14 November 2025
EMA/MB/313357/2025 - adopted
Management Board

Minutes of the 129th meeting of the Management Board

Held virtually in Amsterdam on 2 October 2025

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair confirmed the quorum and welcomed the newly appointed civil society representative, Marko Korenjak (European Liver Patients Association), and the new European Parliament representatives as of July, Christian Busoi and Kristina Garuolienė. The Chair also welcomed the new member representing Greece, Spyros Sapounas (President, National Organization for Medicines), alternate representing DG Research and Innovation of the European Commission, Maria Pilar Aguar Fernández (Director) and alternate representing Liechtenstein, Fabian Kurzemann (Specialist in Therapeutic Remedies, Office for Health).

The Chair and the Board observed a minute of silence in memory of the late former Chair of the EMA Management Board from 2007 to 2011, Professor Pat O'Mahony, who passed away in August.

The Chair informed the Board that during the December meeting, the 2026 Programming Document would be presented, and that he had initiated engagement with the previous year's topic coordinators to confirm their participation. The Chair invited members that would like to join as a topic coordinator for this year to make contact following the meeting. *Post meeting note: Aimad Torqui confirmed after the meeting his engagement as new MB Topic Coordinator together with the previous Topic Coordinators Eija Pelkonen, Grzegorz Cessak and Franck Foures*.

The Chair informed the Board of some changes in Board member's roles across various MB-related groups: Aimad Torqui, in his capacity of vice-chair will be part of the ACT EU Steering Group; Catherine Paugam-Burtz will participate as a new topic coordinator for the next Annual Activity Report (AAR); and Momir Radulovic has agreed to act as the new reporting officer for the EMA's Executive Director annual appraisal on behalf of the Board together with DG SANTE's Director-General, Sandra Gallina.

The Chair also congratulated EMA's Executive Director, Ms Emer Cooke, on her renewal as Executive Director for the period 16 November 2026 to 30 April 2027, following the unanimous MB decision to adopt the European Commission's proposal to renew Ms Cooke's mandate. Additionally, the Chair also informed the Board that a letter will be sent to DG SANTE's Director-General to invite the Commission to provide an update to the Board at the December meeting on the launch of the selection procedure for the Agency's next Executive Director. A member highlighted that the selection procedure should be initiated in a timely manner to ensure a smooth transition and continuity in EMA's leadership. The DG SANTE representative confirmed that the Commission is working towards presenting the draft vacancy notice to the Board in December.

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1. Draft agenda for 2 October 2025 meeting

[EMA/MB/261306/2025] The agenda was adopted with no amendments.

2. Declaration of competing interests related to the 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 topic *'B.7 Revision to the Cooperation Agreement (CA) between EMA and the National Competent Authorities (NCAs) - Addendum 1 to the CA*'. 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 that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 128th meeting, held on 11-12 June 2025 adopted via written procedure

[EMA/MB/189883/2025] The Management Board noted the final minutes, adopted by written procedure on 14 August 2025.

A. Points for automatic adoption/endorsement

A.1 EMA decision on adoption, by analogy, of Commission decision C(2025) 2495 of 13.5.2025 – guide to missions and authorised travel

[EMA/MB/283583/2025], [EMA/MB/283584/2025] The Management Board adopted the EMA decision on the adoption, by analogy, of Commission decision C(2025) 2495 of 13 May 2025 on the general provisions for implementing Articles 11, 12 and 13 of Annex VII to the Staff Regulations of Officials on authorised travel. The Agency received the Commission Decision on 14 May 2025, triggering the nine-month timeline for adoption. As with the previous mission rules, the Agency is proposing to adopt the new decision by analogy to be in full alignment with the Commission. The updated mission rules emphasise environmental sustainability and ethical conduct. In-person meetings are to be replaced by virtual ones when possible, with fewer participants per event. Travel should be greener: trains to be preferred for distances within 550km, direct flights and economy or premium economy to be preferred over business class for long-haul trips. Organiser-paid expenses should be restricted to defined third parties to prevent conflicts of interest. The rules also clarify conditions for combining missions with remote work outside the place of employment. The EMA decision will apply as from 1 January 2026.

B.1 Highlights of the Executive Director

The Management Board noted an oral update from EMA's Executive Director, beginning with recent communications from the United States Administration concerning the use of paracetamol during pregnancy and on COVID-19 vaccines. Following the US statements, the Agency promptly issued a public statement confirming that experience based on data supported the safe use of paracetamol during pregnancy EMA is preparing for reacting to future statements based on experience and evidence. In parallel, EMA and ECDC are exploring options to generate, retrieve and assess additional

real world based evidence for science-based decisions, while also monitoring possible new requirements for clinical data on COVID-19 vaccines.

The Board was updated on the latest developments at the Agency's former London premises. Occupancy at 30 Churchill Place continued to grow in 2025, with new tenants moving in under membership and licence agreements and preparing to occupy additional space.

Concerning staff matters, the Board was informed of the results of the 2025 Staff Engagement Survey (SES), which is held every 2 years and has been conducted since 2013 as part of a joint inter-Agency tender and common methodology. The SES is developed and delivered under an EU framework contract 'Provision of benchmarked EU staff engagement surveys', which includes at the moment 29 EU agencies and joint undertakings in addition to EMA. The EMA survey achieved a high (79%) response rate and showed continued improvement across all indicators, with a 'total favourable' score of 67% and a 88% People Engagement Index score. The survey highlighted four key areas of strength reflecting sustained staff motivation and pride in the Agency's mission: sense of purpose; job commitment; working environment; and supportive relations. Several areas for improvement were also identified, and EMA's Leadership, in consultation with staff, has decided to focus efforts over the next two years on the following areas: cooperation and information-sharing, organisation of work and workload, leadership and strategic vision.
The Board was also informed that, following the review of experience with the model rules on Working Time and Hybrid Working (WTHW) since March 2024, a new Executive Decision took effect on 12 September 2025, introducing a 15-day annual allowance for exceptional teleworking outside the place of employment for imperative reasons such as family or personal health matters, aiming to simplify and streamline the current authorisation process.

On European activities, the Executive Director referred to the conclusions of the European Court of Auditors' report on medicine shortages, the ongoing own-initiative inquiry from the European Ombudsman into revolving-door cases in EU agencies, and EMA's participation to the informal meeting of EU Health Ministers in Copenhagen on 16 September.

The Board was also informed on the publication of the Reflection Paper on Patient Experience Data (PED) on 29 September, launched for a four-month consultation, to promote the inclusion of patient perspectives throughout the medicine lifecycle and also to support international harmonisation.
The Board was also updated on the Access to Documents campaign initiated by the North Group. Over 2,100 requests have been received regarding COVID-19 vaccine applications, with more than 3,000 documents identified for proactive publication. The first publications by EMA were made on 30 June 2025, and the project is expected to continue for approximately one year, with regular publications planned throughout this period.

Finally, the Executive Director also announced the appointment of Franck Diafouka as EMA's 'Head of Internal Audit Capability' as of 1 October 2025, reflecting a new operating model that had been agreed with the Board's MBARG subgroup and the Commission's Internal Audit Service. Recruitment of additional staff is ongoing and an external audit company will provide specialised support. More information on the new audit operating model will be provided at the December Board meeting.

B.2 Report from the European Commission

The DG RTD representative informed the Management Board about the recently published EU Life Sciences Strategy, which aims to position Europe as the most attractive region for life sciences innovation by 2030. The Strategy adopts a broad, sector-agnostic approach, allowing flexibility to support diverse areas across the life sciences ecosystem. It builds on recommendations from the Draghi report and was shaped by extensive stakeholder input. It outlines coordinated actions across

the full life sciences value chain by optimising research and innovation, accelerating market access, and fostering public trust and uptake of new technologies. Flagship initiatives include strengthening the clinical trial infrastructure, establishing ATMP centres of excellence, expanding innovation hubs, and promoting One Health approaches and microbiome research. Research in climate-health interconnections is also prioritised. The strategy also seeks to unlock the potential of data and AI for breakthrough innovation, addressing legal and technical barriers to data access. Regulatory frameworks will be adapted to support innovation through responsive and forward-looking approaches, including the Biotech Act. A dedicated coordination group will be established within the European Commission to monitor implementation and ensure coherence. On 30 September the Council endorsed the Strategy by way of Council Conclusions. Continued collaboration with stakeholders, especially MSs, will be essential. A progress report on the implementation of the Strategy could be provided to the Board by the end of 2026.

The DG SANTE representative informed the Management Board about the latest developments concerning the revision of the Pharmaceutical Legislation, the preparation of the Biotech Act, and the examination of the Critical Medicines Act. An update on Medical Devices legislation was provided as a separate point (see B.3)

The revision of the Pharmaceutical Legislation is progressing steadily. Following the Council's mandate for negotiations with the European Parliament on 4 June, trilogue discussions began on 17 June, with the goal of reaching an agreement by the end of 2025. Technical trilogues have covered so far the chapters of scope (including exemptions), definitions, pharmacovigilance, national procedures, EMA governance, labelling and advertising. Collaboration between EU institutions has been constructive, with a shared willingness to find a compromise on technical amendments. The Commission representative expressed appreciation for EMA's technical input and support to the Commission during the process.

The Biotech Act is under preparation and is expected to be structured around five strategic pillars. These include accelerating time-to-market through: regulatory simplification for health applications, particularly in clinical trials; strengthening biomanufacturing capabilities; enhancing skills development; supporting startups and scale-ups with better access to venture capital; and integrating data and AI to drive innovation. Clinical trial reforms are a central focus, aiming to make authorisation faster and more predictable by shortening assessment timelines, streamlining ethic committee reviews, simplifying application templates, and clarifying the legal basis for personal data collection.

The Critical Medicines Act, proposed by the Commission on 11 March 2025, complements the pharmaceutical reform by proposing industrial measures to address supply chain vulnerabilities and ensuring the availability of essential medicines. The Council completed its first reading in July, with compromise discussions initiated in September. On the Parliament side, the report by Rapporteur MEP Sokol was published in August, with the EP aiming to adopt its position by December. A Staff Working Document has also been published by the Commission, summarising the evidence base supporting the legal proposal.

A MB member noted the significant workload associated with the various legislative initiatives, particularly the pharmaceutical reform, and emphasised the need to begin planning for implementation over the coming years. This includes assessing requirements related to resources, staffing, processes, and IT systems. In response, the MB Chair indicated, in line with what was also discussed at the June meeting, that the December meeting be used to start discussing how best to prepare for implementation of these new pieces of legislation, ensuring MB engagement and also in cooperation with the HMA. Asked by the patient representative about the role of patients within the future EMA governance structures, the DG SANTE representative confirmed that the issue will be addressed during

trilogue negotiations and that the Commission continues to advocate for a strong role for patients at the EMA.

B.3 Update on Medical Device (MD) and *In- Vitro* Diagnostic Medical Device (IVD) activities

The Management Board noted an oral report on the EMA and EC activities on Medical Devices (MD) and In- Vitro Diagnostic Medical Devices (IVD).

Update on EMA activities

The EMA plays a role in three main areas concerning medical devices. First, the Committee for Medicinal Products for Human Use (CHMP) oversees the authorisation and lifecycle of medicines that incorporate or are used with medical devices or health technologies. CHMP also provides scientific opinions on devices containing medicinal substances with ancillary functions and on the suitability of in vitro diagnostics as companion diagnostics. Second, under its extended mandate since March 2022, EMA hosts expert panels for high-risk medical devices and class D *in vitro* diagnostics, supporting their development and clinical evaluation. The 12 groups, comprising over 160 experts, have reviewed more than 200 applications and issued numerous opinions on conformity evaluations conducted by notified bodies and advised manufacturers on clinical investigations/ strategies as well as orphan device status. Soon they will also support and designate "breakthrough" medical devices. Third, since March 2023, EMA contributes via the Executive Steering Group on Shortages Medical Devices to the monitoring and mitigation of shortages of critical medicinal devices during public health emergencies. Additionally, EMA supports EU initiatives such as COMBINE, which aims to streamline the interface between the clinical trials, pharmaceutical and medical device regulations. The Agency also facilitates development via early dialogue and scientific advice on medicines used in combination with a device and provides qualification of biomarkers and novel technologies. The EMA is preparing to launch an operational group on combination products, bringing together notified bodies as well as national competent authorities for medicines and medical devices to foster collaboration and regulatory alignment.

EC Policy update on MD/IVD legislation

The DG SANTE representative explained that the European Commission is preparing a targeted revision of the EU medical device framework, aiming to improve efficiency and to address fragmented practices within the internal market. The reform will also try to enhance the EMA's current role in providing scientific, technical, and regulatory expertise while maintaining the decentralised structure of the medical device framework. Key goals include reducing administrative burden, improving the predictability and cost-effectiveness of notified body assessments, and making requirements more proportionate for lower-risk and special-need devices. The revision also aims to support digitalisation, streamline governance between national authorities and over 50 notified bodies, and align with other EU legislation such as the Clinical Trials Regulation and the AI Act. During the public consultation stakeholders have highlighted the need for stronger EU-level coordination and expertise, particularly to address fragmented practices and support innovation. While an FDA-style system is not being considered, greater involvement of the EMA expert panels could be explored. The urgency of reform is underscored by the increasing relocation of production outside Europe, which is prompting a focused and timely approach. A public call for evidence remains open until 6 October.

The healthcare professionals' representative raised concerns about inconsistencies in performance studies for *in vitro* diagnostics used in immuno-oncology. He noted that manufacturers employ different tests to assess patients' biological states during treatment, often yielding varying results, which complicates the benchmarking of treatment options. He questioned whether discrepancies in

notified bodies' assessment of performance studies could be addressed in the upcoming legislative revision. In response, the DG SANTE representative expressed willingness to explore the issue further with the MB member and EMA.

B.4 EMA Mid-year report 2025 from the Executive Director (January – June 2025)

[EMA/MB/308954/2025], [EMA/283452/2025] The Management Board noted the Mid-year Report from the EMA Executive Director covering the period January to June 2025.

EMA presented its mid-year progress report which provides an overview of the Agency's performance of its medicines' evaluation activities, progress on implementation of the objectives and activities of the work programme 2025, as well as progress on reaching set performance targets and implementation of projects. The report follows the structure of the work programme and is structured around four key areas: key developments in the work programme, application trends, staffing indicators, and budget performance. Achievements were presented around three strategic focus areas: accelerating and optimising medicine assessments, improving accessibility and availability of medicines, and future-proofing regulation. Notable outcomes include: faster timelines, primarily due to -shortened company clock stops; publication of the Clinical Trials map under the ACT-EU programme; and expansion of the DARWIN EU network to more than 30 data partners with access to over 180 million health records. EMA also advanced implementation of the HTA regulation, supported the Critical Medicines Alliance, and launched the European Shortages Monitoring Platform. Additionally, the EMA/HMA joint work plan on Data and AI in medicines regulation was published, setting a strategic direction through 2028. International cooperation progressed through support to the African Medicines Agency and the African Medicines Regulatory Harmonisation Initiative, which completed the assessment and listing of the first five medicinal products at continental-level. EMA also published the first EU-wide surveillance report on antimicrobial sales and use in animals, involving all EEA countries, to inform public and animal health decisions. Cross-agency collaboration continued under the One Health Task Force with ECHA, ECDC, EFSA, and EEA. Most of the work programme activities are on track. Marketing authorisation and scientific advice requests applications for human and veterinary medicines remained stable. Staffing indicators showed positive trends in recruitment timelines, turnover, and occupancy rates. Budget execution is now on track to exceed the implementation targets set by the European Commission.

B.5 Environmental (PESTLE) analysis - navigating the future

[EMA/MB/290390/2025] The Management Board noted an oral report on the Agency's business environment (PESTLE) analysis.

The Agency regularly conducts a structured assessment of the external business environment using the PESTLE framework, which examines Political, Economic, Social, Technological, Legal, and Environmental factors (PESTLE). This analysis is performed in depth every three years, with interim updates in the intervening years. The current cycle involved a more comprehensive review, building on earlier work done in the context of the network strategy development. The analysis identified several major themes. Under 'network resilience', challenges include the availability of assessment resources, strained EU and national budgets, and technological disparities across National Authorities. 'Global instability' grew as a significant factor to take into account, with conflicts risking supply chains and clinical trials, and broader geopolitical shifts such as EU enlargement and health diplomacy efforts in different parts of the globe expected to be impactful. In the social dimension, public trust in EU institutions is shifting, prompting the need for stronger local engagement, to improve health literacy

and counter misinformation. Increasing efforts in the field of transparency remains a significant positive factor, requiring enhanced efforts in publishing clinical data, financial disclosures, and stakeholder communications. Scientific innovation is accelerating, with developments in drug-device combinations, cross-sectoral biotechnology, and the need for faster regulatory pathways. Meanwhile, AI and data governance present new challenges and opportunities, including the validation of complex AI systems, the use of real-world evidence and the implementation of the European Health Data Space.

Considering the long-term trends captured in the environmental analysis, the network needs to reflect on long term requirements and plan for timely preparedness. The Agency's PESTLE analysis feeds into two strategic documents: it informs the Single Programming Document which sets multi-annual objectives, and the EMA's internal risk assessment, which ensures emerging threats are understood and addressed. A similar analysis was taken into account during the preparation of the European Medicines Agencies Network Strategy to 2028. It was noted that the topics discussed in point B.5 present important aspects for future activities.

B.6 Involvement of external experts to support EU regulatory network activities

The Management Board noted ongoing efforts to expand the expert pool, as part of the HMA/EMA Strategic Resource Oversight Group (SROG) priorities for 2025 and endorsed expanding the scope of activities for involvement of external experts based on a EMA public call.

Further to the discussion at the June MB meeting, EMA presented the results of recent surveys of NCAs which provided insights into current practices and their interest in external expert engagement. The results had also been discussed at a recent SROG meeting in September where the SROG had supported the possibility of engaging non-EU/EEA experts in areas where expertise may be lacking, with the decision of use of such experts and remuneration aspects remaining under NCA responsibility and control. The Board agreed to the proposal which would be implemented as an amendment (addendum) to the cooperation agreement and experience would be reviewed within a two-year period.

Additionally, EMA presented the expansion of the scope of additional, complementary (ie non-core assessment) activities that could be included in EMA calls for external experts. The scope would have more of a focus on *ad-hoc* advice and consultations, mentoring, peer reviews, and training. These activities will be separate from core assessment work, which is managed under the NCA fee structure. The Board endorsed the proposal which had also been supported by the SROG.

The Board was also updated on other ongoing initiatives, including the development of a Best Practice Guide for engaging external experts and the proposal to continue the MNAT-expert pilot. Further updates on these matters will be provided by SROG at a future Management Board meeting.

B.7 Revision to the Cooperation Agreement (CA) between EMA and the National Competent Authorities (NCAs)

[EMA/MB/306542/2025], [EMA/306728/2025] The Management Board adopted Addendum 1 to the Cooperation Agreement (CA) between EMA and the National Competent Authorities (NCAs). The Addendum includes amendments to Annex II of the Cooperation Agreement concerning remuneration of NCA staff for priority training services. Following the Board's 2023 decision to include these services, a pilot was launched to test the remuneration model and a lessons-learnt exercise identified the need for some changes. Based on feedback from NCAs and experts, the Agency proposed increasing the

number of days required to deliver certain activities and adding new activities, such as training design and expert review. The descriptions of activities were also refined to enhance flexibility and ensure closer alignment with the EU NTC training curricula.

Furthermore, following the discussion under agenda item 6, the Board also agreed to the proposed amendment to Article 12 of the Cooperation Agreement within addendum 1 to remove the restriction limiting engagement of external experts coming from within the EU/EEA, allowing NCAs to use suitably qualified experts worldwide under existing selection and conflict-of-interest principles.

B.8 Update from Network Data Steering Group (NDSG)

Network Data Strategy

[EMA/128369/2025], [EMA/MB/300628/2025] The Management Board endorsed the first data strategy for the European Medicines Regulatory Network (EMRN). The strategy outlines principles and objectives to ensure that the network's data assets are managed effectively, maintained to high quality standards, and are easily accessible for regulatory decision-making. The focus is on data shared between medicines agencies, including regulatory submissions, master data (e.g. substance, product, organisation and referential (SPOR)), and healthcare data (e.g. spontaneously reported adverse drug reactions; clinical trials data from CTIS). This strategy is a key deliverable of the Network Data Steering Group's 2025-2028 workplan and aligns with the European Medicines Agencies Regulatory Network Strategy (EMANS) to 2028, aiming to leverage data, digitalisation, and artificial intelligence in regulatory processes by focusing on interoperability and aiming to leverage data for better decision-making. The strategy has also been endorsed by HMA on 12 September 2025.

Updated AI Network plan

The Management Board noted updates on the development of the EU Network Roadmap on Artificial Intelligence (AI) and Product Master Data (PMD). The AI roadmap, developed under the Network Data Steering Group, aims to guide the responsible and effective use of AI across the European Medicines Regulatory Network. A workshop held in August 2025 with over 120 participants identified 61 AI use cases across marketing authorisation, clinical trials and pharmacovigilance, focusing on capabilities such as drafting and summarisation, quality assurance and retrieving knowledge. These have been prioritised through a network-wide survey to identify high-impact applications, and a draft roadmap will be presented to the Management Board in December 2025. The Board was also informed of ongoing joint EMA–U.S. FDA work on Guiding Principles for Artificial Intelligence in Medicine Regulation, setting out ten key principles on responsible, risk-based and transparent AI use, expected to be published following CHMP endorsement.

An update on Product Master Data (PMD) was presented by Aimad Torqui, Regulatory Oversight Group (ROG) PMS Operational Group lead, outlining the ongoing feasibility study on data qualification for nationally authorised products. The study evaluates the consistency and mapping of product data across Member States and identifies the resources required to align national systems with central datasets, supporting PMS as a trusted repository for medicinal product data and its integration with the European Shortages Monitoring Platform. Results are expected in early 2026.

The Board was also informed about upcoming key deliverables still expected in 2025, including the publication of the Guiding Principles of Good AI Practice in Drug Development and continued network collaboration on AI training. Further work will focus on reviewing learnings from DARWIN EU® and developing a model for EMRN working arrangements on product master data management, jointly led by the NDSG and ROG.

Members welcomed the progress on both AI and data initiatives and underlined their importance in driving regulatory innovation and digital transformation across the EU medicines network.

B.9 Clinical trials in the EU

CTIS modernisation roadmap

[EMA/MB/301991/2025], The Management Board noted the update by EMA through the latest quarterly report to the Board and was informed of the continued positive progress with clinical trials in the EU. By 31 August 2025, over 12,100 initial clinical trials, including initial, transitional and resubmitted trials, had been submitted to the Clinical Trials Information System (CTIS), with more than 10,000 decisions issued by EU Member States.

Following completion of the knowledge transfer to the new supplier, the CTIS modernisation roadmap has been finalised and has now entered the implementation phase. The roadmap, developed following a comprehensive assessment of the current system in 2023 and aligned with the target architecture and business requirements, sets out a detailed modernisation programme running from 2025 to 2028. Its main objectives are to enhance system performance, improve usability, strengthen long-term readiness and reduce total cost of ownership. The modernisation will include the transition to a modular, cloud-native system architecture, deployment of new features, and improvements to both security and user experience. The roadmap defines specific work packages with clear deliverables up to 2028 and remains a dynamic document, adaptable to emerging requirements, including potential changes to the Clinical Trials Regulation (CTR) arising from the Biotech Act.

With regard to the simplification of business rules, good progress has been made under the CTIS Simplification Task Force. The analyses of several prioritised topics, such as the revised roles matrix and user management, safety module, timetable, quality dossier (IMPD-Q) and ad hoc assessment, have been finalised, and the proposed archiving of notices and alerts has been implemented. Furthermore, significant advancement has been achieved in the analysis of key CTA submission and workflow subtopics

ACT EU highlights

[EMA/MB/301991/2025] The Management Board noted an update on the new metrics framework established to monitor how key EU initiatives (ACT EU, CTR Collaborate, COMBINE, MedEthicsEU and CTAG) contribute to strengthening the EU clinical trials environment. The framework focuses on three main benefits: increasing EU attractiveness; faster access to treatment; and ensuring impactful clinical trials through metrics on access to optimal treatments, innovation and new methodologies. Metrics will be available through a secure EMRN dashboard, updated monthly, and from Q1 2026, progress will be published quarterly on the ACT EU website.

The Board was also informed of ongoing ACT EU activities supporting the implementation of the Clinical Trials Regulation (CTR). The CTIS master sponsor handbook, published in July 2025, has been well received, and simplified CTIS training materials are being developed in collaboration with stakeholders under the Multi-Stakeholder Platform Advisory Group (MSP AG). Further webinars for non-commercial sponsors are being organised with NCAs and the Clinical Trials Coordination Group (CTCG). Translations of the Trial Map into all EU/EEA languages is nearing completion, with publication expected in October 2025. A PHE ethics advisory group has been established to provide input to the Emergency Task Force (ETF), and a public consultation on clinical trials in public health emergencies is foreseen by the end of 2025. The two consolidated advice pilots launched under ACT EU continue to progress well, with positive sponsor feedback and discussions on establishing them as permanent services.

The Danish Member of the Board provided an update on the annual ACT EU Matrix meeting held on 1 October 2025 under the Danish Presidency in Copenhagen, which focused on the publication of new KPIs and future programme priorities. The event covered ACT EU delivery, CTR implementation, data analytics and training, with outcomes expected to inform the next multi-annual workplan. It was highlighted that the meeting had identified pilots for faster authorisation of multinational clinical trials as a high priority. The stakeholder co-chair of the MSP AG reported on recent activities, including focus groups on risk-based approaches and training needs for academia and SMEs, and discussions on cross-border trials and optimisation of CTA processes.

During the discussion, Members welcomed the broad range of activities to further improve and strengthen the EU clinical research environment, with continued coordination between the European Commission, EMA, Member States and stakeholders. The need to better integrate ethics review authorities into the clinical trials ecosystem was also highlighted as key to ensuring timely and efficient clinical trial authorisations.

B.10 Update on international activities

International Coalition of Medicines Regulatory Authorities (ICMRA) activities 2019-2025

[EMA/309905/2025] The Management Board was updated on the activities of the ICMRA, which has been chaired by EMA since 2019. Over the past six years (two mandates), ICMRA has led global efforts to enhance regulatory cooperation, focusing on issues such as antimicrobial resistance, supply chain integrity and public health crisis responses. The visibility and impact of ICMRA have increased significantly, particularly during the COVID-19 pandemic, when it became an indispensable global entity enabling the timely sharing of information, globally agreed responses and regulatory convergence. Under EMA's chairmanship, ICMRA expanded its global reach and geographical balance, welcoming new members from Africa, Asia, Latin America and Europe. The coalition now represents a truly global regulatory footprint, with active participation from major EU authorities and WHO as an observer, allowing ICMRA to speak with a unified global voice. During the pandemic, ICMRA became the focal point for international regulatory cooperation, with WHO recognising its role in transforming regulation from a perceived bottleneck to an enabler of equitable access to medicines. This work has left a lasting legacy, reflected in the WHO pandemic treaty's provisions on international regulatory collaboration.

Following the pandemic, ICMRA streamlined its structure and refocused on forward-looking priorities, including artificial intelligence, real-world evidence, reliance and work-sharing, pharmaceutical quality knowledge management (PQKM) and preparedness. The PQKM initiative has become a flagship project to strengthen regulatory convergence and reliance, with significant potential to transform the management of post-approval quality changes among global regulators. Two collaborative pilots concluded in 2024 and extended for a further year focus on the assessment of manufacturing changes and hybrid inspections. They achieved around 90% harmonised outcomes and considerably reduced approval timelines, improving agility to increase manufacturing capacity and respond to public health needs. Participation was voluntary and included major regulators such as TGA Australia, ANVISA Brazil, Health Canada, EMA, PMDA Japan, Swissmedic, MHRA UK, US FDA and others, with very positive feedback from both regulators and industry. The Board welcomed the update on PQKM and acknowledged its strong public health focus, noting its potential to change the handling of post-marketing changes globally as well as to support global resilience by addressing resource constraints, supply chain challenges and the need for more agile regulatory responses. The initiative has already encouraged broader alignment among regulators and is being considered for long-term sustainability.

EMA's chairmanship will conclude with the ICMRA Summit and plenary meeting 2025, hosted at EMA's premises from 21 to 24 October, bringing together global heads of agencies to discuss reliance pathways, artificial intelligence and the critical role of regulators as communicators in promoting science and trust.

Proposal to expand 'OPEN Framework' scope

[EMA/MB/305339/2025] The Board endorsed the proposal to expand the scope of 'OPEN Framework', following feedback received from OPEN partners and stakeholders, to include all medicines addressing unmet medical needs and advanced therapy medicinal products (ATMPs). Additionally, the Board approved the use of the OPEN Framework for post-authorisation changes, including indications, extensions and post-authorisation change management protocols. A Q&A document on the expanded scope will be released later this year. The OPEN initiative ("Opening our Procedures at EMA to Non-EU authorities"), initially endorsed by the Board in December 2020, allows non-EU medicine regulators and the World Health Organization to participate in EMA's scientific evaluations. Initially focused on COVID-19 vaccines and therapeutics, the framework was previously extended to medicines for other health emergencies, medicines for AMR and certain PRIME-designated medicines.

List of written procedures during the period from 29 May to 22 September 2025:

- Consultation no. 05/2025 on the appointment of Alice Blennerhassett CVMP alternate as proposed by Ireland ended on 23.06.2025. The mandate of the nominee commenced on 24.06.2025.
- Consultation no. 06/2025 on the appointment of Irena Žarković CVMP member as proposed by Croatia ended on 27.06.2025. The mandate of the nominee commenced on 28.06.2025.
- Consultation no. 07/2025 on the appointment of Irena Caleta CVMP member as proposed by Croatia ended on 18.08.2025. The mandate of the nominee commenced on 19.08.2025.
- Consultation no. 08/2025 on the appointment of Nicolas Beix CHMP alternate as proposed by France ended on 22.08.2025. The mandate of the nominee commenced on 23.08.2025.
- Consultation procedure for the adoption of the Agency's final accounts for the financial year 2024. The accounts were adopted.
- Consultation procedure for the adoption of the European Commission's proposal regarding the mandate renewal of EMA's Executive Director's. The proposed mandate renewal was adopted.
- Consultation procedure for the adoption of the 128th EMA Management Board meeting minutes. The minutes were adopted.
- Consultation procedure for the adoption of the updated ETF composition. The updated composition was adopted.

Documents for information

- [EMA/MB/206039/2025] Outcome of written procedures finalised during the period from 29 May to 22 September 2025.
- [EMA/MB/298201/2025], [EMA/85885/2025] Revision of EMA rules governing the secondment of national experts (SNEs) to EMA
- [EMA/MB/293347/2025], [EMA/486654/2016] Multinational Assessment Teams (MNAT) Guide to rapporteurs and coordinators
- [EMA/307851/2025] Summary of transfers of appropriations in budget 2025
- [EMA/MB/288085/2025], [EMA/236334/2025] 20th monthly report on *ex ante* and retroactive evaluation of projects for the period 1 January to 30 June 2025
- [EMA/MB/304792/2025], [EMA/304813/2025] Network Portfolio Report

List of participants at the 129th meeting of the Management Board, 02 October 2025

Chair: Rui Santos Ivo

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	Bogdan Yavorov Kirilov *(member)*
Czech Republic	Tomáš Boráň *(member)* Jiří Bureš *(alternate)*
Croatia	Siniša Tomić *(member)*
Denmark	Nils Falk Bjerregaard (*member)* Mette Aaboe Hansen (*alternate*) Birgitte Faber (*support observer*)
Germany	Karl Broich (*member*) Wiebke Löbker (*support observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Lorraine Nolan *(member)* Rita Purcell *(alternate)*
Greece	Spyridon Th. Sapounas (*member)*
Spain	Consuelo Rubio Montejano[1] *(alternate)* Celia Caballero (*support observer*)
France	Catherine Paugam-Burtz (*member)* Franck Foures (*alternate)* Miguel Bley *(support observer)*
Italy	Robert Nisticò *(member)* Armando Magrelli (*alternate)* Marta Giovanna Toma *(support observer)*
Cyprus	Helena Panayiotopoulou (*member)* Irini Chrysafi Fanidou *(alternate)*
Latvia	Indra Dreika (*member*) Sergejs Akuličs (*alternate*)
Lithuania	Dovilė Marcinkė[1] *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski (*alternate)*
Hungary	Beatrix Horváth (*alternate)*
Malta	Anthony Serracino Inglott (*member)*
Netherlands	Aimad Torqui *(member)* Paula Loekemeijer (*alternate)* Roelie Marinus *(support observer)*
Austria	Günter Waxenecker *(member)* Jan Neuhauser (*alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)*
Portugal	Rui Santos Ivo (*member*) Susana Guedes Pombo (*alternate*) Carolina Albuquerque *(support observer)*

[1] Restrictions applied for agenda item B.7

	Participants
Romania	Răzvan Prisada *(member)*
Slovakia	*Apologies received from Slovakia*
Slovenia	Momir Radulovic *(member)* Sabina Zalar *(alternate)*
Finland	Eija Pelkonen (*member*) Anna Siira**Error! Bookmark not defined.** (*alternate*)
Sweden	Ann Lindberg *(member)* Åsa Kumlin Howell**Error! Bookmark not defined.** *(alternate)*
European Parliament	Kristina Garuolienė *(member)*
European Commission	Rainer Becker (DG SANTE) (*alternate*) Matus Ferech (DG SANTE) (*support observer*) Pilar Aguar Fernández (DG RTD) (*alternate*) Tomasz Dylag (DG RTD) (*support observer*)
Representatives of patients' organisations	Marko Korenjak *(member)* Virginie Hivert *(member)*
Representative of doctors' organisations	Denis Lacombe *(member)*
Representative of veterinarians' organisations	Christophe Buhot *(member)*
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) *(member)* Vlasta Zavadova (Liechtenstein) *(member)* Trygve Ottersen[1] (Norway) *(member)* Katrine Heier (Norway) (*support observer*)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Zaïde Frias Hilmar Hamman Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Alberto Ganán Jimenez Rebecca Harding Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin

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