15 June 2022
EMA/MB/169135/2022 - Adopted
Management Board

Minutes of the 115th meeting of the Management Board

Held in person/virtually on 16-17 March 2022

The Chair of the Management Board opened the meeting which was held for the first time in hybrid format, with Members attending in the room and via videoconference due to the extraordinary circumstances of the COVID-19 outbreak. The Chair confirmed the quorum and welcomed the new members: Sergejs Akuličs, member of Latvia and Peter Potúček, member of Slovakia.

The Chair thanked the three Civil Society members of the Board, Nancy de Briyne, Marco Greco and Wolf-Dieter Ludwig as well as the two European Parliament representatives, Anthony Borg and Matthias Groote, whose mandate also was due to expire on 14 June 2022 for their contributions and support to the Board. The Chair noted that the European Parliament has re-appointed Anthony Borg for another term and Karin Kadenbach as a new EP representative in the Board as of June 2022.

The Chair invited nominations for the Analysis and Assessment of the Executive Director's Annual Activity Report (AAR) 2020 to be delivered at the June meeting. Maria Jesus Lamas Diaz (Spain) and Gytis Andrulionis (Lithuania) were re-appointed.

The Chair also informed that two representatives of DG Health Emergency Preparedness and Response (HERA) at the European Commission would be virtually observing the part of the Board meeting on the EMA's extended mandate in order to learn more about EMA's activities on medical countermeasures during public health emergencies and inform future cooperation with HERA. A member of the European Food Safety Authority's MB Secretariat was also invited as observer and admitted virtually to the meeting after the Chair election on 17 March, to learn how EMA runs its Management Board meeting, as from October 2022 EFSA will also have a new Board composed of MSs, EC, EP and stakeholders' representatives like EMA.

The Chair noted that the election of the new MB Chair would take place on 17 March 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 9:00. [redacted] The election of the Vice-Chair will take place at the June meeting and the MB Secretariat will launch the application procedure after the March meeting.

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1. Draft agenda for 11 March 2021 meeting

[EMA/MB/34198/2021] 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: *6. EMA extended mandate – Regulation (EU) 2022/123: ii. EMA update on implementation activities, c. Chapter III: Medicinal products with the potential to address public health emergencies, including: ETF composition; B.3 EMA Annual Report 2021; B.4 2021 EMA Annual Report on Independence; B.5 Revised implementing rules to the Fee Regulation as of 1 April 2022; B.10 12th Annual Veterinary MUMS/limited market Report; B.12 OPEN Pilot: one-year review and recommendations.* The Secretariat informed the Board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the Chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests 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 114th meeting, held on 15-16 December 2021 adopted via written procedure

[EMA/MB/695181/2020] The Management Board noted the final minutes, adopted by written procedure on 7 March 2022.

4. Election of the Chair of the Management Board

The election was chaired by Christa Wirthumer-Hoche, as her mandate ended on 20 March 2022.

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

- Matthias Groote (European Parliament representative) to Anthony Borg (European Parliament representative)

[redacted]

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

[redacted]

The Management Board elected Lorraine Nolan, representing Ireland, as the Chair with their new mandate starting on 21 March 2022. The newly elected Chair thanked the Management Board and assured the Board of her commitment to role.

Following the election Christa Wirthumer-Hoche continued to chair the meeting.

5. Update on regulatory and coordinating actions arising from the war in Ukraine

The Management Board noted the updates from the European Commission and from EMA on regulatory and coordinating actions arising from the war in Ukraine.

The representative of DG SANTE recalled the main European Commission actions in support of refugees from Ukraine, including instruments at the EU level to allow relocation of patients across Member States. In Poland more than 1 million children have arrived from Ukraine and the consequences on hospitals are becoming significant. The Commission has activated the Civil Protection Mechanism and DG SANTE is in contact with the pharmaceutical industry and considering possible flexibilities on medicine labelling and packaging to ensure continued availability of medicinal products. No critical shortages of medicines have been reported so far. The risk for outbreaks of measles and polio is high and is being further analysed by ECDC.

EMA presented to the Board on its preparedness activities to help Member States manage some medicines-related impacts of the war in Ukraine. The Agency reported that no critical shortages have been identified via the EMA's Network of Single Points of Contacts so far, but the situation is evolving rapidly. EMA is in routine contact with industry associations so as to be alerted of any arising issues. Areas of high demand in Ukraine are medicines for HIV, tuberculosis and cancers, as well as vaccines for children. [redacted]. The Agency is compiling an inventory of ongoing clinical trials in Ukraine and is in contact with the Clinical Trial Facilitation Group to assist if any trial subjects in Ukraine can be moved to the EU. [redacted]

Several members reacted to the updates. The representative of veterinarians' associations explained their own support activities for Ukraine, including coordinating professional recognition of veterinarians fleeing from Ukraine and help with rabies testing of companion animals imported to the EU by war refugees. The patients organisations' representative explained that many national associations are doing their utmost to support their members in Ukraine, especially chronic disease patients. Solutions for a more rapid sharing of prescriptions across Member States would be helpful. National patient

associations are crucial to inform regulators about medicines shortages and the European Patient Forum is willing to continue its dialogue with EMA and national agencies in that area. [redacted] It was suggested that EMA continues to share regular information on such national measures among National Competent Authorities.

6. COVID-19

EMA Status Report

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

In terms of the Omicron variant, available evidence indicates reduced cross-neutralisation for current vaccines, but also indicates the importance of a vaccine booster dose in continuing to improve the overall level of protection. Data emerging from real-world evidence (RWE) is currently too limited for regulatory decision on a 4th dose (2nd booster). There has also been a loss of efficacy for some of the antiviral monoclonal antibodies, with only Xevudy and Evusheld appearing to maintain some activity. With regards to possible vaccine strain updates, EMA expects first data on modified mRNA vaccines in Q2 2022 which, if positive, should be in time for potential vaccination campaign in Autumn/Winter.

For the most recent product-related outcomes since the last Board meeting, EMA finalised the assessment in December of the fifth vaccine (first protein-based), Nuvaxovid. In February, EMA concluded variations to extend the indication for Spikevax from 6 years of age and lower age limit for Comirnaty booster dose (from 12 years of age). The product information for mRNA vaccines was also revised to update on the use in pregnancy. For ongoing activities, there are active rolling review of vaccines from Sanofi Pasteur and Valneva. A further extension for Comirnaty for below 5 years of age is also expected. Concerning COVID-19 therapeutics, a marketing authorisation for an oral antiviral Paxlovid (ritonavir) was granted end of January/beginning February. There are marketing authorisation procedures under evaluation for Evusheld (tixagevimab/ cilgavimab) and Lagervio (molnupiravir). In addition, the extension of indication for use in COVID-19 of the immuno-modulator Olumiant (baricitinib) is ongoing. EMA is in contact with developers of several additional therapeutics and vaccines, with the relevant reviews to start later in 2022.

EMA provided a progress update on the EMA/HMA Workshops as part of the ongoing work on the COVID-19 lessons learned review. The Agency has agreed with Heads of Medicines Agencies (HMA) on several follow up recommendations and actions from both the workshops (the first workshop on sustainability and resourcing of the network and optimisation of processes and the second workshop on cooperation and communication with institutions and stakeholders outside the network). Discussions are currently ongoing between EMA and HMA on the approach to implement the agreed actions and nomination of leads from both HMA and EMA. The biweekly European Medicines Regulatory Network (EMRN) meetings and regular press briefings continue to take place. Furthermore, EMA continues to interact with international regulators on COVID-19 through the ICMRA. The Agency is planning on resuming face-to-face meetings in the EMA building for Committees.

7. EMA extended mandate – Regulation (EU) 2022/123

[EMA/555794/2021] The Board noted an update on the Agency's plans for implementing the Regulation (EU) 2022/123 on the EMA's reinforced role in crisis preparedness and management for

medicinal products and medical devices and adopted the Composition of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 pandemic.

The representative of DG SANTE informed the Board on the status of adoption and on the key elements of the other legislative proposals in the European Health Union package proposed on 11 November 2020. These include the Cross Border Health Threats regulation, which is currently still under negotiation between the European Parliament and the Council, and the regulation for an extended mandate of ECDC, which was agreed at political level on 29 November and will be published in the Official Journal when final agreement has been reached on the Cross Border Health Threats regulation. The Health Union package also includes a proposal for a Council Regulation on the emergency framework regarding medical countermeasures, which was agreed by Council at political level in December 2021 and is currently being prepared for publication in the EU Official Journal.

EMA informed the Board on how the Agency is transitioning from the informal temporary structures set up at the start of the COVID-19 pandemic into the formal structures established by the new Regulation 2022/123. Members were informed of timelines and actions needed to implement additional tasks and activities under the EMA's extended mandate, with a focus on: management of shortages of medicines and medical devices (Chapter II and IV), support to medicinal products with the potential to address public health emergencies (Chapter III), management of medical devices expert panels (Chapter IV). The Board was informed that the adopted Regulation differs substantially from the original Commission proposal while the Regulation's Financial Statement has not been updated accordingly. Therefore, the planned Union contribution for the EMA's extended mandate does not cover the additional tasks introduced by the EU co-legislators, such as the EU Shortages Monitoring Platform (ESMP), which requires significant IT and business resource investment by EMA. The Agency is engaging with the European Commission on how to resource these additional tasks. A feasibility study on options and approaches to deliver the ESMP is in progress and will be presented to the Board in a future meeting.

As regards activities on shortages, some members commented that Member States will try to appoint to Medicines Shortages Steering Group (MSSG) the same representatives that were previously in the EU Executive Steering Group on Shortages of Medicines caused by Major Events, which in 2021 transitioned to a wider group including all Heads of Agencies, under the name of the European Medicines Regulatory Network meetings. It was asked if EMA would adopt an Agile way of working to develop the IT systems foreseen by the Regulation 2022/123 and EMA confirmed that such systems will be developed with Agile methodology and integrated in the agile project portfolio of the Agency. Some members stressed that monitoring shortages of medical devices is a very challenging and resource intensive task for National Competent Authorities and they asked if EMA would be relying on EUDAMED for it. EMA explained that the Regulation recognises that EUDAMED is currently not ready for tracking stocks of devices yet, and that in the meantime EMA can rely on available national databases, which are currently being mapped by the Agency. EMA recognised that, even with those tools, monitoring shortages of medical devices will be a major challenge for EMA and welcomed the support offered by national agencies with more experience in the medical devices' area. [redacted] Furthermore, as many national medicines agencies also have a responsibility for medical devices, it was asked if the same authorities could be represented in the MSSG and in the Medical Devices Shortages Steering Group (MDSSG) and if the two Steering Groups would be assisted by the same secretariat. The representative of veterinarians' associations asked if veterinarians could be systematically involved in the MSSG as most emerging diseases and health threats are of zoonotic origin.

The representative of DG SANTE commented that the EU4Health programme could offer resources for Member States to build IT systems for medicine shortages via the recently launched EU Joint Action on shortages. For medical devices the critical list of products to be monitored by EMA is likely to be fairly

limited. The importance of ensuring interoperability of shortages systems to be developed at EMA with EUDAMED was also stressed. EMA added that the Regulation allows the Agency to invite observers and in practice veterinarians will be invited for all MSSG meetings. Both MSSG and MDSSG will be served by the same secretariat and during public health emergencies they could also meet in joint meetings on a regular basis. Furthermore the Regulation allows Member States to appoint the same representatives to both MSSG and MDSSG. The EU Joint Action on shortages includes two work packages relevant to the European Shortages Monitoring Platform (ESMP) and EMA will link with the Joint Action when developing the ESMP. EMA informed the Board that the current Incident Review Network will continue its incident management activities but escalate to the MSSG when an actual or imminent major event needs to be addressed. The final Rules of Procedure of the Medicines Shortages Steering Group will be circulated for adoption via written procedure in April 2022.

After adoption of the composition of ETF, EMA informed that the current ETF composition may be reviewed and adapted at the initiative of the ETF co-chairs e.g. following a declaration of a new public health emergency. Furthermore, after a public health emergency is declared to have ceased, the ETF co-chairs will trigger a revision of the emergency-specific ETF membership to focus on preparatory measures, and this new membership would also have to be adopted by the Board via a written procedure. The draft ETF rules of procedures were presented to the Board for preliminary discussion and input, noting that they would have to be adopted by the newly appointed ETF on 29 March 2022 and then by the Board via written procedure in April. The new ETF will then become fully operational under the new rules and procedures in the second half of April 2022. The existing COVID-19 EMA Pandemic Task Force (COVID-ETF) will continue to address the ongoing emergency until the ETF becomes fully operational. As regards Article 37(2) of the Regulation which states that "The Agency shall remunerate the assessment activities of the rapporteurs in relation to the ETF under this Regulation" EMA explained that the necessary financial arrangements established by the Management Board will be prepared in Q2 2022 and will be based on the exceptional flat-rate top-up payments for COVID-19 assessment services agreed by the Board in August 2021. A revised Management Board decision will be circulated for adoption via written procedure or at the June meeting. Members asked if additional experts from Member States could attend ETF meetings as observers, which was confirmed by EMA. Observers cannot vote, but they can actively contribute to ETF discussions with their expertise and are, already under the current EMA COVID-19 Task Force, regularly kept informed of relevant discussions.

EMA informed the Board that the transfer of the secretariat for the Expert Panels on medical devices had been successfully accomplished on 1 March 2022 and that the transition from the EC Joint Research Centre went smoothly. An overview of the tasks of the Expert Panels and of their secretariat was provided to the Board. The EMA Expert Panel (EXPAMED) secretariat shall: coordinate the overall functioning of all expert panels and the Coordination Committee; provide the technical and administrative support to the experts; align evaluation processes to the EMA's work environment and provide for continuous improvements of the clinical and performance evaluation consultation procedures; ensure the independent advice of the experts (Declarations of Interests) and quality of opinions and views produced by the panels; support the experts to prepare advice to the Commission and Member States on performance and safety issues of high risk medical devices and in vitro diagnostics. In future, most likely after 2024, this Secretariat might also support the provision of scientific advice to manufacturers, with potential synergy with scientific advice for medicines/medical devices combinations.

The Board heard a presentation of the EMA's communication and stakeholder engagement plan which outlines how EMA will communicate and engage with its external stakeholders and partners to inform about the implementation of the new tasks under its extended mandate.

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, legislative and strategic milestones, update on Aducanumab application for treatment of Alzheimer's disease, Hopveus General Court judgment court case, Nitrosamine update, reactivation of face-to-face meetings and EMA Organisational update.

The Executive Director was invited with the EU Health Commissioner and other Directors of ECDC, EFSA and HERA to an informal Health Council meeting on 10 February in Grenoble to discuss options to strengthen the European Health Union. The Agency was also invited to an ad-hoc Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting on 14 March 2022 to contribute to a discussion on the EU's response to the crisis in Ukraine. EMA continues to support the European Commission (EC) on the implementation of the EU Pharmaceutical Strategy and the upcoming revision of the EU pharma legislation. At the international level, EMA continues to work closely with the USA Food and Drug Administration (FDA). It was also noted that a new US FDA Commissioner, Dr Robert Califf had been appointed. More details on international activities are covered under agenda item B.12.

In early 2022, EMA continued to deliver on several important legislative and strategic milestones. The Clinical Trials Information System (CTIS) was successfully launched on 31 January 2022 and on that day the Clinical Trials Regulation entered into application. The European Commission, the Heads of Medicines Agencies (HMA) and EMA launched a joint initiative to transform how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). On 28 January 2022, the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) became applicable and the related IT systems went live. On 9 February 2022 the contract for the establishment of Coordination Centre for the Data Analysis and Real-World Interrogation Network (DARWIN EU®) was awarded following a call for tender process. On 16 December 2021, EMA recommended the refusal of the marketing authorisation for Aduhelm (aducanumab), for the treatment of Alzheimer's disease, based on insufficient efficacy and identified safety concerns. A re-examination of EMA's opinion started on 22 February 2022 and a Scientific Advisory Group will be convened, involving clinicians, patients and carers representatives. The Agency recognises the enormous impact of Alzheimer's disease on patients and their families and is committed to support early access to new medicines in this area of unmet medical need but also the need to ensure regulatory standards are met.

On 2 March 2022, the General Court ruled in favour of EMA and the Commission, which had refused the granting of a conditional marketing authorisation for Hopveus. The General Court confirmed that the CHMP has full discretion to consult an Ad Hoc Expert Group, even when there is an already existing permanent SAG. In addition, the General Court expressed support for EMA's Policy 44 and endorsed its implementation.

In 2020 the Network agreed on approaches to manage the risk assessment and testing of all human medicines for possible presence of nitrosamine. This "call for review" is entering the final steps for chemical medicines and the Network is experiencing an increase in reporting from marketing authorisation holders (MAHs), together with a rise in reporting of new nitrosamines. In order to agree on the best approach for managing the ongoing process and newly emerging products or Active Pharmaceutical Ingredient issues, it was suggested that a meeting between EMA and HMA could be organized.

With regards to reactivation of face-to-face meetings at EMA, a plan has been established for EMA Committees, CMDx and SAWP to resume meetings from May to July 2022 with a 50% room capacity, similarly to the pilot that was launched in October 2021. As of 28 March, EMA staff would be present in

the EMA building for 40% of their working time to ensure a gradual safe return to the office. The board paid tribute to the Head of Clinical Studies and Manufacturing Task Force ahead of his retirement at the end of May 2022. The board warmly thanked Fergus Sweeney for his significant contributions to the Agency for over 23 years and for his relentless commitment to promoting innovation and research in the European Union.

B.2 Report from the European Commission

The representative of DG SANTE provided an update on the revision of the general pharmaceutical legislation and of the orphan and paediatric regulations, which are part of the implementation of the Pharmaceutical Strategy for Europe. The Joint Action under the EU4Health programme on Increasing Capacity Building of the Regulatory Network, which is planned to be launched in September 2022, was briefly presented. An update on the status of implementation of an International Cooperation Platform for National Competent Authorities for medicines for Human Use was also provided. The Platform aims to coordinate EU Member States in international fora, with a primary focus on the International Coalition of Medicines Regulatory Authorities. A proposal for the revision of the EMA Fees Regulation is planned in the summer 2022. The legal proposals for the European Health Data Space and for the revision of the blood, tissues and cells directives are planned for publication in Q2 2022. Clarifications were requested to the European Commission about the International Cooperation Platform and to EMA about the EU support to the African Medicines Agency.

The representative of DG RTD presented on the plan to create a European clinical trial network on COVID-19 therapeutics. The Commission is working to create a Trial Coordination Board bringing together three EC funded networks of Adaptive Platform Trials (REMAP-CAP, EU-SolidAct, ECRAID-PRIME projects), other European and international platform trials and relevant EU regulators. The intent is to develop an ever-warm clinical trial network to be prepared also for future public health emergencies and discussions are ongoing at the Commission on how best to move this project forward. The Collaborative Network for European Clinical Trials for Children (IMI2) project and a number of other EU funded projects on real world data collection for COVID-19 cohort research were also briefly outlined. The ERA4Health European Partnership on Investigator Initiated Clinical Studies was presented as a new partnership with research funders addressing potential areas of important public health needs, such as repurposing of off-patent medicines, it was expected that this will become an important network for medicines regulators in the future. Upcoming funding calls in 2022 under the Horizon Europe Cancer Mission for clinical trials were described. It was reminded that a call for proposals on methods for using real world data in regulatory and HTA decision-making is closing on 21 April and EMA and national agencies will be invited to participate in the selected projects. The initiative is expected to contribute to DARWIN EU. Under the new Innovative Health Initiative Joint Undertaking with healthcare industries, the first two calls for proposals in 2022 will focus on access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need and harmonised methodology to promote the uptake of early feasibility studies. Questions were asked about the projects on real world data and repurposing, stressing the need to avoid duplication with existing activities. The representative of veterinarians' organisations enquired if there would be a follow up to the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU JAMRAI). The representative of DG RTD explained that further collaboration between Member States on AMR using a one health approach is planned for 2023; in addition, the Commission is promoting innovative procurement practices and exploring potential incentives in legislation for new classes of antibiotics. DG RTD also works closely with DG HERA on AMR. Some members requested that a presentation would be given at a future Board meeting on, EU funded research and development projects for new veterinary medicines, and in particular new antibiotics for animals.

B.3 EMA Annual Report 2021

[EMA/MB/107705/2022, EMA/74495/2022] The Board adopted the EMA annual report 2021.

The Board heard a short presentation on the main topics in the EMA Annual Report 2021, which will focus on the EMA's strategic priorities and the response to the COVID-19 pandemic. In addition to the traditional print-ready PDF version, EMA will publish an interactive digital version of the report, with an enhanced timeline of activities, additional audio-visual materials, infographics and videos. A draft version of the report was circulated in advance of this Board meeting and comments from members are being implemented. Key figures for activities on human and veterinary medicines were presented for information.

B.4 2021 EMA Annual Report on Independence

[EMA/MB/149373/2022, EMA/759921/2021] The Board noted and endorsed the 2021 EMA Annual Report on Independence and its recommendations and planned initiatives.

This Annual report on independence reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff), including their implementation as of the end of 2021. The Board were informed of key changes that were introduced in 2020 and the key facts and figures in 2021 for each of the independence policies. EMA also presented the initiatives that were taken in 2021 and the identified recommendations for further improvement. The planned initiatives for 2022 were explained with particular actions linked to the new Regulation extending the Agency's mandate (Regulation (EU) 2022/123).

The representative of DG SANTE provided some verbal comments related to sections 2.2.1 and 3.2.1 of the report. Additional text will be included in the report to reflect the comments provided.

B.5 Revised implementing rules to the Fee Regulation as of 1 April 2022

[EMA/MB/407922/2021, EMA/MB/408059/2021] The Board adopted a revision of the Fee Implementing Rules coming into force as of 1 April 2022.

The Board was informed about the main modifications to the Implementing Rules, which include amendments for: yearly adjustment to inflation in 2020 and 2021; clarifications on fees for inspections and cancellations of inspections that trigger a (cancellation) fee; fees for vaccine antigen master files and vaccine platform technology master files for veterinary medicines; scientific advice fee incentives deriving from EMA's extended mandate; introducing a fee reduction for maximum residues limit fees (establishment or extension) for veterinary medicines for limited markets; and additional editorial changes. **Post-meeting note**: The Board had adopted the Implementing Rules to the EMA Fee Regulation on the condition that the European Commission gives a favourable opinion. Minor editorial changes were suggested and included removal of the references to the financial arrangements to be developed for the remuneration for assessment activities for public health emergencies under Regulation (EU) 2022/123. These references were deemed not necessary as the provisions of Article 37(2) of Regulation (EU) 2022/123 and Article 62(3) of Regulation (EC) No 726/2004 are compatible with a decision of the Management Board separately from Annex V of the implementing rules of Council Regulation (EC) No 297/95. 'Commission Regulation (EU) 2022/510 of 29 March 2022 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2022' was published in the Official Journal ahead of the entry into force on 1 April 2022.

B.6 Composition of the Paediatric Committee – Joint PDCO/CHMP membership

[EMA/MB/64247/2021, Ref. Ares(2017)446809 - 27/01/2017, EMA/64249/2022] The Management Board noted the letter by the CHMP Chair notifying that CHMP is currently not in the position to appoint five joint CHMP-PDCO members and that CHMP agrees to apply the 2016 proposal by the European Commission also for the next 3-year mandate of the joint CHMP-PDCO memberships (2022-2025). Under the 2016 proposal, the European Commission suggested that, in such an exceptional circumstance, in order to avoid vacant positions in PDCO, Member States not represented through the CHMP appointment can directly appoint additional members to PDCO according to article 4(1)(b) of the Paediatric Regulation.

EMA explained the context of the CHMP letter to the Board and outlined the other ways, besides joint membership, in which coordination between PDCO and CHMP is established by EMA. These include: ad hoc participation of PDCO members in CHMP meetings for specific topics and vice-versa; ad hoc interaction between CHMP and PDCO members on common procedures; discussions on ways to further strengthen collaboration during Strategic Review and Learning Meetings; supervision of committee activities by the Scientific Coordination Board. EMA further noted that the situation in which CHMP is unable to appoint joint members with PDCO is likely to arise again in 2026 and therefore a solution should be considered in the future revision of the EU pharmaceutical legislation. This view was also supported by a number of Board members, in view of the high workload of CHMP.

B.7 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/64550/2022, EMA/64551/2022] The Management Board noted the report on the implementation of EU IT systems required by the Clinical Trial Regulation.

The Board was informed about the successful launch of the Clinical Trials Information System (CTIS) on 31 January 2022. EMA provided facts and figures on the number of sponsor and Member State users logging into CTIS, number of clinical trials applications entered and under evaluation, and the type of sponsors (academia and industry) and Concerned Member States currently using the system. The SOLID-ACT, a platform trial for COVID-19 therapeutics, was highlighted as example of a trial application being transitioned from the Clinical Trials Directive to the Regulation and to CTIS and an illustration of good collaboration between national competent authorities, sponsors and EMA. A status update was provided on the implementation of the CTIS public website, CTIS authorities and sponsors workplaces and on the Implementing Regulation on safety assessment of clinical trials. Key activities in the CTIS Programme for 2022 include a six-month hyper-care and stabilisation period, which is focussed on incident management, technical deliveries, support to Member States and sponsors, and a period of analysis of feedback and setting priorities for further CTIS functionality development.

Board members welcomed the successful launch of CTIS and the close collaboration between EMA, EC and HMA which was crucial in delivering this important project. Special thanks were addressed to Fergus Sweeney at EMA and Xavier de Cuyper as Chair of the Clinical Trials Regulation Coordination Group. The launch of CTIS was highlighted, together with the ACT EU programme, as a major opportunity to strengthen the organisation of clinical trials in Europe.

B.8 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 since its endorsement by the Board in December 2021.

The Board were reminded of the main goal of the joint HMA-EC-EMA initiative to transform the EU clinical research environment in support of medical innovation and better patient outcomes, building on the momentum of the Clinical Trials Regulation (CTR) and CTIS. On 13 January 2022, the ACT EU initiative was announced on HMA, EC, and EMA websites and the ACT EU Steering Group mandate was endorsed by written procedure on 24 January. The tasks of the Clinical Trials Regulation Coordination Group will be transferred to the ACT EU Steering Group (ACT SG) which will steer clinical trial transformation and continue to act as an oversight group for CTIS. A call for membership to join the ACT EU SG was closed on 18 February. A virtual kick-off meeting of the ACT EU SG took place on 8 March, which was chaired by European Commission and involved representatives from EC, HMA and EMA as well as a representative from the Network Portfolio Advisory Group (NPAG) and chairs of the EMA Management Board, Clinical Trials Coordination Group and Committee for Medicinal Products for Human Use (CHMP). The ACT EU SG agreed on several key outcomes at the kick-off meeting including: a process to appoint action leads; a preliminary high-level communication strategy with key deliverables; and the approach for a draft list of Key Performance Indicators (KPIs) to monitor the implementation of the CTR and ACT EU actions. An ACT EU information session is planned on 22 March 2022 for the Clinical Trials Advisory Group (CTAG) and the Clinical Trials Expert Group (CTEG). The draft list of KPIs will be consolidated at a workshop and then subsequently endorsed by CTAG on 29 April. The ACT EU SG will then formally adopt the list of KPIs. The ACT EU SG will meet monthly and the EMA will provide the secretariat. The next meeting is scheduled on 28 April and members hope to confirm the action leads, and start identifying deliverables for prioritised actions with appropriate timelines. A detailed delivery plan will be developed and presented at a future Board meeting.

The representative of DG SANTE clarified that they will regularly liaise with DG RTD with regards to the number of EU funded projects related to clinical trials to ensure that the advantages of these initiatives/projects can be linked to the work of ACT EU SG.

B.9 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 welcomed the entry into application of the new regulation on 28 January 2022 and explained that, since the last MB meeting, the 'Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals' has been published in the EU Official Journal. The priority for the European Commission is now to finalise the two remaining Acts which needed to be in place before or by the date of application, i.e. the Delegated Regulation on rules on imports of animals and products of animal origin and the Implementing Regulation on the list of antimicrobials to be reserved for the treatment of certain infections in humans.

EMA thanked Member States representatives for a successful preparation for the entry into application of the new regulation and presented the ongoing implementation activities. Three of the four databases established under the Regulation 2019/6 went live on 28 January, while the development of the Antimicrobial Sales and Use database started in January 2022. In May 2022, the Union Product

Database will be expanded to include parallel traded products and homeopathic products. At time of presenting, 65% of the legacy data expected to be submitted by National Competent Authorities into the Union Product Database had been completed. National Competent Authorities were reminded of the request to inform EMA as soon as possible once their data submission is completed and of the dedicated helpdesk service available at EMA. Since the go-live, the HMA Task Force for the Coordination of the Implementation of the Veterinary Regulation held two ad-hoc meetings with industry stakeholders (Animal Health Europe and Access VetMed) to discuss the first experiences with the new IT systems.

The representative of the veterinarians' organisation congratulated the EC and EMA on the successful launch of the new IT systems; congratulations and appreciation to EMA, EC and HMA for the successful implementation and coordination across the Network were expressed also by other Board members.

B.10 12th Annual Report Veterinary MUMS/limited market

[EMA/MB/52895/2022, EMA/573681/2021] The Board endorsed the 12th annual report on the operation of the Minor Use Minor Species (MUMS)/limited market scheme for veterinary medicines.

B.11 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 and also an update on two BDSG recommendations: DARWIN EU (recommendation 1) and raw data pilot of clinical trials (recommendation 6).

The BDSG continues to remain on track with the different workstreams included in the workplan 2021-2023. The BDSG Annual Report 2021 was published in February 2022 and provides a summary of the main activities and achievements of the BDSG. Key BDSG highlights in 2021 and planned initiatives in 2022 were presented in the context of the priority recommendations. The first edition of the Big Data newsletter was also published in February and reports on the implementation of the HMA-EMA BDSG workplan 2021-2023 and the links to the data and digital pillar of the joint European Medicines Agencies Network Strategy to 2025. Preparation for the revision of the BDSG workplan 2023-2025 has started with the aim to have the workplan adopted by end of Q2-2022. By the end of 2022, there will also be a review of the BDSG in the context of overlaps and synergies with the EU Network Data Board.

On 8 February the contract for a service provider for the Coordination Centre (CC) for the Data Analysis and Real World Interrogation Network (DARWIN EU®), was awarded to Erasmus University Medical Centre Rotterdam, following an open call for tender published in June 2021. EMA has the oversight role with the appointed Coordination Centre and will oversee the deliverables and monitor its progress with performance indicators. In the next 3 to 6 months, the service provider will set up DARWIN EU's operational processes, establish the governance structures and contract models. The CC will also run real-world data pilot studies and in addition pilot the connectivity with the European Health Data Space (EHDS).

The main scope of the raw data pilot project is to clarify the benefits and practicalities of access to individual (raw) patient data from clinical trials in the assessment of medicines. The pilot is expected to start in the third quarter of 2022 and will analyse raw data from 10 selected marketing authorisation applications (MAA) based on a pre-defined selection criteria to support the CHMP assessment. Interested applicants will be invited to take part via a letter of intent and different operating models for raw data analysis are to be explored considering available capacities and resourcing of the network. The pilot phase will end in Q2-2023 and the results will help the EU medicines regulatory network to

make an informed decision on the benefits and/or implication of the utilisation of more raw data in the regulatory decision-making.

The representative of DG SANTE asked if the current legislative framework would allow RWE, including raw data analysis and if any recommendations for change had been identified so far. EMA explained that analysis of RWE is already possible within the current framework, but internal discussions in Network have highlighted that there are some operational uncertainties. An explicit legal basis for regulators to initiate and conduct RWE studies to support EMA scientific committees and down-stream decision-makers in their decision-making would be helpful.

B.12 OPEN Pilot: one-year review and recommendations

[EMA/MB/113300/2022, EMA/6881/2022] The Board endorsed the report on the one-year review of the Opening Procedures at EMA to Non-EU authorities (OPEN) pilot and recommendations for improvement.

After a year of experience following the endorsement of the pilot by the Board in December 2020, the EMA conducted a review of the pilot's operation and assessed its impact on the global regulatory system. This pilot allowed non-EU regulators and organisations (TGA Australia, Health Canada, MHLW/PMDA Japan, Swissmedic, WHO) to be involved in the assessment of 11 vaccines and therapeutics against COVID-19 up to December 2021 and 7 more products are currently under review under the OPEN pilot. The OPEN pilot has been an exceptional opportunity to promote the EU regulatory system and EU contribution to global health. The pilot has enhanced communication channels with non-EU regulators and enabled global assessment of similar data. This has allowed for accelerated COVID-19 medicines assessments and access to patients, with reduced duplication of questions to applicants and alignment of labelling. A notable illustration of the global health impact of OPEN has been the involvement of the WHO Prequalification Team, which used the CHMP assessments of 5 approved COVID-19 vaccines to facilitate the WHO Emergency Use Listing (EUL). Through reliance, this has allowed almost 160 national regulatory authorities in low- and middle-income countries to speed up registration of these COVID-19 vaccines.

Based on the one-year review outcomes, the EMA put forward some key recommendations for improvement to the Board. The consolidation of OPEN should take place in a stepwise approach, improving first the operation of the current initiative and later broadening the scope to areas that would benefit the most from international collaboration and provide value-add and visibility for the EU. The first recommendation was to develop strengthened terms of reference and better integration into the CHMP workplan. Secondly, the OPEN initiative would be expanded to other high-impact areas starting with antimicrobial resistance (AMR), and collaborative assessments of chemistry, manufacturing and controls (CMC). In a second phase, the initiative would extend to priority medicines designated under the PRIME scheme, and medicines responding to health threats or public health emergencies. Furthermore, there is a need to increase visibility of the OPEN initiative through more systematic communication. An action plan for 2022 was also submitted for endorsement as part of the OPEN recommendations to the Board.

EMA informed the Board of the announcement during an African-EU summit on 15 February where the European Commission, EMA and EU Member States with existing collaboration programmes with Africa, such as Belgium, France and Germany, and the Bill & Melinda Gates Foundation have committed to mobilise more than 100 million euros over the next five years to support the recently ratified African Medicines Agency (AMA) and other African medicines regulatory initiatives at regional and national levels. The European Commission has put forward a proposal that part of this funding should go to EMA as coordinator for Team Europe for regulatory system strengthening.

The Agency also informed that, in order to involve all EU Member States in this and future international initiatives, the EC has requested EMA to create a European Medicines Network International Cooperation Platform (IntCoP). The Platform, which will in principle meet virtually and have its secretariat at EMA, aims to facilitate the exchange of information between national authorities, EC and EMA, enabling enhanced coordination and alignment of various international collaboration activities within the European network.

EMA thanked all colleagues involved in the success of the first year of OPEN and thanked in particular the CHMP and ETF Rapporteurs and Secretariats. The Board endorsed the recommendations and highlighted in particular the stepwise approach for expanding the scope of OPEN. A question was raised on whether veterinary medicines would fall under the remit of the AMA and of IntCoP. EMA clarified that the AMA would only focus on human medicines. While the IntCoP in its initial phase will focus primarily on issues relating to medicines for human use, veterinary agencies can be added a at later stage.

B.13 Agile transformation progress update

The Board noted an update on the Agile transformation and progress on implementation since the last Board meeting, the goals for 2022 and the proposed protocol for selection of National Competent Authority and Industry Subject Matter Experts.

Building on the successful start and the first round of Agile ceremonies in 2021, the main goals of 2022 will be to ensure consistent and continuous optimization and operationalise of the Agile ways of working. The 2022 Workplan provides an overview of the agile transformation activities for 2022 and how it supports IT delivery. The Portfolio objectives will be formalised and transformed into a Roadmap to be communicated with stakeholders and partners. Metrics will be applied to measure the success of agile implementation and an audit process will be launched to monitor the application of the safe agile methodology.

Effective communication to external stakeholders is also envisaged. As a first step, a Network IT Portfolio website was launched following the end of the first cycle of Agile ceremonies. The publication of the first NPAG newsletter and a calendar of Agile ceremonies were included. In addition, a very successful first system demo session was organised to the public on 15 March and dedicated meetings with industry associations and NCA IT Directors are planned in April. In line with the new Agile approach, a new Network Portfolio report has been established (in replacement of the EU Telematics report, agenda item C1). It will complement the various Agile ceremonies (and their summaries) which provide more transparency and more regular insight into the progress made with the Network Portfolio. The main mission by the end of 2022 is to ensure that the whole portfolio for 2023 will be fully agile and based on value streams and the agile methodology.

A new phase of the Agile transformation has started with the launch of the Value Streams. Value streams help to organize the portfolio into sub-portfolios to support long-term strategic goals and have assigned business owners with fixed budget and resources. A major part of the portfolio has already transitioned into this new structure and have been organised into five different Value Streams: Agency Management; Research and Development; Product Lifecycle Management; Monitoring; Technology Lifecycle Management and Information Security. The Value Stream leaderships were appointed and introduced at the Strategic Portfolio review. In the scope of Agile portfolio for 2022, Value Streams and Epics (work packages) were acknowledged and agreed. The Epics that depend on shared technology, such as IRIS/SPOR, were highlighted and essential NCA Product Owners (POs) and NCA/Industry Subject Matter Experts (SMEs) were identified. A new protocol has been designed for POs/SMEs from the network and external stakeholders (NCAs, Industry, patient organisations, academia, etc.) to be nominated to participate in Product Teams at the execution level. Product Owners are responsible for

outcomes for a project. The role of an SME is to provide input on a specific business process and to assure consistent process enhancement upon request from the Value Stream. Experts from industry and other stakeholders will have an opportunity to become more closely involved in the development of solutions. The process ensures an Agile approach, as well as transparency, consistency and balanced representation. The Value Stream leadership with the support of Portfolio Board will identify the need for NCA SME input and/or an NCA Product Owner and will set up a call for nomination based on specific criteria related to the role. On-boarding session and training is foreseen for selected SME/POs. The EMA informed that the SME protocol is formalised will also be presented to the HMA in early May. The final protocol will be presented to the Board for endorsement at a later stage.

The Chair asked for a clarification on the start for the call for nomination for SMEs. EMA clarified that the process will be gradual. The first calls for nominations will be launched after the HMA meeting

B.14 Stakeholder engagement biennial report: engaging with patients, consumers, healthcare professionals and academia

[EMA/MB/138446/2022, EMA/562976/2021] The Board noted the biennial 'EMA Stakeholder Engagement report: engaging with patients, consumers, healthcare professionals and academia' for 2020-2021.

The Board was informed about the background and the major highlights of the report, which was first requested by the MB in 2007 to have an annual overview of the Agency's interactions with patients, consumers, healthcare professionals and academia. Because of the Business Continuity Plan, since 2018 the report has been prepared biannually and, given the positive feedback, this frequency will be maintained in the future. The report describes the stakeholder activities during the COVID-19 pandemic, and the regular interactions with patients, consumers, healthcare professionals and academia in the period 2020-2021. It also outlines future EMA activities with these stakeholders which includes strengthened engagement during public health crises as required by the EMA's extended mandate, expanding the collection and use of patient experience data in medicines development and regulatory decision-making and revising the EMA's framework for interaction with healthcare professionals and their organisations. An industry engagement report will also be circulated to members ahead of the June MB meeting.

List of written procedures finalised during the period from 26 November 2020 to 12 February 2021

- Consultation no 12/2021 on the appointment Konstantina Alexopoulou as CHMP member as proposed by Greece ended on 3 December 2021. The mandate of the nominee commenced on 4 December 2021.
- Consultation no 01/2022 on the appointment of Maria Grazia Evandri as CHMP alternate as proposed by Italy ended on 1 February 2022. The mandate of the nominee commenced on 2 February 2022.
- Consultation procedure for the adoption of the updated version of "EMA framework for interaction between EMA and patients and consumers and their organisations", held on 6 January 2022. The procedure was adopted.
- Consultation procedure for the endorsement of the mandate of the ACT EU Steering Group document, held on 17 January 2022. The procedure was endorsed.

- Consultation procedure for the endorsement of the Joint Controllership Arrangement for the Union Product Database document, held on 20 January 2022. The procedure was endorsed.
- Consultation procedure for the adoption of the minutes of the 114th Management Board meeting, held on 14 February 2022. The procedure was adopted.

Documents for information

- Report on EU Telematics
- Feedback from the Heads of Medicines Agencies
- 2021 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2021
- 13th six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2021
- Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2021
- Outcome of written procedures finalised during the period from 25 November 2020 to 18 February 2022
- Summary of transfers of appropriations in budget 2021 and 2022
- EMA working document on building 2022

List of participants at the 115th meeting of the Management Board, held in a hybrid format on 16-17 March 2022

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová *(member)* Jiří Bureš (*alternate*)
Croatia	Siniša Tomić (*member*)
Denmark	Lars Bo Nielsen (*member*) Mette Hansen *(alternate)* Nikolas Jørgensen *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk (*membe*r)
Ireland	Lorraine Nolan (*member*) Rita Purcell *(alternate)*
Greece	*Apologies received from Greece*
Spain	María Jesús Lamas Diaz *(member)* César Hernández *(alternate)* Sonia García Pérez (*observer*)
France	Christelle Ratignier-Carbonneil (*member*) Jean-Pierre Orand *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta (*alternate*) Manuela Bocchino (*observer*)
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akuličs *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Mátyás Szentiványi *(member)* Beatrix Horvath *(alternate)*
Malta	Anthony Serracino-Inglott *(member)* John Joseph Borg *(alternate)*
Netherlands	Paula Loekemeijer (*member*) Tina Leguijt (*alternate*) Michiel Hendrix *(observer)*
Austria	Thomas Reichhart *(alternate)*
Poland	Grzegorz Cessak (*member*) Marcin Kolakowski *(alternate*)
Portugal	Rui Santos Ivo *(member)* Maria João *(oberver)*
Romania	Razvan Prisada *(member)* Felicia Ciulu Costinescu (*observer*)
Slovakia	Peter Potúček *(member)* [1]
Slovenia	Momir Radulović *(member)*

	Participants
Finland	Eija Pelkonen *(member)*
Sweden	Bjorn Eriksson (*member*) Asa Kumlin Howell *(alternate)* Hannes Eintrei *(observer)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 6, B.3, B.4, B.5, B.10, B.12.*

European Parliament	*Apologies received for EP member* Anthony Borg
European Commission	Andrzej Rys *(alternate)* (DG SANTE) *Irene Norstedt (alternate) (*DG RTD*)* Kristof Bonnarens (DG SANTE) (*observer*)
Representatives of patients' organisations	Marco Greco (*observer*)
Representative of doctors' organisations	Wolf Dieter Ludwig
Representative of veterinarians' organisations	Nancy de Briyne
Observers	Runa Hauksdottir Hvannberg (*member*) (Iceland) Vlasta Zavadova (*member*) (Liechtenstein) Audun Hågå (*member*) (Norway) Marit Hystad (a*lternate*) (Norway) Sindri Kristjansson *(observer)* (Iceland)
HERA observers	Maja Leon Grzymkowska Philipp Wolfgang
EFSA observer	Gian Luca Bonduri

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Melanie Carr Nerimantas Steikūnas Fergus Sweeney Hilmar Hamann Anthony Humphreys Alexis Nolte Pierre Pradal Stefano Marino Martin Harvey Maria Alves Hilde Boone Marco Cavaleri Monica Dias Manuela Mura Juan Garcia Riccardo Mezzasalma Marie-Agnes Heine Frances Nuttall Apolline Lambert Olga Oliver-Diaz