14 December 2022
EMA/MB/815892/2022 - Adopted
Management Board

Minutes of the 117th meeting of the Management Board

Held on 6 October 2022

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting, with some Board members joining virtually. The Chair asked for confirmation of the number of participants and of the quorum and received this assurance from the Management Board secretariat. The Chair confirmed the validity of the meeting and welcomed the new alternates for France, Paule Carnat-Gautier, for Spain, Consuelo Rubio Montejano, for the Netherlands, Aimad Torqui and for Slovakia, Marián Gajdoš. A new alternate representatives of DG SANTE, Anna Eva Ampelas, was also confirmed.

The Chair informed the Board that the MB (Management Board) Topic Coordinators for the Programming document of the previous year, Rui Santos Ivo and Grzegorz Cessak had agreed to continue their engagement also for the 2023 EMA's Programming Document. In addition, the Chair informed that two Board members, Christelle Ratignier Carbonneil and Despoina Iatridou, have also expressed an interest to be Topic Coordinators.

1. Draft agenda for 6 October 2022 meeting

[EMA/MB/598368/2022] The Board adopted the proposed agenda 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 agenda were identified concerning topics *B.6 Revised Cooperation Agreement for ETF (Emergency Task Force) scientific advice remuneration* and *B. 8 Update of the CHMP and CAT rules of procedure.* 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 return to this issue.

Members were asked to declare any specific interests that could not be drawn from their 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 116th meeting, held on 15-16 June 2022 adopted via written procedure

[EMA/MB/592684/2022] The Board noted the final minutes, adopted by written procedure on 6 October.

A. Points for automatic adoption/endorsement

A.1 Amendment to Management Board decision on the EMA policy on protecting the dignity of the person and preventing psychological harassment and sexual harassment

[EMA/MB/373855/2022; EMA/MB/854173/2016; EMA/MB/259770/2022] The board adopted the amendment to the Management Board decision on the EMA policy on protecting the dignity of the person and preventing psychological and sexual harassment, which explains more specifically and updates how confidential counsellors for staff may appointed. EMA appointed *interim* internal confidential counsellors in 2018 and have renewed them pending the establishment of a formal inter-agency network of confidential counsellors. The current amendment of the Policy gives EMA the option to launch a call for expression of interest internally to guarantee the long-term continuation of the role of confidential counsellors at the Agency, while keeping the option to appoint such counsellors following a call at inter-agency level.

A.2 Management Board decision on application by analogy of Commission Decision C (2022) 1715 final of 24 March 2022 on home leave for officials, temporary staff and contract staff serving in a third country

[EMA/MB/574561/2022; EMA/MB/574554/2022] The board adopted a decision on application by analogy of Commission Decision C (2022) 1715 final of 24 March 2022 on home leave for officials, temporary staff and contract staff serving in a third country. The Commission Decision increases the amount of home leave for such staff.

B. Points for discussion

B.1 Highlights of EMA's Executive Director

The Board noted an oral update covering the Clinical Trial Information system (CTIS), COVID-19 status update, the regulatory and coordinating actions arising from the Monkeypox outbreak, EMA's activities with EU institutions and agencies, international cooperation, establishment of an EMA Data Board, information on face-to-face meetings, some challenges encountered with international transfer of personal data originating from EudraVigilance, progress of the Tactical Group on resourcing, information on World Antimicrobial Awareness Week and internal organisational changes at the EMA.

In relation to CTIS it was noted that during the transition phase, most clinical trials submitted through the system have been approved successfully from start to finish. The Board were informed that technical issues have emerged and have been discussed in various fora including the Clinical Trials Coordination Group (CTCG) and ACT EU Steering Group. It was agreed that the key focus and priority is the preparations for the mandatory use of CTIS as of 31 January 2023. EMA will continue to be transparent and provide the Board with regular updates.

The Board was informed on the Agency's recent activities related to the response to both COVID-19 and monkeypox. It was noted that the monkeypox outbreak is the first new Public Health Emergency of International Concern (PHEIC), declared by the WHO on 23 July, since EMA's extended mandate came into operation. Consequently, EMA has adapted quickly to the formal requirements in the context of Regulation EU 2022/123. Imvanex was formally authorised as the only vaccine for prevention of monkeypox and Tecovirimat has been approved currently as the only antiviral therapeutic. Both products were included in the list of critical medicines for the treatment and protection against monkeypox that was adopted by the Executive Steering Groups on Shortages of Medicines (MSSG) on 23 August 2022. ETF also provided recommendations on the possibility of a dose-sparing intradermal administration of Imvanex in cases where there was limited supply. in addition to the actions identified above, the ETF was formally expanded to include monkeypox related activities and has been working on coordinating and supporting clinical studies to treat or prevent monkeypox.

In the area of EU cooperation, EMA hosted, in September, a delegation from the European Parliament's Special Committee on COVID-19 pandemic (COVI), including the Chair and 8 Members of the European Parliament (MEPs). COVI was set up in March 2022 to prepare a report on 'lessons learned' and recommendations on how to make EU better prepared for future crises. The COVI delegation visited the Agency to better understand the key role it had played during the COVID-19 pandemic. EMA was also invited to present to an informal meeting of the Health Ministers (EPSCO council) on 7 September on the latest COVID-19 assessments and the Agency's efforts to combat disinformation and vaccine hesitancy. EMA also attend the HERA Board meeting at ministerial level which took place the same day. The Heads of EU Agencies meeting was also due to take place on 7 October, including a session on exchange of views on lessons learned for crisis management and communication. The EMA's Executive Director will have her annual exchange of views with the European Parliament's ENVI Committee on 25 October 2022. The Board was also informed that a Memorandum of Understanding (MoU) between HERA and EMA is being finalised and is expected to be signed in the coming weeks. At the international level, EMA has been reappointed for another three-year term as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) and the next face-to-face plenary meeting will be hosted by the Health Products Regulatory Authority (HPRA) in Dublin. In the context of recent Ebola outbreaks in Uganda, EMA is actively engaging with the WHO and relevant regulators in affected countries. There continues to be interest from EMA's international partners on the ETF and CHMP assessments of the COVID-19 and monkeypox vaccines, facilitating greater international reliance.

The Agency has formed an internal Data Board to further data governance at EMA. This was recommended following an internal audit on data governance in 2021. The EMA Data Board will deliver recommendations for improved data governance within EMA and will develop an EMA Data Strategy. An issue with international transfer of some sensitive data from EudraVigilance system is under investigation with the US authorities involved with this issue. Regular updates have been circulated to the Heads of Medicines Agencies, Pharmacovigilance Risk Assessment Committee (PRAC) and the EudraVigilance Data Protection Contact Points and will be provided to the Management Board.

The HMA/EMA Tactical Group on Resourcing has been working extensively since its initial meeting and have agreed concrete activities to help address the resourcing bottlenecks and improve process efficiency. The group will focus on 3 actions in the initial phases in the area of oncology. With regards to face-to-face (f2f) meetings at EMA, the pilot has been completed successfully and a mix of f2f and virtual meetings will take place going forward. The Management Board Chair suggested that from 2023 onwards, 1-day Board meetings would be conducted virtually, and 1.5-days meetings would be organisedf2f. The Board noted the proposal. The Board also welcomed the appointment of Franck Diafouka as *ad interim* Head of Audit, following resignation of the previous Head of Audit. The Audit

team will deliver its core auditing activities as per the annual audit plan approved by the Management Board in December 2021.

EMA's initiative on extending shelf-life of vaccines was commended by a Board member as this will assist in ensuring that the timing of supply can better meets the needs. EMA confirmed that it is liaising closely with companies to provide data as early as possible to approve the extension of shelf-life variations. In response to a question on the formation of the internal EMA Data Board, EMA explained that this is an internal strategic group initially tasked to provide direction across the data life-cycle within EMA. A gap had been identified in EMA's internal governance structure following an internal audit. The group will act as an internal forum to develop EMA's views and agree EU positions on data standards. It will also contribute to the review of the Big Data Steering Group and EU Network Data Board mandates with a view to subsequently working on the overarching EU Network data strategy.

B.2 Report from the European Commission

The Board noted an oral update from the representatives of DG SANTE and DG Research and Innovation (DG RTD) on their latest activities with relevance to medicines development and regulation.

The representative of DG RTD informed the Board that a Horizon Europe call for proposals on methodologies for effective use of real-world data in regulatory and HTA decision-making has recently closed and the projects that will eventually be selected in 2023 will entail close collaboration with medicines regulators. The Innovative Health Initiative (IHI) Joint Undertaking has come into operation following 14 years of experience with the Innovative Medicines Initiative. The IHI has been extended in scope to include the medical devices industry, as innovation is increasingly coming from integrated products. A lot of research projects under IHI will also require early engagement of the consortia with medicines regulators. Several IHI calls have already been launched and many more will start in 2023.

As regards support to large clinical trials, the focus of DG RTD is in the following six areas: 1) establishment of clinical trial networks and coordination of studies (e.g. ECRAID); 2) maximising public health impact through adequate trial design; 3) collaboration with EU Member States and agencies (e.g. EDCTP3 Global Health Joint Undertaking); 4) strengthening the knowledge by academia of the regulatory environment (e.g. the STARS project and the ACT-EU programme); 5) supporting through research infrastructures, such as the European Clinical Research Infrastructure Network (ECRIN) and the European Rare Disease Registry Infrastructure (ERDRI); 6) preparation of future work programmes for IHI and Horizon Europe. Input from Board members on research needs that should be addressed in the IHI work programme 2024-25, which will start to be developed early next year, is welcomed by DG RTD.

The representative of doctors' organisations noted that it still takes on average one or two years to launch clinical trials in Europe, while the timeframe for the EU projects is usually five years long, which leaves little time to generate adequate results. In addition, EU regulations such as the GDPR, the Clinical Trials and Medical Devices Regulations can generate additional work and costs for researchers. The representative of DG RTD acknowledged the point and added that for this reason the focus of the European Commission is increasingly on clinical trials networks and platforms, as this should help reduce timelines for ethic committee approval and patient recruitment, rather than funding specific clinical studies. The representative of veterinarians' organisations inquired about the focus on One Health in the research work of the European Commission. The representative of DG RTD confirmed this is a priority and that a One Health AMR networks with MS research funding organisation are currently in development.

The representative of DG SANTE provided an update on the revision of the general pharmaceutical legislation and the Orphan and Paediatric Regulations, the internal reorganisation of DG SANTE, the launch of the preparatory process for a targeted revision of the Variations Regulation to be published at the end of 2023, and the preparatory study supporting the report on trends in Directive 2011/62/EU (Falsified Medicines Directive) which is due to be published by February 2024.

Board members inquired about the preparation of the EMA Fees Regulation and the involvement of National Competent Authorities in the EU research projects on real world data. The representative of DG SANTE explained the legal proposal on EMA fees could be adopted by the end of the year (Q4 2022). The representative of DG RTD promised that as soon as the RWE projects are awarded, their details will be shared with EMA. Board members congratulated the previous alternate representative of DG SANTE, Dr Andrzej Rys, on his new role at DG SANTE and thanked him for his contribution to the work of the Management Board since 2014.

B.3 EMA Mid-year report 2022 from the Executive Director (January – June 2021)

[EMA/MB/785153/2022; EMA/697686/2022] The Board noted the EMA mid-year report 2022 from the Executive Director.

The report provides an update on the Agency's implementation of its work programme in the first half of this year, including trends in the workload, budget performance and staffing. EMA achievements and results described in the report include the work on COVID-19, the launch of CTIS and the systems under the new Veterinary Medicines Regulation, the implementation of the EMA's extended mandate, the work on AMR and Real-World Data, the implementation of the Agile Methodology for information management projects, the strengthening of the EU Network Training Centre and the work on internal digital transformation. The number of initial Marketing Authorisations for 2022 was 17% lower than 2021, while PRIME, ATMP classification and variation procedures remain stable compared to the previous years. The workload for scientific advice and inspections has increased. Initial Marketing Authorisation procedures for veterinary medicines are also increasing. Budget performance is healthy, with revenue in line with updated forecasts and expenditure implementation rate in line with budgetary KPIs. An occupancy rate by end of the year of 100% is expected for Temporary Agent staff, while it is projected that the rate for Contract Agent staff will be approximately 96%. The latter category of staff is subject to a higher turnover. The number of applications per selection procedure has reduced compared to the same period in 2021 and the Agency is monitoring whether this represents a trend.

The representative of doctors' organisations emphasised the need to keep working on post authorisation evidence generation, including collaboration with HTAs, and asked why parallel scientific advice procedures with HTAs have been reduced. EMA explained that this is a temporary reduction due to the transition period until the HTA Regulation becomes applicable.

B.4 Update on implementation activities of EMA's extended mandate

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.

The update focussed on: i) the implementation activities around shortages of medicines including the European Shortages Monitoring Platform (ESMP); ii) the preparation for implementation of activities to monitor and mitigate shortages of medical devices; iii) data on the activities of the Expert Panels on

Medical Devices from March to September 2022, in compliance with reporting requirements set by art.30 (h) of Regulation EU 123/2022. As regards medicine shortages, all structures foreseen in the Regulation have been established and preparedness activities have focussed on assessing the impact of the war in Ukraine and most recently with potential shortages of thrombolytics. As regards the ESMP, a Working Group of the MSSG has been created in September 2022 and the project has started under the SAFe Agile way of working. As regards medical devices, a call for nominations to the Medical Devices Shortages Steering Group (MDSSG) will be launched with Member States in Q4 this year. As regards the expert panels, 27 applications for Clinical Evaluation Consultation Procedures were received and, after screening, it was decided to provide opinions for 6 procedures, which were delivered according to the legal timelines. One Performance Evaluation Consultation Procedure application was received, and an opinion delivered on time.

Board members asked if the activities of the Executive Steering Group on Shortages and Safety of Medicines (MSSG) and its Working Party would also investigate the root causes of shortages, e.g., low competition, low prices, and parallel trade, and if the membership of the Shortages Steering Groups for medicines and medical devices should overlap. EMA explained that the root causes of shortages have been investigated by the European Commission in a recent study, whose findings are still being discussed in the EMA-HMA Availability Task Force. Root causes of shortages are also being analysed and discussed at the level of the SPOC WP (Single Points of Contact in NCAs). Formally the memberships of the Shortages Steering Groups must be established separately but it is anticipated that the membership will mostly overlap since many NCAs cover both medicines and medical devices. The Regulation also foresees cooperation between the MSSG and the MDSSG (Article 31).

B.5 Report from ETF Co-Chairs

The Management Board noted the oral report from the Emergency Task Force co-chairs.

The EMA co-chair provided an overview of the ETF activities since the start of the pandemic and under the extended mandate. As an advisory body to the CHMP, ETF has a membership based on expertise, including from clinical authorities, patients and health care professionals, and works on: rapid scientific advice and support to setting up multi-national clinical trials; review of scientific literature; public health recommendations, such as those with ECDC on COVID-19 heterologous use and boosters. ETF provided support to CHMP for Article 5.3 opinions on many antivirals and at present is reviewing data on *Sabizabulin* for COVID-19 (article 18 procedure under Regulation 123/2022). As of September 2022, ETF has held 226 meetings and provided 201 scientific advices since the start of the pandemic. A webpage and guidance to industry on how to interact with ETF have been developed and as of mid-October 2022 developers will be able to use the IRIS platform to provide data to ETF. As regards preparedness, ETF is working closely with WHO, ECDC and HERA to monitor possible or future outbreaks and to provide scientific advice to applicants developing the most critical pathogens.

The CHMP co-chair noted the ETF is working very efficiently after more than two years of operation and it has been particularly helpful to support CHMP is adopting Rolling Reviews, thanks to the ETF work in between the CHMP monthly meetings. Many network experts attend the weekly ETF meetings and regular reports are provided to the CHMP and PRAC.

Several board members congratulated the ETF on its crucial work and leadership during the pandemic and asked whether its scientific advice activities, particularly in between health emergencies, would not duplicate the work of the Scientific Advice Working Party or create confusion for industry. The ETF co-chairs explained that the ETF scientific advice procedures in times of preparedness was expected to be very limited, e.g., 10 procedures per year, focussing only on pathogens that might lead to public health emergencies in future and cannot be easily developed (e.g., on the WHO Global Priority

Pathogens List) especially if developed by academia. Most of the other products for infectious diseases would still be handled by SAWP.

Some members inquired how chemical, biological, radiological, and nuclear (CBRN) threats would be considered by ETF. ETF is engaged in horizon scanning activities and has adopted a list of products that can be used as CBRN countermeasures in case of attacks. If such an emergency is declared, a different set of expertise for ETF would have to be created in order to provide the required support to developers.

B.6 Revised Cooperation Agreement for ETF scientific advice remuneration

[EMA/645415/2022; EMA/MB/700235/2022; EMA/697270/2022] The Board adopted a revision of the Cooperation Agreement for ETF scientific advice remuneration.

EMA explained that the possibility for the ETF members to conduct scientific assessments as coordinators in the context of scientific advice procedures outside of a declared public health emergency is not expressly foreseen in Regulation (EU) 2022/123. Following a thorough assessment, it has been concluded that Article 57(1)(n) in combination with Article 62(3) of Regulation (EC) No 726/2004, and together with an explicit reference to these services in the Cooperation Agreement signed with the National Competent Authorities constitute the legal basis. The adopted revision consists of the addition of a paragraph in Section I of Annex I clarifying that the Cooperation Agreement covers the scientific advice services provided by NCAs to the Agency through ETF members appointed as scientific advice co-ordinators outside of a declared public health emergency.

The representative of DG SANTE noted that this topic should be further considered in the context of the revision of the general pharmaceutical legislation. One member inquired about the remuneration level for ETF and the EMA clarified that the approach is the same as for the ordinary scientific advice.

B.7 EMA Independence policies:

- **Revision of EMA policy on the handling of declarations of interests of scientific committees' members and experts (Policy 0044)**
- **Revision of EMA policy on the handling of competing interests of Management Board members (Policy 0058)**

[EMA/MB/785279/2022] The Board noted an update on the revision of EMA independence policies; EMA policy on the handling of declarations of interests of scientific committees' members and experts (Policy 0044) and EMA policy on the handling of competing interests of Management Board members (Policy 0058). EMA presented to the Board a proposal for the general principles guiding the revisions of EMA's two independence policies for competing interests of Scientific Committees' members and Experts and of Management Board members. In addition, a similar revision was proposed for the MB Decision on rules concerning the handling of declared interests of EMA staff. This review follows the entry into application of EMA's Extended Mandate Regulation (Regulation (EU) 2022/123) and the new Medical Device and in vitro Medical Device Regulations (Regulations (EU) 2017/745 and 2017/746), which increase EMA's role in the Medical Device (MD) and IVD (in vitro Medical Device) areas. The CHMP and the CAT, where appropriate, are responsible for preparing the scientific opinions of the Agency related to the consultation procedure initiated by notified bodies on specific categories of

medical devices, e.g., companion diagnostics, devices made of substances that are systemically absorbed or related to consultation procedures initiated by the European Commission on the regulatory status of 'borderline products'.

Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, has established 3 new entities, the Executive Steering Group on Shortages and Safety of Medicines (MSSG), the Executive Steering Group on Shortages of Medical Devices (MDSSG) and the new scientific body, the Emergency Task Force (ETF). Since March 2022, the Agency has also taken on the support for the expert panels on medical devices (EXPAMED). Specific provisions in Regulation (EU) 2022/123 refer to the obligation of the Agency to ensure the independence of the work of these new entities.

An overview of the proposed main changes to Policy 0044, Policy 0058 and MB Decision for handling declared interests of EMA staff were presented. The definition for "medical device company", replacing the current definition of "medical device sector" (linked to ATMPs) and the main principles for a phased approach for declaring and handling the possible medical device interests were described. EMA will request members of the CHMP, CAT, ETF, MSSG and MDSSG to declare any medical device interests in the Agency's current declaration of interest (DoI) form as of 1 January 2023. Similarly, the Agency is also proposing to ask Management Board members to declare any medical device interests in their DoI form. The Agency will check the updated DoI forms and apply the necessary restrictions, where relevant. Moreover, EMA is currently working on a new Experts Management tool, which will include a new DoI form. This updated DoI form will also include a dedicated new section to declare medical device interests and the necessary restrictions will be applied after review.

For the Agency's staff, following consultation with the Staff Committee on the proposed new rules, EMA is proposing to ask all EMA staff members to declare any medical device interests in the staff DoI form, and relevant restrictions will be applied as appropriate. Medical device related declarations are however already being requested from newly EMA recruited staff, and their managers apply restrictions where new staff are going to be involved in medical device related procedures.

The Management Board noted and agreed the proposed main principles for the revision of independence policies and the MB Decision on staff rules so that EMA can implement the detailed revisions to these documents for subsequent adoption by the MB through written procedure in order to prepare for implementation. Once adopted the documents will be published on EMA's website.

B.8 Update of the CHMP and CAT rules of procedure

[EMA/637844/2022; EMA/CAT/45446/2008; EMA/MB/728451/2022] The Board adopted a favourable opinion on the proposed amendments to the Rules of Procedures of Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT) in accordance with Article 61(8) of Regulation (EC) No 726/2004. The revised Rules of Procedures (RoP) will apply as of 20 October 2022.

Following the entry into force of the new Medical Device and in Vitro Diagnostics Regulations (Regulations (EU) 2017/745 and 2017/746), changes to the RoP of the CHMP and the CAT are required in order for the legislative provisions related to the work of the EMA in the area of medical devices to be fully reflected. Additional amendments have been included to reflect the possibility of the CHMP to liaise, where appropriate, with the ETF following the entry into force of Regulation (EU) 2022/123. EMA also took the opportunity to introduce minor changes in the CHMP RoP for consistency reasons. An overview of the above-mentioned modifications included in both CHMP, and CAT rules of procedures were presented to the Board.

The revised CHMP RoP had been adopted by the CHMP and the CAT. Following the favourable opinion received from the European Commission and also from the Management Board during their October meeting, the revised Rules of Procedure will be published on the EMA website.

B.9 Review of activities of the Working Parties of the EMA - Update from the Implementation Task Force

[EMA/MB/785186/2022] The Board noted an oral update from the Implementation Task Force of the new operational model for the Review of the Activities of the Working Parties of the EMA.

The Board was reminded of the benefits of the new model which has been designed to deliver the strategic, tactical, and operational goals of the network. The new model supports product development while ensuring strong and managed interaction with relevant stakeholders. Its architecture combines groups based on expertise, and inclusive membership through the European Specialised Expert Community (ESEC), to provide for optimal information flow and knowledge management. The new Working Party model is being implemented in a two phased approach. EMA reported on the lessons learned from the successful implementation of the first phase, which started in Q1 2022 and focused on the reorganisation of the Working Parties (WPs) for the Nonclinical, Methodology and Clinical Domain. The new model provides greater flexibility in terms of expertise and activity. There has been a high level of engagement across the regulatory network and many experts interested in joining WPs, Operational Expert Groups (OEGs) and DGs as well as taking part in training. Most WPs have adopted their workplans for 2022 and are starting to prepare their 2023 work plans. Drafting Groups (DGs) are being formed to draft guidelines based on the adopted workplans. The Board was informed of the outcome of the pilot phase for the Oncology ESEC with a membership that was nominated through a wide participation of assessors and experts with clinical expertise and interest in the regulation of oncology drugs. The Oncology ESEC main deliverables are aimed to build knowledge in the Network through trainings and strive towards optimising cancer treatments and patients' timely access to new medicines. The ESEC pilot for oncology gives confidence for expanding to more expert communities. The second phase of the implementation plan is intended to focus on the establishment of the new expertise-based model for the Working Parties (WPs) within the Quality Domain. This new model is expected to address the expertise needed to deliver the workplan of the Quality Domain while at same time increasing knowledge sharing through wider listener participation, for sharing experience and learnings through the ESEC.

An extensive discussion on this second phase took place after the presentation. A number of Board members expressed views in support of member state representation in an expertise-based model for BWP and QWP. Other issues highlighted by Board members included the need for alignment of approach across all working parties with an "as needed" expertise composition. Resulting from this discussion and in view of the letter from the chairs and vice-chairs of the BWP and QWP requesting additional transitional time in order to take into account the high workload of the two WPs concerned, it was agreed that further discussions will take place with the Chairs and vice-Chairs of the BWP and QWP. The discussion will further clarify how the expertise-based model would be applied to the operations and future structures of the BWP and QWP and consider transition timelines in light of their request. The MB Review Group will continue to update the Board as to the outcome of these discussions and follow up actions being pursued by the implementation team.

B.10 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation

[EMA/MB/699655/2022; EMA/699656/2022] The Management Board noted a progress report on the implementation of IT systems required by the EU Clinical Trial Regulation (CTR).

Since the successful launch of the Clinical Trials Information System (CTIS) on 31 January 2022, sponsors can apply for clinical trial approval through the Clinical Trial Regulation (CTR) via CTIS or can continue via the Clinical Trials Directive (CTD). Up to the 30 September, 85 clinical trial applications had been authorised and 147 are under evaluation. EMA provided key metrics on the current use of the CTIS, including the number of substantial modification applications filed, the clinical trial types and therapeutic areas, and the number of Concerned Member States involved. For comparison, Clinical Trials Directive metrics were also presented with completed data until the end of September. The key objectives of the transition year are to allow all sponsors and Member States a smooth transition period and for users to familiarise with the system and identify any potential issues. Some users have experienced technical difficulties with the system, this was somewhat anticipated. These have required intervention by the technical team to progress. One issue impacted the CTIS Public Portal leading to an unintentional publication of an approved clinical trial which was designated for a deferred publication. The issue has been addressed in the meantime. Another technical challenge encountered was related to a large and complex clinical trial from a sponsor which incurred delays and required intensive support from the Reference Member State, EMA and sponsor itself due to bugs in the system. Work arounds were successfully deployed, and the trial has now been authorised by 11 Member States. The definitive resolution of the root causes are in progress and is planned for imminent deployment. The cooperation between Member States, sponsors and EMA together with the excellent reporting of issues were crucial to finding successful resolutions.

The Board were reminded of the CTIS Delivery plan. The initial phase of Hypercare concluded in July 2022 and is now continued in an enhanced transition phase until January 2023. The ACT EU Steering Group was mandated by the HMA and the Board to ensure that CTIS is optimised by overseeing the CTIS implementation delivery plan. For Q4 2022, the baseline scope of the delivery plan consists of known problems and technical items that are required to ensure the system is stable, performs well and can be scaled up for the mandatory use as of January 31, 2023. Therefore, the current delivery plan will mainly concentrate on implementation of the additional high priority disaster recovery scenarios, find resolutions for high priority issues coming from incidents in production or from the backlog of problems and find manual workarounds for blocking issues. Furthermore, assessment of the areas that require refactoring to increase maintainability will be included. The progress on the implementation of the burndown is proposed to be monitored bi-weekly and a status update as of 28 September was provided to the Board. In addition, the planned October release to resolve 17 issues was presented. To ensure successful CTIS delivery, the supplier team is being adapted and extended in order to be able to effectively meet the needs of the transition period. The Agency's team is also being reinforced in parallel. A total 20% capacity increase is expected by end of October 2022.

The Agency continues to provide hands-on support to Member States and Sponsor users including by strengthening its collaboration with Clinical Trials Coordination Group (with the CTCG chair attending the CTIS Situation room meetings), training events as well as increased and targeted communication to the CTIS user community. Monthly walk-in clinics have been scheduled until the end of the year, with CTIS experts answering users' questions related to system functionalities. Bite-size talks on specific topics are also scheduled on a regular basis. The first inaugural CTIS Forum will be held on 12 October 2022, bringing the wider CTIS stakeholder community together to discuss and provide updates on the system. On 1 July 2022, a CTIS webinar took place with over 1000 viewers where the main discussion revolved around lessons learned from Member State and sponsor experience with CTIS. The next webinar event is scheduled on 16 November 2022. A total of 24 online CTIS training modules

have been published on EMA website and monthly Organisation Management Service (OMS) support sessions have been launched for CTIS users. On 14 July 2022, EMA hosted a dedicated workshop with CTIS user community on the draft guidance on the protection of personal data and commercially confidential information (CCI) in CTIS. EMA will consider the feedback provided during the workshop, in addition to the contributions from the 5-month public consultation.

The member from Sweden presented the Member States perspective on CTIS implementation and recognised that the focus remains on continuing to stabilise the system including the resolution of critical issues before submission of initial clinical trial application through CTIS becomes mandatory on 31 January 2023 as highlighted in the EMA delivery plan for Q4 2022. A recent survey by the European Commission (EC) highlights concerns from sponsors on Member States' (MSs) readiness, and also on CTIS. Therefore, the ongoing collaboration between Sponsors, MSs, EMA, EC remains critical for a successful transition and harmonised implementation of CTR and CTIS. Recent and planned communications to sponsors and users is key to reassure them that the Network is focussed on the stabilisation ahead of the mandatory use of the system. EMA confirmed and concluded that it is working collaboratively with IT supplier and intensively with the Member States and sponsors to ensure an improved CTIS user experience with no blocking issues for core processes by the time of compulsory use. A CTR 'get ready' communications campaign will be launched in October. Additionally, EMA proposed to defer any decisions on 2023 delivery of new functionalities to the December EMA Management Board meeting.

A few members of the Board thanked EMA for their transparency on current issues. The representative of DG SANTE echoed the comments made on the excellent collaboration and acknowledged the increase in capacity to ensure the system is fully ready by end of January 2023, complying with the legal framework, in particular regarding the Minimum Viable Product (MVP). The representative of DG SANTE called also on Member States to step up and allocate further resources and shared the same concerns highlighted by Sweden. A question was raised with regards to long term planning of the system. EMA will do its outmost to ensure that the MVP will be ready and will prepare a high-level outline plan for the coming years. A member of the Board asked if there would be any testing on the possible large volumes of applications which may submitted from February 2023. A newly established Transition Task Force will conduct proactive testing of complex scenarios anticipating the high volumes of trial submissions to ensure the system will scale and perform under the expected load under the mandatory use of CTIS.

B.11 Update on Accelerating Clinical Trials in the EU (ACT EU)

The representative from Sweden provided an update on the initiative Accelerating Clinical Trials in the EU (ACT EU) and its key developments.

On 30 August, the ACT EU Steering Group adopted the multi-annual ACT EU work plan for 2022 to 2026 and this was jointly published on the European Commission (EC), the Heads of Medicines Agencies (HMA) and the EMA websites together with joint press release. The work-plan highlights key focus areas such as innovation in clinical trials, robust methodologies, and collaboration across stakeholders into phased deliverables and timelines for 2022 to 2026. The ACT EU work-plan is structured in line with the ten priority actions identified in the ACT EU Strategy paper which were based on the recommendations of the European Medicines Agencies Network Strategy (EMANS) to 2025 and the European Commission's Pharmaceutical Strategy for Europe.

Some key achievements in 2022 were presented, including the activities undertaken to address the low uptake of the CTR such as the communication campaign to remind sponsors of the training available to address and the ACT EU sponsored multi-stakeholder workshop on decentralised clinical trials which was held on 4 October. In 2023, the main priorities will include: focus on CTIS and CTR training

activities and trouble-shooting any issues encountered by clinical trial sponsors; creating a support process aimed at academic sponsors to make the EU a more attractive region to conduct clinical research; establishing a multi-stakeholder platform to facilitate the evolution of the clinical trials environment and to find practical solutions to enable and drive change; modernising good clinical practice by supporting and implementing revised ICH guidelines in technology and clinical trial design; publishing a methodology roadmap to identify and prioritise key advances in clinical trial methods.

In addition to the work-plan, the Board were also informed about the preliminary analysis of CTR implementation survey where Member States readiness was flagged as the main concern ahead of those relating to CTIS. Following the success of the first ACT EU matrix meeting held in person at EMA on 19-20 September, it was agreed to organise this meeting as a yearly event to allow relevant Network experts to connect and collaborate. The main next steps of the ACT EU Steering Group will be to initiate delivery and realisation of the benefits of the main actions of the work-plan. A progress update on each key deliverables will be presented at the next EMA Management Board meeting.

B.12 Big Data Steering Group progress report

Due to time constraints the item was cancelled. The presentation was circulated for information after the meeting and written comments were welcomed.

B.13 Agile transformation and Portfolio progress update

[EMA/MB/762395/2022; EMA/762399/2022] 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.

The EMA provided an update on the Agile transformation and progress on implementation since the last Board meeting. The new Agile way of working and governance requires the pre-Agile governance bodies to transition to the new approach of ceremonies, governance bodies and external representatives joining Product Teams in Agile roles. Within Product Teams, the Agile role of Network Product Owner is to act as a business lead and to ensure the product roadmap aligns with the needs of the Network. The Network/Industry Subject Matter Expert contributes to the design and delivery of epics/products and ensures business requirements are understood, while developed solutions are fit for purpose. Several ceremonies organised in September with partners and stakeholders were presented.

As regards the implementation of the Information Management Portfolio, activities carried out in 2022 were presented under the four Portfolio Objectives 2022-2025: i) legislative priorities, including projects for CTIS, veterinary regulation and extended mandate; ii) data-driven Network, with a focus on enabling the use of ISO IDMP compliant data in human variation procedures (DADI); iii) digital Network, including adopting the IRIS, ServiceNow and SharePoint IT platforms; iv) cybersecurity and technology modernisation, including the implementation of a state-of-the-art 24/7 Security Operations Centre.

B.14 Update on preparation for implementation of Veterinary Medicinal Products Regulation

The Board noted an oral update from the DG SANTE representative and EMA on the implementation of the Regulation on veterinary medicinal products.

The representative of DG SANTE noted work is ongoing on the finalisation of the remaining Acts which needed to be in place before the date of application, based on the scientific advices of the Agency.

Work has started on the other delegated/implementing acts which need to be in place by 2025. Since the last Board meeting, the European Commission has adopted Commission Implementing Regulation (EU) 2022/1255 on the list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Currently, DG SANTE is finalising the adoption of detailed rules on imports of animals and products of animal origin required under Article 118 of Regulation 2019/6 and on a Delegated Act on the requirements for compliance with Good Laboratory Practice for veterinary medicinal products set out in Annex II of the veterinary medicines regulation. A draft report to the European Parliament and the Council on the feasibility of alternatives to Environmental Risk Assessment (monographs) under Article 156 is also under finalisation and should be published soon. Preparation for the Report to the European Parliament and to the Council on the situation with the medicinal treatment of equids and their exclusion from the food chain, including with regard to imports from third countries, under Article 158 has started and a tender for a supporting study should be launched in the first quarter of 2023.

EMA presented the ongoing work on two advices in preparation of implementing acts, i.e., the Advice on list of substances not to be used or used subject to certain conditions under the so-called 'cascade' and the Advice on the good manufacturing practice for veterinary medicinal products and active substances used as starting materials (by end of 2023). As regards the four databases: the Manufacturer and Wholesale Distributors database is finished and entering maintenance phase; the development of the Union Product Database has encountered some delays it will transition to agile governance in December; the Union Pharmacovigilance Database improvements are progressing well but are partially dependent on outstanding functionality of the Product Database; the Antimicrobial Sales and Use database will have a first launch of the submission module by end of the year. As regards legacy data submission in the Product Database, the national dataset completeness rate is 95% and NCAs are being contacted and supported individually to reach completion. Training and webinars to manage the change to the new system continue on a regular basis.

The representative of veterinarians' organisations thanked EMA and DG SANTE for the progress and noted that several questions have been received by their members regarding the strict interpretation of Article 106 concerning prescription only according to the Summary of Product Characteristics. Strict implementation of this article in practice can sometimes go against the responsible use principles or creates important ethical issues for the prescribing veterinarians, while national derogations can be applied individually by the national authorities to address the issue, this can lead to difference approaches between Member States.

List of written procedures finalised during the period from 08 June 2022 to 26 September 2022

During the period from 08 June 2022 to 26 September 2022, the Board was consulted 10 times via written procedure, of which 4 consultations concerned membership in the CHMP and CVMP, and 6 additional consultations, as listed below:

- Consultation no 06/2022 on the appointment of Nadya Ognyanova Vladimirova as CVMP member as proposed by Bulgaria ended on 24 June 2022. The mandate of the nominee commenced on 25 June 2022.
- Consultation no 07/2022 on the appointment of Alexandra Branchu as CHMP alternate as proposed by Luxembourg ended on 16 August 2022. The mandate of the nominee commenced on 17 August 2022.
- Consultation no 08/2022 on the appointment of Hjalti Kristinsson as CHMP alternate as proposed by Iceland ended on 24 August 2022. The mandate of the nominee commenced on 25 August 2022.
- Consultation no 09/2022 on the appointment of Finbarr Leacy as CHMP alternate as proposed by Ireland ended on 27 September 2022. The mandate of the nominee commenced on 28 September 2022.
- Consultation procedure for the adoption of the minutes of the 115th Management Board meeting, held on 14 June 2022. The procedure was adopted.
- Consultation procedure for the endorsement of the Protocol selection and Terms of Reference for Product Owners and Subject Matters Experts ended on 15 June 2022. The procedure was endorsed.
- Consultation procedure for the endorsement of "Joint Controllership Arrangement for the EudraVigilance Human (EV)" ended on 29 June 2022. The procedure was endorsed.
- Consultation procedure for the adoption of the Agency's final accounts for the financial year 2021 ended on 27 June 2022. The procedure was adopted.
- Consultation procedure for the adoption of Revision of Fee Implementing Rules VRA veterinary medicines, including annexes ended on 20 July 2022. The procedure was adopted.
- Consultation procedure for the adoption of the Amending Budget 01/2022 (AB01-22) ended on 19 August 2022. The procedure was adopted.
- Consultation procedure for adoption of the ETF composition for the COVID-19 and monkeypox PHE ended on 30 August 2022. The procedure was adopted.

Documents for information

- Feedback from the Heads of Medicines Agencies
- [EMA/MB/792353/2022] Outcome of written procedures finalised during the period from 8 June 2022 to 26 September 2022
- [EMA/MB/771230/2022] Summary of transfers of appropriations in budget 2022
- [EMA/MB/637332/2022, EMA/637333/2022] Fourteenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 January to 30 June 2022

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List of participants at the 117th meeting of the Management Board, held in person and virtually on 6 October 2022

Chair: Lorraine Nolan

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	*Apology received from Bogdan Kirilov (member)*
Czech Republic	*Apology received from Irena Storová (member)*
Croatia	Siniša Tomić (*member*)
Denmark	Mette Hansen *(alternate)* Brigitte Faber *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk (*member*)
Ireland	Rita Purcell *(alternate)*
Greece	Dimitrios Filippou (*member*)
Spain	María Jesús Lamas Diaz *(member)* Consuelo Rubio Montejano *(alternate)*[1]
France	Christelle Ratignier-Carbonneil (*member*) Paule Carnat-Gautier *(alternate)*[1] 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	John Joseph Borg *(alternate)* Caroline Muscat *(observer)*
Netherlands	Paula Loekemeijer *(member)* Aimad Torqui (*alternate*)[1] Michiel Hendrix *(observer)*
Austria	Thomas Reichhart (*alternate*)
Poland	Grzegorz Cessak (*member*) Marcin Kolakowski (*alternate*)
Portugal	Rui Santos Ivo *(member)* Maria João Morais *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Marián Gajdoš (*alternate*)
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(member)*
Sweden	Björn Eriksson (*member*) Åsa Kumlin Howell *(alternate)*

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points B.6 and B.8*

European Parliament	Karin Kadenbach *(member)*
European Commission	Anna Eva Ampélas *(alternate)* (DG SANTE) Irene Norstedt *(alternate)* (DG RTD) Martina Ciccarello (*observer*) (DG SANTE) Fergal O'Donnelly (*observer*) (DG RTD)
Representatives of patients' organisations	Marco Greco Virginie Hivert
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	Despoina Iatridou
Observers	Rúna Hauksdóttir Hvannberg (*member*) (Iceland) Vlasta Zavadova (*member*) (Liechtenstein) Audun Hågå (*member*) (Norway) Marit Hystad (a*lternate*) (Norway)

Guest speaker	Bruno Sepodes (ETF co-chair)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Melanie Carr Nerimantas Steikūnas Hilmar Hamann Anthony Humphreys Alexis Nolte Zaide Frias Franck Diafouka Stefano Marino Martin Harvey-Allchurch Steffen Thirstrup Maria Alves Hilde Boone Riccardo Mezzasalma Marie-Agnes Heine Frances Nuttall Marco Cavaleri Manuela Mura Dimitris Panidis Luc Van Santvliet Salvador Ruiz-Carrillo Apolline Lambert Sara Giorgi Marco Capellino Olga Oliver-Díaz Adeline Bessemoulin