24 April 2026
EMA/MB/57340/2026 - Adopted
Management Board

Minutes of the 131st meeting of the Management Board

Held virtually in Amsterdam on 12 March 2026

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair confirmed the quorum and welcomed the new member and alternate for Ireland, Ms Gráinne Power (Chief Executive, Irish Health Products Regulatory Authority (HRPA)) and Mr Larry O'Dwyer (International and Policy Manager, HPRA), the new member for Hungary (previously alternate), Ms Beatrix Horvath (Head of Department, Hungarian Ministry of Interior) and the new alternate member for Spain, Ma Antonio Blázquez Pérez (Head of Human Medicines Department, Spanish Agency of Medicines And Medical Devices).

The Chair informed the Board that the work of the Management Board (MB) Topic Coordinators for the assessment of the Executive Director and the Annual Activity Report (AAR) 2025 will need to commence ahead of the June Management Board meeting. The Chair thanked the previous Topic Coordinators for their contributions and confirmed he would approach them to see whether they would be willing to continue in their roles. The call for expressions of interest to serve as a Topic Coordinator for the 2025 AAR remains open to other Board members. [Post meeting note: AAR 2025 topic coordinators will be Momir Radulović, Gunther Waxenecker, Franck Foures, Nils Falk Bjerregaard]

The Chair also reminded the Board that the vacancy notice for the next Executive Director of EMA had been published in the Official Journal on 19 February, with the application period concluding on 19 March. The DG SANTE representative confirmed that the procedure was on track, with a pre-selection panel to be established, evaluation criteria set and interviews expected by early June.
The Board would be regularly informed of progress at future meetings by both the European Commission and the Board's appointed observer.

1. Draft agenda for 12 March 2026 meeting

[EMA/MB/29027/2026] 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. No conflicts of interests related to the agenda topics had been identified. The Secretariat informed the board that all concerned members had been informed accordingly before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests 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 130th meeting, held on 17-18 December 2025 adopted via written procedure

[EMA/MB/389167/2025] The Management Board noted the final minutes, adopted by written procedure on 18 February 2026.

A. Points for automatic adoption/endorsement

A.1 Revised charters for tasks and responsibilities of the Executive Director as authorising officer and for the Accounting Officer

[EMA/MB/321163/2025], [EMA/MB/336944/2025], [EMA/MB/360758/2025] The Management Board adopted a Revised Charter of tasks and responsibilities of the Executive Director as authorising officer and a Revised Charter of the Accounting Officer of the EMA. These Charters specify the roles and obligations of both functions in accordance with EU financial rules and form an annex to the internal rules governing the execution of EMA's budget. The updates align the Charters with the revised European Commission's model charter and the recent recast of the EU Financial Regulation applicable to the general budget of the Union.

A.2 Management Board meeting dates 2026 (rev) and 2027-2028

[EMA/MB/44754/2026] The Management Board adopted the meeting dates for 2026 and 2027, including revised dates for the December 2026 meeting, and noted the provisional meeting dates for 2028.

A.3 Revision of policy 0082 Union Product Database (UPD) Access Policy and Joint Controllership

[EMA/354254/2025], [EMA/366104/2021], [EMA/MB/24124/2026] The Management Board adopted the revised UPD Access Policy (Policy 82) and endorsed the revised Joint Controllership Arrangement (JCA) for the Union Product Database. The policy defines access rights to veterinary product data for regulatory authorities, industry and the public. The JCA governs the processing of personal data contained in the UPD between EMA and Member States. Both documents were amended to reflect Commission Decision C(2025) 6269 granting the United Kingdom partial access to the UPD in respect of Northern Ireland under the Windsor Framework, and the renewal of the EU adequacy decision for the UK under the GDPR.

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

[EMA/MB/279597/2018], [EMA/MB/40815/2026] The Management Board adopted the revised rules for reimbursement of expenses for delegates attending EMA meetings. The rules were updated to align with the European Commission's revised mission rules, including changes to daily allowance and hotel

ceilings, and to reflect the amended Executive Director Decision on the establishment of a pool of external experts that can be remunerated in accordance with Article 93 of the EMA Financial Regulation (EMA/394602/2025).

A.5 MB Decision on empowering ED to request derogation from Commission decision on geographical balance of staff

[EMA/MB/389779/2025], [Ares (2025)9975581], [EMA/MB/24149/2026] The Management Board adopted the decision empowering the Executive Director to request a derogation from Commission Decision C(2025) 7357 on geographical balance. The Commission had confirmed that the decision was not suitable for application by analogy by agencies, given the different nature of their activities, locations and staffing arrangements, and had agreed to prepare a model decision tailored to agencies' needs. Pending the adoption of this model decision, a formal derogation was required to suspend the nine-month legal timeline under Article 110(2) of the Staff Regulations. The Agency's Staff Committee had no objections to the proposed course of action.

B.1 Highlights of the Executive Director

The Board noted an oral update from EMA's Executive Director, who began by informing the Board that the final report on EMANS to 2025 was under final review and on track for publication at the end of March 2026. Reporting activities for EMANS to 2028 had also commenced, aligned with EMA and HMA implementation timelines, with an initial status update planned for the third quarter of 2026.

Regarding international activities, the Board was informed of EMA's new roles in the International Coalition of Medicines Regulatory Authorities (ICMRA), including co-chairing the PQKM Working Group and contributing to forthcoming work on reliance. EMA had also co-led the finalisation of the 3Rs 'Call to Action' statement, which was now ready for adoption. The resumption of FDA fellowships for EMA staff was also highlighted, following a pause since 2019, with the first exchange in the veterinary area completed successfully and further collaborations planned in 2026 on Artificial Intelligence (AI) and New Approach Methodologies (NAMs).

On European activities, the Board was briefed on progress with the 2024 discharge procedure, where recommendations to grant discharge had advanced through both Council and Parliament SANT committees ahead of the EP plenary vote at the end of April. An update was provided on EMA's participation at the informal EPSCO Health meeting held in Nicosia on 25-26 February 2026, covering the development of a European Centre of Clinical Excellence for Pharmaceuticals, mental health and inclusiveness, and EHDS Regulation implementation. Following the meeting, the Executive Director visited the Pharmaceutical Services Department of the Cypriot Ministry of Health. The Board was also informed about preparations for a joint EMA-ECHA stakeholder meeting in June 2026, aimed at providing more clarity on collaboration and on input opportunities for EMA’s stakeholders in ECHA’s activities.

An update was also provided on ongoing supply chain pressures. Regarding the conflict in the Middle East, EMA, the MSSG and the SPOC Working Party are closely monitoring the effects on medicine supply in the EU. No critical shortages had been reported to date, though companies had flagged varying degrees of logistical disruption and rising costs. The situation remains dynamic. An ad-hoc MSSG meeting had been convened on 5 March to address shortages of ifosfamide and cyclophosphamide, anticipated across most Member States due to significant manufacturing issues. Coordinated actions were under way and MSSG recommendations were being finalised. The methodology to identify vulnerabilities in supply chains of critical medicines had also been adopted and published on 10 March, with an exercise covering several active substances set to begin in 2026.

Additionally, the Board was informed of two key upcoming events. EMA's 2026 Development Day would continue as a permanent annual event under the HR Strategy, with an expected 600 staff members participating in thematic streams reflecting EMA's four strategic priority domains: excellence in science and regulation; digital, data and AI transformation; public-health preparedness and sustainability; and people and culture. As part of its outreach and communication activities, EMA would also participate in Amsterdam WorldPride 2026, with a float at the Canal Parade on 1 August 2026 under the theme "United for Health," promoting EMA's mission, the EU's fundamental values and the Agency's commitment to diversity and inclusion through a programme covering patient engagement, HIV treatment and women's health. The Board was also informed about a joint Best Practice Guide on the use of external experts being developed within the EMA-HMA Strategic Resource Oversight Group.

A few members of the Board stressed the importance of close monitoring of supply chain disruptions in particular with the conflict in the Middle East and requested for regular updates through the MSSG. The Executive Director provided reassurance that extensive supply chain monitoring was under way, with some 500 INNs assessed, and committed to providing a detailed briefing to the Management Board ahead of the MSSG meeting on 23 March. Several Board members also suggested that the potential impact of PFAS restrictions on medicine availability should feature in the planned EMA-ECHA Stakeholder meeting. The DG SANTE representative stated the need for caution on non-core expenditure and encouraged NCAs' engagement in the forthcoming ECHA public consultation on PFAS. The Executive Director clarified that the EMA-ECHA Stakeholder meeting would focus on ways of working rather than on specific regulatory interventions, but undertook to explore with ECHA whether complementary information sharing with the NCAs on PFAS could be considered.

B.2 Report from the European Commission

The Management Board noted updates from the representatives of DG SANTE and DG RTD.

The DG SANTE representative presented the next steps in the adoption of the new EU pharmaceutical legislation, the aspects relevant to EMA in the legal proposals for the Biotech Act and the revision of the EU medical device legislation, and a state of play on the Critical Medicines Act. The new pharmaceutical legislation is expected to enter into force in Q4 2026 and become applicable two years thereafter, except for some specific provisions with earlier applicability.

The Biotech Act proposal combines regulatory streamlining and simplification with industrial policy measures, to boost the competitiveness of the EU biotechnology sector. Besides amendments to the Clinical Trials Regulation, it streamlines rules in three EMA-relevant areas: ATMPs, regulatory facilitation, and veterinary medicines. For ATMPs, it introduces a risk-based GMO exemption for clinical trial authorisation, designates ATMP Centres of Excellence as High-Impact Strategic Projects, and updates definitions. On regulatory facilitation, it creates an EU Biotechnology Support Network to help navigate the regulatory system, a Foresight Panel to facilitate cross-framework dialogue on emerging technologies, and a last-resort regulatory sandbox for novel biotechnology products not covered elsewhere in EU legislation. For veterinary medicinal products, it mirrors the risk-based GMO derogation, expands variations not requiring assessment, adds incentives and a sandbox mechanism, and, to remove any legal uncertainty, clarifies that administering veterinary medicinal products does not place treated animals or their products under the Union GMO legislation.

The revision of the medical devices legislation proposes, amongst other aspects, to strengthen EMA's role in supporting the regulatory framework thanks to its technical and scientific contributions, without altering Member States' competences. Key proposed changes for EMA include reinforced management of expert panels, broadened panel membership to incorporate regulatory expertise, and an expanded use of the panels' advice to support national and EU level decisions, such as on product classification and the recognition of breakthrough and orphan devices. EMA would also provide technical support to

coordination of national activities on borderline and classification issues, clinical and performance investigation and evaluation, vigilance, market surveillance, and derogations to conformity assessment procedures in emergency situations. In addition, the revision mandates EMA, in collaboration with MDSSG, to develop a Union list of critical devices (including its methodology) and to support, where needed, the European Commission in developing and maintaining a central IT tool for reporting and information exchange regarding cases of interruption or discontinuation of supply.

The interinstitutional negotiations on the Critical Medicines Act are ongoing and the Cyprus presidency of the Council is planning to conclude them by June. The Board was also informed that a call for evidence to prepare the Global Health Resilience Initiative will be launched shortly and the initiative will be published as a Commission Communication in Q2 of this year.

Two Board members noted the additional tasks for Member States, such as operating national sandboxes and closer monitoring of Notified Bodies, and asked how these will be organised and funded. The healthcare professionals' representative welcomed the Biotech Act for introducing clearer definitions for minimally invasive and low-intervention clinical trials and enabling potential simplification. He also stressed, however, that Europe's clinical trial landscape remains complex, with sometimes overlapping regulations and guidelines adding further administrative burden. The DG SANTE representative noted that, although the medical devices legal proposal introduces new obligations for Member States, it is expected to deliver net benefits by eliminating disproportionate tasks that do not enhance patient safety. He emphasised that regulatory sandboxes under the Biotech Act will remain an exceptional mechanism for products not adequately addressed under the existing frameworks. He reiterated the European Commission's commitment to simplifying first the primary legislation on clinical trials, and then the related implementing acts and guidances, which would help reduce workload.

The DG RTD representative provided an update on the European Life Science Strategy, recalling the flagship Biotech Act and the open call for ATMP Centres of Excellence. She highlighted the establishment of a new internal Life Sciences Coordination Group within the Commission, designed to strengthen coherence across services and support more structured engagement with Member States and stakeholders. The group held its first meeting in February and is currently defining its working methods and priorities. She also reported a major development in global health: EMA's recent positive scientific opinion on acoziborole, the first single-dose oral treatment for sleeping sickness. This achievement results from extensive collaboration under the Global Health EDCTP3 partnership. On regulatory sandboxes, she introduced the BRIDGE project recently launched under the Innovative Health Initiative (IHI). Although a research project, BRIDGE is intended to generate regulatory science insights to inform future regulatory frameworks by examining existing options, developing fitness criteria and possible implementation pathways.

The DG RTD representative further presented the ONC-NGS project, which is focussing on next-generation sequencing (NGS) for cancer. Using a pre-commercial procurement model, public healthcare providers jointly procure R&D services to test prototypes which are not yet on the market but could meet the buyers' needs. This practice is being tested in eight hospitals across five EU Member States. She encouraged reflection on regulatory support for such demand-driven innovation. Finally, she also drew attention to an ongoing Horizon Europe call on advancing regulatory science, advising regulators to participate, and announced a major co-funded EU Partnership on New Approach Methodologies (NAMs) to be launched by the European Commission in the second half of 2026.

A Board member commented that investments in areas such as NAMs and NGS are welcome, and suggested that research organisations should be primarily involved, because of challenges for medicine National Competent Authorities to contribute beyond core operational duties. The importance of the Lifescience Coordination Group for advancing a One Health approach and fostering cooperation across

sectors was emphasised. The new Coordination Group should therefore ensure that availability is considered alongside safety objectives. The DG RTD representative noted the comments but reiterated the need for regulators to join the Horizon Europe regulatory science project, even with limited capacity, stressing that strong consortia and successful project completion require their involvement.

B.3 Update on the preparations for implementation of the new EU pharmaceutical legislation, once adopted

The Management Board noted an oral update from the European Commission and from EMA on the preparations for implementation of the new EU pharmaceutical legislation, once adopted.

The DG SANTE representative outlined the implementation timeline of the new pharmaceutical legislation, explaining that the majority of provisions in both the regulation and the directive will apply 24 months after entry into force. If adoption occurs in late 2026, most obligations would therefore become binding towards the end of 2028, by which time all regulatory systems and processes at EU and national level must be fully operational. Several provisions, however, apply earlier. Measures related to security of supply, regulatory sandboxes, AMR incentives, and certain provisions for financial and international collaboration will take effect immediately upon entry into force. Provisions concerning availability monitoring and shortages management will apply after six months, while access-related obligations will apply 12 months after entry into force. The environmental risk-assessment prioritisation programme for legacy products authorised before 2005, as well as the register of designated orphan medicines, will become applicable six months after the general date of entry into application. Effective implementation will require close coordination among the European Commission, EMA and national competent authorities. More than 30 implementing and delegated acts must be adopted by the Commission before the date of application, each requiring formal procedures and consultation with Member States and the regulatory network. Joint work, such as on the electronic product information (ePI), was highlighted as essential for meeting legal obligations and ensuring coherent EU-wide implementation.

EMA provided an update on preparatory activities since the previous Management Board meeting and work planned until June. Governance nominations agreed in December 2025 - covering the Oversight Group, Management Board co-sponsors and EMA co-sponsors - have been confirmed, and coordination among co-sponsors has begun. On 6 March, EMA met with the Chairs of the scientific committees and CMDh to discuss their involvement in implementation of the new legislation. The Oversight Group is meeting on 12 March for its first organisational session to discuss working practices and governance arrangements. Delivery streams are analysing the legal text, as a basis to define work plans and integrate them into a consolidated implementation roadmap to support a formal programme launch in the margins of the June Management Board meeting.

The Chair welcomed the progress and reiterated the need for strong coordination across the EU Medicines Regulatory Network and reaffirmed the importance of the Governance for the effective implementation of such structural changes. A Board member asked about a comparison between the new and existing legislation, to support national implementation activities. EMA indicated that it could present an overview of major changes at the June kick-off meeting.

B.4 EMA Annual Report 2025

[EMA/17207/2026], [EMA/MB/41617/2026] The Management Board adopted the EMA Annual report 2025.

The Annual Report outlines EMA's strategic priorities, key accomplishments and contributions to public and animal health across Europe. The opening chapter covers major developments in 2025, including highlights of the evaluation and monitoring of human and veterinary medicines, EMA's 30th anniversary, and high-impact activities across three strategic areas: accelerating and optimising the assessment of key medicines, facilitating the path to accessibility and strengthening the availability of medicines, and enhancing the sustainability of the network. The second chapter offers a selection of key figures covering human and veterinary medicines, inspections and compliance, and medicine shortages. In 2025, EMA endorsed 104 human medicines for marketing authorisation, 38 of which contained a new active substance, including the first oral therapy for postpartum depression, a bladder cancer treatment and a vaccine against Chikungunya virus. In veterinary medicine, EMA endorsed 30 medicines, the highest tally for a second-year running, including 16 vaccines, seven of which received approval under exceptional circumstances to respond to animal health emergencies. The report, including an interactive digital version, will be published in May 2026.

B.5 2025 EMA Annual Report on Independence

[EMA/8063/2026] [EMA/MB/36377/2026] The Management Board adopted the 2025 EMA Annual Report on Independence.

The Agency presented its annual report on the application of EMA’s independence and conflict of interest (COI) policies and rules applied for scientific committees’ members and experts, for Management Board members, for EMA staff and for the expert panels in the field of medical devices. The report describes the activities performed in 2025 to implement these policies and rules, provides facts and figures (including on Breach of Trust procedures), gives information on initiatives taken in 2025 and identifies recommendations for further improvement in 2026.

A central focus in 2025 was the implementation in May 2025 of the revised COI policies for scientific committee members (Policy 0044), Management Board members (Policy 0058). The policy revisions were adopted by the Management Board in December 2024 to align with the findings of two rulings of the Court of Justice. This was enabled by the provision of information and updated guidance documents and training offered to all committee members and experts.

All experts and committee members were requested to update their DOIs via the updated Expert management Tool in accordance with the new policies by 1 May 2025. As a consequence of the revision, an increase in the number of scientific committee members and experts with indirect interests was noted compared to 2024. This is mainly due to the new requirement for members and experts to declare current affiliation to a research organisation as an indirect interest, as many members and experts also work for universities or hospitals. However, instances where members or experts would be subject to restrictions to their participation in light of these new declared interests from the revised policy were very limited, as universities or hospital are rarely applicants of submissions to EMA.

The report also includes information on ex post control performed on a sample of declaration of interests for scientific committee and other groups members, management board members and advisors in the expert panels in the field of medical devices. Overall, the control showed that the system for handling declarations of interests works well with no major weaknesses identified in the processes in place. Where required, corrective actions have been taken for some minor findings following the controls (e.g. correction of DOI) as well as a few process improvements.

The Board was also informed that the expert witness provision did not need to be used in 2025. Other key initiatives completed in 2025 included supporting HMA’s revised COI guidance, updates to staff rules, the EMA Code of Conduct, and the revision of EMA’s breach of trust procedures.

For 2026, no major new initiatives are planned; the focus will be on continued monitoring of policy implementation activities, expertise availability and DOI controls.

B.6 Draft ePI roadmap

[EMA/MB/33111/2026] The Management Board noted an update from Member States and EMA on the draft Road Map for implementation of the electronic Product Information (ePI) for human medicinal products.

The Board member from Spain introduced the ePI initiative, which aims to provide authorised, statutory product information for EU medicines - including the SmPC, labelling and package leaflet - in a semi-structured digital format. Using the FHIR standard, ePI can be accessed through web platforms via an application programming interface or printed as a traditional leaflet. The ePI key principles, including the use of a global standard, were jointly agreed by EMA, HMA/NCAs, the European Commission, and representatives of industry, patients and healthcare professionals. The initiative seeks to deliver timely, accurate and continuously updated information to patients and healthcare professionals, while increasing regulatory efficiency. Key advantages include enhanced accessibility, alignment with future EU legislation (which will make ePI mandatory), GDPR compliance, and interoperability with national and global standards. Major milestones so far included publication of the ePI principles (2020), harmonisation of the EU ePI Common Standard (2021), and integration of ePI into the EMA's Product Lifecycle Management (PLM) Portal FHIR repository. A 2023–24 pilot involving 23 companies and five agencies successfully generated ePIs in real procedures.

EMA outlined the ongoing work to prepare processes, guidance and IT systems for implementation. Business processes for centrally authorised products are being adapted, user acceptance testing is ongoing, and ePI functionality is being fully embedded into the PLM Portal. Implementation will start at the end of 2026 with a stepwise approach: vaccines first (due to frequent updates and accessibility needs), followed by oncology products and then other therapeutic areas. Initially, ePI creation will be an additional procedural step after the scientific assessment, with full integration into digital assessment processes planned later. ePI will first be available in English only, with multilingual versions optional and becoming mandatory once the revised legislation becomes applicable. The central EU repository at EMA is ready to scale up as more ePIs are submitted. For national use, Member States will need to undertake preparatory work, including adapting their national systems and developing their own implementation plans and guidance. Spain, as network product owner, will coordinate rollout with EMA support, starting with a workshop at EMA on 10 June to assess NCAs' readiness, after which Member States' timelines will be consolidated into a final roadmap by year-end.

During the discussion, the Chair welcomed the strong alignment of ePI implementation with the upcoming legislation. Board members praised the work and stressed the need to onboard more NCAs. One Board member asked whether ePI could support shortages management in small markets; it was explained that its multilingual, structured format facilitates cross-border information-sharing, voluntary solidarity mechanisms as well as identification of therapeutic alternatives and analysis of manufacturing options. Industry feedback also indicates that multilingual ePI may help generics launch products in small markets where paper requirements may currently discourage marketing.

Other Board members emphasised the importance of readability, integration with national systems and maintaining NCAs as the authoritative source of product information. EMA confirmed that authorities, not marketing authorisation holders, will continue to publish ePI and that the digital format enables significant accessibility improvements, such as adaptable layouts and enhanced navigation. The Commission underscored the need to expand from early adopters to a second wave of NCAs and reiterated its support for coordinated EU-wide implementation.

B.7 2024-2025 biennial report on stakeholder engagement

[EMA/149424/2025] The Management Board noted a presentation from EMA on the 2024-2025 biennial EMA report on stakeholder engagement.

The biannual stakeholder report highlights the essential contributions made by stakeholders to the Agency and the wider EU regulatory network. Covering 2024–2025 and coinciding with the Agency's 30th anniversary, the report emphasises how collaboration with patients, healthcare professionals, industry and academia has shaped regulatory achievements. For the second time in a row, the report includes a section on multi-stakeholder engagement, illustrating its increasing importance to support major initiatives, such as progress on the Medicines Agencies Network Strategy to 2028, activities under the ACT EU multi-stakeholder platform, efforts to address medicine shortages and contributions to the Agency's anniversary activities. The report then describes activities in the different stakeholder groups. Key developments include the introduction in 2025 of remuneration for patients and healthcare professionals participating in Agency's work, recognising the critical role of their expertise in regulatory decisions. The report also highlights strengthened support for academia, including fee reductions for scientific advice and the launch of the EMA/HMA European Platform for Regulatory Science Research. For industry, the Agency has strengthened structured dialogue through the Industry Standing Group, which provides an important channel for dialogue, and will continue to be used during the implementation of the new pharmaceutical legislation. After presenting the report, the Agency reaffirmed its commitment to strong, structured stakeholder involvement to ensure timely, high-quality outputs, and expressed gratitude for stakeholders' continued collaboration.

B.8 Update on cybersecurity management at EMA

The Board noted the annual update on cybersecurity management at EMA. Key highlights from 2025 include the launch of role-based access to EMA's document management system, adoption of an Identity and Access Management (IAM) policy, enhanced Security Operations Centre (SOC) monitoring, and initiation of supplier cybersecurity risk assessment processes. EMA is compliant with the EU Cybersecurity Regulation, with all deliverables supplied to the Interinstitutional Cybersecurity Board (IICB) in a timely manner. The SOC processing volume increased by 238%, with 90 malicious incidents detected and contained, and vulnerability management coverage rising from 70% to 95% with significantly improved remediation times. Looking ahead, EMA will update its cybersecurity strategy for 2026-2030 including by addressing emerging risks from AI exploitation by threat actors, AI adoption risks, and advances in quantum computing. Key 2026 priorities include cyber risk-based auditing of top 10 suppliers, IAM policy implementation, strengthening security culture through training, and improving SOC capabilities.

Board members asked questions on the potential budgetary impact of the updated strategy, digital sovereignty and EU dependency on non-European IT providers, and cybersecurity requirements in procurement. EMA confirmed that cybersecurity is operated within a ring-fenced budget and would not divert resources from other activities. On digital sovereignty, it was noted that the topic was being discussed within the Network ICT Advisory Committee and would be addressed at the IT directors meeting in April, with a potential future discussion at Management Board level. On procurement, an auditing system is being established to verify supplier compliance with cybersecurity obligations.

B.9 Clinical trials in the EU

- Policy and legislative update (EC)

The Board noted the legislative update on clinical trials presented by the DG SANTE representative, who outlined the state of play of the legislative process of the Biotech Act at the Council and in the European Parliament. A joint opinion from the European Data Protection Board and the European Data Protection Supervisor has been issued on 10 March, confirming agreement with a single harmonised legal basis for personal data processing in the context of clinical trials. The FAST-EU initiative was also progressing, with seven clinical trial applications under assessment and a third call set to open on 23 March. The DG SANTE representative stressed the importance of preserving the ambition and scope of the key simplification objectives set out in the Commission proposal throughout the legislative discussions in particular at technical level. On the implications for EMA, a revised CTIS development plan would need to be submitted within one month of the Biotech Act's entry into force, whilst 12 additional FTEs and €15 million are foreseen for CTIS from 2028. Since much of the CTIS work would need to take place before formal adoption, possible solutions to address the earlier Agency resource needs will need to be explored.

The DG RTD representative presented the Clinical Research Investment Plan, a non-regulatory flagship action under the European Life Sciences Strategy aimed at facilitating funding for multi-country clinical trials and developing European research infrastructures, with a vision of a single EU market for clinical research. Targeted stakeholder consultations have been held, with key recommendations including more agile funding instruments, a single-entry point for sponsors, support for SMEs, and leveraging AI in clinical research. The Board welcomed the Clinical Research Investment Plan and noted that AI was already being implemented by sponsors, particularly for protocol development.

- CTIS update and ACT EU highlights

[EMA/MB/29027/2026], [EMA/42932/2026] The Management Board noted the report and was informed of continued progress with CTIS. The quarterly KPI report showed most indicators meeting or exceeding targets, with system performance remaining under monitoring. The Board was informed of the formal Internal Audit Service audit expected to start in the coming weeks and the report anticipated in late July 2026. CTIS change management activities were under way, structured around communication, engagement and training. The CTIS modernisation roadmap, presented in Q4 2025 has entered its implementation phase, setting out deliverables through to 2028, from foundational architecture through core capabilities modernisation to a fully modernised system with advanced technologies including AI. Provisions in the Biotech Act, such as proposed changes to assessment workflows, submission rules, low-intervention trials, product core dossiers, combined device trials and AI, were expected to substantially impact the CTIS architecture. The modernisation roadmap would need to be significantly reshaped to combine existing modernisation objectives with Biotech Act functional readiness, with key challenges around managing uncertainty while the Act was not yet adopted and ensuring sufficient resources before 2028. A detailed discussion on this matter is foreseen for the June Board meeting. In the discussion, members expressed support for progress made but emphasised the need for a thorough discussion, noting open questions on timelines and what could realistically be achieved before 2028. The Chair confirmed that the June meeting would provide an opportunity for such a discussion, based on a structured analysis of legislative developments, ongoing initiatives and resource implications to be presented ahead of the meeting.

On ACT EU, the DG SANTE representative presented updates on governance and strategic direction. The ACT EU Multi-Stakeholder Platform Advisory Group had appointed Catherine Paugam-Burtz (France Member) as the new regulatory co-chair for a two-year mandate. The Board expressed sincere appreciation for the significant contribution of the outgoing co-chair, Maria Lamas (Spain Member). A call for nominations for a new stakeholder co-chair would be launched on 20 March 2026. The ACT EU workplan was being revised to align with provisions in the Biotech Act proposal, the Clinical Research Investment Plan and current needs, with endorsement by the Steering Group expected by end of April and publication in May 2026.

EMA presented an update on monitoring the EU clinical trials environment. Key performance indicators launched in 2025 were now being measured against targets for increasing the attractiveness of the EU for multinational trials and faster patient access to treatment. Early data showed performance behind target on both metrics, though these were five-year targets and performance was expected to improve as the Biotech Act, the Clinical Research Investment Plan, FAST-EU and other ACT EU actions begin to show impact. In addition, an interactive dashboard specifically aimed at the Network has been launched in January 2026 to support the network in monitoring clinical trials data. Additional ACT EU priority actions include a methodology guidance roadmap, an interim report on consolidated advice pilots, draft guidance on clinical trials during public health emergencies under consultation until 30 April, and continued support to non-commercial sponsors.

- Joint Controllership Arrangement (JCA) for CTIS

[EMA/541334/2021], [EMA/MB/41030/2026] The Management Board endorsed the revised Joint Controllership Arrangement. The proposed updates were of a technical nature, including referencing the revised CTIS transparency rules, and updating the annexes to reflect current Member States data protection contact points and the CTIS data protection notice.

B.10 Update from Network Data Steering Group (NDSG)

[EMA/MB/49487/2026], [EMA/51241/2026] In agreement with Board members, due to time constraints, this topic was not discussed. The revised Network Data Steering Group workplan for this topic, along with the presentation, was circulated to the Board for information following the meeting with the opportunity for comments and questions.

B.11 Status update on African Medicines Agency (AMA)

In agreement with Board members, due to time constraints, this topic was not discussed and will be tabled for the June Management Board meeting.

List of written procedures during the period from 5 December 2025 to 3 March 2026:

- Consultation no. 09/2025 on the appointment of Mojca Ogriz as CVMP alternate as proposed by Slovenia ended on 05.12.2025. The mandate of the nominee commenced on 06.12.2025.
- Consultation no. 01/2026 on the appointment of Ruth Kieran as CHMP alternate as proposed by Ireland ended on 20.01.2026. The mandate of the nominee commenced on 21.02.2026.
- Consultation no. 02/2026 on the appointment of Sonia Gil Morales as CVMP alternate as proposed by Spain ended on 05.02.2026. The mandate of the nominee commenced on 06.02.2026.
- Consultation no. 03/2026 on the appointment of Birgit Aasmäe as CVMP alternate as proposed by Estonia ended on 10.02.2026. The mandate of the nominee commenced on 11.02.2026.
- Consultation procedure for the adoption of the 130th EMA Management Board meeting minutes. The minutes were adopted.
- Consultation procedure for the adoption of non-automatic carry forward of appropriations from 2025 to 2026. The non-automatic carry forward appropriations 2025-2026 were adopted.

Documents for information

- [EMA/MB/316806/2025] Outcome of written procedures finalised during the period from 5 December 2025 to 3 March 2026
- [EMA/MB/36132/2025], [EMA/371010/2025] 2025 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2025
- [EMA/MB/25406/2026], [EMA/17537/2026] Twenty first, six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2025.
- [EMA/MB/50799/2026], [EMA/50755/2026] Network Portfolio Report
- [EMA/MB/29027/2026] Summary of transfers of appropriations in budget 2025
- [EMA/MB/50522/2026], [EMA/43071/2026] Annual Activity Report (AAR) 2025
- [EMA/MB/29770/2026], [EMA/29769/2026] EMA working document on buildings
- [EMA/MB/29027/2026], [EMA/40110/2026] Report on external experts remunerated under Article 93 of the EMA Financial Regulation – Calendar year 2025
- [EMA/MB/29027/2026] Management Board Audit and Risks Group (MBARG) – Minutes of 4 February meeting

List of participants at the 131st meeting of the Management Board, 12 March 2026

Chair: Rui Santos Ivo

	Participants
Belgium	Hugues Malone *(member)* Charles Denonne *(alternate)*
Bulgaria	Bogdan Yavorov Kirilov (*member*)
Czech Republic	Boráň Tomáš *(member)*
Croatia	Siniša Tomić *(member)*
Denmark	Nils Falk Bjerregaard (*member)* Mette Aaboe Hansen (*alternate*)
Germany	Karl Broich (*member*) Wiebke Löbker (*support observer*)
Estonia	Katrin Kiisk *(member)*
Ireland	Grainne Mary Power (*member*) Laurence O'Dwyer *(alternate)*
Greece	Spyridon Th. Sapounas (*member)*
Spain	María Jesús Lamas Díaz *(member)* Antonio Blázquez (*alternate*) Celia Caballero (*support observer*)
France	Catherine Paugam-Burtz *(member)* Franck Foures (*alternate)* Isabelle Puff (*support observer)*
Italy	Marta Giovanna Toma *(support observer)*
Cyprus	Helena Panayiotopoulou (*member)*
Latvia	Sergejs Akuličs (*alternate*)
Lithuania	*Apologies sent from Lithuania*
Luxembourg	*Apologies sent from Luxembourg*
Hungary	Beatrix Horváth (*member)*
Malta	Anthony Serracino Inglott (*member)*
Netherlands	Paula Loekemeijer (*member)* Aimad Torqui *(alternate)* Roelie Marinus *(support observer)*
Austria	Günter Waxenecker *(member)*
Poland	Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (support *observer*)
Portugal	Susana Pombo *(alternate)* Maria João Morais *(support observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Roman Dorčík (*member*) Katarína Massányiová (*alternate)*
Slovenia	Momir Radulović *(member)* Sabina Zalar (*alternate*)
Finland	Eija Pelkonen (*member*) Anna Siira (*alternate*)
Sweden	Ann Lindberg (*member*)

	Participants
	Åsa Kumlin Howell *(alternate)*
European Parliament	Kristina Garuoliene *(member)* Cristian Busoi *(member)*
European Commission	Rainer Becker (DG SANTE) (*alternate*) Matus Ferech (DG SANTE) (*support observer*) Maria 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 (Norway) *(member)* Sayeh Ahrabi (*alternate*) Katrine Heier (Norway) (*support observer*)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Zaïde Frias Hilmar Hamann Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Steffen Thirstrup Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Monika Benstetter Rebecca Harding Juan García Violeta Pashova Zahra Hanaizi Apolline Lambert Olga Oliver-Díaz Riccardo Mezzasalma Adeline Bessemoulin Andrea Tzoneva