget, which recorded a positive outturn of 0.8%. The agency managed to comply broadly with the ceilings/KPIs for the expenditure implementation (96%), implementation of carry overs from 2020 (93%) and the appropriations carried forward from 2021 to 2022 (title I: 5.75%, title II: 24.31%, title III: 37.59%). With regards to staffing, the 2021 occupancy rate amongst temporary agent staff was 98% with a turnover rate of 4.9% for TA and 5.8% for CA. 35 external selection procedures were initiated in 2021 with an average time span of 2.9 months and for which 3,844 candidates applied. A review of EMA's internal control system and control standards was carried out and confirmed that it is functioning reasonably well with some improvements identified. European Court Of Auditors (ECA) carried out 2 audits and 1 external audit of the accounts with positive results but the report did include emphasis of matter in relation to London premises. The Executive Director signed the declaration of assurance with no reservations, however the attention of the Board was called on the two points on the Emphasis of matter with regards to the adequacy of staffing and resources available to the Agency, and the uncertainty linked to the lease agreement for EMA's previous premises in London requiring political resolution.

The topic coordinators presented the highlights of the proposed Board's assessment. The Board acknowledged the results presented in the annual activity report 2021 and recognised that the Agency, after successfully adjusting to the new working environment, continued to fulfil its mission to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health. The Topic Coordinators praised the Agency and the EMRN for the outstanding service provided to the European citizens during an unprecedented public health crisis and recognised the introduction of a variety of measures and regulatory flexibilities as part of its response to the COVID 19 crisis. The Board welcomes the outcome of the COVID-19 lessons learned exercise which was initiated in 2021. Important achievements were accomplished in the areas of AMR, of availability of medicines and safety, as well as on the CTIS and ACT-EU, Big Data, DARWIN EU and enhancing IT security. 92 human medicines, of which 54 were a new active substance, were recommended for marketing authorisation and for the veterinary medicines 12 new medicines, including 7 new active substances. The Agency was congratulated for the complete preparations for the implementation of the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), the Clinical Trial Regulation, EU-DPR, and the Medical Devices Regulation. The Topic Coordinators praised the EMA for its preparation for the implementation of the EC legal proposal for a reinforced role for the Agency in crisis preparedness and management for medicinal products and medical devices. Concerns were raised with regards to the adequacy of the EU network and Agency's staffing levels in light of the continuously increasing workload, the significant responsibilities assigned to the Agency and the NCAs over the last years. The Coordinators called for an EU action at a political level to resolve the current unsustainable situation with the EMA premises in London which forces the Agency to act as a landlord, diverting resources to perform an activity outside of its legal mandate. The Agency and the EMRN were commended for its contribution to the pharmaceutical strategy and the activities being made to foster innovation and to

lead the digital transformation in the benefit of public health. The Topic Coordinators recommended the adoption of the Board's Assessment of the Annual Activity Report 2021 and note the Annual Activity report 2021.

B.4 Preparation for written procedure on Amending Budget

[EMA/MB/251052/2022] The Board noted the preparation for written procedure on Amending Budget.

Article. 34 of the Agency's Financial Regulation (FR) stipulates that any amendments to the Agency's budget, beyond the modification authorised under Arts. 26(1) and 38(1) , shall be the subject of an amending budget adopted by the same procedure as the initial budget of the Agency.

The Agency is continuously monitoring revenue and expenditure and making projections for the annual outturn to ensure compliance with key performance indicators for budget implementation. As part of this continuous monitoring, the Agency will assess the overall budget situation based on actual performance at the end of June 2022 for both revenue and expenditure, and if necessary, will propose to the Management Board whether an amending budget is required in order to manage the budgetary outturn at year end. This updated monitoring may result in changes to the draft figures presented to the Board at the June meeting, including the possible need to propose changes to the level of EU contribution foreseen for 2022. Consequently, EMA explained that there may be a need to launch a written procedure to request the Management Board's approval of an amending budget to be implemented before the October meeting.

B.5 Cooperation agreement and renumeration of Committee chairs

[EMA/MB/267129/2022, EMA/270417/2022] The Board adopted an Addendum to the Cooperation Agreement between EMA and National Competent Authorities (NCAs) on compensation for services as Chair of EMA scientific committees, as a pilot and interim measure until a sustainable and long-term solution is found in the revision of the EU pharmaceutical legislation.

The Chair and EMA explained that the new Addendum establishes a flat rate amount, set as per Article 93 of the EMA Financial Regulation, which can be paid to the NCAs in relation to the time the Chair devotes to the preparation and performance of the Committees activities, covering five days of preparation before and after each committee week. The remunerated services include the participation of Committee Chairs to the Committee meetings, substantial preparation for those meetings, including review of all scientific documents, preparatory conference calls, follow-up responsibilities, coordination with other Chairs of EMA's committees and representation, within the remit of the Chair appointment, to other fora than the Committee meetings. The issue had previously been discussed at the Management Board and has recently increased in urgency due to the COVID-19 workload. The Addendum should be requested by the interested NCAs.

The representative of DG SANTE abstained from the decision and explained that, while the European Commission understands the need to remunerate the Committees' Chairs in view of the time dedicated to EMA activities, this important issue would need to be addressed with a long-term solution in the context of the revision of the EU pharmaceutical legislation. Concern is expressed towards any solution that would have no sound legal basis and/or could set precedents for other agencies, or other members of committees. However, the representative of DG SANTE understands that, in the meantime and until the new legislation adopted, a short-term solution needs to be explored and agreed upon. The representative of the European Parliament also abstained due to the limited time to prepare for this topic.

Several members, as well as one representative of patients' organisations, strongly supported the adoption of the Addendum as a pilot solution until a more permanent measure is set via legislation, noting the significant workload of the Committee Chairs, which has been further increased during the COVID-19 pandemic.

B.6 Update on implementation activities of EMA's extended mandate

[EMA/MB/558961/2022] The Management Board noted a progress update from the Agency on the implementation of Regulation EU 2022/123 on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices.

As regards shortages of medicines the Medicines Shortages Steering Group (MSSG) and the Single Points of Contact Working Party have been established and are operational. On 11 May the MSSG adopted the Methodology for the establishment of lists of "main therapeutic groups" and of "critical medicines" in crisis preparedness and management and on 7 June adopted the List of critical medicines for the COVID 19 public health emergency, while the List of Main Therapeutic Groups will be adopted before the legal deadline of 2 August 2022. The List of critical medicines for COVID-19 triggers several reporting requirements for industry and Member States and will be updated as necessary. A feasibility study for the European Shortages Monitoring Platform has been performed and the Platform will be built on existing functionalities for reporting marketing status and cessation and will be delivered incrementally with a Minimum Viable Product approach using SAFe Agile methodology. Data interoperability, security by design and ISO IDMP compliance are requirements, so it will be compatible with SPOR and it will also link with the Joint Action on medicine shortages. EMA will set up a dedicated Working Group of the MSSG on the Platform and in September-October organise a workshop with IT Directors and the SPOC Working Party in order to share best practices from existing national shortage systems. Activities on shortages of medical devices will mirror the ones for medicines, including the development of a methodology and a critical list, and the Agency is preparing for implementing those by 2 February 2023 in close consultation with the European Commission and the Medical Devices Coordination Group.

EMA presented on the Emergency Task Force (ETF), whose revised Rules of Procedure and composition were adopted and published in April. On crisis preparedness, the ETF is handling activities for monkeypox as potential emergency and based on article 12.5(c) of the extended mandate is supporting sponsors to facilitate large clinical trials on the use of tecovirimat for monkeypox, for instance by reviewing study protocols and endpoints so that they can be harmonised and re-used in multiple Member States. ETF is also supporting with the filing of these trials via the new Clinical Trials Information System. To support the work of the ETF, EMA is improving its internal IT tools and developing a closer collaboration with the European Centre for Disease Control and Prevention (ECDC) to create a Vaccines Monitoring Platform. The EMA-ECDC Vaccines Monitoring Platform will include a joint Advisory Board composed of ETF, CHMP, PRAC members with expertise in vaccine observational studies and of representatives of all public health authorities in the EU/EEA. As regards the medical devices expert panels, a new dedicated office has been established and the Agency is working to improve the efficiency of the operations of the panels, which are active on Clinical Evaluation Consultation (CECP) and Performance Evaluation Consultation (PECP) procedure dossiers since 1 March. To date, 11 CECP applications have been received and one opinion has been issued, while no new PECP procedures have been received for the In Vitro Diagnostic expert panel since November 2021. EMA is also preparing for providing Scientific Advice to medical device manufacturers and the start of this activity will depend on the expected CECP and PECP workload, which is estimated to substantially increase in 2023-24. The plan to inform stakeholders and receive feedback on the

implementation of the EMA's extended mandate is being rolled out with dedicated news items, revised webpages, updates through the Patients and Consumers and Healthcare Professionals Working Parties and the creation of a Standing group with industry stakeholders to be first convened in June.

Some members welcomed the involvement of IT Directors in the development of the European Shortages Monitoring Platform and suggested the latter should build on existing national shortages monitoring systems and databases. Questions were raised on: the development of a list of critical medical devices, whether the appointment of alternates to the MSSG is possible, whether the Platform could be made compatible with the veterinary Union Product Database to manage shortages of veterinary medicines and if the Vaccine Monitoring Platform and ETF would focus on veterinary vaccines, the possibility for EMA to recruit expert panel members from academia, and on plans to stagger submission of CECP applications to manage workload peaks in future. The representatives of DG SANTE and of DG RTD asked if the Vaccine Monitoring Platform will be linked to DARWIN EU and if it will reuse the deliverables of the IMI DRIVE project.

EMA replied the Vaccines Monitoring Platform with ECDC will be a programme of observational studies and build on the work of the IMI DRIVE and ACCELERATE projects; it will make use of DARWIN EU as a vehicle for delivering research, together with the other framework contractors of EMA for observational studies. The feasibility study for the European Shortages Monitoring Platform has explored the use of the European Medicines Verification System for falsified medicines and concluded that major adaptations would be needed before the latter could be used by EMA to monitor stocks. When developing the Shortages Platform, EMA will also consider the work of Work Package 7 of the Joint Action on medicine shortages which will develop a concept paper on how to harmonise national shortages monitoring systems. The Shortages Monitoring Platform will only cover human medicines, but the EMA/HMA Availability Task Force will assess the feasibility of extending it to veterinary medicines after 2025. The development of a list of critical medical devices will be challenging and EMA will look at national systems for monitoring devices and further update the board on that. The SPOC Working Party already includes veterinary agencies and already shares information on shortages of veterinary medicines. The regulation does not foresee the possibility of alternates to the MSSG. The ETF will involve veterinary experts, including for vaccines, in case of public health emergencies which are zoonoses. For future CECP dossiers, EMA is discussing with the Commission and MDCG on how to plan and prioritise submissions from Notified Bodies as well as extending the existing pool of experts by recruiting also from academia.

B.7 HMA/EMA Task Force on availability of medicines (TF AAM) progress report

[EMA/MB/267001/2022, EMA/69599/2022, EMA/61299/2022, EMA/857232/2016-Rev.2] The Board adopted the new the new structure and composition of the Task Force, its work programme to 2025, the updated Terms of Reference and agreed on the extension of the mandate of the TFAAM for a further 3 years.

The activities of the HMA/EMA Task Force on availability of medicines (TF AAM) have been temporarily suspended due to COVID-19 Business Continuity Plan (BCP). The TF AAM has subsequently gone through a transitioning phase as both TF Co-Chairs have been replaced due to the retirement of Noel Wathion and Kristin Raudsepp's departure from the Estonian Agency. New Co-Chairs have been appointed at the end of last year (EMA - Monica Dias, HMA- Hugues Malonne) and the activities have recently resumed with the 1st teleconference of the Steering Committee was held on 15 December 2021.

At the Heads of Medicines Agency (HMA) meeting in November of 2021, it was agreed that a new structure and composition of the TF AAM was necessary to ensure alignment of the activities within the EU Regulatory Network (European Medicines Agencies Network Strategy (EMANS) to 2025; EU4Health Joint Action on shortages; EMA extended mandate). The new composition and structure will streamline processes, foster synergies and avoid duplication of work within the network. The TFAAM work programme has also been reviewed in line with the EMANS 2025 and was adopted by the Steering Committee at their meeting on 28 January 2022. The work programme builds on the objectives described in theme 1 of the EMANS to 2025 and includes actions from: HMA MAWP; EMA Single programming document (SPD); ongoing actions from previous work programme; and existing actions related to availability of medicines assigned to standing working groups. The work programme has also been aligned with the JA on shortages and the EC Pharmaceutical Strategy to prevent duplication of work within the EMRN. The Terms of reference (ToR) of the TF AAM was initially drafted in 2016 and the current mandate will end in December 2022. The ToR has been updated in view of the new developments in the area of availability and shortages, the new structure of the TF AAM and the need to extend the mandate for a further 3 years. The new composition of the TFAAM, the revised work programme and the updated mandate have been adopted by HMA.

The topic of availability of medicines was highlighted by several Board members as a key focus area of the Network and welcomed the clear explanations on the different initiatives across the supply and availability landscape and the involvement of HMA/EMA TF AAM. A Board member inquired on whether the EC study on shortages was considered and EMA confirmed that it has also been taken into account. A question was raised on whether the tracking of shortages of non-critical medicines, during or outside of a Public Health Emergency (PHE), could be included in the future through the European Shortages Monitoring Platform (ESMP). EMA informed the Board that the Regulation 2022/123 does foresee the possible expansion of the ESMP beyond critical medicines.

B.8 Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency

[EMA/MB/559127/2022, EMA/209787/2017 Rev.2] The board adopted the Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency.

The Internal Audit Charter sets out the mission, objectives, reporting and working arrangements of the internal audit capability of the Agency and it was last approved by the Management Board in June 2017. The current review aims to fill some identified gaps compared to the latest International Standards for the Professional Practice of Internal Auditing. The main changes were briefly presented to the board by the Head of Audit at EMA.

B.9 Annual report of internal audit and advisory activities at the European Medicines Agency 2020

[EMA/MB/169623/2022, EMA/53489/2022] The board adopted the annual report for 2021 on the internal audit and advisory activities at the EMA.

This report is presented to fulfil the obligations of the Financial Regulation and international standards, which require the Head of Audit to report annually to the Management Board on the internal audit activities. The Head of Audit confirmed that in 2021 his function had the full organisational independence necessary to effectively carry out its responsibilities and was free from interference and conflicts of interest. In 2021 it conducted three audits, which resulted in 14 major recommendations, and participated in other six audit engagements, including the external audits on the Clinical Trials Information System and Medical Literature Monitoring. It also focussed on the monitoring the

implementation of existing recommendations from previous audits. The annual report confirms that the internal control system put in place by the Agency, in a period marked by the COVID-19 pandemic, provides reasonable assurance regarding the achievement of the business objectives in line with Business Continuity Plan arrangements. It also includes some recommendations for further improvement of the internal controls and procedures which will be implemented in 2022.

B.10 Report from the Director of the Internal Audit Service EC (IAS)

The board noted a presentation by a representative of the Internal Audit Service of the European Commission on the outcomes of the IAS internal reorganisation in 2020 and on its implications in terms of reporting requirements for EU agencies, including EMA.

The reorganisation aims to re-focus the IAS portfolio of audits and structure to reflect EU policy priorities rather than organisational entities. In this way IAS will have a better understanding of the operating context of agencies. The IAS remains the auditor of EMA and, as new development to the approach, it will start to undertake multi-entity audits on risk-based approach, i.e. it will be able to combine separate entities in one single audit, for example in order to assess interactions between agencies and partner DGs where necessary. Although the reporting obligations of EMA do not change, the reorganisation will allow IAS to audit EMA together with other EU agencies operating in health and with DG SANTE. In this context, in 2022 the IAS is planning a "limited review on the adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to cross-border health emergencies in HERA, SANTE, EMA and ECDC".

Members asked if the limited review of EMA, SANTE, HERA and ECDC will look into the financial resources available to agencies and when this will happen. The representative of the European Parliament asked about the differences in role between IAS and the European Court of Auditors (ECA). The IAS representative noted that the scope of the limited review is not defined yet and will be clear only after a preliminary survey has been carried out, as per standard practices. It is planned for the review to start by end 2022, but this timeline depends on the IAS capacity which will be re-assessed in the coming weeks and it might also be postponed until 2023. IAS has separate objectives from the Court, but it cooperates closely with ECA and covers similar areas. IAS shares findings and audit planning with ECA, in order to avoid overlap and duplication of coverage. The Head of Audit of EMA stressed the Agency's internal audit is regularly in touch with both IAS and the ECS, and with the latter mostly in order to provide its independent assessment on the annual accounts of EMA.

B.11 Annual report 2021 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use

[EMA/MB/258790/2022, EMA/136886/2022] The board endorsed the Annual Report 2021 on Key Performance Indicators for the evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use.

EMA noted the annual report is presented in the context of the implementation plan endorsed by the Management Board on 10 June 2010 with the aim to provide transparent reporting of the performance of NCAs under the Cooperation Agreement between NCAs and EMA for services provided. The report shows no major changes in multi-annual trends or deviations in 2021 compared to 2019 and 2020. However, some improvements can be observed in meeting targets for GMP inspections, human

medicines rapporteur reports for initials and line extensions, and in scientific advice and evaluation reports of veterinary medicines. Challenges to meet targets in 2021 can be seen primarily for human scientific advice joint assessment reports, while GCP inspection and PhV inspection reports faced specific issues due to the context of COVID-19 (remote assessments due to travel restrictions). Delays in appointing Rapporteurs or Scientific Advice Coordinators and in starting some procedures are not visible in this report, but they exist and are of concern for EMA and for industry. A dedicated group between EMA and the Heads of Medicines Agencies is looking into how to mitigate the issue and facilitate the work of assessment teams in CHMP and SAWP.

B.12 Review of activities of the Working Parties of the EMA - Update from the Implementation Steering Group

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 Board were reminded of the timelines of the restructuring of the Working Parties (WP) following the endorsement of the revised high-level implementation plan at the March 2021 Management Board meeting. The kick start of the implementation plan was only launched in September 2021 due to the COVID-19 crisis. The benefits of the new model were restated with the potential to deliver strategic priorities of the Domains, being adaptable to future needs and being able to reach out to relevant stakeholders (i.e. industry & learned society and universities). Other benefits of the new model are to redistribute expertise in a more agile structures (such as Operational Expert Groups, OEGs) and the consequent reduction in number and membership of standing working parties. European Specialised Expert Community (ESEC) in particular will introduce efficiency, inclusivity and consistency by providing information flow to the network, training development and source of expertise. The new WP model is being implemented in a two phased approach with a number of steps needed. Regular meetings of the MB Review Group have taken place to provide status reports on the implementation of the new model.

EMA reported that there was successful start of implementation of Phase 1 of the project, with the reorganisation of the working parties to deliver on the workplans for the Nonclinical, Methodology and Clinical domains. Expertise in the WPs was varied across the Member States and experience was retained with a majority of experts having previous experience in WPs/Committees. Elections of the Chairs and Vice-chairs of the Working Parties were held during the April and May CHMP plenary meetings. Unfortunately, there were only a few members that volunteered for the positions of Chair and/or Vice Chair. EMA noted that there is a lack of leadership observed within a few WPs which could be related to high workload of experts or inactivity of the WPs. The pilot phase for the Oncology ESEC has also started with oversight from the Clinical domain and Oncology WP. Oncology ESEC pilot is an important new step in creating inclusion and knowledge sharing across the Network. A lesson learned exercise is planned in August 2022 to gather feedback on the implementation of phase 1 and also includes Oncology ESEC pilot. This exercise will also help embed and design the roadmap for Phase 2 (Quality Domain) of the implementation of the new model of working parties which is envisaged to start in December 2022.

The presentation was followed by a number of interventions from Board members. The EMA were commended by several members on the progress of the implementation of the new model. Some members inquired about the nomination of experts for the ESECs as these submissions would be handled by Committee members from NCAs and therefore may restrict experts working outside of NCAs. EMA stated that ESECs would be an inclusive community which will be accessible to experts from the NCAs, SAGs, CHMP members but also academic organisations that are or will be contributing to the regulatory system. As the roll out of ESEC is currently in the pilot phase, there are still principles

and processes to be created to ensure full exclusion of experts from outside NCAs. A request for observers status of experts in the different WPs and OEGs was also suggested to allow access to the knowledge and to facilitate building the experience of junior experts. EMA explained that the WPs would be open to any experts that wish to listen in on the discussions through new interactive tools and this process is already taking place for the Vet Domain. A question was raised on the criteria for the selection procedures of the different WPs for the Domains in Phase 1. EMA confirmed that the selection of experts were expertise driven but the panels tried to distribute expertise across the Network. The final list of experts was also put forward for recommendation to the CHMP. A few members still have reservations with phase 2 of the implementation of the working parties for the Quality Domain. A request for continuing full representation of Member States in QWP and BWP was again proposed. EMA took note of the concerns and explained that the plans for phase 2 are still being drafted so that the lessons learned from phase 1 can be embedded. EMA will come back to the Board at its October meeting to provide further information on preparations of phase 2. The Chair noted that the yearly operational work plans should be circulated after the meeting.

B.13 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/223704/2022, EMA/223705/2022] The Management Board noted a progress report on the implementation of IT systems required by the EU Clinical Trial Regulation.

EMA provided some key metrics on the initial use of the Clinical Trials Information System (CTIS), including the number of trial authorisation and substantial modification applications filed, the clinical trials types and therapeutic areas, and the number of Concerned Member States involved. During the current hyper care and stabilisation phase, a process for incident management has been put in place. A CTIS Early Phase Oversight Group has been established to manage critical issues, and to advise on system fixes/evolutions with significant impact on users. It will report as necessary to the ACT EU Steering group, which is overseeing CTIS operations. The ACT EU Steering group is also further streamlining the CTIS governance by empowering Member States Product Owners to be more involved in incident resolution and increment planning (formerly called 'release' planning). Member States and Sponsor Experts are also actively involved in the backlog prioritisation exercise. About 96% of the CTIS training module catalogue is available on the EMA website and the first Member States Training Expert panel workshop took place on 28 April 2022. The member from Sweden presented the Member States perspective on CTIS implementation and recognised that the need to address challenges in conducting clinical trials in Europe is a priority for the Member States. CTIS is a major instrument to deliver on this priority and a significant work has been done at national level to adapt national legislation, templates and fees in line with the new Clinical Trials Regulation. A number of national processes will have to be fine-tuned over time and Ethics committees and sponsors will need to be more closely involved by Member States authorities. It is clear that CTIS will significantly help in conducting clinical trials evaluations and ultimately do good for EU patients.

One board member noted significant problems remain with the helpdesk, collaborative space and some procedural aspects of CTIS, which will require further consideration and improvement from EMA. The representative of DG SANTE noted that by 31 January 2023 all new trials in the EU will have to be submitted via CTIS and so after the summer the engagement to sponsors at national level, especially in academia, should be intensified. Some board members stressed the need to constantly remind stakeholders of the benefits of CTIS. The representative of DG RTD noted the funding of multinational clinical trials is challenging due to the delays in getting ethics committees' approval and to national programs usually being able to fund only national trials. DG RTD is also working on actions to improve the conduct of clinical trials, including on promoting them within universities, and can present more

details on these plans at future MB meetings. EMA recognised the persistence of bugs and noted work is in progress in order to prioritise the backlog, improve the functioning of the helpdesk and increase the communication campaign to promote and explain the benefits of CTIS.

B.14 Update on Accelerating Clinical Trials in the EU (ACT EU)

The representative of DG SANTE provided an update on the ACT EU initiative and its key developments.

As announced at the last Board meeting, a detailed programme delivery plan has been developed by HMA, EC and EMA. Co-leads for all ten priority actions (PAs) have been confirmed. In addition, a preliminary stakeholder mapping has also been completed. ACT EU Steering Group (ACT EU SG) is also delivering on a number of key outputs such as the Key Performance Indicators (KPIs) to monitor the implementation of the Clinical Trial Regulation (CTR) which was adopted on 12 May. A Questions and Answers (Q&A) document on complex clinical trials was also adopted in May and will provide guidance for sponsors, clinicians, and companies involved in the planning and conduct of complex clinical trials. At the next meeting of ACT EU SG on the 24 June, a prioritisation exercise will be undertaken to prioritise the deliverables. The ACT EU programme team will also consolidate the deliverables and identify dependencies and synergies with PA leads. The outcome of the exercise will help with the finalisation of the ACT EU work plan which will be structured in line with the ten priority actions. The final work plan will be finalised and adopted by the ACT EU SG through a written procedure during the summer and be presented to the EMA Management Board in October. As HMA, EC and EMA colleagues have been identified across the Network to collaborate on all the priority actions, a face-to-face ACT EU Matrix meeting will be organised on 19 and 20 September at EMA. This meeting will be an opportunity for colleagues to meet and agree processes and approaches for productive collaboration. The programme is aiming to have this be a yearly event.

The representative of DG SANTE and EMA also informed the Board that calls for Seconded National Experts (SNEs) to support the activities of either the European Commission or the Agency in the area of clinical trials will be launched.

B.15 Agile transformation progress update

The EMA provided an update on the Agile transformation and progress on implementation since the last Board meeting.

The main goal of 2022 is a full roll-out of the agile way of working towards a fully agile portfolio for 2023. An essential step in operationalising the agile governance is the participation in product teams as Product Owners (POs) and Subject Matter Experts (SMEs). The Terms of Reference for POs and SMEs and the protocol selection was endorsed by the Board via written procedure. ePI and Product Management Service (PMS) project team were included in the pilot phase and calls for expression of interest were launched in May 2022 for nominations of relevant Network POs, network SME, and Industry SMEs. Upcoming calls are planned in the summer for a Network SME for PMS project and SMEs/POs for ESMP (European Shortages Monitoring Platform) project.

To ensure continued collaboration with the NCA IT community, a virtual IT Directors meeting hosted by the HMA French Presidency took place on 25 April. The main topics of discussion were on the engagement between Network ICT Advisory Committee (NICTAC) and NCA IT Directors, agile transformation update, NCA perspective on the implementation of the CTIS and EMA/Network Technology and Cloud strategies. The next virtual meeting will take place in autumn 2022 under Czech Presidency and the Swedish Presidency are planning to organise face-to-face meetings in 2023. The Network ICT Advisory Committee (NICTAC) has also been meeting regularly since its inauguration in

autumn 2021. The first face-to-face meeting took place on 18 May at EMA premises. Updates were presented on access management of external users, UPD and CTIS, Portfolio roadmap status and ESMP. An overview of the scope and priorities of the EMA's five Value Streams were presented by Value Stream Owners. Continuous engagement with Industry is being achieved through a number of channels, including an Industry associations meeting on agile transformation which was organised on 6 April. Industry representatives were also invited to the Quarterly Strategic Portfolio Review (QSPR) meeting on 14 June. Representatives of industry organisations will be invited to every other QSPR, ie. twice a year. Summaries of Agile ceremonies are also published on the EMA website to regularly inform industry and other stakeholders. The next steps of the transition to agile includes the finalisation of the 2023 Portfolio objectives which will feed into the EMA's Single Programming Document (SPD) and be transformed into a Roadmap. The IT Portfolio and Budget for 2023 will be discussed at the Management Board meeting in December and will follow the Agile methodology.

A member of the Board asked about the first QSPR meeting with Industry stakeholders and if there were any issues raised during the meeting. The meeting received very positive feedback and Industry associations only had a few questions on the Industry SMEs representation and Agile Portfolio Roadmap. This could be facilitated through the Network Strategy consultation and possibly the Regulatory Optimisation Group (ROG).

B.16 Technology Capability Investment Plan

[EMA/MB/264841/2022, EMA/571550/2022] The Board noted the Technology Capability Investment Plan, which replaced the Information Management Strategy 2020-2022 and will cover a time frame till 2025.

The Technology Capability Investment Plan (TCIP) provides strategic guidance for meeting the digitalisation objectives of the EMRN and its stakeholders, addressing emerging information management needs driven by new legislation and enabling Network as a data-driven, knowledge and information-based entity. The TCIP also provides direction for the investment of human and financial resources for the delivery and application of technology capabilities from 2022 to 2025. The Agency's vision is to enable an all-digital, modern, efficient and data-driven Network of Regulatory Agencies of the future and to establish the EMRN as a global reference authority. From an Information Management perspective, EMA's goal is to become a digital hub providing high-quality data and information services by enabling a connected, interoperable medicines regulatory platform for the Network and its stakeholders.

The TCIP builds on the EMA Cloud Strategy from 2022 and its fundamental purpose is to establish the necessary technology and agile delivery foundation to support the implementation of the Regulatory Science Strategy, European Medicines Agencies Network Strategy, EMA Security Strategy, EMRN Data Standardization Strategy as well as to enable the efficient and effective delivery of the EMA multiannual work programme. The document focuses on the strategic direction for the next 3 years, resulting in key operational and technology investments in the short term to achieve this direction. The TCIP will serve as a guideline for the Enterprise Architecture Board to make recommendations regarding technology selection, technology adoption and target enterprise architecture. NCA IT Directors were regularly consulted on the TCIP and feedback was collected through a series of interviews by NICTAC NCA members. The TCIP was also presented to the Network Portfolio Advisory Group (NPAG) at a Quarterly Portfolio Sync meeting on 14 June 2022. It is presented to the Board for information and will be published in July 2022 on the EMA website as a living document. The document will be reviewed annually and updated as needed.

A few members of the Board requested that regular communication to the Network and IT Directors should be envisaged on the key milestones of the TCIP and not only through the NICTAC. EMA

explained that an engagement plan, prepared in collaboration with NICTAC, is underway to keep the Network regularly informed. Concerns were also raised with regards to the NCA Product Owners (POs) and to ensure that the decisions made by POs are in agreement with and in the interest of the Network. EMA agreed that POs will need to be connected with the strategic direction of the HMA and the involvement of POs could be discussed at a future HMA meeting.

B.17 Portfolio Report to the Network

[EMA/MB/571057/2022, EMA/571059/2022] The Board noted the Portfolio Report to the Network which provides a progress update for Programmes and Projects, Agile Value Streams and monitoring of IT Operations from 1 March to 30 April 2022.

In line with the new Agile approach, the Network Portfolio report was established and provides an overview of the performance and achievements of the Agency's programmes and projects during a certain reporting period. RAG status is used in the report to denote the status of a project or tasks. The portfolio of programmes and projects is currently composed of 5 formal programmes (from which 3 programmes are active: CTIS, Data Integration and Veterinary Medicinal Product Regulation (VMP-Reg) and a cluster of ongoing standalone projects, including Business Intelligence at Admin, DREAM to SharePoint migration and External User Journey. Most of the projects are expected to transition to the Agile approach during 2022 and 2023. Resourcing issues were reported for a number of programmes/projects including VMP-REG, Data Analytics Programme (currently on hold), Business Intelligence at Admin and European Substance Reference System (EU–SRS).

The Agile Value Streams dashboard currently has four streams that have started and are regularly discussed during the Programme Increment (PI) Planning and Monthly Sync ceremonies. The fifth value stream on 'Technology Lifecycle Management and Information Security' will be include onwards from June PI Planning. The report also presents the monitoring results for different IT operations including systems availability, incident resolution and service request and customer satisfaction. Over the reporting period, the EU systems were available on average for 99.75% of the required time and an average of 68% of incidents related to EU Telematics systems were resolved within the required Service Level Agreement (SLA) resolution time. Additionally, an average of 82% of service requests was fulfilled within the required SLA resolution time (See Picture 3). An overall 80% customer satisfaction rate was achieved from 1 March to 30 April 2022.

B.18 Update on implementation of Veterinary Medicinal Products Regulation

The Board noted an update from the European Commission and from EMA on the implementation of Veterinary Medicinal Products Regulation.

The representative of DG SANTE explained work is ongoing to adopt the last two pieces of a set of 25 priority instruments of implementing legislation, i.e. the Delegated Act on imports of animals and products of animal origin and the Implementing Act on a list of antimicrobials reserved for the treatment of certain infections in humans. The implementation of the Delegated Act runs until 2027 so there is more time for industry to prepare. The draft Implementing Act on the list of reserved antimicrobials was notified to WTO and will be discussed at the Standing Committee meeting on 4 July with a view to a possible vote.

EMA informed that the EMA-HMA Task Force on the Veterinary Medicinal Products Regulation is meeting regularly to discuss issues, such as bug fixing and adding more functionalities, in the three new databases that went live on 28 January 2022. Only 15% of the legacy data remain to be uploaded

in the Union Product Database and upcoming IT releases will allow Member States to notify to EMA what cannot be uploaded. The VMP implementation is still in a transition phase and issues will be solved gradually but most issues should be overcome by the end of this year. Interest is high and an Information Day was organised by EMA on 11-12 May with hundreds of participants. Industry is helping to point out bugs and in refining the interpretation by sending many regulatory questions. The Veterinary System Improvements Advisory Group (VSIAG) has been created and it will help EMA to prioritise functionalities that need to be developed for regulators, industry and veterinarians. A lot of these will be on searchability of the public portal of the Union Product Database. Work is in progress on the collection of use data and in 2030 this activity will be extended to also cover companion animals.

The board was informed that a written procedure will be launched to amend the Fee Implementing Rules and establish a reduced fee for a veterinary variation requiring assessment, scope G.I.18, which is a mandatory action that Marketing Authorisation Holders have to take to be able to maintain their product on the market after the cut-off date of 29 January 2027. The written procedure will run in summer, with a targeted implementation day for the changes expected for 1 August.

The representative of veterinarians' organisations congratulated EMA on the robust assessment on the Implementing Act on the list of antimicrobials to be reserved in humans and on the support given to veterinarians in implementing the new regulation via a series of joint webinars with the Federation of Veterinarians of Europe.

B.19 Update on the conclusion of Agriculture Council on highly pathogenic avian influenza (HPAI)

The Board noted an update provided by the alternate from France on the recent Council Conclusion on highly pathogenic avian influenza (HPAI).

During the French EU Presidency, the Council discussed animal health issues faced in Europe due to the autumn migrations of wildlife birds from the Northern to the Southern hemisphere, which generate frequent outbreaks of avian influenza in rearing birds. In recent years, several European countries had to slaughter millions of laying hens due to vaccination programmes being generally avoided since many third countries refuse to import products from vaccinated animals. The Presidency negotiated with third countries to accept the principles of the World Organisation for Animal Health and import products from vaccinated animals, while Chief Veterinary Officers presented a paper to the Council of Agriculture in May 2022 to promote vaccination campaigns against avian influenza. The Council Conclusions call for the organisation of vaccination campaigns, the development and authorisation of new vaccines for different species of poultry and the establishment of a system for their strain update. An EU action plan to promote these vaccinations is being prepared and EMA will be consulted on it soon. The board thanked the French presidency for focusing on this important topic linked to the preparedness for veterinary health emergencies and the representative of veterinarians' organisations stressed the need for the Agency to support further initiatives in this area.

B.20 Big Data Steering Group update

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

A selected number of highlights were presented to the Board as the different workstreams included in the HMA-EMA Joint BDSG workplan 2021-2023 remain on track. The Agency and HMA in collaboration with TEHDAS (Joint Action 'Towards a European Health Data Space') held a Data Quality Framework workshop on 7 April 2022. The workshop aimed to share the current progress on the establishment of

an EU framework for data quality for medicines regulation as one of the priority recommendations of HMA-EMA joint Big Data Task Force. The input from the workshop will be taken into consideration when drafting the general scope of the Data Quality Framework during 2022 that will also be complemented by a written stakeholder consultation. In line with the BDSG workplan and the EMRN Strategy to 2025 action on data discoverability, and through consultation with its stakeholders, the EMA published a final list of metadata for describing real world data (RWD) sources and studies following adoption by BDSG. A call for Big Data Curriculum tender was launched on 13 April 2022 with a closing date of 31 May 2022 to select contractors able to develop training courses on Big Data with the signature of the framework contract expected in Q4 2022. These trainings will increase the capability of the EU Regulatory network to understand, analyse and interpret Big Data. A first forum meeting between BDSG and industry was organised on 30 May 2022 to gather industry's views on big data priorities and needs for the coming years as industry is not represented within the BDSG. Industry suggestions received during the meeting could be considered and fed into the Big Data Steering Group workplan's 2025 finalisation.

With regards to the integration of the RWE pilots through DARWIN EU®, nearly all EMA Committees have agreed use cases definitions and embedded RWE use cases in their workplans. EMA will discuss further the particular use cases which could be addressed by DARWIN EU®, with CMDh, HTA and Payers. At a recent DARWIN EU Advisory Board meeting, representatives from HTA bodies and Payers organisation were invited to presented the use cases of RWE for HTA bodies and Payers. The Advisory Board recognised the good overlap between the HTA /Payers use cases and those identified for the EU Regulatory Network. A set of primary and secondary criteria for the selection of data partners have been agreed by the Advisory Board. Based on these criteria, the selection and onboarding of data partners will start very soon. A data protection impact assessment for the Coordination Centre for DARWIN EU® will be finalised by end of June. EMA has recently signed off a data use agreement template which will be used between the Coordinator Centre and the data partners.

The Board was informed about the launch of the clinical trials raw data pilot, which was postponed to September 2022 following feedback received from the Network. The pilot is now expected to last up to two years with final decision-making in 2024 and a public communication on the pilot is expected in July 2022. An interim report on the pilot will be presented to the Board in 2023 and the Management Board could decide, based on pilot's interim results, if there is sufficient evidence for earlier decision making. A transition phase is planned before full implementation with a focus on change management and training. In addition, the Clusters of Excellence Discussion Paper, led by the Danish Medicines Agency, was explained. The paper provides a framework to embed data analytics into the daily work of EMRN through the six building blocks of data access, legal aspects, capabilities, infrastructure, methods development and artificial intelligence. During the work on the discussion paper, different clusters for collaboration were identified in the areas of Artificial Intelligence, High Performance Computing, Real World Data and Patient level data analysis. A list of 11 recommendations were identified for the revision of the BDSG workplan. In line with the EU Network Strategy to 2025, a third joint HMA-EMA Big Data Steering Group (BDSG) workplan will be adopted in June 2022 by BGSG and subsequently published in July 2022. The work plan will re-enforce existing Big Data activities and identify gaps for 2023 to 2025. A questions was raised with regards to the change management elements on the different projects within the workplans. EMA confirmed that these elements will be featured in the next workplans.

B.21 Preparation for written procedure on EudraVigilance Human Joint Controllership Arrangement

[EMA/MB/329099/2022, EMA/137320/2022] The Board noted the preparation for written procedure on EudraVigilance Human Joint Controllership Arrangement.

On 29 April 2022, EMA informed the EMA Management Board about the preparation of a dedicated Joint Controllership Arrangement (JCA) for the EudraVigilance Human (EV) system, similar to the JCA for the CTIS endorsed in 2021. EMA scheduled a dedicated meeting on 16 May 2022 with Data Protection Officers (DPOs) of Member States' NCAs and the European Commission to discuss and agree a Joint Controllership Arrangement (JCA) for EudraVigilance Human. Members of the Pharmacovigilance Risk Assessment Committee (PRAC) and the Clinical Trial Coordination Group (CTCG) will be kept informed about all steps in the review process.

The JCA addresses the roles and respective responsibilities of EMA, European Commission (EC) and NCAs as regards to the processing of personal data for the safety reporting and monitoring obligations as set out in the pharmacovigilance and clinical trials legislation and in accordance Article 28 of Regulation (EU) 2018/1725, the European Data Protection Regulation (EUDPR), as well as relevant European Data Protection Supervisor (EDPS) Guidelines. The European Data Protection Supervisor (EDPS) confirmed EMA, EC and NCAs of Member States as joint controllers, whilst marketing authorisation holders and sponsors of clinical trials are separate controllers for their personal data processing activities.

A written procedure will be launched shortly after the Board meeting for endorsement of the final version of the EV Human JCA and the Board will be invited to make written observations within a two-week time-frame.

List of written procedures finalised during the period from 19 February 2022 to 8 June 2022

- Consultation no 02/2022 on the appointment of Róbert Pórszász as CHMP member as proposed by Hungary ended on 15 March 2022. The mandate of the nominee commenced on 16 March 2022.

- Consultation no 03/2022 on the appointment of Aaron Emmanuel Sosa Mejia as CHMP alternate as proposed by Denmark ended on 30 March 2022. The mandate of the nominee commenced on 31 March 2022.

- Consultation no 04/2022 on the appointment of Eszther Kollár-Nagy as CVMP alternate as proposed by Hungary ended on 07 April 2022. The mandate of the nominee commenced on 08 April 2022.

- Consultation no 05/2022 on the appointment of Katarína Massányiová as CVMP alternate as proposed by Slovakia ended on 02 May 2022. The mandate of the nominee commenced on 08 May 2022.

- Consultation procedure for the adoption of the Rules of Procedure of Executive Steering Group on Shortages and Safety of Medicinal Products (Medicines Shortages Steering Group-MSSG) ended on 7 April 2022. The procedure was adopted.

- Consultation procedure for the agreement of the Emergency Task Force Rules of Procedure ended on 19 April 2022. The procedure was agreed.

- Consultation procedure for the adoption on the "Decision of the European Medicines Agency to request for EMA derogation from Commission rules on working time and hybrid working" ended on 25 May 2022. The procedure was adopted.

- Consultation procedure for the adoption of the Management Board decision on exceptional NCA remuneration for COVID-19 assessment activities ended on 7 June 2022. The procedure was adopted.

Documents for information

- Biennial Report on EMA's interaction with industry stakeholders
- Feedback from the Heads of Medicines Agencies
- Outcome of written procedures finalised during the period from 19 February 2022 to 8 June 2022
- European Court of Auditors (ECA) Annual report on EU agencies for the financial year 2020
- Summary of transfers of appropriations
- Summary of implementation of assigned revenue

List of participants at the 116th meeting of the Management Board, held in a hybrid format on 15-16 June 2022

Chair: Lorraine Nolan

	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 Hansen *(alternate)* Stine Gregers Hørsøe *(observer)* Brigitte Faber *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk (*membe*r)
Ireland	Lorraine Nolan (*member*) Rita Purcell *(alternate)*
Greece	Dimitrios Filippou (*member*) Maria Gazouli *(alternate)*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)*
France	Christelle Ratignier-Carbonneil (*member*) Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta (*alternate*) Manuela Bocchino (*observer*) Agnese Cangini (*observer*)
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akuličs *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Mátyás Szentiványi *(member)* Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)* John Joseph Borg *(alternate)*
Netherlands	Tina Leguijt (*alternate*) Michiel Hendrix *(observer)*
Austria	Christa Wirthumer-Hoche *(member)*
Poland	Grzegorz Cessak (*member*)
Portugal	Rui Santos Ivo *(member)* Maria João *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Peter Potúček *(member)* [1]
Slovenia	Momir Radulović *(member)*
Finland	Johanna Nystedt *(alternate)*
Sweden	Bjorn Eriksson (*member*) Asa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points B.7,*

European Parliament	Karin Kadenbach Anthony Borg
European Commission	Sandra Galline (member) (DG SANTE) Andrzej Rys *(alternate)* (DG SANTE) Irene Norstedt *(alternate)* (DG RTD) Kristof Bonnarens (*observer*) (DG SANTE) Christina Modoran (*observer*) (DG SANTE) Thomas Van Cangh (*observer*) (DG SANTE) Fergal O'Donnelly (*observer*) (DG RTD)
Representatives of patients' organisations	Virginie Hivert *Apologies received from patient's representatives*
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	Despoina Iatridou
Observers	Runa Hauksdottir Hvannberg (*member*) (Iceland) Vlasta Zavadova (*member*) (Liechtenstein) Audun Hågå (*member*) (Norway) Marit Hystad (a*lternate*) (Norway) Sindri Kristjansson *(observer)* (Iceland)

Guest speaker	Jeff Mason (IAS)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Melanie Carr Nerimantas Steikūnas Hilmar Hamann Anthony Humphreys Alexis Nolte Zaide Frias Pierre Pradal Stefano Marino Martin Harvey Maria Alves Hilde Boone Steffen Thirstrup Monica Dias Manuela Mura Riccardo Mezzasalma Marie-Agnes Heine Jean-Michel Becar Salvador Ruiz Apolline Lambert Olga Oliver-Diaz Adeline Bessemoulin