6 August 2026
EMA/MB/134603/2026
Management Board - Adopted

Minutes of the 132nd meeting of the Management Board

Held in Amsterdam on 10-11 June 2026

The Chair of the EMA Management Board (MB) opened the meeting, which was held as a face-to-face meeting, with a few Members joining via videoconference. The Chair confirmed the quorum and welcomed the new alternate for Greece, Mr Symeon Psomiadis (Vice President of the Greek National Organization for Medicines (EOF)).

The Chair informed the Board that the work of the Management Board (MB) Topic Coordinators for Single Programming Document will need to commence ahead of the December 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 Single Programming document remains open to other Board members.

1. Draft agenda for 10-11 June 2026 meeting

[EMA/MB/87650/2026] 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. Some potential competing interests relating to the day's agenda were identified concerning topics 'A.3 Revision to Single Programming Document', 'A.4 Revision of the CAT Rules of Procedure', and 'B.12 Fee Regulation working arrangements rev. 3'. The Secretariat informed the board that all concerned members had been informed before the meeting. Should the need for a vote on the above topics arise, the chair would take up the matter again.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

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3. Minutes from the 131st meeting, held on 12 March 2026 adopted via written procedure on 24 April 2026

[EMA/MB/57340/2026] The Management Board noted the final minutes, adopted by written procedure on 24 April 2026.

A. Points for automatic adoption/endorsement

A.1 Inflationary adjustment for rates payable to EDQM for sampling and testing activities in 2027

[EMA/MB/46621/2026] The Management Board endorsed a 2.3% inflationary adjustment for rates payable to European Directorate for the Quality of Medicines & HealthCare (EDQM) for sampling and testing activities on centrally authorised medicinal products in 2027. The annual adjustment is foreseen in accordance with the EMA–EDQM Cooperation Agreement and is based on the inflation rate measured by Eurostat in December 2025.

A.2 MB Decision on implementing provisions on reimbursements of expenses for missions to the UK

[EMA/MB/71642/2026], [EMA/MB/71363/2026],[EC-Ares(2026)2485874] The Management Board adopted a Decision on the adoption by analogy of Commission decision C(2026)634 final of 5 February 2026 amending Decision C(2002)98 fixing the rates of the daily subsistence allowances and the ceilings for the reimbursements of hotel expenses for missions outside the European territory of the EU, specifically updating rates for the UK. The EC decision had been notified to EMA and other EU decentralised agencies in February 2026.

A.3 Revision to Single Programming Document

[EMA/MB/122309/2026], [EMA/MB/122306/2026] The Management Board adopted an amendment to Annex XI "Plan for grant, contribution and service-level agreements" of the EMA 2026–2028 Single Programming Document. The amendment covers three new grant-related actions planned since December 2025, including potential EMA participation in a Horizon Europe grant application and two additional grants under the EMA-AMA (African Medicines Agency) Contribution Agreement. The amendments are needed in line with requirements of the Financial Regulation.

The Management Board was also informed about a possible written procedure for an Amending 2026 Budget later in the year. After the conclusion of the quarterly budget monitoring exercise in June, the Agency will assess its financial position and, if the current trends showing higher fee revenue and increased expenditure to MSs are confirmed, will present an amending budget, either at the October MB meeting or earlier via written procedure, to align the budget to the emerging trends.

A.4 Revision of the CAT Rules of Procedure

[EMA/68867/2026], [EMEA/45110/2007 Rev. 6], [EMA/MB/77410/2026], The Management Board adopted the revised Rules of Procedure of the EMA Committee for Advanced Therapies (CAT). The revision introduces provisions to enable international cooperation under the OPEN framework, which was established during the COVID-19 pandemic to facilitate the exchange of expertise with non-EU authorities and extended in October 2025 to include ATMPs. The CAT Rules of Procedure had not

previously been updated in this respect, as no relevant applications had been submitted. The update is prompted by a forthcoming product authorisation application to be discussed by CAT in July, which will be evaluated under the OPEN framework. Accordingly, a new Article 19 has been added, aligned with similar provisions in the CHMP Rules of Procedure. The opportunity was also taken to introduce minor amendments to align the CAT Rules with those of the other EMA Committees.

B.1 Highlights of the Executive Director

The Board noted an oral update from EMA's Executive Director, who began with an update on crisis preparedness regarding the ongoing Bundibugyo ebolavirus outbreak. No specific vaccines or therapeutics are approved at this stage, though several therapeutics and vaccine candidates are being considered for clinical trials or limited use. EMA is supporting preparedness activities through the Emergency Task Force, engagement with developers, collaboration with African regulators, and support to the possible use of investigational medicines. A brief update was also provided on the situation in the Middle East, with the impact on the supply of medicines in Europe remaining limited to date.

The Board was also informed of the EMA meeting with senior representatives of pharmaceutical companies held on 17 April 2026. Key priorities emerging from the discussions included strengthening patient centricity, sustaining public trust, reducing fragmentation, accelerating innovation, and ensuring that ongoing legislative and policy initiatives translate into real-world impact. In this context, participants emphasised the need to address structural challenges across the system, including further modernisation of regulatory processes and practices, greater support for early-stage development in Europe, and improved coherence between regulatory decision making and pricing and reimbursement pathways.

A MB member raised concern regarding recent industry benchmarking reports comparing EU and FDA regulatory performance, considered to rely on a misleading methodology. The Executive Director shared this concern and emphasised that effective delivery on the new pharmaceutical legislation would itself help shape a more accurate narrative.

As regards European activities, the Board was informed of the European Ombudsman's own-initiative inquiry into former senior EU agencies staff and Management Board revolving door cases, in which EMA was commended in two instances, and which would result in 'best practice' guidelines for all EU agencies. The topic will be brought back to the Board for further discussion in Q3/Q4 2026. The Board was informed that the European Parliament had granted discharge of EMA's 2024 accounts on 29 April, and that her annual exchange with the European Parliament's SANT Committee will take place on 14 July. The Board was further informed of the annual bilateral meeting between EMA and DG HERA leadership on 3 June, covering outbreak response, support to the development and availability of medicines for health threats, clinical studies in emergencies, supply chain strengthening, and stakeholder engagement, with both sides confirming their commitment to cooperate in a complementary manner.

On international activities, the Board was updated on leadership changes at the US FDA, noting that operational leadership and technical cooperation nonetheless remained in place, and that EMA had welcomed Daisuke Iwata as the new MHLW/PMDA Liaison Official at EMA from 13 May 2026.

The Board was also informed of the forthcoming Multistakeholder Workshop on Women's Health, to be held on 28-29 September 2026 at EMA. The workshop would highlight the contributions of EMA and EMRN partners to women's health, take stock of current gaps and challenges, and identify priority areas and measurable actions, with the aim of agreeing on priorities to be captured in a public report.

The Board was also updated on the EMA Development Day held on 4 June 2026, comprising four thematic streams, 23 sessions all developed by EMA staff, 60 presenters and 120 contributors, with over 400 staff participating on site. The event featured a keynote address by Manuel Muñiz, Rector of IE University in Madrid, on geopolitics, technological transformation and the future of work.

On EMA leadership changes, the Executive Director paid tribute to Ivo Claassen, Head of the Veterinary Medicines Division and Deputy Executive Director, who will retire in July 2026. The Board was informed that Melanie Carr would take over as Deputy Executive Director from the date of his departure, and that Franck Fourès had been appointed following an external selection procedure as new Head of the Veterinary Medicines Division from 1 September 2026. Finally, the Board was informed that, following the Dutch municipal elections in March, the city of Amsterdam had announced on 3 June not to proceed with the Amsterdam Erotic Centre project.

Board members welcomed the comprehensive update and thanked Ivo Claassen for his service as Deputy Executive Director and Head of the Veterinary Medicines Division, while congratulating Melanie Carr and Franck Fourès on their appointments.

B.2 Report from the European Commission

The representative of DG Research and Innovation (DG RTD) provided an overview of ongoing EU-funded activities in clinical research and in the advancement of non-animal methods (NAMs) in biomedical innovation. She also informed that EU continues to fund, via CEPI, vaccine development for the Ebola Bundibugyo strain, notably the VSV IAVI vaccine and the ChAdOx1 vaccine by University of Oxford and Serum Institute of India, with a new EDCCTP call launched to further reinforce these efforts. Among other key EU projects on Ebola, one project focusing on prophylaxis and monoclonal antibodies has been identified by Africa CDC and WHO as particularly promising, with additional funding directed towards targeting the Bundibugyo strain.

As regards clinical research, work continues on the implementation of the EU Clinical Research Investment Plan, with emphasis on facilitating multinational clinical trials through both traditional grants and blended funding mechanisms, and on improving the efficiency and accessibility of existing but fragmented clinical research infrastructures in the EU. Close alignment with ACT EU initiatives was highlighted, including planned joint activities such as a webinar on contractual agreements (April 2026) and a workshop with patient organisations (May 2026).

A significant focus has been placed by DG RTD on NAMs, recognising the limitations of animal models in replicating human physiology and the high attrition rates of new molecules in preclinical research. While recent European Parliament actions, European Citizen Initiatives, and the Commission's June roadmap on phasing out animal testing in chemical assessments support and call for transition to non-animal alternatives, challenges remain in translating NAM research into regulatory practice and uptake in the EU has been slow. To address ongoing barriers, a new European Research Area (ERA) Action on NAMs has been launched by DG RTD to coordinate stakeholders, strengthen regulatory engagement, and accelerate adoption, with participation from multiple national authorities and experts from the EMA 3R Working Party. Mid and long-term goals of the ERA Action include establishing EU-wide training and accreditation, increasing routine use of NAMs, and ultimately enabling faster regulatory approvals based on these approaches.

The representative of DG SANTE provided a comprehensive update on key Commission activities related to public health. He started with a report on a cluster of Andes Hantavirus cases linked to a Dutch-flagged cruise ship: as of 20 May 2026, 13 cases (11 confirmed, 3 fatalities) had been identified among passengers, with no evidence of secondary transmission. EU-level measures included activation of the Union Civil Protection Mechanism, ECDC assessments indicating very low risk, deployment of the

EU Health Task Force, and strengthened diagnostic support via the EU Reference Laboratory network. He also reported on the Ebola Bundibugyo outbreak, with over 500 confirmed cases and more than 90 deaths in the Democratic Republic of Congo as of early June, and a limited number of cases in Uganda. WHO declared a Public Health Emergency of International Concern on 17 May 2026. The EU response included six Health Security Committee meetings with discussions on travel measures and public health guidance. ECDC risk threat assessments confirmed very low risk to the EU/EEA, and expert were deployed in mid-May to support the African response.

The DG SANTE representative then provided an update on the Critical Medicines Act (CMA), noting that a political agreement between the EU co-legislators had been reached on 12 May 2026. After outlining the main pillars of the Regulation, he referred to the work of EMA and MSs to support the implementation of the CMA, including the planned adoption of a Union list of critical medicines by the end of 2026 and ongoing work at MSSG on vulnerability evaluations, which will inform public procurement preferences, prioritisation of funding to strategic projects, and joint purchasing initiatives across MSs under the CMA framework.

As regards progress on the revision of the medical devices and in vitro diagnostics legislation, he noted that the Council Cyprus Presidency has completed an initial read-through of the legal proposal and is working towards a general approach by December 2026, while a draft European Parliament position is expected in July. Additional updates on medical devices included the launch of an EMA pilot programme for breakthrough medical devices and diagnostics, the adoption of implementing rules for notified bodies, and the mandatory use in the EU of four modules of EUDAMED from 28 May 2026. Regarding the Biotech Act, a Commission Staff Working Document was published on 26 May 2026 providing an assessment of the expected impact of the proposal. A Council position is planned for the Directive on 16 June and for the Regulation by the end of the year. The European Parliament will prepare its draft report in June and plans to adopt it by early 2027. Trilogues can be expected in the first half of 2027.

He also covered the implementation of the Health Technology Assessment Regulation, highlighting that, since January 2025, 18 Joint Clinical Assessments (JCA) had been initiated, including the first JCA assessment report published on 9 June 2026, and seven Joint Scientific Consultations had been completed. The start of JCAs for medical devices and in vitro diagnostics is planned for June 2026.

Finally, the DG SANTE representative addressed broader policy developments, including EU enlargement prospects (with Montenegro targeting accession by 2028 and Albania, Ukraine, and Moldova aiming for accession before 2030), and provided an update on the EMA Fee Regulation. He explained that a Delegated Act will adjust fees to reflect the actual inflation rates for 2023–2025, with updated fees expected to apply from January 2027, including specific provisions for veterinary medicines. He concluded with a status update on the recruitment process for the next EMA Executive Director, outlining the next steps in the selection procedure planned to result in a shortlist of candidates adopted by the College of Commissioners to be sent to the Management Board towards the end of the year.

On NAMs, a MB member stressed the need for a science-based communication on non-animal methods, cautioning against oversimplified messaging and emphasizing that no single method can fully replace established non-clinical studies; robust validation takes several years and clear communication to manage expectations is essential. Referring to geopolitical considerations, he also highlighted the need for an aligned communication strategy across MSs addressing pressures on pricing and emphasising the value of HTA collaboration. The representative of doctors' organisations noted rising clinical trial costs in the EU and called for risk-based, proportionate approaches and efficiencies for low-intervention clinical trials, for example reducing duplication in contractual arrangements at Member State level. The representative of veterinarians' organisations welcomed progress towards a

harmonised interpretation of the EU rules on the use of medicinal products in animals outside the terms of the marketing authorisation, as well on the use of medicinal products for food-producing aquatic species.
The DG RTD representative underlined the importance of regulatory involvement in research projects on NAMs to ensure regulatory uptake and highlighted the potential of AI in advancing non-clinical research. The DG SANTE representative welcomed the call for stronger coordination on HTA in the current geopolitical context and noted that simplification for low-intervention clinical trials will be further supported under the Biotech Act by introducing a new category of 'minimal-intervention' clinical trials.

B.3 Preparation for implementation of the new EU pharmaceutical legislation

a) Legislative update (EC)

The DG SANTE representative highlighted key milestones and priorities for implementing the New Pharmaceutical Legislation (NPL), which has been agreed by the co-legislators and is expected to be published around November 2026, entering into force shortly thereafter and becoming fully applicable two years later. Certain measures such as regulatory sandbox, vouchers, security of supply, international cooperation, and grants will already apply from the day of entry into force, requiring immediate implementation, He emphasised that the implementation work will be a joint effort between EMA, Member States and the European Commission.

b) Update from the NPL Oversight Group & c) Implementation Roadmap

After the introduction by the Chair of the Management Board, recalling the objectives of the NPL implementation programme, the EMA Head of Human Medicines Division updated the Management Board on the kick-off meeting of the NPL Oversight Group that was held on 10 June. The meeting focused on further aligning the governance framework established in March and on providing a shared understanding of roles and responsibilities of various actors in the implementation programme. A six-delivery stream structure is supported by an overarching programme framework, including an Oversight Group composed of Management Board members, senior EMA managers and an EC representative. Delivery Stream teams are led by co-sponsors from MB (including civil society members and from EMA management). These bodies are responsible for steering the work, coordinating across the network, and ensuring timely decision-making, including the endorsement of key outputs. Drafting of relevant or revised guidance, as well as technical input for Delegated and Implementing Acts, will require inputs by MS experts and will be coordinated by Delivery Stream teams building on the existing structures and expertise in the network, such as scientific committees and working parties.

The NPL Programme Roadmap includes multiple large-scale projects across the delivery streams, covering areas such as procedures, committees, development support, non-clinical evaluation, quality and manufacturing and shortages. Priorities are also informed by industry feedback to the extent possible, highlighting key areas of focus. During the kick-off meeting several NPL Oversight Group members and delivery stream co-leads emphasised the importance of planning for change management, promoting simplicity, involving the right expertise from the Member States, and a forward-looking mindset. The kick-off meeting marked the transition from implementation planning to full implementation phase.

During the discussion, a representative of the European Parliament highlighted the high expectations placed on the EMA under the new legislation, noting that the Agency's mandate now extends beyond medicines evaluation to include coordination in crisis preparedness, shortages monitoring, and critical medicines management, in close cooperation with Member States. He stressed the importance of dialogue with national authorities and suggested increasing engagement through tools such as webinars and the importance of clarifying responsibilities. MB members praised the progress made in preparing the programme's governance structure but warned that success will depend on managing complexity and ensuring effective oversight. He underlined the importance of a shared responsibility across the network, particularly in mobilising subject matter experts and sharing resources efficiently for the implementation work, while also encouraging a forward-looking mindset; concerns were also raised about limited human resources and increasing workload at national level, stressing the need for proportionality, prioritisation, and a focus on practical, fit-for-purpose solutions. The DG SANTE representative reinforced the importance of a transformative yet lean implementation.

The MB Chair concluded by emphasizing that the implementation programme, with the governance model involving the European Medicines Regulatory Network, is designed to deal with all the issues rightly identified and ensure strong alignment between EMA and national competent authorities

B.4

a) Assessment of the Executive Director's Annual Activity Report (AAR) 2025

[EMA/MB/107691/2026], [EMA/MB/120285/2026], [EMA/95458/2026] The Management Board noted the Executive Director's Annual Activity Report (AAR) 2025 and adopted the Board's Assessment of the Executive Director's AAR 2025 which had been prepared by the MB topic coordinators Nils Falk Bjerregaard, Franck Fourès, Momir Radulović and Günter Waxenecker.

The AAR 2025 details the EMA's management and control systems and the implementation of its work programme. Prepared in accordance with Article 48 of the EU Financial Regulation, it is part of the discharge process. The AAR is submitted to the Management Board for assessment, and, by 1 July, the assessed AAR is to be sent to the Court of Auditors, the Commission, the European Parliament, and the Council.

The topic coordinators presented a summary of the main elements of the proposed Management Board's assessment of AAR 2025. The year 2025 marked the Agency's 30th anniversary, celebrated through a series of events including a scientific conference under the theme 'Medicines, regulation and the future' and the Agency's first public Open Day on 9 May, on the occasion of Europe Day. The year also marked the 25th anniversary of the EU Orphan Regulation and the 20th anniversary of the implementation of the SME Regulation.

In human medicines, the Board noted that EMA had recommended 104 human medicines for marketing authorisation in 2025, including 38 containing a new active substance. The Board acknowledged the Agency's initiatives to accelerate and optimise assessment processes, including measures to reduce clock-stop duration, enhance the predictability of submissions, and update assessment templates through streamlined co-authoring. On clinical trials, the Clinical Trials Regulation became fully applicable in January 2025, with more than 5,000 clinical trials transitioned to the Clinical Trials Information System (CTIS) as the single-entry point for sponsors and regulators. CTIS was designated as a primary registry of the WHO International Clinical Trials Registry Platform. The revised ACT EU workplan for 2025–2026 and the FAST EU initiative launched by the Heads of Medicines Agencies were also noted. The Board acknowledged the continued growth of the DARWIN EU® network, with 33 data partners providing data from over 180 million people across 16 European

countries from 2022 to 2025, and progress under the joint work plan on data and AI in medicines regulation to 2028, including the AI Observatory report and the guiding principles on the use of large language models in regulatory science. Implementation of the HTA Regulation, applicable from January 2025, was noted, with support for joint clinical assessments, parallel joint scientific consultations, and the exchange of information for planning and horizon scanning. On the availability of medicines and security of supply, the Board welcomed the recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to address supply chain vulnerabilities, the European Shortages Monitoring Platform (ESMP) becoming fully functional in January 2025, and the voluntary solidarity mechanism, which was invoked six times in 2025. The Board further noted the adoption of the governance structure to guide and oversee implementation of the pharmaceutical legislation and initiatives supporting future readiness, including scenario planning and a raw data pilot to support more systematic evaluation of clinical trial data submitted at the time of marketing authorisation.

Key outcomes in veterinary medicines were noted, with EMA recommending 30 veterinary medicines for marketing authorisation, representing the highest number of recommendations in a year for a second consecutive year, including 16 vaccines, seven of which were approved under exceptional circumstances to respond to animal health emergencies. Continued work to address antimicrobial resistance was acknowledged, alongside the activities of the 3Rs working party and related guideline development. Under the 'One Health' approach, the Board noted continued cooperation within the cross-agency 'One Health Task Force framework for action' with ECHA, ECDC, EFSA and EEA, the publication of the first and second European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) reports on 31 March and 9 December 2025, and the first exercise of the project on Dosage Review and Adjustment of established veterinary Antibiotics (ADRA).

On international affairs, the Board noted EMA's continued support to strengthen regulatory capacity, including cooperation with African partners towards the establishment of the African Medicines Agency, the successful assessment and listing of the first five medicinal products under the African Medicines Regulatory Harmonisation initiative, and EMA's end of mandate as chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) and the successful organisation of the ICMRA summit. The Board also noted that EMA hosted the African Medicines Agency Governing Board in Amsterdam together with colleagues from African national regulatory agencies, African Union bodies, HMA, the European Commission and the WHO.

On EU institutional engagement, the Board noted the political agreement reached by the EU institutions on the revision of the general pharmaceutical legislation, and that three further legislative initiatives may become applicable concurrently with the new pharmaceutical legislation, representing collectively a unique opportunity to boost Europe's global competitiveness: the Critical Medicines Act, aimed at strengthening the security of supply and availability of critical medicinal products; the European Biotech Act, aimed at creating more favourable conditions for research, development and production of health biotechnology products; and the revision of the rules on medical devices and in vitro diagnostic medical devices, which foresees increased technical and scientific support from EMA. In the area of communication and stakeholder engagement, the Board noted the publication of the EU Medicines Network Strategy (EMANS) to 2028 in March 2025, communication campaigns to counter mis- and dis-information, including the "It takes a team" campaign on medicine shortages, and the first social media campaign with content creators, #HealthNotHype, to raise awareness of the responsible use of GLP-1 receptor agonists.

On corporate governance, the Board noted EMA's continued efforts to maintain a sound control environment, risk management and compliance culture, and the ongoing development of governance and control frameworks in areas including data protection, anti-fraud and conflict of interest

management. EMA's final budget for 2025 amounted to EUR 600,230,000, with 91.4% derived from the evaluation of medicines and other business-related activities. The expenditure implementation rate reached 98.4%, the financial outturn stood at 0.003% of the approved budget, the implementation of appropriations carried over from 2024 was 96.6%, and the Agency reduced its overall carry forward from 16% in 2024 to 12% in 2025, complying with the carry forward KPIs per title. Regarding internal audit, the Board noted that one critical and eight very important recommendations had been issued by the Internal Audit Capability in 2025, with mitigating actions under implementation, and that the Internal Audit Service of the European Commission was conducting an audit of CTIS, to be finalised in 2026. The European Court of Auditors had confirmed the reliability of the 2024 accounts. The Board also noted staff-related developments, including a turnover rate of 3.9% in 2025, an average time per selection procedure of 2.7 months, within the relevant KPI, and 20 selection procedures published during the year.

The Board took note of the Executive Director's declaration of assurance and acknowledged that no reservations were made. It reiterated its deep concern that the Agency remains obliged to manage its former premises in the United Kingdom, diverting resources toward an activity beyond its legal mandate. The Board called on EU institutions to resolve this unsustainable situation at a political level and to ensure continued EU funding so that EMA and national competent authorities can fulfil their public and animal health responsibilities without disruption.

The Board welcomed the assessment prepared by the topic coordinators and commended the excellent work of the Agency throughout 2025. The Board was also informed of plans to streamline the 2026 mid-year report, to be presented at the October Management Board meeting, focusing on key achievements, milestones but noting significant deviations, which the Board welcomed as a positive development.

b) Annual accounts 2025 and launch of written procedure

[EMA/MB/112418 /2026] The Management Board noted the draft annual accounts 2025 in preparation for its opinion, to be given by written procedure following the June meeting.

Following the presentation on Agency’s 2025 accounts by the Accounting Officer, the Board acknowledged full compliance with budgetary KPIs and the Agency's strong financial position at year-end. The Board further noted that the Court of Auditors had issued a positive opinion on the accounts, with an emphasis of matter regarding the uncertainty over the former London premises. As per Article 102.3 of the Agency's Financial Regulation, the Accounting Officer will finalise the Agency's accounts, which will undergo a written procedure for adoption by the Management Board after the June meeting. Subsequently, the final accounts, together with the Management Board's opinion, will be transmitted to the EU institutions by 1 July 2026.

B.5 Annual report of 2025 on Key Performance Indicators (KPIs) for pre-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use

[EMA/32231/2026], [EMA/MB/90942/2026] The Management Board endorsed the Annual Report 2025 on Key Performance Indicators (KPIs) for pre-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use.

The EMA recalled that it monitors a number of annual KPIs under the cooperation agreement between the EMA and national competent authorities (NCAs), measuring whether procedural deadlines are met

and classifying performance as on target, after target, or as an unacceptable delay. As announced at the March Management Board meeting under the Executive Director's highlights, this year's report focuses on pre-authorisation, inspection and scientific advice procedures and does not include post-authorisation metrics for which procedures were transitioned to a new IT system (IRIS) in 2025. The report comprises detailed reporting of results for each NCA, together with a cover note providing an overview dashboard of results and highlighting trends rather than single-year performance.

The EMA highlighted the major trends in the 2025 results since 2018. Performance on rapporteur assessment reports for marketing authorisation applications had improved, though it remained an area of continued concern, with 72% on target. Human scientific advice remained the area of greatest concern, with the timeliness of joint assessment reports having declined and around half submitted after the KPI threshold. GMP inspection reporting showed a slow improvement on target since 2018 despite a drop in 2025, while pharmacovigilance inspection reporting continued to worsen. Veterinary scientific advice continued to perform well.

The Board noted that overall performance in 2025 remained broadly stable compared with previous years. Board members expressed support for focussed action and simplification in the scientific advice area. A few members also noted the importance of assessing how performance might change under the new pharmaceutical legislation and suggested that a review of the current metrics would be beneficial, as some may be suboptimal in terms of their measurement methodology and the insights they provide. The Executive Director committed to pursuing dedicated action on scientific advice improvements, including through the SROG actions already initiated.

B.6 Update on 'One substance - One assessment' (OSOA) framework

A representative of the DG Environment (DG ENV) from the European Commission presented the implementation of the One Substance One Assessment (OSOA) framework, describing it as a key pillar of the EU's zero pollution and One Health approaches. She explained that the initiative aims to improve efficiency, consistency, and transparency in chemical safety assessments, which are currently fragmented across more than 40 pieces of EU legislation. The reform consolidates scientific and technical work across EU agencies, including ECHA, EFSA, and EEA, strengthening cooperation, harmonising methodologies, and enabling coordinated prioritisation of substances. A central element is the creation of a Common Data Platform for Chemicals, hosted by ECHA and designed to integrate data from agencies, Member States, and industry, improve data sharing and reuse, and support evidence-based decision-making while maintaining confidentiality safeguards.

She highlighted EMA's important role in providing non-clinical, environmental risk assessment and Maximum Residue Level data to the Common Data Platform, noting that integration will follow a phased approach, with data for medicines authorised by EMA since 2026 to be incorporated by 2029 and data on medicines authorised until 2025 (legacy data) by 2036. Additional resources have been allocated to EMA to support the data submission to the Platform. The implementation is supported by an inter-service group at the European Commission including EU agencies' representatives, an expert group involving Member States.

The DG SANTE representative informed the Board about related provisions in the new pharmaceutical legislation on cooperation and digitalisation, highlighting EMA's mandate to collaborate with EU agencies and strengthen data sharing and scientific methodologies. They also underline EMA's role in ensuring coherent scientific opinions by resolving divergences early through close inter-agency cooperation, supporting a single, consistent EU scientific view.

Several Board members intervened on the DG ENV presentation, addressing different aspects, such as the experience of an NCA covering food safety and medicines, noting that effective cooperation requires recognising the differences between substance-level and product-level assessments, particularly for medicinal products, where benefit–risk and availability considerations are critical. It was noted that challenges such as the lack of a common language across regulatory frameworks, the complexity of maintaining shared data systems and uncertainty around how divergences between agencies would be resolved, especially when therapeutic benefits must be weighed against environmental concerns. These challenges call for pragmatic solutions that avoid duplications and unintended impacts on patients. The importance of a coherent and coordinated EU regulatory approach was emphasized, while underlining that medicines are fundamentally different from other products due to the absence of choice for patients and the need to ensure availability, particularly in smaller markets. She cautioned against approaches that might inadvertently create conflicts between safety-based environmental assessments and the benefit–risk framework for medicines, stressing the need for pragmatic implementation that safeguards supply across the EU.

Other Board members raised questions such as implications of Article 32 (Review clause) of Regulation (EU) 2025/2455 and sought to understand the important possible consequences of extending the scope of the Platform to nationally authorised medicinal products. One member cautioned against framing the issue as a choice between protecting the environment and saving lives, stressing the real-world challenges of supply disruptions in a globalised production system, and calling for realistic, gradual solutions. Another MB member noted that while eco-friendly approaches are desirable and innovations such as bio-based pharmaceuticals should be explored, accepting certain environmental risks may sometimes be necessary to achieve significant medical benefits, particularly for treatments such as cancer . Patient organisations' representative called for careful benefit–risk assessments with patients in mind and suggested considering clear exceptions for medicines, stressing that transparency and availability are both key to maintaining trust in the regulatory system.

Board members clearly underlined that medicinal products present specificities that need to be reflected in the OSOA framework, given the key role of benefit–risk assessment and the current absence of substitutable alternatives which may lead to unintended consequences for patients, highlighting the importance of a shared regulatory language and clear processes for managing any divergences between environmental, hazard-based assessments and the benefit–risk framework applied to medicines.

In response, the DG ENV representative clarified that the OSOA framework does not aim to add complexity, arguing instead that it would enhance consistency by bringing together scientific expertise while respecting existing regulatory boundaries. She stressed the importance of transparency and a balanced approach that considers both environmental protection and public health needs, noting that the objective is not to remove essential medicines from the market but to improve risk management measures and reduce pollution. She also underlined that ensuring medicines availability remains a priority and that the framework is designed to support more consistent, balanced, and forward-looking decision-making across the EU.

In conclusion, the Chair emphasised that the discussion must be focused on patient access and medicines availability, noting that the issue for medicines is extremely complex and multifaceted, with the potential for high public and animal health impact.

B.7 Update on Audit topics

a) Update on MB Audits and Risks Group (MBARG)

The Chair of the MB Audits and Risks Group (MBARG) reported that since December 2025 two new members had joined the group and two meetings had taken place, focusing on formalising risk analysis, strengthening synergies between internal audit and risk management, and addressing the sustainability of EMA's internal audit capability's resourcing. She noted that the MBARG reviewed the 2025 risk management outcome, which documented 16 corporate risks, and discussed key issues related to specific risks such as cybersecurity and the impact of new legislative developments. She stressed the need to keep a forward-looking risk-management approach together with pursuing the work in 2026 on a risk assessment methodology to improve transparency and monitoring over time. She outlined the progress on the audit side, including preparation of a new co-sourcing model, sustainable recruitment of internal auditors and development of an assurance map. The MBARG Chair encouraged the MB to endorse the 2025 internal audit activity report, highlighting the internal audit capability's resilience, successful recruitment plan, and delivery of key audits, and concluded by noting the ongoing work on the learning and development needs of the MBARG.

b) 2025 activity report of the Agency's Internal Audit Capability

[EMA/91988/2026], [EMA/MB/91989/2026] The Management Board adopted the 2025 activity report of the Agency's Internal Audit Capability.

The Head of the Internal Audit Capability (AF-IAC) presented the 2025 activity report, noting that it had been shared in advance and that MB comments had been incorporated. He confirmed that the internal audit capability operated with full organisational independence, reporting directly to the Board and conducting its work in line with international audit standards and the audit charter approved by the MB, while applying ethical and risk-based principles. He further highlighted progress in stabilising the audit team's human resources following the successful recruitment of two internal auditors. He summarised key audit activities in 2025, including completed audits on environmental management, data exchange with international partners and metadata management, as well as ongoing work on audits on variations for human medicines, management of Periodic Safety Update Reports. He highlighted the administrative and operational support provided by AF-IAC to other auditing entities such as the Internal Audit Service (IAS) of the European Commission reviewing the Clinical Trial Information System and the European Court of Auditors (ECA) which have reviewed the management of critical shortages.

c) 2026 half-year report of the Agency's Internal Audit Capability

[EMA/MB/91989/2026] The Management Board noted the 2026 half-year report of the Agency's Internal Audit Capability.

The Head of the Internal Audit Capability (AF-IAC) explained that AF-IAC has progressed towards a new operating model, with the recruitment of two internal auditors and the signing of a co-sourcing contract with an external audit service provider following a tender process. The internal auditors have allocated their respective audit portfolios to be carried out with the new co-sourcing partner which will practically operate shortly. He noted ongoing audits in the first half of the year and highlighted that the ongoing transition towards the new operating model requires the adjustment of practical working arrangements, while enabling greater focus on staff development. He further reported on preparations for the upcoming 5-year external quality assessment scheduled in 2027 to assess the internal audit capability's alignment with the Global Internal Audit Standards. He also informed the Board about the

revision of GVP Module 4 on Pharmacovigilance Audits, which should be published for public consultation later in the year, and ongoing work on an assurance mapping tool to provide a comprehensive overview of processes, control, risks and assurance activities across the Agency. A Board member welcomed the stabilisation of the AF-IAC, stressing its importance for trust and transparency, and suggested placing greater emphasis on KPI measurement and prioritising audits in weaker areas, including training staff on lean and agile approaches.

B.8 Clinical trials in the EU

• Policy and legislative update (EC)

The Board noted a policy and legislative update from the DG SANTE representative on the Biotech Act, which includes amendments to the Clinical Trials Regulation (CTR). The DG SANTE representative outlined the expected timeline, noting strong momentum under the Irish presidency and in the European Parliament. A Commission Staff Working Document published on 26 May 2026 set out the expected impacts of the amendments, including a projected increase in clinical trials in the EU alongside economic and public health benefits. It was emphasised that the fast delivery of the Biotech Act changes to the CTR will require CTIS to be significantly modified to support its timely implementation. An update on ongoing activities in CTR implementation was reported by the DG SANTE representative, including, under the EU4Health programme, grants to Member State authorities to support non-commercial sponsors and the implementation of the CTR, and, under MedEthicsEU, the publication of a template for recruitment and informed consent procedures.

The MB representative of doctors' organisations welcomed the Biotech Act, including its new definition of minimally invasive trials, while suggesting that further consideration could be given to the simplification of low-intervention trials, drawing on practical experience with such trials. He also noted the importance of supporting non-commercial and multinational clinical trials in the interest of public health. The DG SANTE representative welcomed these reflections and encouraged the sharing of concrete suggestions for further refinement.

• Update on Clinical Trials Information System (CTIS) roadmap and budget

[EMA/MB/122260/2026], [EMA/122221/2026] The Management Board noted the update and was informed of continued progress with clinical trials in the EU.

The EMA presented the latest figures, on implementation of the Clinical Trials Regulation. Since CTIS went live in 2022, more than 14,000 clinical trial applications have been submitted, with a steady pace of over 200 new initial applications per month. Progress was also reported against the EU's 2030 clinical trial targets. On increased attractiveness of the EU, 19 additional multinational trials had been authorised above the historical average by end-March 2026. On faster access to treatment, 40.5% of trials met the target of recruiting participants within 200 days of submission, compared with the 2030 goal of 66%. The Board noted the publication of the first quarterly progress report for 2026 on International Clinical Trials Day (20 May 2026). The IAS internal audit of CTIS was under way, with the draft report expected in July and the final report in September 2026. Launched on 13 May 2026, the former CTIS Simplification Taskforce had been refocused as the CTIS Taskforce, to advise in an informal capacity on the business requirements for CTIS functionalities to be developed in line with the proposed Biotech Act.

On the CTIS development roadmap, the Management Board recalled that, at its March meeting, it had noted the need to significantly reshape the current modernisation roadmap to combine existing objectives with Biotech Act functional readiness. The EMA emphasised that the current system (referred to as CTIS 1.0), which started development in 2014, carried structural limitations and accumulated technical debt, and that the Biotech Act proposal entails a major rewrite of the CTR, with

a significant proportion of current CTIS functionality requiring change. An updated roadmap was presented by EMA targeting go-live of phase I of the Biotech Act requirements by end-2028. To support delivery, alongside the frontloading of additional EMA human resources for the Biotech Act, the CTIS budget for 2026 may have to be increased, subject to the annual budget approval process.

Members welcomed the significant progress made across the clinical trials programme and the investments to support CTIS modernisation, while expressing concern regarding the timing of CTIS readiness in relation to the application of the Biotech Act. Members sought clarification on whether the pace of delivery was constrained by financial or technical factors and emphasised that a contingency approach may be needed to ensure that the functionalities are delivered by the time the new rules applied and that CTIS overall functionality is ensured at the same time. The DG SANTE representative clarified that the trilogues were anticipated to begin in early 2027 and that delivery of the first phase of CTIS functionality by end-2028 would follow shortly after the anticipated application of the Biotech Act, noting a shared sense of urgency and focus among the co-legislators. In response to a question, EMA clarified that functionality for the combined assessment of clinical trials and medical device investigations is expected to be part of the second implementation phase. Drawing on the experience of the current system, members underlined the importance of avoiding past difficulties by keeping requirements stable and ways of working efficient and stressed the need to ensure that national competent authorities would also be ready in time. The EMA acknowledged these concerns, noting that stable requirements and a focused approach would be essential to timely delivery. The Chair suggested that given the importance and complexity of the matter, consideration should be given to having a dedicated discussion at the October meeting, while preparatory work continued in the meantime.

• Update on other CT initiatives

The Board was updated on the revised ACT EU workplan, aligned with the key performance indicators on the attractiveness and speed of clinical trials in the EU and reflecting policy developments including the Biotech Act and the Clinical Research Investment Plan. The new areas of focus included patient involvement through the piloting of disease-specific patient panels, better access to clinical trials data from CTIS to support inclusive trials, communication campaigns on the timely submission of high-quality results, and dialogue with sponsors on the use of AI in clinical development.

The new regulatory co-chair of the ACT EU Multi-stakeholder Platform Advisory Group, the French MB member, presented the role and forthcoming agenda of the Advisory Group, noting the appointment of a new stakeholder co-chair. Appreciation was expressed for both the new co-chairs and the contribution of the outgoing co-chairs.

The Board was also informed of recent ACT EU priority activities and of progress on guidance on regulatory flexibilities for conducting clinical trials during public health emergencies, which, together with a simplified application package, would be brought forward for endorsement by the end of 2026.

The DG SANTE representative presented an update on the COMBINE pilot, exploring the coordination of Member State assessments across the Clinical Trials Regulation and the IVDR or MDR, noting that the first application had been authorised in March 2026 and that a second phase would launch in June 2026.

The Austrian MB member presented an update on the HMA-led FAST EU initiative, which continued to demonstrate the ability of national competent authorities to authorise within shorter timelines, providing real-life input to inform the feasibility of the legislative proposal.

B.9 Network Portfolio Report

[EMA/115010/2026] The Management Board noted the Network Portfolio quarterly status report and an introduction to the value streams poster session.

The Board was reminded of the longer-term vision behind the Network Portfolio, namely, to build an end-to-end, digitally connected and data-driven regulatory ecosystem for medicines that supports public and animal health and the infrastructure required by the EMANS strategy and the new legislative acts. On governance, the portfolio was described as sitting between the strategy and execution levels, with the Network Portfolio Advisory Group (NPAG) providing Management Board and HMA representation and the five value streams acting as the bridge to the product and IT delivery teams. EMA acknowledged the active engagement of MB NPAG members in the quarterly strategic reviews.

As an example of the network's digital transformation, EMA presented a recent strategic proposal for a Central Repository, intended to create a unified, secure, EU-wide platform for the submission of applications for both human and veterinary, centrally and nationally authorised products, replacing the current fragmented environment of separate submission channels, repositories and review tools. On the portfolio objectives and roadmap, the Board was shown how the EMANS strategic goals had been translated into nine objectives, comprising some shared across the network alongside others specific to human or veterinary medicines, all delivered through the value streams. The Board was also presented with the 2026 Q1 portfolio dashboard and the major milestones delivered in the quarter, including the go-live of the CTIS business intelligence dashboards for monitoring the clinical trials environment in the EU/EEA, and of the Scientific Explorer search tool covering the European public assessment reports of initial marketing authorisation applications.

The Vice-Chair, as an NPAG member representing the Management Board, commended the considerable work undertaken by the teams and subject-matter experts, and stressed the importance of viewing the portfolio not as an IT exercise but as a business-driven transformation building the shared infrastructure needed to keep the network sustainable. The Chair invited members to the ‘poster session’ on the different value streams, to be held during the lunch break and presented by each value stream owner, providing an opportunity to explore each area in more detail and to engage directly with the value stream owners.

B.10 Status update on African Medicines Agency (AMA)

The Management Board noted a status update on EMA's support to the African Medicines Agency (AMA).

Since the June MB 2025 meeting, at which EMA had hosted the AMA Governing Board, progress had accelerated significantly following the Director-General, Dr Delese Mimi Darko, officially taking office in October 2025. To date, 32 of the 55 African states had ratified the AMA Treaty. In addition, the EMA Emergency Task Force, AMA and African regulatory authorities recently joined forces in discussions with companies and researchers on the Bundibugyo ebolavirus outbreak response.

EMA provided an update on its support to the project across the three priority areas: AMA operationalisation, for example through technical support to the AMA Secretariat and Technical Committees; capacity strengthening, including grants awarded to EU national competent authorities for tailored training to African regulators; and alignment with partners. The Management Board alternate representing Poland provided their experience of an EMRN sub-grant supporting Botswana and Ethiopia, covering assessment, clinical trials and pharmacovigilance, noting strong engagement from both countries and the value of the dialogue in both directions. On the project implementation timeline, it was noted that the Commission had approved a no-cost extension of the Contribution

Agreement until 31 January 2029, with discussions on possible continuation of the programme. The workplan for 2026–2029 was also presented, and opportunities for continued national competent authority involvement were highlighted, including applying for the upcoming second round of sub-grants, mobilising experts to deliver or review training, and participating in the EMRN Alignment Platform.

The Board underlined the importance of the network's strategic partnership with African regulator, and EMA encouraged continued national competent authority engagement in supporting AMA and the African regulatory network.

B.11 Update from Network Data Steering Group (NDSG)

The Management Board noted an update from the Network Data Steering Group (NDSG) on the revised workplan on data, AI and on progress across its key activities.

Regarding the revised NDSG workplan 2026–2028, the EMA explained that the workplan had been adopted in February 2026 and aims to guide the network's data and AI work in support of the new pharmaceutical legislation and the European Health Data Space, and bridging to the development of the next network strategy.

The EMA presented an update on key activities linked to the delivery of the workplan, covering the Product Management Service (PMS), AI and real-world evidence (RWE). For the PMS, one of the main developments was the release in June 2026 of a beta public Application Programming Interface (API), which would enable machine-to-machine access to product master data ahead of a full release in early 2027. This will support a wider range of use cases, including cross-border prescription under the European Health Data Space, with work continuing on data quality and network engagement. On AI, a small AI Guidance Coordination Group, comprising HMA, EMA and Commission members under the NDSG, was being established to ensure the coherent development of guidance, reduce duplication and gaps, and align with the anticipated Biotech Act. Other activities in this area included the successful roll-out of the AI literacy programme through the EU Network Training Centre, the publication of the second annual AI Observatory report for 2025, and the expanded release of the Scientific Explorer knowledge-mining tool to cover assessment reports for the centralised procedure. For RWE, DARWIN EU® had completed four years of operation, with more than 100 studies initiated since 2022 and 40 data partners onboarded covering over 250 million patients. A competitive tender for the next DARWIN EU® coordination centre had been launched on 15 May 2026, and this includes additional provisions in anticipation of the European Health Data Space. A new annual report on EMA's use of real-world evidence, covering the period from February 2025 to February 2026, was also presented. The report demonstrated the growing value of RWE in building regulatory knowledge. Of the studies assessed, around a third directly informed a formal regulatory decision, while others improved clinical or methodological understanding or supported preparedness in areas such as shortages and antimicrobial resistance.

Members of the Board thanked the NDSG for the impressive work. A few members stressed the need to ensure that AI guidance should not be too prescriptive, and that basing such guidance on real examples would maximise its utility. The EMA agreed on the need for an agile approach to be grounded in practical experience. The Board will be kept updated on progress on the main workplan deliverables.

B.12 Fee Regulation working arrangements rev. 3

[EMA/183645/2024 Rev. 3], [EMA/MB/110072/2026] The Management Board adopted the third revision of the working arrangements to Regulation (EU) 2024/568 on fees and charges payable to EMA.

The EMA Head of Administration outlined the main proposed amendments in the revision, starting with Article 29 of the Paediatric Regulation, where he explained that a fee is being introduced for referrals on paediatric indications, set at the level of a Type II variation, but fully waived for applicants to incentivise submissions and support paediatric medicine availability, while still allowing reimbursement of costs for MSs, with minimal expected budget impact on the Agency. He then described a proposal to introduce fee incentives for scientific opinions on products intended exclusively for non-EU markets when submitted by non-commercial entities, including possible fee reductions or waivers, in response to emerging demand and to ensure consistent handling of such cases. Other minor changes are more of an administrative nature.

Documents for information

- [EMA/MB/68666/2026] Outcome of written procedures finalised during the period from 5 March 2026 to 3 June 2026
- [EMA/MB/66679/2026] Summary report of implementation of assigned revenue June 2026
- [EMA/MB/122820/2026]. Summary of transfers of appropriations in budget 2026
- [EMA/MB/103245/2026] Extension of mandate for Quality Working Party (QWP) and Biologics Working Party (BWP) members

List of participants at the 132nd meeting of the Management Board, 10-11 June 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*) Birgitte Faber (*support observer*)
Germany	Karl Broich (*member*) Wiebke Löbker (*support observer)*
Estonia	Katrin Kiisk *(member)*
Ireland	Grainne Mary Power[1] (*member*)
Greece	Spyridon Th. Sapounas (*member)* Symeon Psomiadis (*alternate)*
Spain	María-Jesús Lamas Díaz *(member)* Antonio Blázquez[1] (*alternate*)
France	Catherine Paugam-Burtz *(member)* Franck Foures (*alternate)* Miguel Bley *(support observer)* Isabelle Puff *(support observer)*
Italy	Robert Nisticò *(member)* Marta Giovanna Toma *(support observer)*
Cyprus	Helena Panayiotopoulou (*member)*
Latvia	Sergejs Akuličs (*alternate*)
Lithuania	Dovilė Marcinkė[1] *(member)*
Luxembourg	Anna Chioti *(member)*
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	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (support *observer*)
Portugal	Susana Pombo *(alternate)* Maria João Morais *(support observer)*
Romania	Razvan Prisada *(member)*
Slovakia	Roman Dorčík[1] (*member*)
Slovenia	Momir Radulovic *(member)*

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	Participants
	Sabina Zalar(*alternate*)
Finland	Anna Siira[1] (*alternate*)
Sweden	Ann Lindberg (*member*) Åsa Kumlin Howell[1] *(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[1] (Norway) *(member)* Sayeh Ahrabi (*alternate*) Katrine Heier (Norway) (*support observer*)

[1] Restrictions applied for agenda item A.3, A.4, B.12

Guest Speaker	Veronica Manfredi, European Commission, DG GROW - Director

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 Paola Samassa Rebecca Harding Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin