



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 May 2025
EMA/MB/87893/2025 - Adopted
Management Board

Minutes of the 127th meeting of the Management Board

Held virtually in Amsterdam on 13 March 2025

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair confirmed the quorum and welcomed the new member for France, Ms Catherine Paugam-Burtz (Director General, French National Agency for the Safety of Medicine and Health Products, ANSM).

The Chair thanked the two European Parliament representatives, Karin Kadenbach and Giovanni La Via whose mandates are set to expire at the end of April 2025, for their valuable contributions and support to the Board. The Chair informed the Board that the process of appointing new European Parliament representatives for EMA's Management Board is ongoing and that the current members may be renominated. Regarding the civil society representatives of the Board, the Chair noted that their current mandates will conclude after the June meeting. The process of appointing new representatives is also underway, following a call launched by the European Commission in the summer of 2024, which is expected to be finalised in early June 2025.

The Chair informed the Board that the Management Board (MB) Topic Coordinators for the previous year's Annual Activity Report (AAR), Virginie Hivert, Momir Radulović, and Franck Foures, had confirmed their commitment to continue in their roles for the 2024 AAR. Furthermore, the Chair highlighted that the call for expressions of interest to serve as a Topic Coordinator for the 2024 AAR remained open to other Board members.

The Chair noted that the election of the new MB Chair was going to take place in the morning of this meeting. A call for nominations had been launched in mid-January and [REDACTED], had been received ahead of the March MB meeting.

The Chair also provided an update on the current mandate of EMA's Executive Director, Emer Cooke, which will end on 15 November 2025.

[REDACTED]



[REDACTED]

Post-meeting note: A letter from the European Commission consulting the Management Board on the possible renewal of EMA's Executive Director's mandate [REDACTED], was received on 2 April. An extraordinary Management Board meeting will be set-up at the end of April for this purpose.

1. Draft agenda for 13 March 2025 meeting

[EMA/MB/45410/2025] The agenda was adopted with no amendments.

2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the day's agenda were identified concerning *topics 'A.1 Revised Rules of Procedure of Emergency Task Force (ETF)', 'A.1 Revised composition of the ETF for preparedness', 'B.3 European Medicines Agencies Network Strategy to 2028'*. 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.

3. Minutes from the 126th meeting, held on 11-12 December 2025 adopted via written procedure

[EMA/MB/580677/2024] The Management Board noted the final minutes, adopted by written procedure on 7 March 2025.

4. Election of MB chair

The election was chaired by Lorraine Nolan, whose mandate was going to end on 21 March 2025.

In accordance with the election procedure the Chair announced votes by proxy as follows:

- Denis Lacombe (doctors organisation representative), to Virginie Hivert (patients organisation representative)

The Chair asked [REDACTED], to briefly present [REDACTED] background and motivation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Board appointed observers from Iceland, Liechtenstein and Norway, Runa Hauksdottir Hvannberg, Vlasta Zavadova and Trygve Ottersen, to act as vote tellers. The vote took place by digital secret ballot.

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

The Management Board elected Rui Santos Ivo, representing Portugal, as the Chair with his new mandate starting on 22 March 2025. The newly elected Chair thanked the Management Board and reaffirmed his commitment to the role.

The EMA’s Executive Director extended congratulations to the new Chair on behalf of the Agency, highlighting his many years of collaborative service across various roles and expressing full confidence in his ability to lead the Board effectively. In addition, she acknowledged Lorraine Nolan’s leadership over the past three years, highlighting how her strategic vision and steadfast dedication have significantly reinforced the network’s ability to protect public health throughout Europe.

Following the election, Lorraine Nolan continued to chair the meeting. She congratulated the newly elected Chair and thanked the Board for the trust and confidence they had placed in her throughout her three-year tenure as Chair. Furthermore, she informed the Board that, as Rui Santos Ivo currently serves as Vice-Chair, a new Vice-Chair will be elected at the June meeting, with the Management Board Secretariat set to launch the application process in due course.

A. Points for automatic adoption/endorsement

A.1 Emergency Task Force (ETF)

[EMA/MB/54675/2025, EMA/36439/2025, EMA/35247/2025] The Management Board agreed the revised Rules of Procedure and adopted a favourable opinion on the revised composition of the Emergency Task Force (ETF), as per article 15 of Regulation (EU) 2022/123.

The Rules of Procedures have been amended to reflect that the ETF’s evaluation of scientific advice applications will be performed by two coordinators as opposed to one coordinator as per current practice. This change is in line with the approach of other scientific advice procedures. As regards the ETF composition, the ETF co-chairs have proposed to replace the members that had left the Task Force with four new experts with similar expertise and to add one EMA staff member and one new expert from the Infectious Diseases Working Party to enrich the expertise of the Task Force on health threats of biological nature and on medicines against antimicrobial resistant pathogens.

A Board member requested more information on the types of emergencies that the ETF is preparing for and asked whether these include zoonotic diseases, suggesting a CVMP member should be added to the Task Force. The ETF Co-Chair and ETF secretariat clarified that per legislation the Emergency Task Force is focused on medicinal products for human use, but Article 2 of the ETF Rules of Procedure foresees that Co-Chairs can appoint external experts also from the veterinary sector, and this will be done in future in order to address preparedness activities in a One Health perspective.

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update from EMA's Executive Director, who began by outlining several events planned for 2025 to celebrate EMA's 30th anniversary. This included a staff event on 24 January 2025, marking the launch of EMA's new vision statement and the dedication of EMA's auditorium to Noël Wathion (now called 'the Noël Wathion auditorium'). Other key events planned at the Agency include a public Open Door Day, Friends and Family Day, EMA fundraising events, and a scientific conference focusing on medicines, regulation, and the future.

The Board was also informed that, following an audit of its environmental management system, EMA had earned an EMAS (EU Eco-Management and Audit Scheme) certification for its environmental efforts. This certification, which will be valid for three years, recognises the Agency's commitment to environmental sustainability.

Regarding European activities, the Executive Director updated the Board on her meetings in early February 2025 with the new Commissioner for Health and Animal Welfare, Mr Olivér Várhelyi and Commissioner for Equality, Preparedness and Crisis Management, Ms Hadja Lahbib. Commissioner Várhelyi had also visited the Agency in February, where he met with EMA's leadership and presented at an all-staff session. The Board were also informed that, an official delegation from the European Parliament's Public Health Committee (SANT) will visit EMA on 27 March 2025.

For international activities, the Board was made aware of a visit in mid-February 2025 by Dr Yasuhiro Fujiwara, Chief Executive of Japan's Pharmaceuticals and Medical Devices Agency (PMDA), to discuss Japan's evolving pharmaceutical landscape and opportunities for international alignment in clinical trials. Regarding the Food and Drug Administration (FDA), the Board was updated on recent leadership changes. An update was also provided on the African Medicines Agency (AMA) Project, highlighting that AMA grants were now fully operational, and the appointment of the new Director was imminent.

She also informed the Board that EMA's scientific advice procedure for certain high-risk medical devices had been officially launched in February 2025, following a successful pilot procedure in February 2023. The initiative is aimed to drive innovation and expedite patient access to safe devices.

An update was provided to the Board on the recent HMA/EMA Strategic Oversight Group meeting, which had been attended by the Chairs of the CHMP and PRAC. The meeting led to several key actions aimed at addressing network resourcing challenges, including training for new assessors, improving process efficiency, expanding the pool of experts, and enhancing both productivity and motivation among experts.

The Board was also updated on the situation regarding EMA's former London premises, 30 Churchill place. All rent and service charges had been paid up to March 2025 by WeWork. Pitch Golf, WeWork's subtenant, has also opened at the end of February 2025. WeWork's first quarterly financial report for 2025 is due in May, and a more detailed presentation of the report and next steps will be provided at the June MB meeting.

B.2 Report from the European Commission

The Management Board noted an oral update from the representatives of DG SANTE and DG RTD.

The representative of DG SANTE informed the Management Board about the status of the revision of the pharmaceutical legislation, the publication and key elements of the Critical Medicines Act, the activities to support the implementation of the Clinical Trials Regulation and the medical devices legislation and the planned EC initiatives regarding the use of titanium dioxide in medicinal products.

The Council is making good progress on revising the pharmaceutical legislation, with the Polish Presidency aiming to complete the technical discussions by May. The Critical Medicines Act (CMA) was adopted by the Commission and published on 11 March. The proposal aims to strengthen security of supply and availability of critical medicines by addressing supply chain vulnerabilities, reducing Europe's dependencies, and improving availability and accessibility of other medicines of common interest where a market failure exists. The DG SANTE representative highlighted key elements of the Act as well as the proposed role of EMA and MSSG in the CMA.

The Board was also informed about an upcoming study on the implementation of the Clinical Trials Regulation to support a Commission report by early 2027 as well as other studies in the context of the preparation of the European Biotech Act, and about the ongoing COMBINE programme, which focuses on the interface between medicines and in vitro diagnostics regulations as regards the assessment of clinical trials/investigations.

The Commission is progressing both short- and medium-term actions to improve the implementation of the medical devices legislation, and a targeted evaluation is being prepared. As regards titanium dioxide, in 2024 EMA submitted its updated analysis on the feasibility of alternatives to replace titanium dioxide in medicines, and on that basis in the second quarter of 2025 the European Commission will publish a report on the use of titanium dioxide as per Commission Regulation (EU) 2022/63.

During the following Q&A, the Commission clarified that the vulnerability evaluation under the CMA is expected be performed by the MSSG. Once a common methodology is available, MSs may also perform vulnerability evaluations individually. The definition of critical medicines refers to products on the published Union List, which will be updated regularly. Some members representing MSs expressed concerns about potential lack of coherence due to numerous legal proposals on availability of medicines. They also stressed the need to recognise the important resource implications for vulnerability evaluations, which will be significant given that most products on the Union list are generics produced by several manufacturers. Patients' organisations welcomed references to joint procurement in the CMA. They also raised concerns about recent discussions at Council level to remove voting rights for patients and healthcare professionals in the scientific committees of the Agency. The DG SANTE representative clarified the Commission's position on voting rights, as set-out in the published legal proposal. He also acknowledged the complexity of vulnerability evaluations and noted that the CMA does not mandate it for all substances on the Union list, but only ad hoc where special measures justify it, for example the requirement to produce in the EU.

A Board member congratulated the Commission on the COMBINE programme and urged a rapid evaluation of possible improvements to the Clinical Trials Regulation. Asked for comments on the legal complaint filed by some industry associations against the urban wastewater treatment directive, the DG SANTE representative noted that the right to invoke concerns in court is open to all EU citizens and is respected by the Commission.

The representative of DG RTD informed the Management Board about the upcoming European Life Sciences Strategy, recent funding opportunities for multi-country clinical trials and recent EU activities

in support of research on women's health. The Life Sciences Strategy is scheduled for publication in summer 2025 and will cover many sectors, including health. This will pave the way for the Biotech Act in 2026 and will link to an updated EU bioeconomy strategy to be presented by the Commissioner for environment. The Call for Evidence for the Life Sciences Strategy will be published in March 2025 and Board members were invited to contribute. The European Research Area for Health (ERA4Health) recently published its first call for proposals, which is for multi-country investigator-initiated clinical studies and health technologies addressing public health needs. Projects will be awarded after the summer.

In response to previous questions regarding the new US policies on gender health research and to mark International Women's Day, the representative of DG RTD informed the Board about recent RTD activities on research on women and men's health. Over EUR 1.3 billion have been invested in more than 700 R&I projects related to women's health under Horizon 2020 and Horizon Europe, focussing for instance on cardiovascular risk assessment in menopausal women (Caramel project) and better monitoring and communication of medication safety in pregnancy and breastfeeding (IMI ConcePTION). Gender equality will be a strengthened crosscutting priority in Horizon Europe.

Members welcomed the updates and agreed to continue the discussion on EU research on gender and health at the next Management Board meeting.

B.3 European Medicines Agencies Network Strategy to 2028

[EMA/376542/2024] [EMA/MB/76785/2025] The Management Board adopted the European Medicines Agencies Network Strategy (EMANS) to 2028.

The EMANS 2028 titled "Seizing opportunities in a changing medicines landscape" is a comprehensive update of the 2021-2025 Strategy that will guide the EU medicines regulatory network in addressing emerging challenges and opportunities. The update reflects progress to date, with more emphasis on the competitiveness of the EU in the development and manufacture of medicines, as well as incorporating technological and environmental developments that are reshaping the regulatory landscape. It also provides the foundation for preparing the network for the implementation of the revised EU pharmaceutical legislation.

EMA presented the results of the two-month public consultation, launched in October 2024 with the aim to gather and incorporate stakeholder perspectives into the final strategy. The consultation received 77 contributions from industry, patient and consumer organisations, healthcare professionals, research bodies, and public institutions, with around 78% of stakeholders expressing a positive view of proposed strategy. Notable comments highlighted the need to strengthen the One Health approach and update references to cross-sectoral legislation, such as environmental policies, and single-substance assessments.

Following the adoption of the EMANS by the Board and Heads of Medicines Agencies (HMA), the final strategy will be published on both the EMA and HMA website. Specific actions, timelines, and measurable outcomes will be detailed in the EMA's multiannual work programme and the HMA's multiannual work plan. The implementation of the strategy will be monitored through the HMA/EMA coordination implementation group and a mid-point report is foreseen in 2027.

B.4 EMA annual report 2024

[EMA/38990/2025] [EMA/MB/67605/2025] The Management Board adopted the EMA annual report 2024.

The Annual Report focuses on EMA's strategic priorities, major achievements and contributions to public and animal health in Europe. The first chapter highlights the evaluation and monitoring of human and veterinary medicines and other high-impact activities related to EMA's strategic priorities for 2024. This chapter also features interviews from scientific committee chairs on major achievements in 2024 and priorities for 2025. The second chapter presents a selection of key figures illustrating the range of activities in the regulation of medicines in EU, including marketing authorisation and safety monitoring of medicines for human and veterinary use, inspections and compliance and medicine shortages. In 2024, EMA recommended 114 medicines for marketing authorisation for human medicines, 46 of which introduced new active substances, including treatments for Alzheimer's, allergic reactions, and severe infections. In veterinary medicine, EMA recommended 25 medicines, including vaccines developed through biotechnology.

A demonstration of the interactive digital report was also presented to the Board. The digital report features embedded media, infographics, and an enhanced timeline of key 2024 activities in EU medicines regulation. Board members welcomed the report, which highlights the Agency's key achievements in 2024 in both a very accessible digital format and a downloadable PDF version.

B.5 Audit - Revised Global Internal Audit Standards

[EMA/209787/2017]; [EMA/MB/105013/2023]; [EMA/MB/66687/2025] The Management Board adopted an updated Internal Audit Charter for EMA and an updated Management Board's decision establishing the Management Board Audits and Risks Group (MBARG).

The EMA's Internal Audit Function generally conforms with the audit standards issued by the Institute of Internal Auditors. A new version of these standards (so called Global Internal Audit Standards (GIAS)) entered into force on 9 January 2025. As a result, the EMA's Head of Audit *ad interim* presented the Agency's Internal Audit Charter which had been updated to align its content with the mandatory GIAS and related model internal audit charter. This alignment required an update of the Agency's Internal Audit Charter as regards the following sections: 1) purpose and mission of the internal audit function; 2) conduct; 3) authority and reporting; 4) responsibility. A more detailed plan for the implementation of the new GIAS will be presented to the MBARG and then to the Board at the June 2025 meeting. The Management Board's Decision on the establishment of the MBARG dated 24 May 2023 has been amended to reflect the reference to the new GIAS and the possibility to appoint an MBARG vice-chair to ensure continuity.

The Chair of the MBARG confirmed the Head of Audit *ad interim* had presented the new GIAS and their impact on the EMA Internal Audit Charter to the group in October 2024. Via written procedure in advance of the current Management Board meeting, the MBARG was consulted and had provided comments on the revised Charter and the MB Decision on the MBARG. She suggested a simplification in the wording of paragraphs 2.2 and 2.4 of the Annex to the MB Decision on the MBARG, which refer to the appointment of a Vice-Chair, and an addition in the Charter to emphasise the need for staff in the EMA's Internal Audit Function to be appropriately trained at all times. The MBARG Chair also highlighted that the Charter foresees a role for the Management Board in providing input regarding the appropriate resourcing of the Agency's internal audit function.

B.6 MB Decision of the EMA rules concerning the handling of declared interests of staff members and candidates before recruitment

[EMA/MB/259494/2016]; [EMA/MB/59912/2025] The Management Board adopted the Management Board Decision of the EMA rules concerning the handling of declared interests of staff members and candidates before recruitment.

At the December 2024 Board meeting, EMA announced that the MB Decision on EMA rules concerning the handling of declared interests of EMA staff members would be aligned with the revised EMA independence policies that were adopted during that meeting. The EMA rules for staff were revised to include definitions aligned with policy 0044, a unified three-year cooling-off period, a ban on financial interests in medical device companies, and new rules regarding interests in research organisations. In addition, the revision simplifies the process by categorising staff into two groups: those with scientific or regulatory duties and those with administrative or technical duties. Restrictions may apply to both groups based on their responsibilities rather than seniority or contract type; these changes will streamline the process and strengthen oversight. The revised rules take effect on 1 May 2025, followed by the annual declaration of interest renewal exercise for EMA staff to ensure compliance.

B.7 2024 EMA Annual Report on Independence

[EMA/573980/2024]; [EMA/MB/65819/2025] The Management Board endorsed the 2024 EMA Annual Report on Independence.

EMA's senior policy specialist presented the 8th Annual Report on Independence to the Board. This report describes the activities performed in 2024 by the Agency to implement each of independence policies (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 provides facts and figures (including on Breach of Trust procedures), gives information on initiatives taken in 2024 and identifies recommendations for further improvement in 2025. In 2025, the EMA plans to implement the revised Policies 0044 and 0058, update the Experts Management Tool and related guidances, and provide information sessions and trainings to members, experts and EMA staff. The implementation of the revised policies will be monitored particularly regarding the use of expert witnesses and the access to relevant expertise. The EMA code of conduct will also be revised to align aspects related to competing interests with the recent revision of the Policies. EMA reporting officers will receive training on the revised MB decision on rules for EMA staff. EMA will continue to conduct ex ante and ex post controls. The 2024 EMA Annual Report on Independence will be published on the Agency's website.

B.8 2024 EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy

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

B.9 African Medicines Agency Governing Board visit to EMA MB June

[EMA/MB/48720/2025], [EMA/592532/2024] The Management Board noted that the African Medicines Agency (AMA) Governing Board will observe the afternoon of the first day of the June 2025 MB meeting.

The Board was informed that the AMA Governing Board, the newly elected Director-General, and heads of eight leading African national agencies will attend a two-day event at the Agency on 11-12 June 2025. The visit is intended to support regulatory system strengthening and the operationalisation of the AMA through EMA's current grant from the European Commission's DG INTPA. The event aims to foster dialogue and strengthen partnerships between AMA, EMA, and HMA, laying the foundation for longer-term cooperation. It will focus on AMA's progress, the African regulatory network's status, regulatory reliance at continental, regional and national levels, and sharing EMRN's experience in managing cross-national regulatory environments. EMA proposed inviting the AMA Governing Board, Director-General, and heads of leading African NCAs to observe the afternoon session of the MB meeting on 11 June. Additionally, a separate meeting with the HMA Management Group will be held on the morning of 11 June to share EU regulatory network experiences. The Board agreed for the AMA delegation to observe the Board meeting in June and welcomed the initiative. The representative of patient organisations highlighted that they are in contact with patient organisations in Africa through the Rare Disease International network and offered to assist in making connections if needed.

B.10 Update on cybersecurity management at EMA

In agreement with Board members, due to time constraints, this topic was not discussed. A briefing note on this topic, along with the presentation, was circulated to the Board for information following the meeting with the opportunity for comment and questions.

B.11 Clinical Trials in the EU

- Update on CTIS and ACT-EU

[EMA/MB/64937/2025], [EMA/64938/2025] The Management Board noted the report and was informed that since the Clinical Trials Regulation (CTR) EU 536/2014 came into effect and as of the end of February 2025, over 10,000 clinical trials (incl. transitional trials) have been submitted to the Clinical Trials Information System (CTIS), with more than 8,800 decisions issued.. A survey was launched by the Clinical Trials Coordination Group (CTCG) to gather data on ongoing clinical trials, and several Member States intend to take action to address the remaining small number of trials that have not yet transitioned to the CTR. The Board also received an update on the 2025 development plans for the CTIS. These plans include transitioning maintenance and development services to a new provider, implementing further system improvements, and focusing on simplification and technology modernization, beginning with the safety module.

The Board commended the progress made. The representative of DG SANTE emphasised the importance of reminding stakeholders about the necessity of a full transition to the CTR. Regarding the proposals for modernisation and simplification, he underscored the need for prompt and effective implementation.

In addition, the Board was presented with the third ACT EU workplan for 2025-2026, adopted by the ACT EU Steering Group in December 2024. The workplan, which incorporates feedback from the multi-stakeholder platform advisory group (MSP AG), focuses on key areas such as the operation of the Clinical Trials Regulation, maximising trial impact, and addressing trials in public health emergencies. New initiatives to support CTR implementation tackle the most pressing stakeholder challenges. Maria Lamas, MSP AG Regulatory Co-Chair, presented feedback from a stakeholder meeting discussing their concerns, including requests for information, strengthening the RMS role, and addressing training needs for academia and SMEs. Ongoing consultations and focus groups are addressing specific issues.

- Demo of CTIS Trial Map

The Board received a live demonstration of a new 'clinical trial map' which has been introduced on the CTIS public website. Developed in response to patients requests for a more user-friendly CTIS dashboard, the map improves access to clinical research and helps stakeholders, particularly patients, locate relevant trials across Europe. It provides patients and healthcare professionals with real-time information on clinical trials, including recruitment status and site contact details.

B.12 Network Data Steering Group update

The Management Board noted an oral report from the EMA co-chair of Network Data Steering Group (NSDG).

The Board was reminded that the NDSG was established in Q4 2024 as a strategic advisory group aimed at maximising data interoperability and utilisation across the EU network, enhancing access to data, generating evidence, and leveraging AI. The NDSG kick-off meeting took place in person on 28-29 January 2025, focusing on work planning and a target operating model for product master data as a key priority for 2025. The second virtual meeting on 4 March 2025 continued discussions on the development of the NDSG work plan. The work plan is set to be presented for adoption at the next NDSG meeting on 31 March 2025. Following this, a written procedure for the endorsement of the work plan by the EMA MB and HMA will be launched in April. Once endorsed, the work plan will be published on both the EMA and HMA websites.

List of written procedures during the period from 05 December 2024 to 03 March 2025:

- Consultation no. 10/2024 on the appointment of Diana Laura Bassula as CVMP alternate as proposed by Romania ended on 18.12.2024. The mandate of the nominee commenced on 19.12.2024.
- Consultation no. 11/2024 on the appointment of Emilia Mavrokordatou as CHMP member as proposed by Cyprus ended on 20.12.2024. The mandate of the nominee commenced on 21.12.2024.
- Consultation no. 12/2024 on the appointment of Katerina Savvidou as CHMP alternate as proposed by Cyprus ended on 10.01.2025. The mandate of the nominee commenced on 11.01.2025.
- Consultation no. 01/2025 on the appointment of Vaida Kurapkienė as CVMP alternate as proposed by Lithuania ended on 27.01.2025. The mandate of the nominee commenced on 28.01.2025.
- Consultation no. 02/2025 on the appointment of Nijole Stankeviciene as CVMP member as proposed by Lithuania ended on 20.02.2025. The mandate of the nominee commenced on 21.02.2025.

Documents for information

- [EMA/MB/587514/2024] Outcome of written procedures finalised during the period from 05 December 2024 to 04 March 2025.
- [EMA/MB/48310/2025], [EMA/559856/2024] 2024 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2024

- [EMA/MB/29851/2025], [EMA/29852/2025] Seventeenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2024
- [EMA/MB/54018/2025], [EMA/54023/2025] Network Portfolio Report
- [EMA/MB/63669/2025] Summary of transfers of appropriations in budget 2024
- [EMA/MB/69904/2025], [EMA/69085/2025] Annual Activity Report (AAR) 2024
- ECA Annual report on EU agencies for the financial year 2023

List of participants at the 127th meeting of the Management Board, held in Amsterdam, 13 March 2025

Chair: Loraine Nolan

	Participants
Belgium	Hugues Malone (<i>member</i>) Charles Denonne (<i>alternate</i>)
Bulgaria	Bogdan Yavorov Kirilov (<i>member</i>)
Czech Republic	Boráň Tomáš (<i>member</i>)
Croatia	Siniša Tomić (<i>member</i>)
Denmark	Nils Falk Bjerregaard (<i>member</i>) Mette Aaboe Hansen (<i>alternate</i>) Birgitte Faber (<i>support observer</i>)
Germany	Karl Broich (<i>member</i>) Wiebke Löbker (<i>support observer</i>)
Estonia	Katrin Kiisk (<i>member</i>)
Ireland	Rita Purcell (<i>alternate</i>)
Greece	Evangelos Manolopoulos (<i>member</i>) Spyridon Th. Sapounas (<i>alternate</i>)
Spain	María-Jesús Lamas Díaz (<i>member</i>) Consuelo Rubio Montejano ¹ (<i>alternate</i>) Celia Caballero (<i>support observer</i>)
France	Catherine Paugam-Burtz (<i>member</i>) Franck Foures (<i>alternate</i>) Miguel Bley (<i>support observer</i>)
Italy	Robert Nisticò (<i>member</i>) Armando Magrelli (<i>alternate</i>) Marta Giovanna Toma (<i>support observer</i>)
Cyprus	Helena Panayiotopoulou (<i>member</i>) Irimi Chrysafi Fanidou (<i>alternate</i>)
Latvia	Indra Dreika (<i>member</i>) Sergejs Akuličs (<i>alternate</i>)
Lithuania	Rugile Pilvinienė (<i>member</i>)
Luxembourg	Anna Chioti (<i>member</i>)
Hungary	Rita Pálffyné-Poór (<i>member</i>) Beatrix Horváth (<i>alternate</i>)
Malta	Anthony Serracino Inglott (<i>member</i>) John Joseph Borg (<i>alternate</i>)
Netherlands	Paula Loekemeijer (<i>member</i>) Aimad Torqui ¹ (<i>alternate</i>) Roelie Marinus (<i>support observer</i>)
Austria	Günter Waxenecker (<i>member</i>)
Poland	Grzegorz Cessak (<i>member</i>) Marcin Kolakowski (<i>alternate</i>) Magdalena Pajewska-Lewandowska (<i>support observer</i>)
Portugal	Rui Santos Ivo (<i>member</i>) Maria João Morais (<i>support observer</i>)

	Participants
Romania	Razvan Prisada (<i>member</i>)
Slovakia	Roman Dorčík ¹ (<i>member</i>)
Slovenia	Momir Radulovic (<i>member</i>) Sabina Zalar (<i>alternate</i>)
Finland	Eija Pelkonen (<i>member</i>)
Sweden	Åsa Kumlin Howell ¹ (<i>alternate</i>) Erik Malmström (<i>support observer</i>)
European Parliament	Karin Kadenbach (<i>member</i>) Giovanni La Via (<i>member</i>)
European Commission	Rainer Becker (DG SANTE) (<i>alternate</i>) Matus Ferech (DG SANTE) (<i>support observer</i>) Irene Norstedt (DG RTD) (<i>alternate</i>) Tomasz Dylag (DG RTD) (<i>support observer</i>)
Representatives of patients' organisations	Marco Greco (<i>member</i>) Virginie Hivert (<i>member</i>)
Representative of doctors' organisations	Apologies received from the member
Representative of veterinarians' organisations	Christophe Buhot (<i>member</i>)
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) (<i>member</i>) Vlasta Zavadova (Liechtenstein) (<i>member</i>) Trygve Ottersen (Norway) (<i>member</i>) Audun Hågå (Norway) (<i>alternate</i>) Katrine Heier (Norway) (<i>support observer</i>)

¹Restrictions applied for agenda items A.1 and B.3

European Medicines Agency	<p> Emer Cooke Ivo Claassen Peter Arlett Zaïde Frias Hilmar Hamman Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Steffen Thirstrup Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Rebecca Harding Zahra Hanaizi Ijsbrand den Rooijen Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin </p>
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