26 June 2024
EMA/MB/17597/2023 corr.[1] - Adopted
Management Board

Minutes of the 118th meeting of the Management Board

Held on 14-15 December 2022

The Chair of the Management Board opened the meeting, which was held as a face-to-face meeting, with a few Board members joining virtually. The Chair welcomed the new alternate for France, Mr Franck Foures (Director General of the Agence Nationale du Médicament Vétérinaire).

1. Draft agenda for 14-15 December 2022 meeting

[EMA/MB/817029/2022] The agenda was adopted without amendments. A request had been sent to the MB Chair proposing to discuss the topic on Review Group on Working Parties. The MB chair indicated that the topic would be tabled at a next Board meeting in Q1 or Q2 2023.

2. Declaration of competing interests related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning topics *B.3 Programming 2023-2026 and B.10 CTIS planning 2023-2024.* The Secretariat informed the Board that all concerned members had been informed before the meeting.

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 117th meeting, held on 6 October 2022 adopted by written procedure

[EMA/MB/815892/2022] The Management Board noted the final minutes, adopted by written procedure.

1 The correction is an update in the List of Participants (shown at the end of this document), to reflect restrictions for some members, as announced and applied at the time.

A. Points for automatic adoption/endorsement

A.1 Revision of budget remarks for budget 2023

[EMA/MB/817029/2022] The Board endorsed an update of the EMA's budget nomenclature used in the Agency's Budget for 2023 in line with the Agency's Financial Regulation. The revision does not alter the amounts of the previously agreed budget.

A.2 Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2023

[EMA/MB/858314/2022] The Board endorsed the annual update of the financial compensation to National Competent Authorities (NCAs) for their participation in the linguistic checking of product related information in their respective national languages.
The updated flat hourly rate for 2023 is now set at €49.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update covering EMA's preparation for mandatory use of Clinical Trial Information system (CTIS), COVID-19 status update, EMA's activities with EU institutions and agencies, international cooperation, the 2022 annual meeting of PCWP and HCWP, EC/EMA action plan on paediatrics, progress of the HMA/EMA Tactical Group on resourcing and information about the new Experts Management tool.

CTIS has been a major focus for the Agency, and the Executive Director confirmed that CTIS is on track for its mandatory use as of 31 January 2023. EMA has been stepping up its resourcing and communication in order to resolve any problems and has provided support to users that were facing difficulties. Further discussion on the topic took place under agenda item B.10.

The HMA/EMA Tactical group on resourcing has had regular meetings since the last Board meeting and have agreed on a number of actions for addressing the resourcing issues. This included a proposal to expand the use of multinational assessment teams (MNAT) to line extensions and extension of indication applications for products that had not used MNATs in the pre-authorisation phase. The Board supported the proposal and agreed to endorse the extended MNAT concept via written procedure in Q1-2023. It was also agreed to look into possible further extensions of the use of MNATs and additional flexibilities in the future.

A Board member praised the NCA workshop that was organised on 14 December as part of one of the actions by Tactical group. The workshop brought together a group of operational level representatives working on resource allocation at national level, which could further develop into a resourcing network.

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 SANTE provided an update on the revision of: the EU general pharmaceutical legislation and the EU orphan and paediatric legislations, which are both expected in Q1 2023; the EMA fees regulation, which was published on 14 December 2022; and on medical devices.

Following questions from Board members, the representative of DG SANTE explained that further inputs from NCAs for the EMA fees regulation proposal should be channelled via their representatives in the Council and that more details on the pharmaceutical legislation revision will be provided next year when the EC legal proposal and the impact assessment report are published.

The representative of DG RTD gave a presentation on alternatives to animal testing, including on their importance and on upcoming funding opportunities to increase their uptake in research and regulatory practices. There is a need for preclinical models which are better at predicting clinical outcomes and DG RTD is investing in several projects to advance in this area to help reduce animal research. Current actions by the EC to accelerate uptake of New Approach Methodologies (NAMs) include a revision of REACH and funding of projects promoting sharing of knowledge, experience and confidence in NAMs. EU's support to development of alternatives to animal testing currently amounts to 800 million EUR in total. Under Horizon Europe, two partnerships will work on alternatives to animal testing: the Partnership for Assessment of Risks from Chemicals (PARC), and the Innovative Health Initiative (IHI). Future IHI funding opportunities will be published throughout 2023 and upcoming funding opportunities under Horizon Europe were also highlighted.

Some Board members asked if provisions about alternative methods to animal testing will be considered in the revised pharmaceutical legislation and this was confirmed by the representative of DG SANTE. EMA highlighted that activities on 3Rs key to its 2023 work programme, including the reactivation of the Agency's 3R Working Party.

B.3 Programming 2023-2026

a) Final programming document 2023-2025

b) Preliminary programming document 2024-2026

[EMA/MB/914739/2022, EMA/MB/855412/2022] [EMA/727092/2022, EMA/MB/914861/2022] The Board adopted the 2023-2026 Programming document, including the final 2023 work programme, budget and establishment plan.
The Board's Topic Coordinators Grzegorz Cessak, Christelle Ratignier Carbonneil and Despoina Iatridou, together with the Chair, had examined the documents on behalf of the Board over the past three months and presented the findings of their review to the Board after an introductory presentation from EMA.

EMA presented the focus areas for the Agency's work in 2023, enabling high quality, robust and rapid assessments of key medicines and translating medicines innovation into reach and add value for more patients based on better data and evidence generation. The Agency will also continue its effort to ensure the highest transparency level, by providing timely, accurate and evidence-based information that resonates with a broader audience. By monitoring the evolution of the COVID-19 related workload the Agency plans to lift its business continuity status and gradually reinitiate previously suspended or

reduced activities, notably reintroduced in clinical data publication beyond the scope of COVID-19 and activities of the working parties.

EMA presented the draft 2023 budget which will include increased revenues to €407.6 million (an increase of 9% compared to the amended 2022 budget) due to the impact of inflation and the projected increased number of applications. The 2023 budget will be subject to intensified monitoring due to the uncertainties linked to the evolution of inflation. EMA building cost and other operational costs are stabilising and in line with forecasted normal activities. As regards staffing, the draft budget 2023 includes the 40 time-limited TA posts awarded by the European Commission to address the extra workload linked to the response to the COVID-19 pandemic, 4 TA posts linked to the extended mandate new tasks, as well as 16 TA posts granted for additional product-related workload.

EMA also presented the IT budget and product portfolio which will continue to deliver complex stakeholder requirements based on Agile Value Streams. Also in 2023, there will be a significant project workload and IT budget to deliver the portfolio of epics for the benefit of the Network and the Agency. The Cloud Strategy and Technology Capability Investment Plan (TCIP) were approved and published in 2022. These plans will provide direction for Information management (IM) investments for 2023-2025. Another top priority is to continuously enhance information security.

IT Budget Topic Coordinator, Christelle Ratignier Carbonneil presented her analysis of the IT Budget evolution (€ 83.1 million for 2023 compared to € 67.3 mill in 2022), the 2023 Budget breakdown and the budget outlook for 2024. She confirmed the need for an increased budget due to the estimated inflation and to cover a few activities that could not be committed in 2022. Additional budget has been allocated to stabilise and improve CTIS, continue the investment into the IT systems supporting EMA's extended mandate, and t modernise EMA's IT landscape and move to the cloud. In 2024, the main focus will be on further improving CTIS and VMP Reg usability, increasing efforts for digitalisation of administrative solutions and ensuring a stable budget for agile delivery teams.

The 3 Topic Coordinators confirmed that the budget 2023 is balanced and robust considering the planned activities and joint EMA and HMA work on progressing the European Medicines Agencies Network Strategy (EMANS). The coordinators also highlighted EMA's continuous high-level investment in the evolution of the IT platforms to the benefit of the Network.

Concerning the Work Programme, Topic Coordinator Grzegorz Cessak introduced the multiannual EMA programming document 2022-2025 which has been developed by clustering the activities around 3 main pillars: product-related activities, public health activities and strategies, and programmes and projects. Implementing the COVID-19 lessons learned will be one of the major focus areas for the Agency's Work Programme 2023. EMA's Work Programme 2023 also includes other pivotal activities, such as the improvements toCTIS. The workload related to the non-COVID-19 related products is steadily growing, increasing demand on the Agency's staff and on NCAs' experts. EMA has been able to absorb some of the growth in activities, both fee-related and new legislation-related, through efficiency gains and effective staff reallocation, but also through increased reliance on short-term staffing contracts, Contract Agents and contractors. This is not sustainable in the longer term and is not in the best interest of enabling the Agency to contribute to a robust and sustainable European Health Union. Due to staff capacity constraints, the Agency is unable to fully carry out the required scope of its objectives, therefore some activities linked to the objectives had to be deprioritised.

The Topic Coordinator Despoina Iatridou provided a veterinary perspective to the work programme. She highlighted the need to better articulate a "One Health" approach within the next iterations of the programme document, to ensure EMA allocates enough budget to cover animal health needs and to have in place the tools for measuring the implementation of specific provisions from the veterinary medicines regulation (e.g. innovation, availability).

Following the presentations, EMA was asked to calculate the impact of the Commission legal proposal revising the EMA fees on the draft EMA budget for 2024, including the payments to NCAs. Following a question about the budget allocated to CTIS, EMA confirmed that the estimated 2023 budget for CTIS is adequate and that there is flexibility to bring in more resources, if necessary. A question was raised about the planning for face-to-face meetings of scientific committees in 2023. EMA informed the Board that the current budget foresees that 50% of scientific committee meetings will take place in person and 50% will be organised remotely following a successful pilot in 2022 and feedback received from the scientific committee chairs who were consulted throughout the pilot. A Board member was concerned to hear about a few of the activities that were included under negative priorities and the connotation of this. EMA explained that it is a requirement as per the EC guidelines to include a 'negative priorities' section for the drafting of the Single Programming Document in order to highlight those activities that have been downscaled or deprioritised due to a lack of resources. Despite turning to alternative resourcing streams to fulfil its mission and legal obligations, under-resourcing still hinders the Agency's capacity to adequately deliver on some important activities. The representative of DG SANTE enquired about the increased number of seconded national experts (SNEs). The Agency emphasised the risks associated with the increased reliance on short-term staffing contracts and explained that the additional support from SNEs is needed to support the Agency's activities.

Following the discussion at the Board, the Agency will reflect any comments received in the final document, circulate it to the Board and submit it to the European Commission and other institutions by 31 January 2023.

B.4 Agile transformation and Portfolio progress update

[EMA/MB/895452/2022; EMA/922756/2022] 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.

EMA is continuing its Agile transformation journey, moving from a traditional Waterfall IT Governance Framework towards a Scaled Agile Framework (SAFe) approach. Some of the main successes to date under the Agile transformation were presented and include Quarterly System demos with a total of 1500 participants, four successful IT Directors' meetings to strengthen the IT community and productive l portfolio ceremonies throughout 2022.

EMA presented an overview of the portfolio of Value Streams from 2022 to 2024 including key accomplishments in 2022, expected delivery for 2023 and beyond. Gradually more systems join each value stream in a process known as "on boarding", where governance setup is verified, teams are trained, and structural definition is agreed under the endorsement of the Portfolio Board.

B.5 Audit strategy/plan 2023-2025

[EMA/MB/867727/2022; EMA/560352/2022] The Board adopted the EMA's Audit Strategy 2023–2025 and EMA's risk-based audit plan for 2023. The Audit Strategy defines the following objectives to be achieved by the internal audit function of EMA between 2023 and 2025: (1) sustainably adding value to the achievement of EMA's mission and objectives, by delivering high-quality, impactful and trusted advice; (2) establishing and maintaining strong and fruitful collaborations with internal and external stakeholders; (3) through continuous development of the audit team combined with the use of innovative technologies, building new capabilities and embedding novel approaches into its operations.

The 2023 Audit Plan foresees that EMA will be subject to 14 audits and 4 risk-assessments, plus a new

Benchmarking of European Medicines Agencies (BEMA) self-assessment. Additional activities to be performed by the internal Audit team in 2023 include an audit of communication and stakeholders' engagement, coordination of external audits and assessments as well as monitoring implementation of improvement actions resulting from previous audit recommendations. The 2023 Plan acknowledges the current staffing challenges of the EMA's audit function.

B.6 Biennial report on pharmacovigilance audits

[EMA/MB/735666/2022; EMA/735668/2022] The Management Board endorsed the 5th Report to the Management Board on Pharmacovigilance audits carried out in the European Medicines Agency from 1 July 2020 and 30 June 2022 and presented to the Board in conformity with Article 28(f) of Regulation (EC) No. 726/2004. The report describes developments included in the EU pharmacovigilance system since the last report in mid-2020 and presents findings of the two audits which were conducted in the reference period, despite business continuity plan constraints. These were the audits on management of Post Authorisation Studies for human medicines and on Medical Literature Monitoring. As a result of these audits, several improvement actions have been implemented and no critical recommendations are outstanding or remain open.

B.7 Result of an Independent external validation of AF-AUD's self-assessment 2022

The Board noted an oral update by the interim Head of Audit on the outcome of an external quality assessment of the internal audit function of the EMA. An external review is conducted every five years and is an independent validation against existing international standards of a self-assessment of the internal audit function. The external validation fieldwork was conducted in November 2022 and included an extensive review of the EMA's audit planning processes, audit tools and methodologies, and engagement management processes. The external assessor's opinion is that EMA's internal audit function generally conforms with the Standards, Code of Ethics and the provisions included in AF-AUD's Charter approved by the EMA Management Board in June 2022.

The Board Chair noted the good outcome and the EMA's Executive Director congratulated the internal audit function on its good work despite the capacity challenges. She informed the Board that the recruitment of a new Head of Audit will start in the next quarter.

B.8 Update on the implementation of Veterinary Medicinal Products Regulation

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

The representative of DG SANTE presented on the state of play, noting that 16 legal Acts have been published in the Official Journal so far. Priority for the Commission is adopting the Acts needed by 28 January 2023 (for instance the Delegated Act on detailed rules on imports of animals and products of animal origin under article 118), while work is also progressing on some of those which have to be in place by 2025.

EMA presented an update on the implementation of VMP-Reg programme looking at each individual IT project under the programme and confirming that each IT system (UPD, EVVet and ASU) has transitioned fully to Agile value stream delivery model. Work is ongoing on two CVMP scientific advices in preparation for implementing Acts. Two new mandates are expected from the European Commission

in 2023 on a list of essential medicines for equine species and on essential medicines for aquaculture. As part of the Agile Transformation, calls for expression of interest have been launched to nominate 2-3 NCA Subject Matter Experts and 1 NCA Product Owner by mid-January 2023 for UPD and ASU product teams. The Veterinary Systems Improvement Advisory Group (VSIAG) is now fully operational since mid-2022 and works to prioritise upcoming IT work.

The representative of veterinarians' organisation congratulated the work done and asked if an update of Article 106 on prescriptions is being planned by the European Commission to clarify its implementation and address the concerns of veterinarians. The representative of DG SANTE acknowledged the concerns on Article 106 and promised to further consider them. EMA clarified the VSIAG is only open to Member States, but the Agency will continue to communicate on its work with veterinary stakeholders; in this regard, a veterinary Info Day is planned on 16 February.

B.9 Big Data Steering Group progress report

The Board noted the progress update from EMA co-chair of the Big Data Steering Group (BDSG) on the BDSG significant achievements in 2022 and a brief look forward to 2023.

Some key achievements in 2022 were presented including: the launch of a public consultation for the first draft EU Data Quality Framework for medicine regulation; the publication of the first EU metadata list for real-world data sources and studies; high demand (50 requests) for real world evidence (RWE) studies; the establishment of the DARWIN EU ® coordination centre which has led to the onboarding of the first data partners; the creation of the Methodology Working Party (MWP) and the finalisation of its workplan; the publication of the ICMRA statement on international collaboration on RWE in regulatory decision making; and the adoption of the European Veterinary Big Data strategy 2022-2027. For 2023, some of the main planned activities were highlighted including the launch of a call for expressions of interest for potential new data partners and preparations for a changing policy environment with the future European Health Data Space (EHDS). The Agency hopes to achieve full transformation to data-driven regulation by 2025. The publication of the Big Data Steering Group annual report 2022 is planned for early January 2023 on both the EMA and HMA website.

The Board recognised and commended the Big Data Steering Group on the excellent work that has been accomplished in 2022. A Board member had a question about the rate of feasibility of RWE studies. EMA explained that a total of 25 out of the 50 studies were feasible to be conducted via the Agency’s in-house databases, framework contracts or DARWIN EU®. The proportion of feasible studies will increase steadily as additional data partners are onboarded by DARWIN EU®.

B. 10 Report to the Management Board on the operation of CTIS and the Clinical Trial Regulation

- **CTIS planning 2023-2024**
- **Open letter on EMA's proposed deferral of publication of clinical trial protocols**

[EMA/MB/806898/2022; EMA/806900/2022; EMA/916770/2022; EXT/836727/2022; EMA/MB/836729/2022] The Management Board noted a progress report on the implementation of IT systems (CTIS) required by the EU Clinical Trial Regulation (CTR) and endorsed the CTIS planning for 2023-2024. The Board also noted the open letter sharing concerns on transparency for sponsors

requesting deferral of protocol publication for category 2 trials from a group of organisations and response letter from the MB Chair.

Following a presentation by the member from Sweden of the Member States' perspective on CTIS implementation, the Agency informed the Board that the system delivers the functionality required for new clinical trial applications which will continue to be developed and enhanced. The Board noted the progress towards further stabilisation of the system, which will improve user experience, in preparation for compulsory use. The Agency informed the Board about its delivery plan to ensure no blocking technical issues in the core processes by the legal deadline for mandatory use, and its commitment to this plan. The ongoing collaboration between sponsors, Member States' (MSs), EMA and EC was acknowledged as essential for a successful implementation. Training material is available to help sponsors submit their clinical trial data, and the material is updated regularly to take into account information needs. EMA is running regular training webinars with sponsors to explain the system and listen and address concerns. The Agency also informed the Board of the various potential risk scenarios and of the development of a business contingency plan.

The Board welcomed the 2023 CTIS workplan which focusses on enhancing the user experience by implementing improvements in the most impactful functional areas of the system, future proofing and minimising risks to the technical core of CTIS. While recognising the efforts made to make the CTIS work and the progress achieved, the representative of DG SANTE reiterated the concerns about the IT system achieving full functionality in core processes outlined by the deadline for mandatory use and called also on Member States to commit sufficient resources in time to comply with their legal requirements that stem from the CTR. The EC had previously called for urgent actions to be taken to ensure that mandatory use of CTIS can be complied with by 31 January and asked for a contingency plan. The representative of DG SANTE stressed the importance of focusing the meeting on the short term planning ahead of mandatory use and the contingency measures to allow the board members from MS to confirm their ability to ensure compliance by the date for mandatory use. In addition, the representative of DG SANTE suggested that the risk-based scenarios should be regularly evaluated and updated in the light of the progress with the different bug fixing and release. There should be weekly reports to the Board. Finally, the representative of DG SANTE called for transparency and clear communication on the current applicable measures and procedures and on the upcoming ones.

The Board concluded that it recognised the progress made by the Agency since the October MB meeting. The Board acknowledged that EMA had set out again a clear commitment to delivery its contingency plan to ensure no blocking technical issues in the core processes by the legal deadline. The Board was reassured that based on the planning that had been set out, that there will be a good minimum viable product (MVP) ready for 31 January. The Board noted that regular, clear and transparent communication to all stakeholders and users that are impacted will be provided up until the use of CTIS will become mandatory. The Board welcomed the Agency's commitment to provide weekly reports to the Board on the progress towards stabilisation and functionality improvement of the system and to allow for the Board to make the necessary sound decisions on the proposed mitigation measures, if needed. The MB Chair suggested to plan a placeholder for an ad-hoc MB meeting in mid-January to discuss this topic further, if necessary, depending on the progress made by the Agency.

The Board endorsed the 2023 CTIS workplan with the condition that the system delivers the functionality required by 31 January 2023. The representative of DG SANTE and Malta abstained based on reservations on the stability and functionality of the system in preparation for its compulsory use. As the initiation of this workplan is subject to the stabilisation of the system, the Agency committed to update the Board on a weekly basis on the progress starting on 16 December and stakeholders will also be kept regularly informed.

The EMA also provided information on the planned response to an open letter from 17 October 2022, sharing concerns on transparency re. sponsors requesting deferral of protocol publication for category 2 trials. The Board agreed to review the current rules on disclosure of certain clinical trial documents and a review of CTIS transparency measures for 2023.

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

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

The ACT EU work programme 2022-2026 is starting to deliver and some of the main priority actions were highlighted to the Board. For Priority Action 2 on "Successful implementation of CTR", monthly CTR Key Performance Indicator (KPI) reports have been published since May 2022 and a CTR survey was sent out to sponsors to identify any blocking issues. The issues identified were allocated to relevant subgroups within in EMA and the Network (e.g. Clinical Trials Coordination Group) and an approach for resolution was adopted at Clinical Trials Advisory Group (CTAG) in December. A draft proposal for establishing a multi-stakeholder platform is being prepared within the ACT EU matrix and is expected to be finalised in by latest February 2023 as part of Priority Action 3. At the next EMA Management Board in March, an update will be provided on the delivery and benefits of the priority actions of the work programme.

The Board commended all the work that has undertaken for each priority action and highlighted the importance of clinical research in EU and for patients.

B.12 Report from CAT chair

The Management Board noted an oral update from Martina Schüssler-Lenz, Chair of the Committee on Advanced Therapies (CAT), on achievements of the committee and its current and future perspectives. The CAT Chair highlighted that, since 2017, the CAT has strengthened its clinical expertise and its interactions with the CHMP. So far 13 ATMPs have been authorised in the EU and gene therapies are dominating the ATMP field. Ex-vivo gene therapies, using for example adeno-associated viral vectors (AAV) to correct genetic defects in children, are being increasingly authorised; these are all single administration products so they require long term follow up. Ex-vivo cell-based gene therapies have been approved in the EU since 2018 and are a success story for cancer patients, with 6 CAR-T cell products authorised by EMA to date. In 2023, the CAT will work, inter alia, on revisiting the safety follow-up of CAR-T cells and will finalise a reflection paper on insertional mutagenesis risk of associated viral vectors (AAV) and patient follow-up.
The Board congratulated the CAT Chair for the Committee's achievements. Some members asked how to increase clinical trials for ATMPs in the EU, how to strengthen collaboration on ATMPs with HTA bodies, how to be prepared against acts of bioterrorism using the technology developed for ATMPs, and about the impact of the legal proposal on Substances of Human Origin. The CAT Chair reassured that all AAV products known to date are replication inefficient, therefore of no threat to the public, and confirmed that collaboration with HTA bodies is a priority for the Committee. She also noted that the ATMP regulation provides a good framework for regulating substantial manipulation and non-homologous use, and that it is important to maintain strict quality, safety and efficacy standards for cell-based products.

B.13 Update on implementation activities of EMA's extended mandate – Chapter IV on experts panels

The Management Board noted an oral update from EMA on the medical device Expert Panels' activities in 2022 and on the plan for the expert panels to start providing scientific advice to medical device manufacturers in 2023.

As part of the main activities of the medical device Expert Panels, 41 applications were received in 2022 from notified bodies (NBs) for Clinical Evaluation Consultation Procedure (CECP), and 10 opinions delivered following a positive screening decision; 16 applications were received from manufacturers via NBs. As regards the Performance Evaluation Consultation Procedure (PECP), 16 applications were received, mostly for devices for SARS-CoV-2 detection, and all of them had an opinion delivered by the In-Vitro Diagnostic (IVD) panel. In addition, the IVD Panel has provided advice to the Medical Device Coordination Group (MDCG) on the transmissibility and virulence of certain influenza virus subtypes and strains. The first meeting of the Coordination Committee was held on 14 November 2022. EMA informed of the proposal for the expert panels to start an early pilot phase for scientific advice to manufacturers starting in Q1 2023. This pilot phase will help build an efficient process for after 2024 adapted to the specificities of the medical device sector, including adjusted timelines and costs. The pilot will run until May 2024.

The representative of DG SANTE welcomed the Scientific Advice pilot, which is testing a procedure foreseen in Article 106.10(e) of Regulation (EU) 2017/745 on medical devices, and hoped it would swiftly transition into a routine use by industry. One member asked if the expert panels would provide advice on classification matters and both the representative of DG SANTE and EMA clarified that the scientific advice is expected to focus on the clinical development strategy for certification and be limited to class III and IIB devices.

B.14 HMA/EMA Task Force on availability of medicines update

The Board noted the main milestones accomplished in 2022 by the Task Force.

Since the mandate of the TFAAM was adopted by the Board in June 2022, the Task Force has been transformed to function as a "supply and availability hub" and will track progress of supply and availability activities that the European medicines regulatory network is undertaking under several EU projects, including European Commission's Pharmaceutical Strategy for Europe and Joint Action on Shortages. The mandate of the task force has been extended until December 2025 in order to align the timelines of the activities foreseen in the EMANS to 2025. The work programme 2022-2025 was adopted in 2022 and includes the main deliverables for the two thematic groups within the taskforce and the main actions for tracking activities in the area of availability and shortages.

On 1 and 2 March 2023, the TFAAM will organise a multistakeholder workshop on shortages in the field of human and veterinary medicines. Regulatory authorities, HTA bodies, price and reimbursement authorities, representatives from industry associations, patients/consumers and healthcare associations and academia will be invited.

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

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

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

The Board noted an oral report on the implementation by EMA of the EU Data Protection Regulation (EU DPR).

The EMA Data Protection Officer explained the internal organisation of data protection activities at EMA and gave an overview of data protection achievements in 2022. These include the delivery of four Data Protection Impact Assessments (on DARWIN, raw data pilot, EudraVigilance, Microsoft Office 365) and Joint Controllership Arrangements for EudraVigilance and Lifecyle Regulatory Submissions Raw Data Pilot. Another important area of activity in 2022 has been the international transfer of personal data. This resulted in the delivery of an overall impact assessment report and a set of recommendations to facilitate EMA's compliance with EU DPR issues linked to the international transfer of unredacted case narratives originating from EudraVigilance to US and Canada. Records of 70 Processing Activities and corresponding Data Protection Notices have been reviewed during the year as mandated by Article 31 of the EU DPR. A number of data breaches were recorded, of which three were also notified to the EU Data Protection Supervisor. In this regard, a dedicated training module on data breaches was made available for staff in 2022 and a tailor-made training module for EMA IT contractors will be delivered in 2023.

List of written procedures finalised during the period from 30 September 2022 to 05 December 2022

During the period from 30 September 2022 to 05 December 2022, the Board was consulted three times via written procedure, of which three consultations concerned membership in the CHMP and CVMP, and three additional consultations, as listed below:

- Consultation no. 10/2022 on the appointment of Krasimir Zlatkov as CVMP member as proposed by Bulgaria ended on 24 November 2022. The mandate of the nominee commenced on 25 November2022.
- Consultation no. 11/2022 on the appointment of Vilma Petrikaite as CHMP member as proposed by Lithuania ended on 28 November 2022. The mandate of the nominee commenced on 26 November2022.
- Consultation no. 12/2022 on the appointment of Christian Garner as CHMP alternate as proposed by Austria ended on 02 December. The mandate of the nominee commenced on 03 December2022.
- Consultation procedure for the adoption of the minutes of the 116th Management Board meeting, held on 15-16 June 2022. The procedure was adopted.
- Consultation procedure for the adoption of the minutes of the 117th Management Board meeting, held on 6 October 2022. The procedure was adopted.
- Consultation procedure for the adoption of Agency's revised independence policies (policy 0044and policy 58) and revised associated Breach of Trust procedures documents. The procedure was adopted.

Documents for information

- Feedback from the Heads of Medicines Agencies
- Outcome of written procedures finalised during the period from 30 September 2022 to 5 December 2022 including
- Summary of transfers in budget 2022
- Summary of implementation of assigned revenue
- Revised rules governing the secondment of national experts to the EMA
- EMA's multilingual policy

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List of participants at the 118th meeting of the Management Board, held in Amsterdam, on 14-15 December 2022

Chair: Lorraine Nolan

	Participants
Belgium	Xavier de Cuyper *(member)*
Bulgaria	Bogdan Kirilov *(member)*
Czech Republic	Irena Storová *(member)*
Croatia	Siniša Tomić (*member*)
Denmark	Lars Bo Nielsen *(member)* Mette Hansen *(alternate)* Brigitte Faber *(observer)*
Germany	Karl Broich *(member)* Wiebke Löbker *(observer)*
Estonia	Katrin Kiisk (*membe*r)
Ireland	Rita Purcell *(alternate)*
Greece	Dimitrios Filippou *(member)*
Spain	María Jesús Lamas Diaz *(member)* Consuelo Rubio Montejano *(alternate)*[2]
France	Christelle Ratignier-Carbonneil (*member*) Franck Foures *(alternate)* Miguel Bley *(observer)*
Italy	Francesco Trotta (alternate)
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Sergejs Akuličs *(member)*
Lithuania	Gytis Andrulionis *(member)*
Luxembourg	Anna Chioti *(member)*
Hungary	Mátyás Szentiványi *(member)* Beatrix Horvath *(alternate)*
Malta	John Joseph Borg *(alternate)*
Netherlands	Aimad Torqui (*alternate*)[2] Michiel Hendrix *(observer)*
Austria	Christa Wirthumer-Hoche *(member)*
Poland	Grzegorz Cessak (*member*) Marcin Kolakowski (*alternate*)
Portugal	Rui Santos Ivo *(member)* Maria João Morais *(observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Peter Potúček (member)[2]
Slovenia	Momir Radulović *(member)*
Finland	Eija Pelkonen *(member)*
Sweden	Björn Eriksson (*member*) Åsa Kumlin Howell *(alternate)*

2 Competing interest declared resulting in no participation in decision with respect to agenda points B.3 and B.10

European Parliament	Karin Kadenbach *(member)*
European Commission	Anna Eva Ampélas *(alternate)* (DG SANTE) Martina Ciccarello (*observer*) (DG SANTE) Tomasz Dylag (*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 speakers	Martina Schüssler-Lenz (CAT Chair) Hugues Malonne (TFAAM Co-chair)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Melanie Carr Nerimantas Steikūnas Hilmar Hamann Anthony Humphreys Alexis Nolte Zaide Frias Steffen Thirstrup Stefano Marino Hilde Boone Marie-Agnes Heine Martin Harvey-Allchurch Franck Diafouka Maria Alves Riccardo Mezzasalma Sabine Brosch Salvador Ruíz-Carrillo Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin