EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2026
EMA/148216/2026
Executive Director

Annual activity report 2025

This document (EMA/148216/2026) encompasses both the 2025 Annual activity report (EMA/95458/2026) and the Management Board Assessment Report (EMA/MB/107691/2026) as respectively noted and adopted by the EMA Management Board on its meeting of the 11 June 2026.

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Management Board's assessment report

The Management Board,

- having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,
- having regard to the Financial regulation applicable to the budget of the European Medicines Agency ('the Agency') and in particular Article 48 thereof,
- having regard to the 2025 work programme of the Agency, adopted by the Management Board,
- having regard to the Annual report 2025 of the Agency adopted by the Management Board,
- having regard to the Annual activity report 2025 of the Agency presented to the Management Board,

1. Welcomes the continued implementation of the EU medicines agencies' network strategy to 2028 (EMANS 2028), published in March 2025, and notes its role in guiding the European medicines regulatory network through the evolving medicines landscape.
2. Appreciates the successful organization of EMA's 30th anniversary scientific conference to celebrate three decades of groundbreaking achievements and advancements in the field of medicine and regulatory science.
3. Acknowledges the results presented in the Annual activity report 2025 and the Agency's sustained effort to fulfil its mission while continuing to improve the EU regulatory system, including through timely delivery against new legislation and policy priorities.
4. Appreciates the Agency's contribution towards the European Union's policy agenda, including supporting a strong European Health Union, improving access to medicines through the implementation of the health technology assessment (HTA) Regulation, strengthening preparedness and crisis response capabilities, and advancing the One Health agenda.
5. Welcomes the Agency's continued international cooperation, including contributions to the operationalisation of the African Medicines Agency and broader collaboration with international partners in areas of regulatory science, data, and public health.
6. Welcomes the political agreement reached by the EU institutions on the proposals for the revision of the general pharmaceutical legislation.

EVALUATION OF MEDICINES

7. Notes the work on marketing authorisations via the centralised procedure, both in human and veterinary medicines, which resulted in 2025 in EMA recommending 104 new human medicines, including 38 containing a new active substance, and 30 new veterinary medicines, including 13 containing a new active substance, as well as positive opinions recommending the extension of maximum residue limits (MRLs) for 2 active substances.
8. Notes the Agency's continued focus on enabling timely access to medicines addressing unmet medical needs, including 3 recommendations following accelerated assessment, 8

recommendations for conditional marketing authorisation, 2 authorisations under exceptional circumstances, and 6 PRIME-designated medicines recommended for approval.

9. Notes the Agency's confirmation of 16 orphan-status designations under the EU framework for orphan medicines, supporting development and marketing of medicines for patients with rare diseases.

10. Notes that the recommended 30 veterinary medicines for marketing authorisation represents the highest number of recommendations in a year for a second consecutive year and that among the 30 veterinary medicines authorised, 16 were vaccines, including 7 that were approved under exceptional circumstances to respond to animal health emergencies.

11. Welcomes the Agency's 3Rs work in the veterinary area, including the activities of the 3Rs working party as well as guideline development.

12. Welcomes the organisation of the second edition of the veterinary innovation day.

13. Notes that judicial challenges against the Agency and/or the European Commission remain high; acknowledges that the Agency was involved in 12 cases before the Court of Justice of the European Union (CJEU) during the year and notes that four judgments/orders were delivered in 2025.

ACCELERATING AND OPTIMISING THE ASSESSMENT OF KEY MEDICINES

14. Acknowledges activities carried out to accelerate and optimise assessment processes, including work on updated assessment templates, streamlined collaboration through co-authoring, and initiatives to reduce clock-stop duration; notes that the average clock-stop duration in 2025 was 159 days, representing a reduction compared to the peak in 2022.

15. Commends the completion of the transition to the Clinical Trials Regulation, which became fully applicable in January 2025, including the transition of more than 5,000 clinical trials to the Clinical Trials Information System (CTIS) as the single-entry point for sponsors and regulators.

16. Welcomes the designation of CTIS as a primary registry by the World Health Organisation (WHO) within the International Clinical Trials Registry Platform (ICTRP).

17. Welcomes continued delivery under the Accelerating Clinical Trials in the EU (ACT EU) initiative, including publication of the revised workplan for 2025–2026 and the launch of a clinical trials map in all EU languages to improve public access to information on clinical trials

18. Welcomes the FAST-EU (Facilitating and Accelerating Strategic Trials) initiative launched by the Heads of Medicines Agencies.

19. Notes with satisfaction the continued growth of the DARWIN EU® network, which now includes 33 data partners providing data from over 180 million people across 16 European countries.

20. Acknowledges the progress in the area of data and artificial intelligence, including publication of the joint work plan 'Data and AI in medicines regulation to 2028' and the Agency's publication of an AI Observatory report compiling experience with AI in medicines regulation and the 'Guiding principles on the use of large language models (LLM) in regulatory science and for medicines regulatory activities' which helps to promote the safe, responsible and effective use of this category of AI technology.

21. Welcomes the Agency's internal capability building, including delivery of an AI literacy programme designed to support safe, effective and responsible AI use in line with relevant EU requirements.

FACILITATING ACCESSIBILITY AND STRENGTHENING AVAILABILITY OF MEDICINES

22. Welcomes the Agency's support to the implementation of the HTA Regulation, applicable from January 2025, including support for joint clinical assessments, parallel joint scientific consultations, and exchange of information for planning and horizon scanning.

23. Notes the Agency's continued role in addressing challenges related to availability of medicines and security of supply, including recommendations by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to address vulnerabilities in the supply chain of specific critical medicines.

24. Welcomes the European Shortages Monitoring Platform (ESMP) becoming fully functional in January 2025 and notes its role in enabling direct reporting by marketing authorisation holders and national authorities to support shortage prevention, monitoring and management as well as the role of the voluntary solidarity mechanism to resolve critical shortages which was invoked 6 times in 2025.

25. Acknowledges the Agency's stakeholder engagement and public communication on shortages, including campaigning for shared efforts to prevent and manage shortages across the European Union.

26. Notes the European Commission's proposal for a 'Critical Medicines Act' which aims to strengthen the security of supply and the availability of critical medicinal products within the EU and complements the tools included in the new pharmaceutical legislation, with a strong focus on industrial policy measures.

SEIZING OPPORTUNITIES TO FUTUREPROOF MEDICINES REGULATION IN THE EU

27. Welcomes the landmark political agreement on the reform of the EU pharmaceutical legislation and looks forward to the significant changes it will bring across multiple areas of the Agency's work.

28. Notes that the Management Board has adopted a governance structure to guide and oversee implementation of the pharmaceutical legislation and that early engagement with scientific committees has commenced to explore future ways of working and ensure continuity.

29. Notes the launch and continuation of initiatives supporting future readiness, including scenario planning and the raw data pilot to support more systematic evaluation of clinical trial data submitted at the time of marketing authorisation.

30. Acknowledges the European Commission's proposal for a 'European Biotech Act', which aims to create more favourable conditions for research, development and production of health biotechnology products, and the legal proposal to simplify the rules on medical devices and in vitro diagnostic medical devices, which also foresees increased technical and scientific support from EMA. Notes that these legislative initiatives may become applicable concurrently with the new pharmaceutical legislation and therefore represent a unique opportunity to boost Europe's global competitiveness.

ONE HEALTH AND ANTIMICROBIAL RESISTANCE

31. Notes the Agency's continued cross-agency cooperation on One Health with ECHA, ECDC, EFSA and EEA, supporting integrated scientific advice and strengthened evidence for policy-making.

32. Welcomes progress in veterinary antimicrobial consumption surveillance, including publication of the first and second European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) report on 31 March 2025 and 9 December 2025 and continued capacity building with stakeholders.

33. Acknowledges the initiation of the first exercise of the project on Dosage Review and Adjustment of established veterinary Antibiotics (ADRA) which aims to minimise antimicrobial resistance while safeguarding the availability of first-line treatment veterinary antibiotics in the European Union.

34. Notes continued work to address antimicrobial resistance, including cooperation with partners and actions to improve preparedness and responsible use of antimicrobials.

STAKEHOLDER ENGAGEMENT

35. Notes with appreciation the Agency's stakeholder engagement with the Agency's key stakeholder groups.

36. Acknowledges coordinated communication campaigns with national competent authorities, the European Commission and other partners to provide accurate and reliable information on authorised medicines and to counter mis- and dis-information.

INTERNATIONAL COOPERATION

37. Welcomes the Agency's continued support to strengthening regulatory capacity, including cooperation with African partners and engagement with international organisations and regulators.

38. Praises the EMA's mandate as chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) and the organisation of the ICMRA summit.

CROSS CUTTING INITIATIVES AND PORTFOLIO MANAGEMENT

39. Welcomes continued progress in digital transformation and data-driven operations, including initiatives to strengthen AI adoption and optimise digital delivery across the Agency and the network.

40. Congratulates the Agency for the continued delivery of training and capability building through the EU Network Training Centre (EU NTC), including 121 training events advertised in 2025.

FINANCIAL RESOURCES

41. Welcomes the successful implementation of the new fee regulation, which became fully operational in January 2025. The regulation is an important factor for the sustainability of the European Medicines Regulatory Network.

42. Notes that the Agency's final budget for 2025 amounted to EUR 600,230,000; and notes that of the total income, 91.4% derived from the evaluation of medicines and other business-related activities, 8.3% from the European Union budget, and 0.3% from various sources. Further notes the financial outturn of 0.003% of the approved budget of EUR 600,230,000 (EUR 19,585).

43. Notes with appreciation that the agency budget implementation was 98.4%, well above the 95% target, as well as the successful reduction of the overall level of automatic carry forward in 2025 (from 16.2% to 12.3%). Notes the 2025 provisional accounts and looks forward to giving an opinion on the EMA 2025 final accounts, following the receipt of the European Court of Auditors' observations on the provisional accounts.

HUMAN RESOURCES

44. Welcomes continued investment in staff and organisational capabilities, including recruitment and staff development initiatives supporting delivery of the Agency's mandate and strategic priorities. Welcomes the expansion of staff development and career support initiatives, such as job shadowing, fellowships, and secondments, including interinstitutional job shadowing and secondment schemes, stemming from the EMA HR strategy.

45. Welcomes the Agency's continuous focus on staff wellbeing, including the continuation of the Wellbeing @EMA development programme, and the launch of social assistance programme.

46. Welcomes high response rate of 79% and results of 2025 staff engagement survey, which shows staff engagement levels at an overall total favourable sore of 67% which represent +8 percentage points from the EU inter-agency benchmark. Welcomes that the people engagement index recorded an 88% score which is +11 percentage points from the EU inter-agency benchmark and +4 percentage points from the 2023 staff engagement survey.

47. Welcomes the Agency's high occupancy rates, with 99.6% occupancy of the establishment plan and full occupancy of contract agent and national expert positions.

AUDITS AND INTERNAL CONTROLS

48. Welcomes the results of the audit of the European Court of Auditors (ECA), confirming the reliability of the 2024 accounts and the legality and regularity of the transactions underlying the accounts of the Agency.

49. Notes that the 2024 report of the ECA includes emphasis of matter drawing attention to the uncertainty with the lease agreement for the Agency's previous premises in London and one observation on the legality and regularity of payments made by the Agency under certain framework contracts for IT development. Is satisfied with the progress on the implementation of the recommendations.

50. Notes that the report includes a follow-up of two previous years' observations and welcomes that corrective actions have been put in place by the Agency, leading to the closure of both observations.

51. Notes the result of the activities carried out by the Agency's internal audit capability, with 1 critical and 8 very important recommendations issued in 2025. Invites the Agency to address all outstanding critical and very important recommendations issued by IAC, IAS and all ECA recommendations.

52. Notes the assessment of the effectiveness of the internal control systems as reported, and welcomes continued efforts to maintain a sound control environment, risk management and compliance culture.

53. Takes note of the Agency's ongoing work to strengthen governance and control frameworks, including in areas such as data protection, anti-fraud, and conflict of interest management.

DECLARATION OF ASSURANCE

54. Takes note of the declaration of assurance of the Executive Director as presented in the Annual activity report 2025.

55. Calls for an EU action at a political level to resolve the current unsustainable situation with the EMA premises in London. Remains deeply concerned that the Agency is put in a position to act as a

landlord, in a third country, diverting resources to perform an activity outside of its legal mandate. Acknowledges the Agency's efforts to address the situation, while safeguarding its financial interests. Highly appreciates the European Commission's support in this matter.

ACKNOWLEDGEMENTS

56. Welcomes the efforts of EMA's and national authorities' staff for their collaborative and effective work in protecting and promoting public and animal health in the European Union.

Introduction

This consolidated Annual activity report provides an overview of the activities and achievements of the European Medicines Agency (hereinafter 'EMA' or 'the Agency') in 2025. It is a report of EMA's Executive Director and is a key component of the strategic planning and programming cycle and the basis upon which the Executive Director takes responsibility for the management of resources and the achievement of objectives. It also allows the Executive Director to decide on necessary measures to address any potential management and control weaknesses identified.

The Annual activity report 2025 comprises the following five main parts and annexes:

Part 1: Key achievements in 2025. This section provides information on achievements of objectives and performance indicators set in the EMA annual work programme. It mirrors the structure of the annual work programme of EMA for the year 2025.

Part 2: Management. This section provides an overview of the Agency's major achievements and includes information on EMA governance; budgetary, financial and human resources management; assessment of audit results during 2025; as well as the follow-up on recommendations and action plans resulting from audits. It also includes information on actions EMA took in light of observations from the Discharge Authority.

Part 3: Assessment of the effectiveness of the internal control systems. This section concerns EMA's assessment of the effectiveness of its internal control systems and their components.

Part 4: Management assurance. This section describes the building blocks of assurance and the materiality criteria on the basis of which the Authorising Officer by Delegation determines whether significant weaknesses should be subject to a formal reservation. Any reservations are also detailed in this section.

Part 5: Declaration of assurance. The section contains a declaration of assurance in which the Executive Director, in her role as the authorising officer, takes responsibility for the legality and regularity of all financial transactions.

In the *annexes*, the report provides information on EMA's establishment plan, human and financial resources used by activity, the organisational chart and further specific annexes related to Part 2 and Part 3 of the report.

The Annual activity report 2025 is a public document and is available on the EMA corporate website.

Executive summary

European Medicines Agency in brief

The European Medicines Agency is a decentralised agency of the European Union (EU) created in 1995. The mission of EMA is to protect human and animal health in the EU and to ensure access to medicines that are safe, effective and of good quality. It is the sole EU body responsible for the scientific assessment and monitoring of human medicines for cancer, diabetes, neurodegenerative dysfunctions, viral diseases, acquired immune deficiency syndrome, autoimmune diseases and other immune dysfunctions and rare (or orphan) diseases.

Medicines derived from biotechnology processes (such as genetic engineering) as well as advanced-therapy medicines (such as gene therapy, somatic cell therapy or tissue-engineered medicines) must also be submitted for assessment to EMA on behalf of the EU.

Innovative and technologically advanced veterinary products, in particular those derived from biotechnology, must also be assessed by the Agency.

Through its evaluation, EMA significantly contributes to a single route for the authorisation of innovative medicines in the EU, thus avoiding the duplication of efforts in each of the Member States. This single route for authorisation helps to make highly needed medicines available to all EU citizens within the shortest possible timeframe, whilst guaranteeing a robust scientific assessment process.

In addition, EMA monitors the safety of all medicines authorised in the EU throughout their lifecycle and provides for regulatory action (such as restricting a medicine's use or revoking a medicine from the EU market) within the shortest possible timeframe, where public or animal health is endangered.

Information for patients and healthcare professionals is simultaneously made available in all EU languages, ensuring that consistent information on medicines is provided to all EU citizens. To achieve its tasks, EMA brings together the best scientific expertise on medicines from across the EU.

Today there are seven scientific committees[1] which evaluate medicines throughout their lifecycles, from early stages of development, through marketing authorisation and safety monitoring once the medicines are on the market. These scientific committees are supported by working parties and scientific advisory groups and can draw from a network of over 5,000 scientific experts made available by the Member States to the Agency.

EMA is also involved in other public health activities, such as in stimulating research and innovation in the pharmaceutical sector. It facilitates medicines development by giving scientific advice and guidance to developers of medicines, including on the development of medicines for children or medicines to treat rare diseases. On behalf of the EU, EMA also coordinates inspections to verify compliance with the principles of good manufacturing, clinical, pharmacovigilance and laboratory practices.

Furthermore, EMA is responsible for the provision of data and information technology (IT) services to implement European pharmaceutical policy and legislation. These services are provided to the EU regulatory network, comprising national competent authorities (medicines regulatory authorities in

[1] CHMP: Committee for Medicinal Products for Human Use
CVMP: Committee for Veterinary Medicinal Products
PDCO: Paediatric Committee
COMP: Committee for Orphan Medicinal Products
CAT: Committee for Advanced Therapies
PRAC: Pharmacovigilance Risk Assessment Committee
HMPC: Committee on Herbal Medicinal Products

Member States), the European Commission as well as EMA. In this context, EMA delivers, maintains and provides data services, IT systems and infrastructure to Member States.

On behalf of the EU, EMA hosts a number of databases important for public health, such as EudraVigilance (EV) and the Clinical Trials Information System (CTIS). EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). EudraVigilance receives reports of adverse reactions for all medicines authorised in the EU and is one of the largest pharmacovigilance databases in the world.

CTIS supports the flow of information between clinical trial sponsors, EU Member States, European Economic Area (EEA) countries and the European Commission. It is the single-entry point for sponsors and regulators to submit, assess, and oversee trials across the EU.

In addition, EMA plays a key role in tackling public health threats, such as antimicrobial resistance and public health emergencies. Over the past years, EMA has also become a recognised pioneer in terms of transparency and openness of operation and interaction with patients.

Since its creation in 1995, the environment in which EMA operates has undergone major changes. As a result of the Agency's achievements over the years, EMA's responsibilities have continuously increased, resulting in an agency that is involved in a wide range of activities going beyond the evaluation and monitoring of human and veterinary medicines.

The Agency has a formal role in preparing for and managing crisis situations affecting the European Union (EU) single market for medicines and medical devices, based on legislation that took effect on 1 March 2022 (Regulation (EU) 2022/123), except for the provisions for the management of shortages of critical medical devices, which applied from 2 February 2023.

The legislation formalised some of the structures and processes set up by EMA during the COVID-19 pandemic and assigned new tasks to the Agency in the following areas:

- Monitoring and mitigating potential or actual shortages of critical medicinal products and medical devices;
- Providing scientific support to the timely development of high quality, safe and effective medicines during public health emergencies;
- Ensuring the smooth functioning of expert panels to assess high-risk medical devices and advise on crisis preparation and management.

The success of EMA is based on the EU regulatory system for medicines. At the heart of it is a network of around 50 medicines regulatory authorities from the European Economic Area (EEA) Member States, the European Commission and EMA. National competent authorities (NCA) work closely with EMA, providing scientific expertise to EMA committees, working parties and expert groups for assessing centralised products; supporting innovation, including centralised scientific advice; working on orphan and paediatric medicines; and EU-wide safety procedures.

This network is what makes the EU regulatory system unique. The diversity of the experts from across Europe involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas, and best practices between scientists striving for the highest standards of medicines regulation. The World Health Organization (WHO) has designated the whole European medicines regulatory network (EMRN), including each of the national authorities, as WHO Listed Authorities in 2024. This recognises the EMRN as meeting international regulatory standards, guidelines and practices.

2025 in brief

In 2025, the Agency made substantial progress on the main focus areas for the year, as outlined in the Single programming document 2025-27. These focus areas comprised accelerating and optimising the assessment of key medicines; facilitating the path to accessibility and strengthening the availability of medicines; and seizing the opportunities to futureproof medicines regulation in the EU.

A number of activities carried out with the aim of accelerating and optimising the assessment of key medicines led, for example, to an overall reduction of the time to approval for marketing authorisation applications compared to previous years mostly due to a reduction of the duration of clock stops. The average clock-stop duration in 2025 was 159 days, down 46 days from the peak in 2022. This constitutes approximately a 22% reduction from 2022.

The Clinical Trials Regulation became fully applicable in January 2025, marking the end of a three-year transition period, during which more than 5,000 clinical trials were transitioned to the Clinical Trials Information System (CTIS), the single-entry point for sponsors and regulators for the submission and assessment of applications for clinical trials in the EU.

In the area of real-world data, the DARWIN EU® network now includes 33 data partners providing data from approximately 180 million people across 16 European countries, with the addition of claims data from the US from over 200 million US patients.

EMA, the European Commission and the Heads of Medicines Agencies set new ambitious targets to increase the number of multinational clinical trials taking place in the EU. In addition, the Agency launched a new clinical trials map in all EU languages to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials conducted in their area.

To improve the accessibility and availability of medicines in the EU, the Agency is supporting the implementation of the health technology assessment (HTA) Regulation and coordinating efforts to prevent and mitigate shortages, while strengthening the security of supply chains for critical medicines. The new regulation, which became applicable in January 2025, creates an EU framework for the health technology assessment of medicines and medical devices by fostering collaboration and coordination between EU Member States.

The launch of the European Shortages Monitoring Platform provides a strong technical backbone for the work with EU national authorities and actors across the supply chain to prevent and manage shortages.

With respect to seizing the opportunities to futureproof medicines regulation in the EU, EMA is preparing for the new pharmaceutical legislation. The agreement on the new pharmaceutical legislation is a historic milestone for medicines regulation in Europe and for patients across the EU. The new pharmaceutical legislation will bring significant changes across multiple areas of EMA's work and is an opportunity to become more agile and efficient. EMA's Management Board adopted a governance structure to guide and oversee the implementation of the pharmaceutical legislation.

In the area of 'One Health', EMA continues to strengthen cooperation on the implementation of the One Health agenda in the EU, working with four other EU agencies (The European Chemicals Agency (ECHA), the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Environment Agency (EEA)) on promoting strategic coordination, research alignment, capacity building, communication and stakeholders' engagement on One Health and supporting the development of partnerships through joint activities across these EU agencies.

In addition, the Agency coordinated communication campaigns with national competent authorities, the European Commission, other EU agencies and organisations representing patients and healthcare

professionals and increased the opportunities for the public and relevant stakeholders to engage, as well as to fight mis- and dis-information, by providing accurate and reliable information on authorised medicines.

Key achievements are detailed in section 1, whereas developments are reported in section 2.2. The full set of key quantitative data of the reporting year can be found in section 1 and section 2.

Key conclusions

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the Court of Auditors on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Agency can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

1. Achievements of the year — 2025 at a glance

Human medicines

In 2025, the European Medicines Agency (EMA) recommended the authorisation of 104 new medicines for human use, 38 of which contain a new active substance. The Agency also recommended extensions of indication for 89 medicines already authorised in the EU.

Of the new medicines authorised, 3 received a recommendation for marketing authorisation following an accelerated assessment. This mechanism is reserved for medicines that address unmet medical needs, allowing for faster assessment of eligible medicines by EMA's scientific committees (within a maximum of 150 days rather than 210 days).

Six PRIME-designated medicines (medicines targeting unmet medical need) were recommended for approval. In addition, the Agency confirmed 16 orphan-status designations under the EU framework for orphan medicines, the purpose of which is to encourage the development and marketing of medicines for patients with rare diseases.

In addition, 8 medicines received a recommendation for a conditional marketing authorisation, one of the possibilities in the EU to give patients early access to new medicines. It allows for early approval, on the basis of less clinical data than are normally required, and these authorisations are subject to specific post-authorisation obligations to generate complete data on the medicines.

Two medicines were authorised under exceptional circumstances, which allows patients to gain access to medicines when comprehensive data cannot be obtained, subject to specific post-authorisation obligations and monitoring.

Under EU-Medicines for all (EU-M4All), 3 medicines were assessed. This regulatory procedure is organised in cooperation with the World Health Organization and national regulators in the target countries to support global regulatory capacity building and contribute to the protection and promotion of public health beyond the EU.

The Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion for 7 medicines in 2025.

Veterinary medicines

In the veterinary area, EMA recommended 30 new medicines for marketing authorisation. Of these, 13 contain a new active substance. The use of 11 known medicines was expanded in 2025, either in a new species or for a new indication, offering new treatment opportunities.

Positive opinions were adopted recommending the extension of maximum residue limits (MRLs) for 2 active substances in 2025. The MRLs recommended by EMA reflect how much residue of the veterinary medicine in food derived from a treated animal is safe for consumption. The MRL is established before a medicine for food-producing animals is authorised in the EU and entered in the annex to Commission Regulation (EU) No 37/2010.

The Committee for Veterinary Medicinal Products (CVMP) adopted no negative opinions in 2025.

Main focus areas

The Agency made substantial progress in the main focus areas presented in the Single programming document (SPD) 2025-2027. This section highlights achievements in these areas as well as other key developments that occurred over this period.

Accelerating and optimising the assessment of key medicines

Building on the Agency's experience using cancer medicines as a pathfinder, the Agency is applying the learnings to key medicines in other therapeutic areas. Several activities are ongoing with the aim of accelerating and optimising assessment.

The Revamp Project has updated a number of key templates for assessment and introduced more streamlined collaboration through the implementation of co-authoring in SharePoint for assessment teams. An AI tool is being developed which will help greatly in the quality control of draft assessment reports, ensuring alignment with templates.

The Group for Internal Rules on Extensions of Clock Stops (GIREX) project has introduced a systematic discussion of all clock-stop extension requests sent to the Committee for Advanced Therapies (CAT) and CHMP, leading to better harmonised extensions and a return to the strict implementation of the 2009 guideline on clock-stop extensions. This in turn has seen an overall reduction of the time to approval for marketing authorisation applications, compared to previous years. In addition, work is ongoing on ensuring a change of culture regarding the number of questions raised during evaluations, focussing on the key questions and not the 'nice-to-haves'. Workbooks for clinical and quality assessors have been created, and dedicated workshops were carried out in the second half of 2025.

The Pre-submission Interaction Group (Pre-SIG) project has the objective to fundamentally reshape the pre-submission interactions between the Agency, rapporteur teams and applicants, with the aim of avoiding premature submissions and greatly enhancing submission predictability.

Further measures implemented included a single rapporteurship pilot programme for biosimilar medicines, the development of the new variations guidelines in cooperation with the national competent authorities, as well as the revamp of the good pharmacovigilance practices (GVP) inspection programme.

The Clinical Trials Regulation became fully applicable in January 2025, marking the end of a three-year transition period, during which more than 5,000 clinical trials were transitioned from EudraCT (under CTD) to the Clinical Trials Information System (CTIS), the single-entry point for sponsors and regulators for the submission and assessment of applications for clinical trials in the EU.
The European medicines regulatory network has published a report on EU clinical trials during the 3-year CTR transition period, analysing clinical trial data from 31 January 2022 to 30 January 2025. During the transition period, a total of 10,608 clinical trial applications were submitted via CTIS, with a surge in 'transition' applications between mid-2024 and early 2025, as sponsors worked to meet the legal deadline for transitioning ongoing clinical trials to CTIS. The report shows that since the use of the CTIS became mandatory, an average of 200 new clinical trials were submitted every month. Of these, around 80 applications per month were for multinational clinical trials. The CTR and CTIS are now fully implemented, laying the foundations for a more integrated and responsive clinical trial ecosystem in the EU, with greater transparency, efficiency and collaboration to boost clinical research.

The Accelerating Clinical Trials in the EU (ACT EU) is a collaboration aimed at transforming how clinical trials are initiated, designed and run to promote the EU as a centre for clinical research. In January 2025, the Agency published the revised ACT EU workplan, setting out the programme's deliverables and timelines for 2025-2026. The work plan covers three main areas: the operation of the Clinical

Trials Regulation, maximising the impact of clinical trials, and clinical trials in public health emergencies. It outlines the fundamental role of ACT EU's regulatory partners involved in clinical trials.

As part of the ACT EU workplan, a new clinical trial map was launched in all EU languages as part of the CTIS public website. The map is designed to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials for different medical conditions in their geographic area.

In the area of real-world data, the DARWIN EU® network now includes 33 data partners providing data from over 180 million people across 16 European countries, with the addition of claims data from the US from over 200 million US patients. Three data partners have been onboarded in 2025, to reach a planned total of 40 data partners in the network by February 2026. Forty studies have been completed in 2025, which is the highest annual figure to date.

The third annual report on real-world evidence framework to support EU regulatory decision-making, based on studies EMA conducted using real-world data between February 2024 and February 2025, was published in June 2025. It summarises the progress made to enable the use of real-world data and establish its value in regulatory decision-making.

The results from the studies are shared with the relevant EMA committees and stakeholders to support the evaluation of medicines and publicly disclosed in the HMA-EMA RWD study catalogue.
Overall, the RWD Catalogues contain 272 registered data sources and 3,235 studies as of December 2025.

The Heads of Medicines Agencies (HMA) and EMA published the joint work plan Data and AI in medicines regulation to 2028. It outlines how the European medicines regulatory network plans to optimise the use, exchange and interpretation of data; strengthen access to data and evidence generation; and harness artificial intelligence (AI) to inform more effective decision-making. The workplan lays out a roadmap for managing, analysing and sharing data across the network, while adhering to high data security and ethical standards. It also provides a framework to address new legislation and initiatives in the EU, notably the new pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act.

In addition, EMA published its first AI Observatory Report which compiles the European medicines regulatory network's experience with AI during 2024 in enhancing productivity, automating tasks, and supporting data-driven decisions across a medicine lifecycle. The Agency also published a compilation of examples of AI use in medicines regulation as well as a horizon scanning short report, based on the review of scientific literature and EU-funded projects, which helps to identify gaps, challenges and opportunities for integrating AI in medicines regulation.

Facilitating the path to accessibility and strengthening the availability of medicines

To improve the accessibility and availability of medicines in the EU, the Agency is supporting the implementation of the health technology assessment (HTA) Regulation and coordinating efforts to prevent and mitigate shortages, while strengthening the security of supply chains for critical medicines.

The new regulation, which became applicable in January 2025, creates an EU framework for the health technology assessment of medicines and medical devices, by fostering collaboration and coordination between EU Member States. The Agency is supporting the implementation of the regulation in 3 areas: joint clinical assessments (JCAs) by providing information from the regulatory review; collaboration in parallel joint scientific consultations (JSCs) to facilitate the generation of evidence necessary for both

regulatory and HTA decision-making; and the exchange of information about upcoming applications and future health technologies, both for planning purposes and horizon scanning.

Working closely with Member States, the Agency has also continued to play a significant role in addressing challenges related to the availability of medicines and the security of supply for critical medicines. The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) published recommendations to address vulnerabilities in the supply chain of radiopharmaceuticals and to address vulnerabilities in the supply chain of anti-D immunoglobulins (critical medicines used during pregnancy).The MSSG continued monitoring the shortages of GLP1-receptor agonists (GLP1-RAs). As part of its preparedness activities, the MSSG continued monitoring the availability of antibiotics commonly used for respiratory infections.

The launch of the European Shortages Monitoring Platform (ESMP), which became fully functional in January 2025, marks a key milestone in the management of shortages. The platform facilitates monitoring and management of critical medicines during public health emergencies and major events and, in the context of preparedness activities, by enabling marketing authorisation holders (MAHs) and national competent authorities (NCAs) to directly report information on supply, demand and availability of nationally and centrally authorised medicines during crises and preparedness actions led by the MSSG.

EMA also continued to play a significant role in supporting the European Health Union by working closely with Member States to address challenges related to the availability of medicines and the security of supply for critical medicines including, on request of the European Commission, preparing several initiatives in anticipation of the proposed reform of the EU pharmaceutical legislation. EMA's role has also included, for example, developing a Union list of critical medicines for additional monitoring by Member States and managing requests for exchanging stocks between Member States as part of a voluntary solidarity mechanism established in 2024 under the auspices of the MSSG as a last resort mechanism to address critical shortages of important medicines.

EMA, in collaboration with European healthcare professional and consumer organisations, also launched a new awareness campaign on medicine shortages. The #ItTakesATeam campaign highlights the shared efforts to prevent and manage shortages across the EU and the role of each actor in supporting patients faced with these shortages.

Seizing the opportunities to futureproof medicines regulation in the EU

The landmark political agreement reached by the European Commission, the European Parliament and the Council of the European Union on the comprehensive reform of the EU pharmaceutical legislation represents the most significant overhaul of the regulatory framework in over two decades. The new pharmaceutical legislation will bring significant changes across multiple areas of EMA's work.

EMA's Management Board adopted a governance structure to guide and oversee the implementation of the pharmaceutical legislation. A new group that includes representatives from EMA, its Management Board and the European Commission will oversee this work.

During the legislative process, EMA provided technical support, working closely with the European Commission and network partners to assess the implications of the evolving text. Early engagement has now started with scientific committees to explore future ways of working in line with the proposed committee reform, aiming to ensure continuity and a smooth transition.

In parallel, the raw data pilot is now underway, paving the way for a more systematic evaluation of clinical trial data submitted at the time of marketing authorisation, with the goal of enhancing data quality and regulatory decision-making. Scenario planning is also progressing to anticipate different

implementation paths and ensure the regulatory network remains effective and responsive in the years ahead.

The new EU medicines agencies' network strategy to 2028 (EMANS), published in March 2025, takes into account the ongoing revision of the EU's pharmaceutical legislation, laying the groundwork for its implementation.

The strategy, titled 'Seizing opportunities in a changing medicines landscape', is a comprehensive review and update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). The Strategy draws on the extensive experience gained from tackling COVID-19. It will guide the European medicines regulatory network over the next few years as it meets the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

Other key developments and activities

Health threats and crisis management

In coordination with several EU partners such as the European Commission and several other EU decentralised agencies, including the ECDC, EMA continued to coordinate Member States' activities on preparing for emerging health threats and to enhance crisis management capacity, in accordance with the EU priorities of ensuring that European citizens are safer and more secure. The work concerned, for example, the activities of the Emergency Task Force in supporting the development of promising medicines for public health emergencies and the MSSG in providing guidance and recommendations on preventing the risk of supply disruptions.

One Health and antimicrobial resistance

As part of the implementation of the cross agency One Health Task Force framework for action published in 2024, EMA continued to strengthen cooperation on the implementation of the One Health agenda in the EU, working with four other EU agencies (ECHA, ECDC, EFSA and EEA) on promoting strategic coordination, research alignment, capacity building, communication and stakeholders' engagement on One Health and supporting the development of partnerships through joint activities across these EU agencies.

This collaboration enhances the Agency's ability to provide integrated scientific advice, particularly in areas such as antimicrobial resistance, zoonotic diseases and environmental health risks and it supports EMA's preparedness and response capabilities, ensuring that health policies are informed by comprehensive, cross-sectoral evidence.

In addition, the Agency published its second report on European sales and use of antimicrobials for veterinary medicine together with an interactive dashboard. The data presented in this report have the potential to inform targeted interventions and strategies against antimicrobial resistance and to foster accountability across reporting countries. The findings reflect the current state of antimicrobial consumption in animals in the EU, and the report calls for action to build on progress made, address remaining challenges and work collectively towards consistent and complete reporting.

International cooperation

EMA continued to support the journey towards the establishment of the African Medicines Agency, contributing to the strengthening of regulatory capabilities at national and regional levels. The African Medicines Regulatory Harmonisation (AMRH) Initiative of the African Union Development Agency-New Partnership for Africa's Development (AUDA NEPAD) completed the successful assessment and listing of the first five medicinal products at the continental level as part of a pilot to test regulatory processes and procedures.

EMA and heads of European national agencies hosted the African Medicines Agency Governing Board, together with colleagues from African national regulatory agencies, African Union bodies, the European Commission, and the World Health Organization (WHO). This was the first meeting between the African and European regulatory networks. The meeting, held on 11-12 June 2025, focused on operationalisation of the AMA and reinforcing the African regulatory network.

Communication

The Agency further expanded the transparency of its operations and increased the opportunities for the public and relevant stakeholders to engage, as well as to fight mis- and dis-information, by providing accurate and reliable information on authorised medicines. Coordinated communication campaigns were organised with national competent authorities, the European Commission, our sister agencies and organisations representing patients and healthcare professionals.

Legal developments

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law, transparency law or procedural irregularities continues to remain high. In the course of the year, EMA has been involved in 12 cases before the Court of Justice of the European Union (CJEU), without recourse to external counsel.

During the year, four judgments/orders were delivered by the CJEU.

In Case T-373/24, the General Court rejected as inadmissible a pharmaceutical company's attempt to call into question a 2017 EMA scientific assessment. The order was subsequently appealed before the Court of Justice in Case C-467/25 P.

In Case T-483/22, the General Court confirmed the lawfulness of a decision of the European Commission to not recognise a biological active substance of a medicinal product as a new active substance and to remove it from the Union register of orphan medicinal products. The judgment endorses the respective evaluations performed by two of EMA's scientific committees, namely, the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Orphan Medicinal Products (COMP).

In Case T-623/22, the General Court rejected a challenge brought by a private citizen against a decision of EMA to grant partial access to certain documents, under Regulation (EC) No 1049/2001, relating a COVID-19 vaccine. In its judgment, the Court of first-instance agreed with the assessment that had been performed by EMA, insofar as it had classified detailed information concerning the quality processes for the manufacture of an mRNA vaccine as commercially confidential information. In Case T-520/24, the General Court concluded the proceedings by declaring that the action had become devoid of purpose.

Work programme implementation

This section includes reference to progress against all key performance and workload indicators set in the Single programming document and the annual work programme. The forecasts of the workload indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

Each of the chapters outlines the achievement of the workload and performance indicators included in each chapter of the work programme, as well as covers a set of objectives, with the relevant activities and results outlined.

The work programme consists of four parts: evaluation activities for human medicines; evaluation activities for veterinary medicines; horizontal activities and other areas, and support and governance activities. Each of these is further broken down into chapters covering the Agency's activities in specific areas or stages in the medicines' lifecycle.

Explanation of symbols used
A traffic light system is used to describe performance against objectives and targets.

	Results more than 10% above the 2025 forecast/target
	Results within +/- 10% (included) of the 2025 forecast/target
	Results 10%-25% below the 2025 forecast/target
	Results more than 25% below 2025 forecast/target
	No activity/result to report

In general, the traffic light system reflects the direction and magnitude of changes, as described above.

However, for some performance indicators, where the optimal results should be lower than the targets, such as average assessment or clock-stop days, the traffic light system is reversed to better reflect the essence of these indicators: results below the target are marked green or blue, while results above the target will appear amber or red.

	Results more than 10% below the 2025 forecast/target
	Results within +/- 10% (included) of the 2025 forecast/target
	Results 10%-25% above the 2025 forecast/target
	Results more than 25% above 2025 forecast/target
	No activity/result to report

For indicators that have been included in the work programme for the first time, data on the previous year's results are not provided.

Human Medicines Division

Pillar 1 – Product related activities

1.1. Pre-authorisation activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Total scientific-advice and protocol-assistance requests	833	692	766	720	780
Requests for parallel scientific advice and protocol assistance with international regulators	5	13	1	4	5
Requests for parallel scientific advice and protocol assistance with HTA	4	4	3	8	4
Scientific advice for PRIME products	37	38	42	40	68
Protocol-assistance and follow-up requests	129	119	131	128	133
Requests for qualification of novel methodologies	21	18	14	16	11
PRIME eligibility requests received	45	52	58	60	68
Applications for orphan designation received	269	195	193	210	211
Total paediatric-procedure applications received	755	713	771	799	882
Submitted requests for ATMP classification	51	43	40	40	28

1.2. Initial evaluation activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Non-orphan medicinal products	35	35	33	50	37
Orphan medicinal products	32	23	21	28	23
Similar biological products	11	21	41	24	23
Generics, hybrid, informed-consent applications, etc.	18	20	15	17	15
Scientific opinions for non-EU markets (Art 58)	1	0	1	1	2
Paediatric-use marketing authorisations	2	1	3	3	2
Requests for accelerated assessment accepted	4	7	4	5	8
ATMP marketing authorisation application requests received	1	4	7	5	3
Companion diagnostics opinions	-	9	10	15	12
Reviews on the maintenance of the orphan designation criteria at MAA stage	-	32	30	40	35

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
% of initial marketing authorisation applications that had received centralised scientific advice	-	-	-	70%	68.50%
Average assessment time for new active substances and biosimilars	189.8	200.56	198.45	205	191.91
Average clock-stop for new active substances and biosimilars	182.1	178.29	169.80	180	150.87
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	31.30%	75.00%	75.00%	50%	57.14%

1.3. Post-authorisation activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Type IA variations	3,586	3,864	3,931	4,000	3,831
Type IB variations	3,354	3,332	3,323	3,750	3,490
Type II variations	1,388	1,201	1,333	1,411	1,284
Extensions of marketing authorisations	31	43	33	35	35

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Average assessment time for variations that include an extension of indication	175.19	175.5	184.92	180	182.53

1.4. Referrals

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Pharmacovigilance-related referrals	4	2	2	4	2
Other referral procedures	5	8	3	7	4

1.5. Pharmacovigilance

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Signals peer-reviewed by EMA	1,605	1,364	1,254	1,200	1,201
Number of ICSRs for CAPs (reports received)	2,273,735	1,389,710	1,230,390	1,500,000	1,219,033
Signals assessed by PRAC (validated by EMA)	39	39	39	40	33
PSURs (standalone CAPs only) started[2]	-	584	627	556	575
PSURs single assessment (CAPs with NAPs) started[3]	-	38	49	54	46
PSURs single assessment (NAPs only) started[4]	-	237	234	308	290

1.6. Inspections and compliance

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
GMP (excluding PMF)	96	209	134	405	166
GLP	1	2	1	0	0
GCP	75	75	93	108	117
Pharmacovigilance	12	14	18	11	10
PMF	84	146	76	60	60
Notifications of suspected quality defects	206	257	395	450	553
Medicinal products included in the sampling and testing programme	85	88	83	70	92
Standard certificate requests	3,849	4,817	4,845	9,850	4,704
Urgent certificate requests	1,147	1,117	985	2,488	1,769
Parallel distribution initial notifications	1,816	2,092	2,656	2,800	2,926
Parallel distribution annual updates	5,509	5,477	5,691	5,500	7,132

[2] New indicator introduced in 2022.
[3] New indicator introduced in 2022.
[4] New indicator introduced in 2022.

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Standard certificates issued within the established timelines (30 working days)	100%	100.00%	100.00%	90%	99.83%
Average days to issue standard certificate	3.90	4.40	6.00	15	12.87
Urgent certificates issued within established timelines (2 working days)	100%	99.00%	99.00%	98%	98.33%
Parallel distribution initial notifications checked for compliance within the established timeline	99%	99.00%	98.00%	98%	99.00%

1.7. Committees, working parties, and expert management

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of reimbursed meetings	106	264	257	334	298
Committee meetings[5]	76	76	76	76	76
Working Parties[6]	-	78	60	29	69
Workshops, Forum, Seminars, Infoday[7]	-	87	46	39	57
Other meetings[8]	-	142	104	190	123
Number of virtual meetings (audio-, video- and web conferences)	5,700	4,600	1,609	6,500	1,222
Number of reimbursed delegates	1,980	3,476	3,759	5,000	4,937
Number of non-reimbursed delegates	178	1,008	1,347	1,500	1,968
New herbal monographs	3	1	1	1	2
Reviewed herbal monographs[9]	28	19	15	20	21
Revised herbal monographs	2	3	10	5	4
List entries	0	0	2	1	0

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings	100%	100.00%	100.00%	100.00%	100.00%

[5] Including Management Board meetings.
[6] New indicators introduced in 2024 Work Programme.
[7] New indicators introduced in 2024 Work Programme.
[8] New indicators introduced in 2024 Work Programme.
[9] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Operate the Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative manufacturing technologies and methods Deliver on International activities relating to Pharmaceutical Quality Knowledge Management System (PQKMS) and continue supporting Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	3.1/5.5 (ECP 1 A new plan for Europe)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	Completed	Deliverables of the Quality innovation group in 2025: 1 EMA Listen and Learn Focus Group (LLFG) on personalised medicines + 1 breakout session on modelling Q&A, 12 1-to-1 meetings, 5 plenary meetings, 3 FDA exchanges, 1 site visit. Pharmaceutical Quality Knowledge Management System (PQKMS): collaborative assessment pilot extension ongoing — 3 pilots accepted/started. Risk-based approaches in manufacturing and control strategy/ ICH Q12: Variation Classification Guideline revision finalised, Network training session delivered, Implementing guidance prepared and published: Q&A on complex manufacturing, post approval change management protocols (PACMP), Product Lifecycle Management (PLCM), medical devices, other.
Deliver tailored engagement with academics and the community of ATMP developers (ATMP support pilot) Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant guidance, e.g. on the safety and efficacy follow-up of ATMPs (guidance)	3.1 (ECP 1 A new plan for Europe)	Increased support for ATMP development and better understanding of academic developers need to enhance the integration of scientific and technological progress in the development of ATMPs	Delayed	Guideline on quality, non-clinical and clinical requirements for investigational ATMP finalised and published on 6 February 2025. Fee waiver for scientific advice for non-profit developers integrated into the new fee regulation that came into force in January 2025. Regulatory/procedural and/or administrative support provided to products participating to the ATMP support pilot for academics where relevant. Translation services available to SMEs extended to academic pilot participants in case of a successful marketing authorisation application. Initial results and report on the lessons learnt from this initiative delayed to 2026. Contribution to a training on scientific advice targeted to academics.
Engage actively with International Partners to	5.3	Maintain the effectiveness and	On track	The revisions of the Annex 11 on computerised systems, new

Action	MAWP strategic goal	Expected result	Status	Achievements/results
help increase awareness and facilitate the use of internationally- agreed quality and GxP standards globally. Support Network capacity for 3rd country inspections through reliance, International Regulators collaborative inspection pilots, MRAs extension and stronger EU presence in third countries.		efficiency of GMP oversight by leveraging on collective efforts from global Regulators and greater convergence on internationally agreed quality standards		Annex 22 on artificial intelligence, together with a revised Chapter 4 on Documentation are on track, the group is working on reviewing the comments received during the public consultation to revise the annexes, expected finalised by end 2026. The public consultation of the revised Chapter 1 — Pharmaceutical Quality System (as a result of the revision of the ICH Q9 guideline on Quality Risk Management) has concluded on 3rd December 2025, and the drafting group is currently working on implementing comments received and to finalise the revision of the chapter in collaboration with Pharmaceutical Inspection Co-operation Scheme (PIC/s). The concept paper for the revision of the Annex 15, to reflect the revised ICH Q9 R1 and the sartan lessons learnt recommendation, has been adopted by the GMDP IWG in November 2025 and is expected to be published for consultation by mid-January 2026, following PIC/s adoption. Following the US MRA extension to veterinary products in May 2023, 24 EU veterinary authorities were recognised by US FDA with 2 pending that require further time for implementation at national level. A delay to the entry into force of the batch testing waiver is in place. The EU-US extension and on the recognition of third country inspections was unilaterally progressed by the EU authorities on a preliminary voluntary basis to gather further experience on its applicability. The MRA expansion on vaccines and plasma derived products is currently pending further discussions between EU-US standing committee discussions.
Promote dedicated cooperative and enhanced supervision with strategic international partners for manufacturing sites, such as tailored supervision of API manufacturers and/or large sites that supply a	5.2	Reinforced supervision of API manufacturers	On track	The GMDP IWG (Good Manufacturing and Distribution Practice Inspectors Working Group) has agreed the framework for sharing information and aligning GMP inspections conducted by the EEA Inspectorates for national products and centrally authorised products in November 2025. The

Action	MAWP strategic goal	Expected result	Status	Achievements/results
significant number of markets or products				kick off meeting planned for Q1 2026. The Active Pharmaceutical Ingredient (API) Programme on exchange of information on inspections of API manufacturers is operational. The pilot on international collaboration on finished product inspections has been resumed in September 2025, with a terms of reference currently being put together by participants.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	3.2 (ECP 1 A new plan for Europe)	The ICH E6 (R3) guideline is updated to facilitate a more proportionate application of its principles and the use of alternative trial types/ technologies, and training is available for EU stakeholders	On track	ICH E6 R3 Principles and Annex 1 came into effect in Europe on 23 July 2025. A significant hybrid workshop took place under the ACT EU umbrella in February 2025 for the CT community (2,000 attendees, videos available online), training activities with EU inspectors was conducted, and an online training module (introduction and foundational concepts) was published on the ICH website.
Delivery of the action plan to strengthen the Qualification of Novel Methodologies framework		Explore involvement of additional decision-makers during QoNM: e.g. HTA, MD/IVD regulators Training for methodology developers less experienced in regulatory interactions, e.g. academics, HCPs and patient representatives Publishing specific unmet needs for novel methodologies as identified by Committees or Working Parties and linking to Regulatory Science Research Needs Establish active interaction with more professional societies and patient groups developing COAs Explore feasibility of (automated) monitoring and reporting of evidence generated by qualified methods	Delayed	Draft revised procedural guidance: consultation with SAWP and MWP took place, currently comments received are implemented by the QoNM core group with the aim of publishing this revised guidance in Q1 2026. In parallel, drafting of briefing document templates (general and for registry qualification) is ongoing, with a consultation target in February 2026. Work on various Q&A documents has started but work will take into 2026 in line with the updated action plan as presented in the R&D stakeholder platform meeting in December 2025; work on improving EMRN and external expert involvement is ongoing; work on improving QoNM webpage presentation has started with webteam. Industry trade organisations have agreed on process and format for publication of high-level information on Qualification Advice procedures.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		that has informed regulatory decisions		
Defining operational guidance for EMA responsibilities under the HTA Regulation, in cooperation with the HTA structures Contributing to stakeholder trainings on the implementation of the HTA Regulation Engaging in technical cooperation on evidence requirements for regulatory assessment and HTA, respectively	Legislation	Readiness for the application of the HTA Regulation Effective and efficient interplay between regulatory and HTA processes, respecting remits Support evidence generation plans that address needs for regulatory assessment and HTA Efficient management of resource impact for EMA and the EU Regulatory Network	On track	In relation to support for HTA's Joint Clinical Assessments (JCA) for medicinal products: Establishment of internal operational guidance for coordination across functions (March 2025), and first revision based on initial experience (September 2025) Agreement with the HTA secretariat and Joint Clinical Assessment subgroup (JCASG) on information to be shared during the regulatory assessment (cf CHMP work plan item 1.2.9) Establishment of notification process for MAA submission in scope of JCA production, with first notification submitted (March 2025) Continuous refinement of Letter of Intent (LoI) Notification process together with the HTA secretariat First provision of information from an ongoing MAA to the HTA Secretariat, to inform the JCA production conducted in parallel (July 2025) In relation to parallel Joint Scientific Consultations (JSC) for medicinal products: Establishment of operational touchpoints with the HTA secretariat Contribution to finalisation and publication of guidance and templates for applicants Initiation of procedural management of parallel JSC with first procedure starting in July 2025 In relation to information on forecasting: Establishment of internal data collection and consolidated reporting for medicinal products and medical devices First provision of the annual forecast reporting on medicinal products and medical devices to inform reporting by the EHT SG (April 2025); initiation of quarterly submission of medical device-related information to

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				inform selection for JCA (April/July/October 2025) Stakeholder training through Industry Standing Group and HTA Stakeholder Network, respectively, as well as external events such as DIA Europe, TOPRA, RAPS and other events (e.g. Cancer Drug Development Forum (CDDF) webinar) Publication of the Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions as outcome of a workshop series between HTA bodies and regulators.
Prepare for the new pharmaceutical legislation to future proof medicines regulation in the EU	Legislation	Engage Scientific Committees in the reform and explore ways to optimise regulatory activities	On track	Throughout 2025, while the legislative process was ongoing, the dedicated team conducted early assessments of potential impact areas and implications for ways of working. Following the provisional agreement reached in December between the European Commission, the European Parliament and the Council, the programme began shifting from building a shared understanding of what the reform could mean towards strengthening readiness for implementation. While formal implementation planning will follow adoption of the final text, change management activities started, including staff awareness sessions and continued engagement with committees and key stakeholders to support early alignment ahead of implementation.
Implementation of the EU Regulation on medical devices and on *in vitro* diagnostic medical devices	Legislation	Finalise the consultation procedure for medical devices composed of systemically absorbed substances Finalise the process for handling serious incident reports received by Medical Devices National Competent Authorities for ancillary medicinal substances and companion diagnostics Application of Art 117:	Completed	After holding few meetings with the drafting group to reflect on which substance-based medical devices fall within this procedure and to understand the scope and documentation for the assessment under this procedure and considering that since the entry into force of the MDR no such devices could be identified by various stakeholders, development of the procedural guidance is on hold and would be reactivated based on an actual case. (suspended) Process for handling serious incident received from MD NCAs is ongoing and progress is subject to EC/MDCG PMSV TF (EU Medical Device Coordination Group Post-market surveillance and vigilance Task Force) consultation. (suspended) Further EMA/CMDh Q&A update

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		EMA/CMDh Q&A update		(rev.5) published in January 2025. (completed)

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
ITF briefing meetings requests received	0	10	11	5	9
Scientific advice requests received and validated	39	17	27	20	32
Requests for classification as limited market under article 4(29) and eligibility under article 23	21	17	14	12	17

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Scientific advice procedures completed within set timeframes	100%	100.00%	100.00%	100%	100.00%

2.2. Initial evaluation

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Total Initial marketing authorisation applications	22	25	27	29	34
New MRL applications	0	0	0	0	1
MRL extension/modification applications[10]	1	2	4	2	0
MRL extrapolations	0	1	0	1	0
Review of draft Codex MRLs	16	0	9	5	0

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Initial procedures completed within legal timeframes	100%	100.00%	100.00%	100%	100.00%

[10] Includes reviews requested in line with Article 11 of Regulation 470/2009.

2.3. Post-authorisation activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Total variations	252	337	268	320	299
Variations level 1	2	2	3	2	2
Variations level 2	75	104	63	91	59
Variations level 3	70	76	77	97	83
Variations level 4	105	155	125	110	155
Transfers of marketing authorisations	0	1	3	0	1

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Post-authorisation applications evaluated within the legal timeframes	100%	100.00%	99.00%	100%	100.00%

2.4. Arbitrations and referrals

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Total arbitrations and referrals	5	1	1	3	4

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Referral procedures managed within the legal timelines	100%	75.00%	100.00%	100%	100.00%

2.5. Pharmacovigilance activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Annual recording of signal management results and outcomes (Annual statements)	-	-	271	260	291
Total signals submitted by MAHs of which:	-	-	279	381	316
Emerging safety issues assessed by MAH and leading to regulatory action	-	-	0	1	0
Signals assessed by MAH leading to regulatory action (variations or other)	-	-	25	40	24
Signals classified for close monitoring by MAH	-	-	31	40	70
Signals classified as refuted by MAH	-	-	223	300	222
Signals submitted by Regulatory authorities following risk-based review	-	-	16	40	0
Targeted signal management processes initiated by regulators	-	-	1	4	0
Total ADRs:	167,546	149,059	164,360	150,000	157,712
Total CAP ADRs	95,959	81,845	101,768	75,000	99,023
Total non-CAP ADRs	71,587	67,214	62,592	75,000	58,689

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Implement in the veterinary medicines field the recommendations of the 'Report on development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin'	3.1 (ECP 1 A new plan for Europe)	Harmonised methodology in place: legislation, guidelines and templates revised Exposure assessment tool made available to CVMP experts	On track	A draft version of the common calculation tool was developed by EFSA contractor. The working group met in July 2025. The functional testing of the tool (2 subsequent versions, the second one addressing the main bugs identified in the first one) was conducted from August to October 2025. The working group discussed on 15 October 2025 the errors detected during testing. The developer is in charge of correcting the errors identified. The group worked on the draft report and on the user manual & FAQs documents. In parallel, the need to add a back-calculation module for veterinary MRLs was expressed in the working group and reported to CVMP in September 2025 and to EC on 16 October 2025 (bilateral EMA EC) and 4 December 2025 (trilateral EFSA EMA EC).

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				This requirement, together with some other developments related to pesticides on EFSA side, would require amending the EC mandate and postponing the initial deadline of November 2026.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	3.1 (ECP 1 A new plan for Europe)	Guidance for surveillance and signal detection developed Enhanced communication with the network	Completed	The technical implementation in IRIS of the key aspects of the new process for signal detection and corresponding tutorials have been finalised in Q1 2025.
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required	3 (additional RSS recommendation)	Support EC in the monographs feasibility study Pilot study to be performed for VMPs considering relevant provisions in the New Pharma Legislation for human medicines	On track	The pilot is currently on hold awaiting further specifications.
Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish cooperation with international institutions, academic organisations and relevant initiatives	3 (additional RSS recommendation)	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	On track	In the second half of 2025, EMA participated to following event: KIC ERA & NAMs — AMPHIDEB: Outcomes & insights for advancing ERA (5 December 2025)
Provide scientific support to the European Commission and the EU network, upon request, to ensure that a 'One Health' approach is applied to ERA	3 (additional RSS recommendation)	Support to EC provided 'One Health' approach for ERA implemented	On track	EMA provides input to EC/other Agencies when requested on ERA 'One Health' topics. No specific request was received in 2025.
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1 (ECP 1 A new plan for Europe)	Establish governance for JIACRA report under EMA and CVMP	On track	The mandate for the report was received at end of 2024. So far two interagency meetings have been organised in 2025, and one is planned for 2026. The initial analyses have already been completed. The report is expected to be finalised by the end of 2026.
Implement use data collection by animal species	4.1 (ECP 1 A new plan for Europe)	Collection of data on the use of antimicrobials per animal species and animal categories	Completed	The first 'European Sales and Use of Antimicrobials for veterinary medicine report'

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578		(ESUAvet report) has been published on 31 March 2025.
Communicate effectively on consumption data	4.1 (ECP 1 A new plan for Europe)	The outline of the ESVAC report reviewed to improve communication Group of experts to define the outline of the volumes of sales and use of antimicrobials (Article 17 of the Commission Delegated Regulation (EU) 2021/578)	Completed	The first 'European Sales and Use of Antimicrobials for veterinary medicine report' (ESUAvet report) has been published on 31 March 2025. An info session to veterinary practitioners to introduce the report has been held in June 2025, in cooperation with Federation of Veterinarians of Europe (FVE).
Providing a reflection on the use and availability of diagnostic tests to improve the responsible use of veterinary antimicrobial products	4.3 (ECP 1 A new plan for Europe)	Review availability and characteristics of diagnostic tests	On track	The development of the reflection paper is progressing, and the draft is now expected to be ready for public consultation by Q2 2026.
Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	4.3 (ECP 1 A new plan for Europe)	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	On track	An adjustment of the AMEG categorisation was required to align it with the list of antimicrobials reserved for human use, including both the scientific advice and the infographic. The update has been published on EMA public website in September 2025.
Participate in international initiatives to reduce the risk of AMR	4.1 (ECP 1 A new plan for Europe)	Actively participating in international fora	On track	In the second half of 2025, EMA veterinary colleagues participated in: AMR One Health Network meeting (on-line) on 24-25 November 2025
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 1 A new plan for Europe)	Develop and revise relevant guidance	On track	The 'Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species' was published for public consultation in November 2025.
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received	4.3 (ECP 1 A new plan for Europe)	Reflection paper finalised and published Review of novel risk assessment methodologies for	On track	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper		AMR in the environment		
Develop a regulatory approach/framework to promote products that can assist in the reduction of the use of antimicrobials and novel paradigms	4.3 (ECP 1 A new plan for Europe)	Reflection paper developed Communication with stakeholders	Suspended	This activity is currently on hold pending further clarification.
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	4.3 (ECP 1 A new plan for Europe)	Guidance development Communication with stakeholders	On track	The 'Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions' will be revised once the essential list for horses and the aquatic list are finalised. In 2024 the CVMP started the work on the ADRA project (Dosage review and adjustment of established veterinary antibiotics), which follows the principles laid out in the 2017 CVMP reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation. A priority list of antimicrobial candidate substances was adopted by CVMP in February 2025. Based on this list, the Committee will conduct the reviews under Article 141(1)(i) of Regulation (EU) 2019/6 which mandates the CVMP to provide scientific advice on the use of antimicrobials in animals in order to minimise the occurrence of resistance in the Union. The first Article 141(1)(i) procedure under this project was initiated in November 2025. An info session to industry has been held on 22 May 2025 and a focus group meeting with concerned MAHs took place on 15 September 2025. For more information on this project please refer to Veterinary antibiotics:

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Dosage review and adjustment (ADRA) project | European Medicines Agency (EMA).
Provide scientific and regulatory support to encourage development of veterinary products that can assist in the reduction of the use of antimicrobials, to fill therapeutic gaps, without adversely impacting public health	4.3 (ECP 1 A new plan for Europe)	Guidance development products that can assist in the reduction of the use of antimicrobials	On track	The analysis on the last 5 years advice on products that can assist the reduction of the use of antimicrobials has been completed. The aim of the report is to identify data gaps and areas for further improvement, the draft report is currently under revision.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and products that can assist in the reduction of the use of antimicrobials	4.3 (ECP 1 A new plan for Europe)	Cooperation at EU and international level for events Common approach agreed	On track	In 2025 three TATFAR meetings on activity 1.1. (chaired by EMA) were organised to discuss progress.
Include AMR as a regular topic at meetings with HMA and veterinary stakeholders	4.5	Actively propose AMR topics for HMA and stakeholders' meetings	On track	The EMANS to 2028 final document has been published in March 2025, theme 4 is entirely dedicated to antimicrobial resistance. An overview table outlining activities under this theme has been presented to the EMA Management Board.
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)		Identify different benefit-risk approaches per type of vaccines Guidance on benefit risk	Completed	Activity completed in 2024
Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best practices on the use of veterinary antiparasitic medicines	4 (additional RSS recommendation)	Improve interaction with international organisations Best practices embedded in guidance	On track	EMA continues to attend webinars on acaricide resistance organised by FAO (4 webinars were organised in 2025).
Promote responsible use of antiparasitics in the EU	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	On track	The revision of the 'Guideline for the demonstration of efficacy of ectoparasiticides' started in January 2024. The draft revised guideline has been published for public consultation in January 2026. An infographic on lack of expected efficacy for antiparasitic veterinary medicinal products is under

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				development by EWP-V (EMA CVMP Efficacy Working Party) and PhVWP-V (EMA CVMP Pharmacovigilance Working Party) and is expected to be finalised in early 2026. Further communication and dissemination activities will follow in 2026. A concept paper for the revision of the 'Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees' was developed and published for consultation in 2024. The revision of the respective guideline started in Q1 2025. The draft revised guideline has been published for public consultation in January 2026.
Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision- making	6.2 (ECP 1 A new plan for Europe)	Analysis of current methodologies, development of harmonised approach and guidance	Completed	Activity completed in 2024
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	6.2 (ECP 1 A new plan for Europe)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	On track	The CVMP highlights were revised to make them more accessible to all stakeholders and to closer align with the CHMP highlights, particularly the terminology used was simplified to make them more understandable to the general public.
Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 1 A new plan for Europe)	Compilation of a Veterinary data sources catalogue and metadata analysis	On track	The next Data landscape study phase started in Q2 2025. The goal of this phase is to obtain all metadata for >100 prioritised sources to support an in-depth analysis and evaluate interoperability of data sources. It is expected to upload selected veterinary data sources to the RWE catalogue in Q2 2026.
Contribution to Chemical Strategy for Sustainability, particularly on the 'One substance one assessment' (1S1A) initiative, including the establishment of the EU Common Data Platform for Chemicals (EU-CDPC)	(ECP 1 A new plan for Europe)	EMA data and legal requirements to be provided in the frame of the EU policy- making process Implementation of the initiative as/if required	On track	The regulation has been published in January 2026. EMA continues to participate to regular interactions, as required, and started with the implementation work.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Consequently, implement the initiative as/if required				
Records management	2.4	Ensuring the efficient and systematic control of all EMA records throughout their entire life cycle, regardless of format, location, or hosting system, while maintaining regulatory compliance, operational efficiency, and the preservation of institutional memory	On track	The roadmap for the policy implementation including the revision and alignment of the supporting documents was approved in November 2025.

Task forces

Digital Business Transformation (TDT)

Workload indicators

Procedure		2022 result	2023 result	2024 result	2025 forecast	2025 result
	New scientific, regulatory and network portfolio curricula developed	1	0	2	2	5
	Number of training events advertised to the Network	76	79	158	75	121
	Number of reimbursed training events to the EU Network	4	3	4	8	12
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	11	13	9	10	11
	Number of Epics completed or ongoing[11]	-	-	44	33	35

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Develop a digital skills framework for EMA and lead on digital capability building		Validated Digital Skills framework for EMA Creation of introductory training on topics in the digital skills framework with links to further learning on each topic to enable deeper skill development Creation of a platform to act as entry point to the introductory training content Deliver agency-wide awareness campaign to engage staff and create engagement through gamification and events	Completed	In 2025, the Agency continued to deliver e-learning modules under the Digital Academy framework. In particular, an AI literacy programme, designed to provide EMA staff with the essentials for the safe, effective and responsible AI use at the Agency, in compliance with the AI Act. The AI literacy programme consists of 6 pillars: 1. AI awareness and fundamentals 2. The EU AI Act and compliance 3. Ethical and responsible AI use 4. AI and data protection 5. AI tools 6. Stay up to date on AI The average rating of the AI literacy modules is 4.48 out of 5 To support the launch of the AI programme, an Agency-wide campaign was launched in Q4 2025 together with a 'Virtual AI Magazine' in order to foster staff engagement with the AI literacy programme.

[11] New indicator introduced in the context of EMA Agile transformation.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Support futureproofing of EMA and the Network by developing regulatory capacity through the EU NTC		Training delivered to the EU Network F2F training delivered to the EU Network Extend access to EU NTC training to external audiences including analysis of the existing EU NTC training content Development of processes for providing access to subset of external audiences Investigate whether current platform is suitable or whether a new platform should be considered Investigate the setting up of an engagement portal/entry point to the LMS for external audiences Develop a future state learning delivery model and landscape that serves new and existing audiences, in co-creation with the EU-NTC	Completed	In 2025, a total of 121 training events were advertised on the EU NTC newsletter. In addition, 12 training events benefited from reimbursement from the EU NTC budget. In November 2025, a major milestone was also achieved as the EU NTC provided access to a dedicated training catalogue to African regulators in the framework of the African Medicines Agency project. The first in-person Assessors Day was organised by the EU NTC, attracting over 120 participants and over 20 speakers from EMA, the EU Medicines Regulatory Network and beyond.
Lean Portfolio Management		1 — EMA portfolio processes related are in line with the lean-Agile SAFE framework 2- Standardisation of VS tools, templates and ways of working	Completed	An updated Network Portfolio budget process has been designed and endorsed. Templates and guidance have been put in place to ensure standardisation across five value streams.
Team & technical agility		1- Agile roles and responsibilities are defined within the EMA role description framework 2- Define a process to onboard new team members into the agile roles	Suspended	LACE team submitted the Agile roles proposal to be added into the EMA Competency Framework. Strategy review exercise on Digital, Technology and Data.
Agile product delivery		1- Rest of portfolio teams and platform teams are transition to Agile way of working	On track	Value Stream have fully transitioned into an Agile way of working. Onboarded staff members are being trained and coached as per their role. Next target audience is to coach

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		2- Ensure EMA staff are coached based on their defined Agile role		more members from the Leadership Team.
Lead the Delving AI to EMA initiative (Knowledge Mining and AI Use cases initiative) including: 1) collecting EMA and Networks needs to build the AI implementation roadmap of the Agency and the Network 2) designing and delivering different PoCs under this initiative using design thinking principles		Better knowledge and information management at EMA	On track	1) EMA run a first internal consultation to collect use cases and requirements. This consultation was expanded towards the Network with first a survey at the beginning of 2025 and 2 follow-up workshops in August and October. The first workshop in August aimed to collect business requirements from the end user (assessors) and the second workshop to discuss possible solution with the IT directors from the different NCAs. The outcome of workshop has been translated to an AI workplan presented to EXB and NDSG in December 2025. 2) During the last part of 2024 and the first half of 2025, EMA has been developing different proof of concepts (PoCs) (a total of 19) based on the use cases collected to assess feasibility and complexity. The outcomes of the PoCs and the lessons learned, helped the EMA team to lead the discussions with the NCAs and IT Directors and to define the AI roadmap and how this should be delivered.
Socialize the use of the power platform to business users and develop and maintain citizen developers framework, service and users community on the Microsoft Power Platform to boost digital acceleration		Operational power platform community Increased use of power platform Minimisation of the dependency on IT for the Automation of manual tasks / activity Efficiency gains due to automation	On track	A list of comprehensive recommendations relating to MS power platform adoption to citizen developers that covered areas of technical governance and citizen developers' community enablement was delivered. A 6-month Community pilot, focusing on exploring a self-service model to enable citizen development on MS power platform for personal and team productivity, has been successfully launched in December 2025, with 20 staff members engaged as citizen developers. Trainings and onboarding offer completed on time. Initiative will continue until Q2 2026.
Develop a business architecture practice to support the alignment of EMA and EMRN strategy		Stronger alignment of digital transformation investments with	On track	Procurement process for Business Consultancy services to set up the business architecture framework and

Action	MAWP strategic goal	Expected result	Status	Achievements/results
with organisational structures, processes, data and execution by introducing a structured approach to our Organisational Business Model design in support of: Digital Business Transformation Enterprise Architecture and Portfolio Management aiming to close the Strategy to Execution Gap		organisational strategy Enhanced capabilities to leverage opportunities and support the implementation of changes brought about through new legislation and other external factors		practice set in place in June 2025 Deliverables from business consultancy, including Business capability mapping of EMAs operational model focusing on Human Medicines Management, Value stream mapping and user journey mapping, ongoing and expected to be completed by June 2026
Regulatory Optimisation Group (ROG) reactivation ROG is a joint HMA/EMA group focused on activities for business/regulatory optimisation within the scope of the respective EMANS goals under key business priority 'Optimisation of the regulatory operations' by leveraging digitalisation and innovation		Address prioritisation and challenges faced in the execution of the Network Portfolio building on the strategic needs and priorities	On track	In 2025, the Regulatory Optimisation Group (ROG) convened seven plenary sessions and participated in the F2F Quarterly Strategic Portfolio Review (QSPR) ceremony held in September. ROG organised three meetings of the NCAs Business Community, which currently consist of 13 NCAs with 21 Business representatives, addressing key topics for the EMRN including Product Management Services (PMS), eSubmissions, and electronic Product Information (ePI). Engagement with external stakeholders remained a core focus throughout the year. ROG engaged with industry representatives on four occasions, including two joint sessions with the NDSG dedicated to product master data. The ROG PMS Sub-Group successfully designed, launched, and executed the PMS Data Qualification Feasibility Study, which involved more than 45 participants representing 20 National Competent Authorities. Looking ahead, ROG will continue strengthening collaboration and outreach activities, with particular emphasis on Network and portfolio-level priorities. Notably, ROG is initiating a joint pilot aimed at the digitalisation of minor variations, alongside exploring additional business

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				cases emerging from the new pharmaceutical legislation.
Chair the EUAN Working Group on AI		Collaboration within the European Agencies Network to share knowledge and experience on AI and Digital Solutions	On track	35 Agencies and Joint Undertakings represented across all WG activities 88 SPOCs in total +15 WG on AI sessions hosted (including AI Talks, Maturity Sessions, Physical Working Session, regular WG meetings) +360 total participants across all sessions Physical Working Session held in Amsterdam Launch the EUAN Staff Exchange Programme on AI 7 documents and reports developed and shared with the Network: WG on AI Teams workspace Guidelines WG on AI Governance and Communication Strategy Physical Working Session Report Data Maturity Session Report EUAN Staff Exchange Programme on AI Guidelines document 3 Newsletter editions AI Competency Observatory Handbook (work in progress)
Virtual reality activity		Users are trained through a realistic training scenario allowing them to increase their decisions and actions	Completed	Virtual reality for GMP inspections: over 100 EU/EEA GMP inspectors trained. Virtual reality for staff members for emergency situations: over 100 staff trained. This training will continue in 2026.

Data Analytics and Methods (TDA)

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	1,201	-	1,319	1,200	1,253
Number of EudraVigilance Quality Assurance Test (QAT) requests received	132	-	153	140	99[12]
Number of non-interventional studies initiated	21	-	59	60	53
Number of methodological advice provided on product procedures	-	-	71	80	96
Number of active methodology guideline drafting groups led by MWP	-	-	12	15	13
Number of methodological contributions to guidelines led by other committees and working parties	-	-	11	15	10
Number of business validation for CTIS releases	11	-	20	18	10
Number of KPIs reports published	8	-	11	4	4
Number of EudraCT reports and number of CTIS data analyses and reporting	80	-	144	110	126
Number of ACT EU multi-stakeholder workshops	2	-	10	12	12
Number of regular CTIS/CTR events	70	-	76	86	73
Number of CTIS newsflashes and CT highlights newsletters	20	-	29	19	17

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	-	-	94.00%	90%	90.42%
Percentage of monthly updates of the ADR report website performed according to the timelines	-	-	100.00%	90%	91.00%
Studies performed within less than 26 weeks[13]	-	-	66.00%	60%	81.00%
Non-Interventional Study (NIS) protocols and summary results registered in EMA NIS registry within a month after finalisation	-	-	100.00%	90%	100.00%
Product procedure requests for methodological support completed as per timelines	-	-	100.00%	90%	100.00%
Planned MWP contribution to guidelines led by other committees and working parties	-	-	100.00%	75%	100.00%
RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	-	-	73.00%	90%	70.00%
WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	-	-	100.00%	90%	100.00%
ACT EU multi-stakeholder workshops organised according to workplan	-	-	80.00%	80%	100.00%
News flash to CTIS users	-	-	100.00%	90%	50.00%[14]

[12] Impact of external factors prevented meeting the forecast.
[13] Excluding Framework contract studies.
[14] Newsflash is discontinued as of July 2025.

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Support to the secretariat for CTCG and physical hosting 4 times per year	-	-	100.00%	100%	100.00%
Provide secretariat for CTCG weekly assessors round table	-	-	100.00%	100%	100.00%

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Build capacity and capability to receive, store, manage and analyse clinical study data		Proof-of-concept clinical study data pilot protocol developed CHMP proof-of-concept clinical study data pilot operated Updated pilot report on learnings and recommendations developed Guidance for applicants updated Workshop on the submission and analysis of clinical study data	**On track**	HMA/EMA decided to extend the pilot beyond 2026 following the interim report publication. Guidance to Applicants updated in Q1 2025. Epic hypothesis presented to/accepted by Portfolio Board in Q3 2025. Business requirement collection ongoing with first draft available in Q4 2025. Change management activities intensified in 2025: numerous presentations to EMA and public fora delivered; Industry Focus Group on Raw Data and Network Advisory Group on Raw Data meetings held. Reopening of competition (framework contract) to support IT development and GCP data analyses initiated with project up and running since Q3 2025. Two new procedures included in the pilot in 2025.
Manage the EMA-HMA-EC co-led initiative Accelerating Clinical Trials (ACT EU) to transform CT in Europe. This includes strengthening EU level governance of CT and the CTR implementation; modernisation of CT design and good clinical practice; leveraging data on CT to support regulatory decision making; supporting non-commercial sponsors to conduct more multi-		Strengthened EMA/EC/HMA collaboration within ACT EU via rationalised governance Launch of an action plan to support non-commercial sponsors External stakeholders engaged through the establishment of the multi-stakeholder platform and its advisory group Implementation of revised ICH E6(R3)	**On track**	CTR transition successfully completed and documented in 3-year analysis report (2022/2025 CTIS data); list of most frequently raised RFI part I and part II published; CTIS master sponsor handbook revised; regular CTR monitoring reports published. Action plan to support non-commercial sponsors with mapping of support initiatives and regulatory helpdesk (>2100 tickets resolved in

Action	MAWP strategic goal	Expected result	Status	Achievements/results
national clinical trials; enhanced dialogue between clinical trial stakeholders.		GCP modernisation in the EU region supported Research priorities for better use of clinical trials data defined Stand-alone ACT EU website managed Consolidated scientific and regulatory advice pilots operated and results reviewed and made public Methodological aspects on CT design supported by a best practice on guidance Clinical trials safety aspects, trainings and clinical trials in emergency settings (PHE) delivered		2025) expanded with national webinars. Quarterly meetings of the multi-stakeholder platform advisory group held; focus groups to support the programme delivery created. ICH E6 R3 workshop on principles and annex 1 conducted; dedicated focus group on application of Risk based approaches (RBA) in clinical trials during life cycle created. Initial CTIS — ACT EU trial map launched in Q1, followed by release of multilingual version in Q4. 21 applications for the pilots on consolidated scientific and regulatory advice in clinical trials received with positive feedback from applicants and assessors. Best practice on CT methodology guidance development finalised and disseminated to the EMRN. Safe CT meeting and regular safety assessors round table held. Results of survey on training needs for academia and SME published; to support next deliverables stakeholder focus group created. Public Health Emergency (PHE) Ethics Advisory Group established and collaborating with Emergency Task Force (ETF). Annual ACT EU matrix meeting and multi-stakeholder platform meetings held with strong engagement from the EMRN and stakeholders. KPIs for the EU clinical trials environment were launched to improve attractiveness and speed, supported by the development of an EMRN dashboard.
Business support to operations to Clinical Trials regulation including business support to CTIS		Provide hands on support to the numerous sponsors and MS users of CTIS through the business service desk	**On track**	Continuous support to sponsors and Member states delivered.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		Assure the business testing of the candidate releases		Dedicated support for non-commercial sponsors delivered. List of CTIS functionalities for improvements, based on incidents, prioritised in bi-weekly consultation sessions. Users are informed regularly on CTIS deployed versions via: news flashes; monthly newsletters; quarterly CTIS fora.
Change management activities related to CTR/CTIS		Regular communications in the form of newsletters and news flashes, maintenance of the CTIS training catalogue, and running of regular CTIS events, e.g. walk-in clinics, bite size talks, CTIS forum	**On track**	CTIS stakeholders were supported through following change management activities: 4 CTIS Fora; 6 newsletters (CTIS newsletter is EMA's most subscribed newsletter); 11 newsflashes (discontinued as of July); 4 walk in clinics; 2 bitesize talks; 2 internal workshops to align business requirements; 1 CTIS Info Day; 2 sponsor end user trainings in collaboration with DIA; access to 112 sponsor users to the CTIS Training Environment enabled; initiation of Member State Master Trainer initiative; annual survey to collect feedback on the change management activities and address potential improvement areas launched in December.
Lead the development of the Big Data curriculum on Data Science for the EU Regulatory Network	2.2 (ECP 1 A new plan for Europe)	Training modules published on the EUNTC portal	**On track**	2 trainings modules — Data Quality and Omics Data developed. They are planned for release to EMRN in January 2026.
Development of the EU Data Quality Framework for big data used in the regulatory context and of the DQ considerations for Real World Data (RWD)	2.1 (ECP 1 A new plan for Europe)	Common framework for data quality available for EMRN and industry Specific and implementable	**Delayed**	RWD chapter: public consultation concluded; adopted by NDSG and MWP;

Action	MAWP strategic goal	Expected result	Status	Achievements/results
and for Adverse Drug Reactions (ADRs)		guidelines for ADR and RWD data are available		publication expected in Q1 2026, following an extended re drafting phase to address public consultation feedback, now concluded. ADR chapter finalised and due to be published Q2-Q3 2026.
Ensure compliance with the European Union Data Protection Regulation (Regulation (EU) 2018/1725) and guidance of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB) and provide advice on data protection related matters at EMA		Full compliance with Data Protection legislation Risks managed	**On track**	DPO report to EMA Management Board delivered in December. Three quarterly reports to the EMA ED and the Internal Controllers provided. Q4 report covered by the report to the EMA MB. Training modules released to EMA staff: Data Protection – what do I need to know. Data protection governance at EMA. Personal data protection in your day-to-day work. Personal data breach: awareness and response. How to comply with data subject rights. Data protection training (specialised focus on AI). Adherence to data protection principles. Information to be included in a DPN and RoPA when using AI tools. How to assess data protection risks/concerns related to AI. What is a DPIA and when is it required. Data protection contractual terms — why are they important? Technical and organisational measures to protect personal data: Dedicated data protection sessions provided. 4 DPC meetings organised. Updated EV JCA endorsed by the EMA MB in December 2026.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Timely advice provided for over 100 procurements and license renewals. 41 data protection notices and records of processing activities prepared/updated. response to 14 data subject requests and response to the EDPS survey (self-assessment) on the 'right to erasure'. data protection and security audit of the IRIS platform initiated. all EDPS audit recommendations from 2023 closed. Several DPIAs initiated and are ongoing. Collaboration with DPO Network of EU IBAs on topics of common interest continued.
Strengthen the EU Network on methodology in committee advice and assessment through: guideline development and implementation; the provision of methodological expertise to support EMA scientific committees; capacity building. Harmonisation of international methodological standards Programme management of the Methodology domain Understand and account for external stakeholders' needs	2.2 (ECP 1 A new plan for Europe)	Guidance documents on emerging methodological topics delivered Estimands from ICH E9(R1) implemented in newly written or updated clinical and methodological guidelines, where appropriate Draft methodology research needs listed Operational expert groups established and managed Systematic lessons-learnt process for procedures with complex methodology Training modules for EMRN developed and delivered ICH E6(R3) Annex 2 drafted. ICH E20 step 2 reached EMA Q&A of ICH M12 drafted Yearly revised Methodology Work Plan Embed identification of committee requests with complex	**On track**	Methodology Domain governance meetings held in Q1, Q2 and Q4 2025. Input related to Estimands for 100% of clinical guidelines were MWP was consulted (i.e. GLs for beta-thalassemia and sickle cell disease, PsA, peripheral arterial occlusive disease, anti-cancer) provided. All guidelines and planned workshops progressed as per Methodology Working Party (MWP) workplan with no major delays: workshop on mechanistic models held in Q2 2025; workshop on Bayesian methods held in Q2 2025; workshop on external controls held in Q4 2025. Guidance on RWE, non-inferiority and several product-specific BE guidelines published. Concept papers on external controls and revision on good pharmacogenomic practice published. Comprehensive Estimands training delivered. Active knowledge sharing activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		methodological aspects into EMA forecast and tracking processes Clear roles and responsibilities in the Methodology Domain to maximise resource efficiency established Draft Methodology stakeholder interaction plan Cluster meetings and Interested Parties meetings organised		within Methodology ESEC through SIA meetings. ICH E20 step 2b reached in June; step 3 entered public consultation period. Implementation of comments received during public consultation on ICH E6(R3) Annex 2 ongoing. Revised MWP workplan for 2026-2028 published. Interested Parties meeting held in Q3 2025.
Improve development and implementation of clinical trial methodology guidance in the EMRN. Development of an inventory of training needs.		Methodology workshops, or webinars, with external stakeholders to scope and prioritise clinical trial methodology guidance topics Process for aligning guideline development on multidisciplinary methodology topics involving a large variety of Network expert groups Training plan for new guidance documents and associated process Completion of training needs assessments for regulators and defined stakeholder groups Elaboration of training curriculum	**On track**	Signposting to clinical trial guidance from CTCG, MWP and HTAs took place in Q1 2025. Formal establishment of the regular exchange on guidance development between CTCG, MWP and HTACG chairs completed in Q2 2025. CTCG-MWP-HTA guidance development coordination meetings held in Q1 and Q4 2025. Finalisation of the best practice for guidance development in Q3. Workshop on Bayesian methods held in Q2 2025. Workshop for assessors for clinical trials in paediatric populations held in Q3 2025. Workshop on external controls held in Q4 2025. Clinical trials training needs assessment for academia and SMEs published in Q3 2025. Focus group to assist the clinical trials training mapping and signposting set up in December 2025.
Further develop and maintain a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network — DARWIN EU). To support better decision-making on medicines by informing those decisions with robust and reliable evidence based on	2.1 (ECP 1 A new plan for Europe)	DARWIN EU Coordination Centre maintained Access to various real-world data sources in terms of data type, population covered and geographical coverage increased	**On track**	DARWIN EU Coordination Centre continues to be fully operational. 67 studies (corresponding to 75 study slots) performed. 40 studies completed. This is the highest annual figure to date. 3 data partners onboarded in 2025 (as per Phase IV allocation) to reach planned

Action	MAWP strategic goal	Expected result	Status	Achievements/results
appropriate real-world data.		DARWIN EU pilot with EHDS conducted and informed next steps Processes for EMA oversight of DARWIN EU activities operated and optimised, including review of DARWIN EU deliverables and outputs DARWIN EU studies delivered in line with contract		total of 40 data partners in the network by February 2026. By the end of 2025, the network included 33 data partners, representing over 180 million patients across 16 European countries, with the addition of claims data from the US from over 200 million US patients.
Build appropriate EMA business processes to identify the need for RWE and to generate and deliver that evidence in order to support the regulatory decision-making process.	2.4	Processes to prioritise and triage study requests established Development of a phenotype's library Users' training on utilisation of IHD and analytical templates	**Completed**	The third report, , based on studies EMA conducted using real-world data between February 2024 and February 2025, was published. It summarises the progress made to enable the use of real-world data and establish its value in regulatory decision-making. IHD terminated in December 2024.
Coordinate implementation of HMA EMA AI multiannual workplan. Contribute to implementation of actions led by TDA.		Successful experimentation on the extraction of information using AI/ NLP techniques Reporting to HMA and MB on workplan progress	**On track**	Lessons learnt from AI/NLP pilots in the Health Data Lab concluded in Q1 and reported to Digital Acceleration Leadership Team (DALT) in Q2 2025. Knowledge sharing sessions with Spanish and German NCAs conducted in Q4 2025. Routine reports to HMA and MB on workplan progress provided. Coordination activities of the AI workstream of the HMA/EMA NDSG Data and AI workplan performed, corrective actions to improve monitoring of deliverables identified in Q4 2025.
Further development and use of a monitoring system for the post-authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform).		Processes for the prioritisation, launch and supervision of vaccine studies in place Working arrangements with ECDC operated Processes to identify a need for studies in place Results of studies made	**Completed**	6 DARWIN EU studies conducted under the VMP: 3 finalised: proof-of-concept flu VE (completed); meningo vaccine coverage (completed); coverage pneumo vaccines (not feasible). 1 started: varicella vaccines and risk of encephalitis. 2 at protocol development stage: epidemiology of meningococcal disease;

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		available to EU decision-makers and the public		epidemiology and trends in myocarditis. 1 FWC study — SAFETY-VAC project - completed (preparedness for VS studies). 3 Steering Group (SG) meetings held. Communication plan endorsed by SG. Workshop on vaccine effectiveness with Vaccines Europe held. Annual IVMAB meeting held.
Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data		Health Data Lab operates as a stream under the DigiLab's framework Pilot the experimentation framework with two pharmacovigilance-related use cases	**Completed**	Two pharmacovigilance use cases piloted: ERATO (Enhanced Review of Abstracts with Transformer Models) and EurEKA (EU product information Entity Extraction and Knowledge Acquisition). Early results suggest ERATO filtered out 80% of literature abstracts to screen by the Pharmacovigilance Office in 2025. Value monitoring metrics are being considered in Q1 2026. EurEKA data is being used in the RxLogix Signal Detection tool, delivering efficiency gains in signal detection.
Development and implementation of EMA and EMRN data strategies as part of data governance activities and evolution of EMA data governance including policies, procedures, procedures and responsibilities as well as management of the EMA Data Board and Network data governance		Finalised Network Data Strategy Established plans and activities to implement EMA data strategy EMA data governance structures and activities are in place Plan for EMRN and EMA communications, trainings and stakeholder engagement	**On track**	Network: Network Data Steering Group (NDSG) established and monthly meetings held, workplan adopted. NDSG Network Data Strategy published. NDSG Strategy recommendation for PMS implementation published. Continued support to the stakeholders provided. EMA: Data Board plan approved and executed. Data Owners and Data Stewards training material developed and onboarded. First version of EMA Data Catalogue published

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				EMA Data Asset Maturity Index developed. Continued Data Strategy Areas increased maturation ensured. Monthly Data Board meetings held. Monthly Data Strategy Area leads meetings held. Metadata Audit findings addressed.
Support EMA operations and committees/working parties with advice and epidemiological expertise on: methods for RWD collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; portfolio of RWD sources existing in Europe and elsewhere to answer research questions; identification of research questions appropriate for further investigation and their translation into study protocols; evidentiary standards and formats and contents of RWE submitted by MAAs/MAHs; lessons learnt from review of RWE submitted by MAAs/MAHs; literature review of published articles with RWE on utilisation, safety and effectiveness of medicinal products.		Reflection paper on methodological aspects, formats and contents of RWE used for regulatory purposes Templates and check-lists for feasibility analyses on appropriateness of RWD sources used in regulatory decision-making (e.g. registries, electronic healthcare records) Process of procedure identification, from relevant committees/WPs that require methodological input, participation and contribution to SAWP, pre-submission, PRIME and any other relevant meetings where RWE is addressed	**On track**	Process to screen marketing authorisation applications established and formalised in TDA business process documentation. Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes published in April. Outline of ICH concept paper endorsed by ICH Assembly in May. ICH E23 EWG kick off meeting held in September. ICH Concept Paper endorsed by ICH Management Committee in November 2025. Lessons learnt from review of RWE submitted by MAAs/MAHs progressing.
Implement the Clinical Trials Safety Monitoring regulation		Assure the simplified functional specs of the safety implementation regulation are up to date Provide regular support to the Member States for the safety assessments	**On track**	Safety Monitoring through EudraVigilance and Annual Safety Reports (ASR) is in routine operation. Annual safety training event hosted. Simplified functional specifications delivered. This includes saMS selection and the ASR evaluation specifications.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Following successful technical proof of concept, the development of the new Safety Module, as a Minimum Viable Product, initiated.
Deliver simpler CTIS business rules, which will support future modernisation of CTIS to improve user experience and streamline the operation of the system		Identified areas of the CTIS business rules are covered by Simplification Task Force	**Completed**	The Simplification Taskforce analysed and finalised 10 topics: 1. Safety Module (specifications for saMS selection and revised ASR evaluation). 2. User Management (roles simplification, user administration more efficient and user friendly). 3. IMPD-Q Only Application (maintain the current process, monitor the need for future alternatives, invest in training). 4. Ad-hoc assessment (retain current process, remain open for improvements). 5. Lock mechanism (reduce the number of locks in the RFI section to simplify the RFI responses to sponsors). 6. Document management (two features identified for simplification 'All documents' table and 'Download'). 7. Application submission rules (more flexibility on the submission rules, highest priority to SM/NSM Part II and AMSC). 8. Notices and Alerts (35% reduction of notices and alerts, email notifications introduced, alert reminders less frequent). 9. Workflow automatic triggers (automatic triggers in the system maintained). 10. RFIs and considerations (enhance user experience). Revision of RMS selection process adopted at CTAG in October and possible reduction in timelines based on Euratom rules.
Enable the use of clinical trials data to support medicinal product development, leveraging data standards and the		KPIs for regular measurement via DAP Yearly measurement of ACT EU performance indicators	**Completed**	KPI's for ACT EU published quarterly. Satisfactory progression on the further CTIS — DAP -

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Data Analytics Platform (DAP)		Make available interactive maps for patients		Power BI development and unlocking of data. In 2025 all ACT EU KPI's were delivered in power BI Interactive trial map launched in Q1 2025. Multilingual version released in Q4 2025.
Enable clinical trial data standards in EMA and Network systems and processes		Lead the European contribution to ICH M11 activities Change management strategy developed	**Completed**	Strategic alignment in June 2025 for the roadmap of clinical trial standardisation to align with the CTIS modernisation road map (CTIS conceptual model aligned with M11 conceptual model). Technical Implementation guide (TIG) public consultation successfully occurred from March to April 2025 as planned after the EU party review of the document. The guideline and its deliverables endorsed by the Expert Working Group and the ICH Assembly in November 2025.

Regulatory Science and Innovation (TRS)

Workload indicators

Procedure		2022 result	2023 result	2024 result	2025 forecast	2025 result
	Innovation Task Force briefing meetings conducted	34	29	30	40	27
	Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[15]	1	0	0	4	0
	Portfolio and Technology meetings conducted[16]	21	21	19	20	20
	Academia briefing meetings conducted	-	-	16	16	20
	New involvements in externally-funded regulatory science projects managed	-	-	18	10	26
	Collaborating experts: onboarded or deliverables managed	-	-	17	16	7
	Number of MSSG meetings	10	-	11	8	8
	Management of shortages of CAPs	366	-	1224	750	689
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party	54	-	69	75	70
	Number of requests for information received from the SPOC Working Party and international partners	20	-	26	30	18
	Number of SPOC Working Party meetings (including subgroups)	38	-	18	50	31
	Number of Solidarity Mechanism cases	-	-	7	10	6
	Regulatory assistance, including SME briefing meetings	207	230	249	205	240
	Requests for SME qualification	412	428	374	410	370
	Requests for SME status renewal	1,432	1,432	1,412	1,389	1,444

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1 A new plan for Europe)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	1. Establishment of novel Horizon Scanning process, identification of 12 topics for survey prioritisation and 2026 deep dive report drafting 2. Organisation of webinars, lunch talks and dissemination to Committees and Working Parties of Horizon Scanning reports and Innovation Task Force intel. 3. Publication and dissemination of Horizon Scanning reports including in peer reviewed journals (Engineered living

[15] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[16] Indicator renamed in 2024.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				materials for in situ production of therapeutics (ELMs), New Approach Methodologies (NAMs), Replace-Reduce-Refine (3Rs), Alzheimer disease and other age-related dementias (Alzheimer))
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1 (ECP 1 A new plan for Europe)	New technologies identified and integrated within EU-NTC	**Delayed**	Initiation of EU-Network Training Centre (EU-NTC) Innovation Curriculum incl. integration in DRAFT 2026 EU Innovation Network (EU-IN) workplan
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	**On track**	Finalisation of European medicines agencies network strategy (EMANS) 2028 Theme 3, including integration of the Regulatory Science Strategy (RSS) recommendations as appropriate.
Innovation relevant preparation for the implementation of new legislation (Sandbox, Borderline Classification)		Proposals for re-designed processes to prepare for the implementation of new pharmaceutical legislation	**On track**	1. Offer stakeholder engagement on potential sandboxes 'working towards regulatory sandboxes' on EMA website (interaction like the Innovation Task Force (ITF) – Horizon Scanning) and advertise such. 2. Kick-off meeting of Innovative Health Initiative (IHI) BRIDGE (Breakthrough Regulatory Innovation and Development through sandbox Environments) where EMA is a partner. Monthly meetings for each work package since November. 3. Webinar/workshop scheduled 1 June 2025 connecting different EU sandbox initiatives (New Pharmaceutical Legislation (NPL), Medical Devices Regulation (MDR), Artificial Intelligence Act (AI), Biotech Act etc.) 4. Artificial Intelligence (AI) workshop with sandboxes identified as priority 5. EMA is an observer in the European Blockchain Sandbox project from the European Commission. Webinar on lessons learnt (14 January) 6. Collection of potential use cases based on Horizon Scanning (literature, Innovation Task Force briefing meeting requests etc)

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Preparation for ESMP database Extended mandate activities on shortages of MPs and MDs		Extended mandate activities on shortages of MPs and MDs	**Completed**	The European Shortages Monitoring Platform (ESMP) database became fully operational on 29 January 2025 with a full range of functionalities for marketing authorisation holders (MAHs) and national competent authorities (NCAs), ahead of the legal deadline.
Union list of critical medicines Shortage and mitigation plans (SPMPs) Organisations of SC meetings of the TFAAM (4 per year) TWG1 meetings (30 per year)		Human product availability, veterinary product availability / MUMS	**Completed**	Completed in 2024, work is continuing under the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) mandate. The Union List version 2.1 (2025 annual update) was published in December 2025.
Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients	3.3	Topics for network training identified and communicated to EU-NTC	**On track**	Leading Accelerating Clinical Trials in the EU (ACT EU) Priority action Learning ecosystem, conducted and acted on wide public survey on learning needs, two European platform for Regulatory science research meetings for gathering gaps including knowledge and learning and acting upon these.

Advisory functions (International affairs, Institutional and Policy, Public Health Threats, Chief Medical Officer, Internal audit, Legal department)

Workload indicators

Procedure[17]	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of product-related interactions with international stakeholders – including requests for information and requests for documents	-	279	269	250	252
Number of participations in external forums	-	34	30	40	34
Number of external participants in training organised by International Affairs	-	630	679	750	871
Number of visits to EMA / fellowships organised by International Affairs	-	15	12	12	8

Pillar 2 – Public health activities and Business Services

Action	MAWP strategic goal	Expected result	Status	Achievements/results
ICMRA secretariat management, including operational and financial contribution to ICMRA summit and plenary meetings Participation in and coordination of ICMRA Regulatory Forum, and work streams	1.1 (ECP 1 A new plan for Europe)	Continue demonstrating leadership of ICMRA: Regulatory convergence and in particular, aligning COVID-19 global response and collaboration Regulatory communication	**Completed**	EMA continued its mandate as chair of ICMRA and provided the ICMRA secretariat until 20th October 2025, when after 6 years, it was replaced as chair by TGA (the ICMRA ToR does not allow for more than 2 3-years mandates). In total, EMA coordinated in 2025 3 virtual and 2 face-to-face executive committee meetings, 1 virtual and 1 face-to-face plenary meeting, 3 regulatory forums TCs (focusing on artificial intelligence), 1 ICMRA-related session at the DIA Global Annual Meeting in the USA (focus on regulators as communicators). EMA participated in all 6 active ICMRA workstreams, including as chair or co-chair in 3 of them. A new ICMRA Working Group was formed aimed, with as first deliverable the development of a compendium of terms for development of medicines for small population diseases (further activities might be agreed once the first deliverable is completed). Work started on development of an 'ICMRA statement' on 3Rs (replacement, reduction and refinement of animal testing). A drafting group was formed, to

[17] New indicators introduced in 2023 work programme.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				which EMA provides secretariat support. The annual ICMRA summit was very successfully organised and hosted by EMA in Amsterdam, at its premises (see below).
Support and foster use of the EU-M4all pathway Support applications and scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO This includes early engagement with product developers and related sponsors.	1.2 (ECP 1 A new plan for Europe)	Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	In January 2025, CHMP adopted a positive opinion for Ivermectin/Albendazole (ivermectin/albendazole), for the treatment of infections caused by several types of worm parasites including lymphatic filariasis, a neglected tropical disease. In June 2025, the CHMP recommended an extension of indication for Dapivirine Vaginal Ring 25 mg (dapivirine), a vaginal ring originally approved in July 2020 to reduce the risk of women 18 years and older getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse. The CHMP's opinion extends the indication for this medicine to include its use in women from 16 years of age. In July 2025, the CHMP adopted a positive opinion for Lenacapavir Gilead (lenacapavir) for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents at high risk of becoming infected. This medicine will facilitate PrEP uptake and compliance because it only has to be administered twice a year via a subcutaneous injection. Seven pre-submission interactions with developers to clarify questions related to eligibility, collaboration with WHO and non-EU authorities, active participation by WHO and non-EU experts during scientific advice or evaluation, reliance on EU marketing authorisations to streamline WHO prequalification or support timely national authorisations, parallel EU-M4all and centralised applications, and independence in national decision-making. Support for WHO and national regulatory authority expert

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				involvement for scientific advice on possible EUM4all opinions. Participation in various workshops and public forums to introduce EU-M4all as facilitated tool to promote access to quality-assured medicines.
Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO collaborative registration procedure, facilitated approvals, prequalification and other pathways	1.2 (ECP 1 A new plan for Europe)	Capacity building in low and middle income countries	**On track**	Coordination of 10 collaborative registration procedures (SRA-CRP) with WHO, aimed at facilitating registration of 10 products in 39 countries. This marks an increase in the level of activity and use of EMA as reference authority compared to previous years. Participation in workshops or conferences to promote awareness, engagement and capacity building with CRP including a WHO workshop in El Salvador or other regulatory conferences.
Support continued implementation of the EU- US FDA MRA	5.2	Support for several operational meetings (internal, EC, FDA and NCAs) related to the finalisation of the MRA implementation for veterinary medicines, increase in the efficiency of the MRA for human medicines and preparations for the potential extension to vaccines and plasma derived medicines	**Delayed**	Discussions between the European Commission and US FDA were re-started in Q4 2025, with regular meetings scheduled for 2026. There are two remaining countries still to be recognised by the US FDA.
Provide assistance to candidate countries and potential candidates (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process	6.1	Participating authorities are better prepared for future potential EU accession, and integration to the European medicines regulatory network	**On track**	Annual face-to-face practical training organised in October 2025 which received positive feedback from participants. For the first time, the training was organised in one of the EU candidate countries. Observers from candidate countries took part in 8 EMA working groups and working parties (4 on the human side and 4 on the veterinary side). Over 260 users from all the EU candidate countries have signed up for the EU NTC online training portal. 25 other ad hoc training opportunities were shared with the candidate country network, online and hybrid.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				4 contact points meetings were organised.
Opening our Procedures at EMA to Non-EU authorities: Implementation of new working model as agreed by Management Board March 2022	1.1 (ECP 1 A new plan for Europe)	Collaborative assessment involving OPEN participating regulators Alignment or convergence in regulatory outcomes Accelerated assessment and products approval by OPEN partners WHO participation facilitates PQ approvals and availability in low- and middle-income countries markets	**Completed**	Number of new OPEN procedures initiated: 1 Number of experts registered: 11 Discussions with industry associations took place in March 2025 to gather feedback on the limited use of the OPEN framework. Following industry's comments and consultation with EMA scientific committees and OPEN regulatory partners, the Management Board agreed to expand the scope of EMA's OPEN Framework to include all medicines that target unmet medical needs and advanced therapy medicines products (ATMPs). The Management Board also agreed to allow the use of the OPEN framework for post-authorisation changes, including extensions of indication. A questions-and-answers document on this expanded scope was prepared for publication.
Maintenance, exchange of information and engagement with existing Confidentiality Arrangement partners Establishment of new Ad Hoc Confidentiality Undertakings	1.1 (ECP 1 A new plan for Europe)	Facilitate and foster International cooperation	**On track**	The 'limited disclosure notice' procedure pilot was introduced in May 2025 for when EMA intends to exchange data relating to chemistry, manufacturing and controls with the Agency's trusted partners. There were no new DG SANTE-EMA confidentiality arrangements agreed in 2025.
Active participation in international forums and communication to stakeholders, including but not limited to DIA, ICH, IPRP	1.1 (ECP 1 A new plan for Europe)	Greater visibility of the Agency and of its activities	**On track**	International team carried on its stakeholder engagement and communication in 2025. In addition to internal communication efforts, external stakeholder engagement has included: 22 presentations opportunities at events with external partners 34 missions/duty travel opportunities attended either in-person or remotely
Organisation of awareness sessions and engagement workshops for	1.1 (ECP 1 A new plan for Europe)	Increase Awareness of the EU system Agency public image	**Suspended**	Activity suspended due to change of priorities.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
international regulators				
Data protection impact assessment and simplification of personal data redaction for exchange with international partners		Protection of personal data	**Completed**	Activity stopped due to change of priorities of partners involved.
Under the DG INTPA contract, support creation of AMA and regulatory system strengthening at African continental, regional and national levels	6.1	Establishment of the AMA	**On track**	Grants were awarded in 2025 for five projects prepared by EU NCAs in response to the call for proposals for regulatory systems strengthening bringing the total number of awarded grants under the call to 11. A grant agreement was signed with EDQM focusing on laboratory systems strengthening. Two meetings of the AMA EU alignment platform meeting were organized. E-learning tender for junior African assessors: evaluation ongoing. EMA hosted the historic first visit of the AMA Governing Board, AMA DG designate, African Maturity Level 3 Heads of Agency, WHO, DG INTPA, EMA Management Board and Heads of Medicines Agencies Management Group from 11-12 June. Trainings for regulators: Training on Quality Risk Management provided. Webinar on ICH M7 organised. Training on GMP Data Integrity 13 other ad hoc training opportunities were shared with the African counterparts. EMA created a dedicated AMA domain in the LMS database, which was opened to African regulators in July 2025. Over 50 assessors and inspectors (from 18 different countries) from GMP, EMP TCs, and RECs, have access to the training materials. Currently 44 courses are available. Action Steering Committee meeting with DG INTPA took place in Brussels.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				EMA hosted a full day in person meeting with the 5 RECs coordinators (EAC, SADC, IGAD, ECCAS and ECOWAS) along with AUDA-NEPAD + WHO, in Oct 2025. SCoMRA conference took place in Kenya (Mombasa) on 11-13 November 2025. Five AMA team members attended in person to deliver presentations on updates and lessons learned on the AMA project and chair panels. EMA continued to support the Technical committees (EMP, GMP, Vigilance, RCD, MPRR, AVAREF).
Communication of information, answer to queries, internal coordination Monitoring and tracking of interactions Preparations of visits, missions' preparation, support to international partners, fellowships and expert visits		Streamline and promote awareness of international activities within the Agency	**On track**	Creation of 1 guidance and update of 3 guidance Organisation of 50+ face to face meetings and teleconferences Management of 185 product-related interactions with international stakeholders including requests for information and requests for documents Management of 7 visits organised by International Affairs Management of 30+ meetings related to the preparation of the ICMRA summit 2025 and 15+ meetings related to the responsibility of the ICMRA secretariat in 2025.
Collaboration with WHO to support availability of child-friendly TB medicines in the EU	1.1 (ECP 1 A new plan for Europe)	Approval and availability of paediatric anti-TB medicines for unmet medical needs in the EU	**Completed**	Completed in 2024
Sustained development and operation of the Internation Cooperation Platform	1.1 (ECP 1 A new plan for Europe)	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	**On track**	Two meetings were held in 2025: In-person — 4 June — Warsaw Remote — 27 November
Implementation and support to engagement with US FDA	1.1 (ECP 1 A new plan for Europe)	Maintain and develop relationship between EMA and FDA	**On track**	Two technical meetings with FDA Europe Office to follow-up on agreed actions including discussion on Liaison Program priorities. Supported 2 visits from EMA colleagues to FDA. Secured two

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		Identify and develop existing and new areas of cooperation		EMA staff fellowships at FDA in 2026 Support to Parallel Scientific Advice (9 requests received). Support collaboration on gene therapies for ultra-rare diseases (CoGenT); first pilot procedure ongoing. Several interactions, with EMA participating in FDA internal meetings and meetings with applicant and FDA participating in EMA Committees and Working Parties meetings. Publication of 2 meta-analyses together with FDA, CDC, other regulators and academia globally, on the impact of COVID & its treatments in pregnancy. This is considered a stepping stone towards more RWE studies jointly between FDA and EMA Support to EMA participation in Project Orbis as observer and analysis of the programme Meetings and other interactions with FDA Oncology Center of Excellence to review / progress interactions. Regular interactions include Scientific Advice monthly meetings. Further consolidated collaboration with FDA on 3Rs/NAMS Support to meetings/discussions regarding collaboration in the area of artificial intelligence. Finalisation for subsequent publication of joint AI principles in January 2026 Finalisation of cluster framework, including Cluster Principles and Cluster Good Practice Guide. Continued core engagement and support, including facilitating requests between EMA and FDA, and cluster activities Outreach activities of EMA/FDA Liaison Program and EMA/FDA collaborations, including presentations to FDA Offices/Divisions, to EMA scientific committees, public conferences, EU Member State Health Counsellors meetings and other diplomat events in DC, academia, and other stakeholders.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Organisation of the 2025 ICMRA Summit		Reaffirm importance of global regulatory convergence and collaboration Articulate achievements and impact of 6-years of leadership of ICMRA Promote regulatory communication	**Completed**	The International Coalition of Medicines Regulatory Authorities (ICMRA) held its annual summit on 22nd October 2025. The summit was hosted and organized by the European Medicines Agency (EMA) at its premises in Amsterdam and brought together leading regulators and experts from regulatory authorities around the word and the World Health Organization (WHO). It was the first time that this summit was organized at the premises of the organizing authority. The summit included 3 sessions, focusing on communication aspects, reliance among regulators and the use of artificial intelligence in regulatory processes. 120 delegates, a record number, participated, representing 40 ICMRA authorities and the WHO, from all the continents of the world.
Promoting reliance on EMA scientific outputs	1.2 (ECP 1 A new plan for Europe)	Position and promote EMA role as a leading reliance partner for non- EU regulators and pharmaceutical industry, in line with its responsibilities as a WLA designed authority	**On track**	Participation in the Joint EMA-Industry Focus Group on Regulatory Reliance aimed at promoting the use by industry of EMA scientific outputs for the registration of medicinal products. EMA participation in a number of workshops and regulatory conferences to promote international collaboration and reliance. Supported the launch of 28 pilot procedures in more than 100 countries promoting reliance by international regulators of post-approval changes to demonstrate feasibility and public health benefit of regulatory reliance for post approval changes.
Define approaches for review of data with international regulator 1. Explore options for innovative regulatory science to support regulatory decisions before epidemics 2. Define approaches for review of data		Improved public health preparedness and protection	**On track**	In June 2025, EMA held a workshop centred on discussing primary efficacy endpoints for antivirals and monoclonal antibodies intended for the treatment of COVID-19 and influenza. The event aimed to strengthen regulatory guidance for clinical trials in these therapeutic areas. Additionally, ongoing discussions with the World Health Organization (WHO) were held, focusing on

Action	MAWP strategic goal	Expected result	Status	Achievements/results
with international regulator				advancements in vaccines for influenza and flaviviruses. In November 2025, EMA organized a workshop on animal models for the approval of CBRN medical countermeasures, engaging international regulators, stakeholders, and industry representatives. In parallel, significant contributions were made to international activities aimed at advancing the development of medical countermeasures.
Communicate proactively with key stakeholders on benefit-risk using evidence- based tools to tackle vaccine hesitancy		Better public understanding and confidence in the safety and efficacy of vaccines	**On track**	EMA continues to engage in discussions with the Vaccine Outreach Group (VOG) to enhance vaccine communication strategies, particularly in light of the current geopolitical context in the US. Efforts to strengthen vaccine communication are also ongoing through collaboration with the European Centre for Disease Prevention and Control (ECDC).
Engage with public health authorities and NITAGs to better inform vaccine decisions		More consistent recommendations on vaccinations strategy	**Completed**	EMA's efforts, in collaboration with the European Centre for Disease Prevention and Control (ECDC), have successfully centred on re-launching collaboration with National Immunization Technical Advisory Groups (NITAGs).
Establish a platform for EU benefit-risk monitoring of vaccines post-approval		Evidence to drive benefit risk evaluation and vaccination policy	**On track**	In 2025, significant efforts were made throughout the year to advance vaccine effectiveness (VE) research. In June, the Emergency Task Force and Vaccines Europe convened to discuss the generation of vaccine effectiveness data for influenza vaccines by brand in the EU. Key discussions centred on Vaccines Monitoring Platform initiatives, industry perspectives, and other components for sustainability and applicability to other respiratory viruses. In December 2025, the Immunization and Vaccine Monitoring Advisory Board (IVMAB) met at the European Centre for Disease Prevention and Control (ECDC) to discuss future plans for VE studies. These discussions focused on developing strategies and fostering collaboration to enhance the design and execution of VE studies,

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				ensuring alignment with evolving public health priorities.
Develop and implement the AMR EMA strategy		Have suitable vaccines and therapeutics for treatment of infection including those caused by multi-drug resistant organism	**On track**	In 2025, efforts on antimicrobial resistance (AMR) were strengthened through enhanced collaboration with the WHO on the TB vaccine. The ETF managed scientific advice procedures on AMR pathogens and facilitated informal teleconferences with academia on diagnostics and new treatments. Additionally, work on bacteriophages continues as part of ongoing research and development in AMR solutions.
Operate the ETF during a declared public health emergency and to ensure preparedness		Provide scientific advice to developers, engage in discussions with Academia and relevant EU bodies or International regulators, support sponsors of CT to conduct larger trials	**On track**	In 2025, the Emergency Task Force (ETF) held around 30 meetings, covering over 90 procedures and topics. The ETF handled around 30 scientific advices (SAs) across a broad range of public health matters, including a selection of antimicrobial resistance (AMR) pathogens. The ETF's scope was also extended to oversee SAs related to CBRN (Chemical, Biological, Radiological, and Nuclear) threats. Focusing specifically on AMR, the ETF issued around 9 SAs in this area, addressing both vaccines and therapeutics. Additionally, the ETF conducted around 40 informal teleconferences (TCs), offering informal advice on a variety of topics relevant to public health and regulatory matters. A key development under the ETF remit was the establishment of the ETF SA-CTA scientific advice process, which was designed to address clinical trial aspects in collaboration with the Clinical Trials Coordination Group (CTCG) and the newly formed Public Health Emergencies Ethics Advisory Group (PHE EAG).
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1 A new plan for Europe)	Increased awareness to facilitate the uptake of biosimilars	**On track**	BMWP has released a Draft Reflection paper on tailored development of Biosimilars for public consultation (ended Sep 2025). Final Reflection paper expected on Q3 2026
30 years anniversary conference of EMA		Create awareness of the Agency and its scientific work including the	**Completed**	Successful conference organised and delivered on the 25 June 2025

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		developments over the past 30 years		

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of EPAR summaries and EPAR summaries updates published[18]	204	173	214	170	195
Number of documents published on EMA website	6,403	6,611	7,490	7,500	8,882
Number of pages published and updated on EMA website	2,851	5,105	3,340	3,500	3,382
Number of press releases and news items published	164	124	115	120	119
Numbers of press and other external briefings conducted[19]	15	-	8	2	4
Numbers of social media posts published	704	1,016	501	450	479
Number of completed interviews[20]	36	-	26	20	28
Number of media queries responded	1269	-	781	900	838
Number of reports, brochures, leaflets laid out or printed, social media visuals	811	586	914	900	698
Number of professional membership organisation events attended by participating Agency staff	36	28	29	25	29
Number of sessions with agency representatives	158	168	204	150	196
Number of patients and consumers eligible organisations[21]	-	-	41	42	42
Number of healthcare professionals eligible organisations[22]	-	-	41	44	45
Active patients expert nominated by EMA[23]	-	-	186	180	219
Active healthcare professionals experts nominated by EMA[24]	-	-	84	80	101
Number of messages circulated via 'Early Notification System'	646	616	539	500	529
Number of EMA communications pro-actively sent to stakeholders	206	225	246	200	246
Access to documents, requests received	676	709	520	750	732
Access to documents, documents released	1,128	1,037	1,175	2,000	1,305
Requests for information received	7,342	6,965	7,285	8,000	6,636
Clinical Data Publication (CDP), Procedures published	-	41	73	120	92
Clinical Data Publication (CDP), Documents published	-	714	5,817	8,000	5,370

[18] EPAR summaries have been renamed to medicines overview and medicines overview updates in 2018.
[19] New indicator introduced in 2024 work programme.
[20] New indicator introduced in 2024 work programme.
[21] New indicator introduced in 2024 work programme.
[22] New indicator introduced in 2024 work programme.
[23] New indicator introduced in 2024 work programme.
[24] New indicator introduced in 2024 work programme.

Additional indicator

	Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
	Exceptional Transparency Measures (EXTM) publication of documents related to the Covid-19 mRNA vaccines	-	-	-	300	209

Performance indicators

	Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
	Average rating of pages on corporate website during the year[25]	3.2	3.8	n/a	3.8	3.2
	Satisfaction level of patient and consumer organisations	-	100.00%	-	80%	-
	Satisfaction level of healthcare professional organisations[26]	-	88.00%	-	80%	-
	Triage of incoming requests received via AskEMA within set timelines	99.00%	99.30%	100.00%	100%	99.70%
	Responses to ATD within set timelines[27]	88.50%	93.00%	95.00%	90%	86.00%
	Responses to RFI within set timelines (for EMA)	87.00%	83.00%	84.00%	95%	97.00%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	68.00%	76.00%	77.00%	75%	75.40%
	Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'[28]	76.00%	-	70.00%	n/a	-

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Manage and further develop EMA's social media activities		Expand outreach to broader targeted audience	**On track**	Switch from X to Bluesky in January 2025, following a critical review of engagement results on X; audience growth from 0 to 23,500 within a year. Launch and implementation of social media ambassadors programme, including selection of ambassadors from across the Agency, training organised, pipeline established. EMA is now regularly sharing relevant information on key initiatives with its followers. EMA 'thought leader' programme was launched, with an initial 7 thought leaders. A training was organised and thought leaders

[25] 2023: Based on data up to 5 December 2023 (website relaunch). 2024: Page rating unavailable. 2025: Period covered between March and December — new page rating web tool released on 25 March 2025.
[26] Survey carried out every 2 years. Footnote: Survey will be carried out in 2026 and data will be collected via EMA's perception survey.
[27] Calculated according to the legal timeline stated in Regulation (EC) No 1049/2001 and from the date on which the requester is informed of the start of the procedure
[28] Survey carried out every 2 years.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				are regularly and proactively contacted with proposals for content creation. A very successful example of the power of the thought leader programme was a coordinated reaction of three thought leaders to unfounded concerns regarding vaccines and autism. A project to work with content creators on GLP-1 receptor agonists (GLP-1 RA) medicines was successfully concluded. 7 EU-based content creators were selected; they produced 115 pieces of content and achieved a combined reach of 1.5 million Europeans, who received science-based information on the responsible use of GLP-1 RA medicines. Contract for paid social media ads is in place to support targeted promotion of public health and corporate messages. Diversification of content is progressing, with production of videos, carousels, info cards, and behind the scenes photographs. The Executive Director's LinkedIn account is maintained and grown with posts on a wide range of topics.
Planning of communication activities and campaigns in key topic areas in the annually determined strategic business priority areas		Maximise public health impact of communication	**On track**	Communication plans for topics such as CTIS/ACT-EU, data, AI, cancer, shortages and the review of the EU pharmaceutical legislation are in place and implemented. Human and veterinary medicines highlights were published in January 2025. A press briefing on the highlights of approval of human medicines in 2025 with spotlight on mental health was held in January 2025. Annual report was drafted, agreed and published in an updated format. The European Immunisation Week helped raise awareness with data visualisations and new video format on social media. Production of videos was agreed and contracts signed. The production of the first 3 videos started in 2025. Co-created campaign on shortages with patients and

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				healthcare professional eligible organisations in Q4 2025. Booklet on safety of medicines published Q3 2025). Inside EMA podcast launched; 4 episodes were produced and 2 published in 2025. The falsified medicines campaign in partnership with Europol (Q1 2025) The Veterinary Medicine Safety Day campaign (Q2 2025)
Development of a European medicines web portal		High-quality product meeting both user and business needs, containing information on all medicines authorised in the European Union	**On track**	Preparations for discovery user research to gather requirements for the MVP ongoing. Preparations for the procurement are ongoing.
Finalise strategy and implement phase 2 of the CDP re-launch beyond COVID-19		Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs	**Completed**	The strategy was adopted by EXB in 2024. Implementation started with MAA going for CHMP Opinion from May 2025.
ePI: electronic product information for EU medicines		Generation of all tools and guidance needed for: Updates to tools and processes based on pilot outcome Implementation of ePI into business for CAPs and potentially some NAPs Initiation of phased implementation across member states Readiness for revision of the pharmaceutical legislation	**On track**	ePI pilot epic closed, ePI MVP epic closed, ePI implementation epic initiated. CAP Business process draft completed in collaboration with H-Div group F2F meeting with NCA SMEs to support NCA business process development User Acceptance testing on FHIR import Public consultation on the 'Reflection paper on linking to ePI from EU medicine package' ended on 30 June 2025, analysis of responses in progress Multiple procedure numbers functionality implemented QRD template versioning functionality implemented Styling strategy implemented and style guide published Six Pharma Subject Matter Experts appointed to team
Contribute to the implementation of EMANS (European Medicines Agencies Network Strategy) and RSS		Implementation of strategic plan for stakeholder engagement Support monitoring of implementation, reporting,	**Completed**	Finalisation and publication of EMANS to 2028 in March 2025. Hosting of a multi-stakeholder webinar on EMANS 2028 in

Action	MAWP strategic goal	Expected result	Status	Achievements/results
(Regulatory Science Strategy) ensuring that the views of stakeholders are brought into the process		and review and update of EMANS to 2028		February 2025 following public consultation. Publication of analysis of outcome of public consultation on EMANS 2028. Agreement on activities for implementation of EMANS 2028 and the expected results. Definition of deliverables for 2026 (included in EMA Single programming document). Continued reporting on implementation of EMANS to 2025.
Implementation of scientific publication strategy		Maximise public health impact of communication	**On track**	Delivery of publications: 113 manuscripts reviewed internally and 127 manuscripts published by 31 December 2025, including 67 driven by EMA staff. 91% of all papers published are freely available; EMA reimbursed the publication costs of 25 of these papers following internal evaluation. >80% of all 2025 publications were accepted by the initial target journal. Median impact factor for 2025 publications is 5.3. Policy on publications by EMA staff and EMA scientific committee members on EMA's work (Policy 0015) came into effect in January 2025. Continued established collaboration with several high-impact journals, including BJCP (5 publications), Clinical Pharmacology & Therapeutics (9 publications), and Lancet Regional Health Europe (7 publications).
Collaboration with EC (Sante & HERA)/ECDC and HCIN, to share information and update on communication plans		Aligned and streamlined approach to communication across EU	**On track**	Weekly meetings with EC, HERA and ECDC counterparts held, continuous discussion of upcoming communication activities and alignment of messaging; Monthly meetings with the Heads of communication of the One Health agencies (ECHA, ECDC, EEA, EFSA, EMA) are taking place to identify areas for cooperation and coordination and alignment of messages.
Work with Working Group of Communication Professionals (WGCP) to agree communication plans and appoint		Tailored communication at national level supported by strong co- ordination at EU level	**Completed**	Bi-weekly meetings to coordinate network-wide communication planning are being held. A joint communication plan with WGCP is in place with continuous

Action	MAWP strategic goal	Expected result	Status	Achievements/results
joint leads with EMA, as appropriate				close engagement between EMA and WGCP. Two joint LinkedIn live session were organised: one joint EMA/HMA event on evidence generation 2030, and one joint EC/EMA/HMA event on new EU targets for clinical trials. EMA continues to explore possible bi- or multilateral communication activities with WGCP members. EMA supported WGCP campaign on safe use of OTC medicines. Work with WGCP includes coordination of communications on shortages across EU.
Develop a more proactive approach to countering misinformation		Better and earlier awareness of mis- and/or disinformation, enabling tailored counter-information/transparency	**On track**	Delivered a process and reporting for infodemic management and stakeholders listening on specific issues. Collaboration with partners on tackling mis- and disinformation is ongoing, e.g. with One Health agencies, DG SANTE. Additional trust-building measures are being developed (see above in social media section: e.g. ambassadors programme, thought leaders programme, work with influencers, podcasts, etc). Established a collaboration with the European Academy of Paediatrics (EAP) to enhance vaccine science literacy; delivered a scientific publication on meningococcal B vaccines (coauthored by EAP and Emer) and also produced the first Vaccine Fact Box on meningococcal B vaccines (titled Vaccine Essentials). The fact box has been endorsed by EAP and implementation of comments from stakeholder consultation is currently ongoing. Maintaining up to date the LTT on COVID-19 and LTT on long COVID-19. Regular update of the COVID-19 key facts page. New webpage created on FAQ on vaccines (questions, concerns and false claims).
Ensure day-to-day coordination of the overall Agency's response to ongoing		Ensure that actions required in the context of ongoing crisis events are	**On track**	There have been no crises for Agency in 2025. Coordination activities and monitoring of issues that may potentially

Action	MAWP strategic goal	Expected result	Status	Achievements/results
crises, including public health emergencies		taken in an efficient and coordinated manner		evolve into crises has been ensured. EMA has participated in several external crisis exercises and organised own exercises, including an extensive major event simulation exercise in December 2025. Updates on documents defining incident and crisis response activities have been made as required and internal training on crisis management has been organised to raise awareness.
Review and improve crisis communication processes based on lessons learnt from COVID-19		EMA's ability to communicate effectively during a crisis is reinforced	**Completed**	Updated EMA Crisis Communication Plan endorsed by Crisis Preparedness and Response Steering Group and EXB for implementation finalised in February 2025. Participation in EU Crisis exercise in June 2025 and in EMA Major Event Simulation Exercise in December 2025.
Develop EU regulatory framework to encourage generation and use of patient experience data (PED) in medicines development, evaluation and use		Reflection paper on Patient Experience Data & increased transparency on PED	**On track**	1. Draft paper published for consultation in Sept 2025; 2. Updated CHMP AR published

Information Management Division

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of information services/IT systems provided by EMA	-	28	32	33	33

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Satisfaction of EMA internal and external users	96.00%	94.70%	95.80%	80%	97.60%
Availability of IT systems	98.20%	99.96%	99.97%	98%	99.99%

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Centralising Data Standards	2.1 (ECP 1 A new plan for Europe)	Enable semantic interoperability and exchange of data through the use of standards, terminologies and master data across EMRN and stakeholders	**On track**	Active contribution and/or leadership role in International Organization for Standardization/Technical Committee 215/Working Group 6 (ISO/TC 215 WG6) activities through the development and delivery of data standardisation artefacts (standards, technical specifications) and ballot materials related to the unique identification of medicinal products (IDMP). Contributed consistently to Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) activities and HL7 FHIR Connectathons to ensure regulatory alignment; focus on use cases register under the HL7 Vulcan FHIR accelerator and Biomedical Research and Regulation (BR&R) WG projects and initiatives, such as: Utilizing the Digital Protocol (UDP) implementation guide (IG) project to support the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Clinical electronic structured harmonised protocol (CeSHarP), Substance Product Organisation Referentials (SPOR) use cases on products and substances, European Health Data Space (EHDS) and SPOR interaction for EU, electronic Product Information (ePI)/labeling, and Global Identification Working Group (GIDWG)-related workflows.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Co-Chaired GIDWG and participated in its activities, hosted the 5th international GIDWG stakeholders meeting, and contributed to the development of business rules based on requirements provided by the four focused teams (pharmacovigilance (PhV), cross-border, healthcare, and shortages) established in the previous semester. Chaired and actively contributed to the International Pharmaceutical Regulators Programme (IPRP) IDMP WG activities. Achieved approval of the IPRP IDMP WG 2026 Work Plan by the IPRP Management Committee. Provided significant input to the ICH M2 Expert Working Group (EWG), particularly by coordinating the SDO Subgroup activities related to the ICH Standards Development Organization (SDO) process. Approval of the process-alignment deliverable by the ICH Management. Leveraging data standardisation mappings and expertise for validating consistent data exchange during the Clinical Trial Information System (CTIS) public portal–FHIR interoperability testing. Established the Study Registry Record Profile Working Group within Health Evidence Knowledge Accelerator (HEvKA), focusing initially on registry use cases related to CTIS public portal data.
Develop and maintain EMA and EMRN Enterprise Architectures	2.2 (ECP 1 A new plan for Europe)	Business-driven and strategic Enterprise Architecture supporting implementation of the legislative priorities, security and technology landscape modernisation, data-driven initiatives, and ensuring operational efficiency of the Network	**On track**	EAB endorsed the updated Enterprise Architecture principles Weekly architectural reviews to align digital products with EMA's Technology Capabilities Investment Plan (TCIP) and Enterprise Architecture (EA) (about 35 in 2025) Agency-wide Enterprise Architecture Working Group (EAWG) has assessed application portfolio and provided guidance for modernisation Business and Data Architecture development frameworks have been maturing Architectural vision for Data Platform and Data Products established to facilitate sharing and reuse of data across the Network.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Developed a process for interoperability assessment; European Shortages Monitoring Platform was the first assessed system, results published on EMA's website.
Cybersecurity and Security Operation Centre (SOC)	2.4	Enhancement of the EMA cyber security posture Efficient monitoring of Agency's perimeter and systems Fast adaptation on mitigating the risks stemming from the continuously changing threat landscape	**On track**	The Security Operation Centre (SOC) increased the processing of events by more than 80% during this period. New processes introduced that give the ability to SOC to build new monitoring rules (ad-hoc) based on new type of attacks that are broadly used during the relevant period. Customization and adaptation of the current monitoring ruleset to further reduce the false positives.
Data Management Services Data Stewardship Data Quality services Data related customer service Data Governance Activities	2.1 (ECP 1 A new plan for Europe)	EMA stakeholders have data registered in time and as needed to support their regulatory processes and qualified data that can be reliably used for decision making EMA stakeholders and users are informed and their questions in relation to data are answered Effective and Efficient Managing of enterprise/network data	**On track**	Delivered efficient and effective regulatory data services, meeting Service Level Agreements and Service Quality Indicators for Substances, Organisations, and Referentials. Ran the Data Management Tender that underpins next 6 years of data services provision Scaled up data services to meet growing agency needs — managed a 2–3x increase in workload for Medicinal Product Management System (PMS) and XEVMPD by introducing process simplifications and prioritisation work Enhanced customer satisfaction through updated guidance (SMS Guidance v3.0 and v3.1) and stakeholder engagement (PMS Info Day – 21 May 2025, SPOR quarterly webinar, SPOR Q&A clinics and re-appointing KUG members). Advanced data and information management modernisation with: Product Management Service (PMS) User Interface (UI) single edit Enrichment go-live in January Initiation of XEVMPD web UI replacement PMS UI bulk edit go-live in September PMS application programming interface (API) edit go-live in September Changes to SPOR services via SPOR Portal and ServiceNow

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Administration of Cloud services	2.2 (ECP 1 A new plan for Europe)	Effective and efficient Delivery and Acceleration of Cloud Services EMA stakeholders get reliable and continuous access to the Cloud services Allow EMA to further transform its business and way of working in support of its mission towards public and animal health in the EU	**On track**	In 2025, the Administration of Cloud Services progressed from large-scale migration to sustained operational maturity, strengthening the reliable and efficient delivery of cloud services across EMA. Stakeholders benefited from continuous, scalable access to cloud platforms, supported by improved governance, monitoring, and operational consistency across Azure and AWS. The year marked significant advances in modernising EMA's IT landscape. Legacy workloads continued to be transformed or retired, with increased adoption of cloud-native services. Substantial progress was made in the VMC exit programme through the migration of workloads from VMC-based infrastructure as a service (IaaS) to more efficient cloud-native services, alongside the decommissioning of the legacy non-production Azure tenant, reducing complexity and operational overhead. A key milestone was the delivery of the first tangible results in cloud cost optimisation. Enhanced cost governance, real-time visibility dashboards, and right-sizing actions were rolled out in close collaboration with platform owners. Despite growth in cloud usage, overall consumption costs were reduced compared to the second half of 2024, demonstrating EMA's ability to deliver more value with fewer resources. Overall, these achievements strengthened operational efficiency, improved elasticity and availability, embedded cost awareness, and validated EMA's strategic direction in cloud governance and financial accountability (FinOps)—positioning the Agency to continue accelerating digital transformation and data-driven decision-making.
Administration of digital productivity and collaboration services – Service Desk	2.2 (ECP 1 A new plan for Europe)	Quicker and more effective fulfilment of EMA services to its stakeholders Service desk as operational excellence (SLAs, customer satisfaction) – provide high quality end user services	**Completed**	In 2025, The user satisfaction for Service Desk services scored 97.6%, value obtained from more than 24,000 satisfaction surveys. The response rate increased 14% compared to 2024. The average time a ticket, call, chat or email was pending of triage and initial analysis was 13 minutes, 7 minutes lower than 2024.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				The resolution of requests, incidents and questions was met on the 90.58% during 2025.
CTIS	II — Public health activities	Stakeholders (Public, Sponsors and National Competent Authorities) can use the CTIS for their intended purpose in line with the Clinical Trials Regulation	**Completed**	System availability: 99.5% Performance of the system has remained stable and at a good level, with continues improvements implemented and more planned.
Driving the communication with I-Div stakeholders [external]: Inter-agency collaboration and NCA IT Directors stakeholder engagement and NICTAC secretariat	2.2 (ECP 1 A new plan for Europe)	Foster positive relationship with the Network (NCAs and EU agencies) through regular engagement and communication to facilitate agency collaboration and NCA IT	**Completed**	Building on EMA's successful first inter-agency technology innovation workshop with EU health policy agencies in 2024, EMA actively contributed with several participants and topics to the second edition hosted by EFSA in 2025. The third inter-agency meeting will be hosted by ECHA in 2026. In 2025, NICTAC held eight meetings. Two were hosted face-to-face: by HPRA in Dublin, and by EMA in conjunction with the quarterly agile review ceremonies. During the year, NICTAC significantly progressed on detailing the objectives, scope, resources required, and deliverables of its workplan. 43 out of 45 NCA IT Directors participated in the *'IT Directors survey Q4 2025'* with the aim to establish a baseline of network IT capabilities and resources. A training framework for IT Directors was established and two trainings published. A call for nominees for the network Community of Practice (CoP) for information security was published. In addition, two NCA IT Directors meeting were organised by the Polish and Danish EU Presidencies, respectively hosted in Warsaw and virtually. EMA's Technology Capability Investment Plan (TCIP) was published in December, setting the strategic direction to realise the technology objectives of the European medicines regulatory network until 2028.
Maintenance and optimisation of existing platforms	II — Strategies (EMANS and RSS)	Ensure platforms are performant, stable and resulting in fewer incidents	**On track**	Overall user satisfaction improved to 96,7%, showing an improved overall satisfaction to Information management services provided by EMA. Number P1 (critical) incidents total for 2025 was 28, despite the introduction of several new

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				applications/services throughout 2025.
Promotion of IT value	II — Strategies (EMANS and RSS)	Enhanced stakeholder understanding and advocacy for IT's role in driving business performance, optimizing regulatory processes, and supporting the strategic goals	**On track**	Improved stakeholder perception of IT service delivery following successful vendor transition for UPD, PMS, SMS, OMS, and RMS products. Initiated scoping and analysis for EudraGMDP and EV modernisation, aligned with NPL, supporting target architecture and strategic business alignment. Formed cross-functional scrum teams with key roles (e.g. Business Analysts, Architects) to strengthen collaboration and ensure digital solutions meet regulatory and strategic needs. Increased IT engagement with business counterparts, fostering stronger relationships and positioning IT as a trusted strategic partner. Continuous and regular engagement with Heads of Divisions, Departments, and Task Forces, evidenced through the systematic collection of verbal feedback, inputs, and actionable suggestions during coordination meetings and consultations.
IT Demand management	II — Strategies (EMANS and RSS)	All IT demand coming from both Portfolio and Operations activities is appropriately captured, recorded and priorities, and EMA stakeholders have an overview of the demand	**On track**	Over the past year, significant strides were made in the modernisation and streamlining of operations. Go-live of all post-authorisation procedures on IRIS and structured reporting and analytics capability for IRIS procedure data significantly modernised and streamlined our core operations. New EURS Next dossier platform has been introduced to EMA and NCAs as modern web-based tool for viewing, reviewing and assessing submissions. In terms of regulatory compliance, the full implementation of the new Fee Regulation (NFR) was completed, marking a major milestone and ensuring that the organisation meets all necessary regulatory standards with enhanced transparency. New records management solution, DREAM 2.0, went live. Major step forward in improving how the Agency manages, accesses and safeguards records.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Fieldglass, new contingent workforce management system implementation has concluded with onboarding of IT contractors. Established an appropriate governance structure with key roles and responsibilities that strengthens coordination of PMS Target Operating Model delivery activities while remaining fully consistent with the existing agile governance framework. Major capabilities deliveries continued with update of product information relevant to ESMP (manufacturers and pack sizes) for CAPs via Product UI and PMS API.
Records management	2.4	Ensuring the efficient and systematic control of all EMA records throughout their entire life cycle, regardless of format, location, or hosting system, while maintaining regulatory compliance, operational efficiency, and the preservation of institutional memory	**On track**	The revised Records Management and Archives Policy was approved in April 2025. The Records Management intranet page was re-launched to support awareness and access to resources. A mandatory e-learning course on Records Management fundamentals was made available for all staff. Support for the implementation of DREAM 2.0 (Electronic Document and Records Management System) is on-going.

Administration Division

Workload indicators

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Total TA staff recruited against vacant posts	45	35	47	40	42
Staff turnover rate (staff leaving against total no. of staff TA & CA)	5.30%	4.10%	3.50%	3.50%	3.90%
Total TA, CA, END at the Agency	-	928	969	988	983
Onboarding of staff (TAs, CAs, ENDs)	-	121	96	n/a	n/a
Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing)[29]	-	-	46,500	37,000	28,642
Procurement procedures finalised	39	43	42	46	37
Financial commitments initiated	1,533	1,575	1,666	1,200	2,453
Payment transactions initiated	25,044	35,403	40,638	41,116	49,024
Number of sales orders[30]	-	34,500	36,504	15,000	14,485
Number of registration activities[31]	-	13,200	14,083	14,000	13,408
PRE financial queries and disputes[32]	-	300	493	600	503
Receivable overdue for more than 30 days (including provision for bad debts)	2.54%	4.15%	4.88%	<10%	9.08%

Additional indicator

Procedure	2022 result	2023 result	2024 result	2025 forecast	2025 result
Number of new contracts TA, CA, SNE including contract changes (excluding renewals)	-	-	-	-	130

Performance indicators

Performance indicators related to core business	2022 result	2023 result	2024 result	2025 target	2025 result
Posts on the Agency establishment plan filled	99.40%	97.00%	101.00%	99%	99.60%
Average time to run selection procedures from the publication of the vacancy notice to establishment of reserve list	3.1 calendar months	36% <= 3 months, average 3.5 months	2.95 months, 52% <=3 months	3	2.7
Revenue appropriations implemented	98.35%	97.82%	100.05%	97%	98.38%

[29] New indicator introduced in 2024 work programme.
[30] New indicator introduced in 2024 work programme.
[31] New indicator introduced in 2024 work programme.
[32] New indicator introduced in 2024 work programme.

Performance indicators related to core business		2022 result	2023 result	2024 result	2025 target	2025 result
	Expenditure appropriations implemented	96.80%	99.00%	99.72%	95%	98.80%
	Payments against appropriations carried over from year N-1[33]	95.11%	95.16%	97.08%	95%	96.56%
	The maximum rate of carryover to year N+1, of total commitments within the title:					
	Title 1	4.34%	4.89%	3.07%	10%	3.05%
	Title 2	26.38%	24.86%	13.31%	20%	18.42%
	Title 3	40.06%	32.59%	26.00%	30%	16.78%
	Payment transactions within the Financial Regulation's time limits	97.98%	98.03%	97.18%	97%	93.76%
	Value of the budget for the given year	n/a	341	-	405	608

Achievements

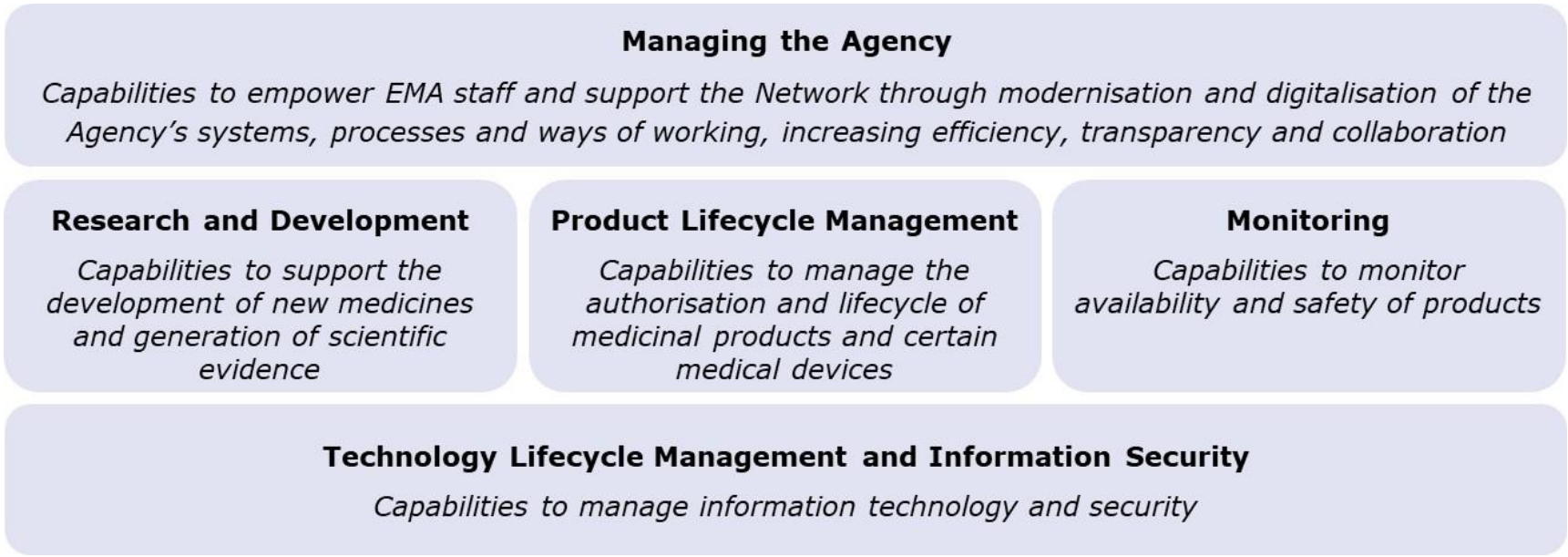
Action	MAWP strategic goal	Expected result	Status	Achievements/results
Implementation of the HR strategy & priorities 2023-2025	6.2	The following improvements are expected by strategic ambition: Sustainable organisation will see improvement in resources and competencies needed versus actually available Talent management will see further improvements in career development tools provided by the Agency Optimised work environment will translate into an increased net promoter score Wellbeing activities will further improve staff wellbeing Staff and managers will show improved	**On track**	Achievements of 2025: 1st EUAN HR Strategy Conference, Compass Employee Assistance Service, Job Shadowing, Gender Equality Plan, Secondments, Fellowship, Gender equality plan, Process reviews. The delivery of Talent Reviews, Strategic Workforce Planning, and Data Management will extend into the end of 2026.

[33] Includes non-automatic carry forward (C2).

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		satisfaction with HR services		
HQ efficiency	6.4	Environmental matters, campaigns, data collection, data analysis, reporting, improvement identification, action implementation	**On track**	Environmental statistics gathered related to building operations and services, monitored GHG emissions and tracked KPIs. To improve environmental performance, two actions were implemented: lowering temperature set points during the summer period to reduce cooling consumption, and upgrading the building management system software. EMA also continued to review its legal compliance on a quarterly basis. In January 2025, EMA achieved EMAS certification and completed its first EMAS validation in November 2025. Facilities contributed to this achievement. In the area of procurement, consultations were undertaken with the Sustainable Public Procurement Helpdesk, and green criteria were established for the indoor office plants and the provision of office furniture procurement procedures. A number of environmental campaigns were organised. The Agency continued to collaborate with other EU agencies by exchanging best practices through the EUAN Greening Network to support alignment with sustainability standards.
Historical Archives — EMA 30th Anniversary		EMA Historical Archives identified and available at EUI from January 2025 at the anniversary of the Agency	**Completed**	First batch of historical records consisting of the Management Board meeting minutes and related records from 1993 to 1995 (11 boxes), was transferred to Florence in November 2025; complying with the EU Council Regulation. Records will be available on the EUI — Historical Archives in Florence from January 2026 following the 30 year publication rule. This activity becomes an annual task, where EMA deposits at EUI are expected to happen annually in line with the 30 year publication rule.

Pillar 3 – Network Portfolio

The Agency's Network Portfolio is organised under five value streams. These reflect the fundamental purpose of the organisation and align to the overall value it provides (e.g. safe and effective medicines for the public, discovery of innovative medicines that address unmet medical needs, etc.). Value streams help organise the portfolio into sub-portfolios that do not have to compete with each other, and that support long-term strategic goals of the Agency. Value streams are stable, with a designated budget, leadership, resources and capacity:



To support the Agency's work and achievement of set objectives, several Agile initiatives are undertaken. The table below details the main products and deliverables (epics) that were planned for 2025; progress and delivery as of 31 December 2025 against what was planned in the work programme 2025 is reported using the following status:

On track
Delayed
Suspended
Achieved

Note 1: The budget figures for 2025 show the total estimated cost of the project, including internal and external costs for the value stream. Budget allocation to products within the value stream is reviewed regularly during the year.

Note 2: Necessary maintenance and improvements to newly developed systems are foreseen, even when not specifically listed as a deliverable.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
Product Lifecycle Management Value Stream (PLM VS) *Capabilities to authorise and manage lifecycle of medicines and medical devices*						**Budget 2025 (M€) 13.6**
Medicinal Product Management System (PMS)	Regulation 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 Regulation (EC) 536/2014, art.81-93) (Clinical Trials regulation) Pharmacovig. fees reg. 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2027	Enable industry, through an application programming interface (API), to enrich PMS with ISO-IDMP compliant medicinal product data needed for European Shortages Monitoring Platform (ESMP) go-live Enable industry, through an API, to enrich PMS with ISO-IDMP compliant medicinal product data beyond the data fields needed for ESMP go-live Enable read access to PMS to the public through an API Perform analysis for a roadmap to replace and decommission the Art. 57/ eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)	**On track**	Implementation of a machine-to-machine solution (PMS API) to allow industry users to enrich PMS data needed for ESMP reporting completed. Analysis for PMS data enrichment beyond ESMP requirements, and SIAMED decommissioning is on track. Implementation of public read-only PMS API ongoing. Analysis being conducted to draft a roadmap for XEVMPD decommissioning. Ongoing bug fixes and database maintenance to continuously enhance quality and reliability of PMS data.
Product Management System User Interface *(part of the Product Lifecycle Management portal)*		2023	2025	Enable industry, through the Product User Interface (PUI), to enrich medicinal product data in PMS needed for ESMP go-live Enable industry, through the PUI, to enrich medicinal product data in PMS beyond the data fields needed for ESMP go-live	**Achieved** **On track**	Functionality for industry users to edit non-centrally authorised products (non-CAPs) pack size and manufacturer data released in January 2025, ahead of ESMP go-live. The bulk write functionality for MAH, enabling updates across multiple products simultaneously, implemented in September. Analysis performed to extend enrichments of medicinal product data in PMS beyond the data fields needed for ESMP go-live. Ongoing maintenance and continuous improvements to the PUI to ensure optimal performance and usability.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
Electronic Application Form (eAF) *(part of the Product Lifecycle Management portal)*		2021	2026	Go-live for eAF for human variations for non-CAPs Maintenance of the eAF for human variations for CAPs and non-CAPs	**Achieved** **On track**	Human variations web-based eAF live for non-centrally authorised products (non-CAPs) through the Product Lifecycle Management (PLM) portal since 11 February 2025. 'Strongly recommended' use from September. The eAF 'integrity stamp' feature launched on 6 March 2025. Maintenance activities, structured changes, bug fixes and performance improvements of eAF for human variations ongoing.
Union Product Database (UPD)	Regulation (EU) 2019/6; associated implementing act	2021		UPD maintenance and improvements, i.e. enhance functionalities, usability and user experience for NCA and Industry	**On track**	Read-API for industry users to full product data and read-API for the public to non-confidential product data released in January. UPD maintenance and improvements ongoing. UPD updated to reflect Commission Implementing Regulation (EU) 2025/163 introducing 54 changes to variations not requiring assessment (VNRA), effective from 20 April 2025. MAH submission of changes to Qualified Person Responsible for Pharmacovigilance (QPPV) and Pharmacovigilance System Master File (PSMF) data in bulk via VNRA possible for non-CAPs. Next generation data quality framework (DQF) completed in September.
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2027	Go-live for the management of post-authorisation procedures (H & V) in IRIS and implementation of the New Fee Regulation Develop capability for procedure management of initial marketing authorisation applications (H & V) (+ Medicines for All & ancillary substances) in IRIS	**Achieved** **On track**	Post-authorisation procedures transitioned to IRIS in January and February 2025. Changes for new fee regulation completed. IRIS portal views and functionalities adjusted to enable collaboration for Network and industry users.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
						Development of capability for pre-submission and initial marketing authorisation processes ongoing.
Electronic Product Information (ePI) *(part of the Product Lifecycle Management portal)*		2022	2026	Implementation of features following findings from ePI pilot Development of functionalities that are essential for go-live	**On track**	Public Fast Healthcare Interoperability Resource (FHIR) import testing completed. Performed a public consultation on accessing ePI from EU medicine packages. The ePI Style Guide published in September to promote consistent regulator-compliant data quality and reusability of data. Findings from ePI pilot implemented.
eCTD4 (eSubmissions incl. EURSnext/Common Repository)		2021	2026	Completion of eCTD v4.0 specification and implementation guide update for the Europe (EU) region Progression towards pilot and optional use support of eCTD v4.0 submissions for centrally authorised products	**Achieved**	Updated eCTD v4.0 specification and implementation guide (CAPs only) published, as outcome of the first phase of eCTD v4.0 technical pilot. Second phase of eCTD v4.0 technical pilot planned. Roll-out of EURSnext review tool to EMA and NCA users. Go-live of EURSNext in December 2025 Supporting the submission of nitial marketing authorisation applications for centrally authorised products (CAPs) in eCTD v4.0 (optional use).
European Medicines Web Portal (EMWP)	Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2027	Perform user research and initial UX design to support the design and future development of EMWP	**Delayed**	*Epic not prioritised for 2025.* Preparations for exploratory user research to gather requirements ongoing.
Research and Development Management Value Stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*						**Budget 2025 (M€) 13.6**
Regulatory Procedure Management (RPM) for R&D *(part of the IRIS portal)*		2023	2026	Pre-authorisation processes onboarding onto IRIS	**On track**	Changes for new fee regulation completed. Development of capability for pre-authorisation processes (eligibility request, intent to submit, pre-

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
						submission meeting and support, notification of change /withdrawal) ongoing (in parallel to the initial marketing applications).
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82	2014	tbc	CTIS maintenance and continuous improvements, further improve stability, usability and user satisfaction CTIS Public Portal maintenance and improvements Continue the simplification principles of CTIS functionalities in preparedness for CTIS modernisation in 2025 and beyond Deliver new epics based on business value to enable CTIS modernisation over time CTIS Business Intelligence (CTIS BI) maintenance, improvement and further development to ensure alignment with CTIS improvement activities	**On track**	CTIS and CTIS Public Portal maintenance and continuous improvements ongoing. Simplification task force work ongoing. Review of modernisation roadmap, technology and architecture completed. First CTIS modernisation epic approved and ongoing, includes new capabilities for clinical trials' safety monitoring The clinical trial map for information on clinical trials in the European Union and European Economic Area launched on 3 March and is accessible on the CTIS public website. The clinical trial map multilingual interface and search capabilities in all official EU and EEA languages from 29 October. CTIS BI maintenance and improvements ongoing.
Scientific Explorer		2020	2025	Scientific Explorer II to expand capabilities of Scientific Explorer I to bridge evidence generation and evaluation support	**Delayed**	*Epic not prioritised for 2025.* European public assessment report (EPAR) ingestion and user interface improvements ongoing, AI extraction capability expanded, under maintenance activities.
Knowledge Mining		2025	2025	Develop knowledge mining and AI capabilities for EMA and the Network (custom products)	**Delayed**	*Epic not prioritised for 2025.* Collection of use cases through a workshop with over 120 NCA participants and ongoing experimentation and prioritisation
Monitoring Value Stream (MON VS) *Capabilities to monitor availability and safety of products*						**Budget 2025 (M€) 4.7**
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2025	ESMP minimum viable product (MVP) go-live in February 2025	**Achieved**	ESMP fully deployed on 2 February 2025. Gap analysis and impact assessment for ESMP interoperability with European

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
				allowing the entry into force of the regulation Maintenance and improvements to MVP		Medicines Verification System (EMVS) completed. New features such as the voluntary solidarity mechanism, critical shortages and testing of vulnerability assessment methodology are in progress.
Regulatory Procedure Management (RPM) for Monitoring *(part of the IRIS portal)*		2023	2025	Maintenance and improvements on inspections and parallel distribution, including new fee regulation (NFR)	**Achieved**	Inspections and parallel distribution updated in January to reflect new fee regulation.
Union Pharmacovigilance Database (UPhV, formerly EVVet3)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2024	Product development completed in 2024, maintenance to continue in 2025 European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) decommissioning	**Achieved**	UPhV maintenance and improvements ongoing.
Antimicrobial Sales & Use (ASU)	Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578 Commission Implementing act 2022/209	2021	2024	Product development completed in 2024, maintenance to continue in 2025	**Achieved**	ASU maintenance and improvements ongoing. ASU public dashboard published on 9 December. The ESUAvet antimicrobial sales dashboard includes new sales data from the ASU platform with data visualisations at EU and country level. ESVAC decommissioning completed.
Signal and Safety Analytics (SSA) [new]		2025	2025	SSA minimum viable product (MVP) go-live	**Achieved**	MVP go-live in December 2025 for EMA Pharmacovigilance office and selected Network users. Roll-out to all NCAs planned for 2026.
Managing the Agency Value Stream (MTA VS) *Capabilities to empower EMA staff and support the Network through modernisation and digitalization of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration*						**Budget 2025 (M€) 5.0**
SAP Finance replacement		2023	2026	Finalise analysis and technology selection	**On track**	Architecture analysis including drafting of target architecture completed. Fit gap analysis for SUMMA finalised. Technology selection ongoing.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
SAP HR replacement		2023	2025	SAP HR Core replacement	**Delayed**	Development, testing and data migration ongoing including new scope (Onboarding V2 & Time Tracking) Statement of Work (contractors) module completed.
New Fee Regulation	Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency	2023	2025	Go-live in January 2025 Integration of latest regulatory processes with the new fee system	**Achieved**	All systems related to the new fee regulation (NFR) were successfully updated to reflect the regulation that entered into force on 1 January 2025.
Document Management System replacement		2023	2025	Implementation of document management system replacement	**Achieved**	Go-live of new document management system on 23 June 2025.
AskEMA replacement		2024	2025	AskEMA replacement implementation	**Suspended**	*Epic not prioritised for 2025.*
Anonymisation@EMA		2025	2025	Enable automated anonymisation of commercially confidential information (CCI) in large sets of documents	**On track**	Analysis and technology selection (personal/clinical data) completed, move to implementation phase in Q1 2026.
Customer Relationship Management (CRM) tool		2025	2026	Start analysis and technology selection	**On track**	Business consultancy tender process concluded. Collection of business requirements ongoing.
Workplace Experience		2024	2027	Finalise analysis and technology selection	**Suspended**	*Epic not prioritised for 2025.*
Early Notification System (ENS) [new]		2025	2025	Secure communication platform to deliver emerging safety information to NCAs, international partners and EMA staff.	**Achieved**	ENS platform go-live in November, providing a secure and easily accessible channel for notifying the EMRN about emerging public health threats.
Technology Lifecycle Management and Information Security Value Stream (TLM VS) *Capabilities to manage information technology and security*						**Budget 2025 (M€) 3.0**
Information Security and Cyber Security enhancements		2022	2025	Cyber & Information Security enhancements Operational Security enhancements Application Security enhancements	**On track**	Continuous improvements to information security and cyber security.
Legacy application modernisation		2023	2025	Horizon 25 Modernisation Factory: move the legacy applications that	**On track**	Legacy modernisation activities ongoing. The majority of the scope, including

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results 2025
				are running on outdated technologies into a modern, stable and secure environment ('re-platforming')		initiatives such as CTIS and EudraGMDP modernisations, has been allocated to R&D and Monitoring value streams respectively.

2. (a) Management

2.1. Management Board

The Management Board (MB) is the European Medicines Agency's governance body. It has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.

The Board's operational tasks range from adopting legally binding implementing rules, to setting strategic directions for scientific networks, to reporting on the use of European Union (EU) contributions for the Agency's activities. The tasks and responsibilities of the Management Board are set out in the Agency's founding Regulation (EC) No 726/2004 of the European Parliament and of the Council.

Important milestones related to the EMA Management Board in 2025 included:

- **Election of Rui Santos Ivo as Chair of the EMA Management Board:**
  - At its March meeting, the Board elected Rui Santos Ivo as new chair of the Board for a three-year period. Mr Santos Ivo is president of the Portuguese National Authority of Medicines and Healthcare Products (Infarmed) and an associate professor of medicines regulation at the University of Lisbon, Faculty of Pharmacy. He has been a member of the EMA Management Board since 2016 and served as its vice chair since October 2024.

- **Election of Aimad Torqui as Vice-Chair of the EMA Management Board:**
  - At its June meeting, the Board elected Aimad Torqui as its new vice-chair, with a three-year mandate from September 2025. Mr Torqui currently serves as Division Head and Deputy Director at the Medicines Evaluation Board (MEB) in the Netherlands and is a member of the MEB executive management team. He has been a member of the EMA Management Board since 2022.

- **Renewal of EMA Executive Director mandate:**
  - At an extraordinary meeting held on 28 April 2025, the Management Board was consulted by the European Commission on the possible renewal of EMA's Executive Director's mandate, in accordance with Article 64 of Regulation (EC) No 726/2004. The Board provided its positive opinion to the Commission on the possible renewal.
  - Following the European Commission's formal proposal, the Management Board unanimously adopted, by written procedure in September 2025, the renewal of Ms Cooke's mandate as Executive Director for the period 16 November 2026 to 30 April 2027.

- **Selection procedure for the next EMA Executive Director:**
  - At its December meeting, the Board was informed by the European Commission of the preliminary timelines for the appointment of the successor of the Agency's Executive Director, whose renewed mandate expires on 30 April 2027. A draft vacancy notice was consulted with Board members by written procedure ahead of the December meeting and was considered acceptable by the Board. The Commission published the vacancy notice on 19 February 2026.

- **New representatives of the European Parliament and civil society on the Board:**
  - In July 2025, two new representatives of the European Parliament, Cristian Silviu Buşoi and Kristina Garuolienė, were appointed to the Management Board. Mr Buşoi is a medical doctor, a former Member of the European Parliament and was the EMA contact MEP. Ms Garuolienė is a former Vice Health Minister of Lithuania and currently an associate professor at Vilnius University.
  - The Board welcomed, in October 2025, a new civil society representative, Marko Korenjak, Director of European Liver Patients Association, appointed as a representative of patients' organisations. Three of the current civil society representatives were reappointed by the Council for a second three-year mandate: Virginie Hivert, Therapeutic Development Director of EURORDIS (Rare Diseases Europe), representing patients' organisations; Denis Lacombe, Chief Executive Officer of European Organisation for Research and Treatment of Cancer (EORTC), representing doctors' organisations; and Christophe Buhot, representing veterinarians' organisations.
- **Management Board meets the African Medicines Agency Governing Board:**
  - At its June meeting, the Management Board welcomed the African Medicines Agency (AMA) Governing Board and heads of African national agencies as observers in a first-of-its-kind meeting between the European and African regulatory network. The delegation was led by Dr Yossounon Chabi, Chair of the AMA Governing Board and Director-General of the Benin Agency for Medicines and Health Products, and included Dr Delese Mimi Darko, the newly elected AMA Director-General Designate and Chief Executive of the Ghana Food and Drugs Authority. Representatives from the European Commission's Directorate-General for International Partners (DG INTPA) and the World Health Organization (WHO) also participated. The meeting is part of EMA and the European network's commitment to supporting the AMA and strengthening regulatory systems in Africa more broadly. Organised by EMA, the project is funded through the European Union (EU) Global Gateway Initiative.
- **EMA's 30th anniversary:**
  - In 2025, EMA celebrated its 30th anniversary. The Board was informed of the series of events held throughout the year, including the Agency's first public Open Day on 9 May (Europe Day). Board members were also invited to the scientific conference held on 25 June under the theme 'Medicines, regulation and the future', opened by His Majesty Willem-Alexander, the King of the Netherlands.

The most significant issues discussed at the Management Board in 2025 included:

- **European Medicines Agencies Network Strategy to 2028:**
  - At its March meeting, the Board adopted the joint European Medicines Agencies Network Strategy (EMANS) to 2028, titled 'Seizing opportunities in a changing medicines landscape'. The strategy extends the timeframe of the previous EMANS 2025, taking into account technological advances, environmental challenges and other developments reshaping the regulatory landscape. This will lay the groundwork to prepare the network for the implementation of the revised EU pharmaceutical legislation.
- **New EU pharmaceutical legislation (NPL):**

- The Board received regular updates from the European Commission at each meeting on the progress of the revision of the EU pharmaceutical legislation, from the Council's negotiation mandate in June through to the conclusion of trilogue negotiations in December.
- At its December meeting, the Management Board endorsed a governance structure to guide and oversee EMA's implementation of the new pharmaceutical legislation. A NPL Oversight Group, including representatives from EMA, the Management Board and the European Commission, will oversee work across six delivery streams covering the centralised procedure and committees, development support, environmental risks, quality and manufacturing, shortages and other regulatory and legal aspects.

- **EU Legislative and policy updates:**
  - The Board received regular updates from the European Commission on the preparation of the proposed Biotech Act at its June, October and December meetings. At its December meeting, the Board welcomed the publication of the Commission's proposed Biotech Act, which is designed to further boost biotech innovation and research in the EU and includes several amendments to the EU Clinical Trials Regulation.
  - At its October meeting, EMA presented an update on its activities under the medical devices framework, including the work of its expert panels for high-risk medical devices and class D in vitro diagnostics. At the December Board meeting, the Commission updated the Board on the proposals for a revision of the Medical Device Regulation ((EU) 2017/745) and the In Vitro Diagnostic Medical Device Regulation ((EU) 2017/746), which assign new responsibilities to EMA regarding the management of medical device expert panels, to work with the Commission to set up and manage an IT system for reporting and sharing information on supply interruptions or discontinuation of critical medical devices, and to provide support to the national competent authorities for medical devices to facilitate the exchange of experience, cooperation and coordination in certain areas.
  - The Board also received regular updates from the European Commission on other legislative and policy developments related to the Agency, including the Critical Medicines Act, the European Health Data Space (EHDS) Regulation and the EU Safe Hearts Plan.
  - On research and innovation, the Board was updated on the EU Life Sciences Strategy, published in July 2025 with 24 actions to make Europe the most attractive global hub for life sciences by 2030, including a Clinical Research Investment Plan and the establishment of ATMP Centres of Excellence. The Board also noted updates on Horizon Europe funding opportunities for health-related research, the Innovative Health Initiative (IHI) project on regulatory sandboxes, One Health research including a new European Partnership on AMR, and joint EMA–HMA–Commission recommendations for advancing pharmacogenomics in medicine regulation.

- **Medicines Shortages Management**
  - The Board received regular updates from the Executive Director on the work of EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Medicine Shortages Single Point of Contact (SPOC) Working Party. Throughout 2025, the MSSG continued to monitor, manage and prevent critical shortages, taking preventive actions to safeguard supply of essential medicines across the EU. The Board noted the full launch of the European Shortages Monitoring Platform (ESMP) in January 2025, following the initial go-live with core functionalities in November 2024. The ESMP is a critical tool to strengthen the monitoring of medicine supply and support early detection and management of potential shortages across the EU. The Board was also informed of the conclusions of the European Court of Auditors' report on medicine shortages, discussed at its October meeting, and of EMA's continued support to the Critical Medicines Alliance to address supply chain vulnerabilities and prioritise resilience measures.

- **Clinical trials in the EU:**
  - Throughout 2025, the Board was updated on the continued progress of the Clinical Trial Information System (CTIS). At its March meeting, the Board received a live demonstration of the new clinical trial map accessible from the CTIS public website, developed in response to requests from patients. In April 2025, CTIS was officially designated as a primary registry by the World Health Organization. The Board noted the completion of the knowledge transfer to a new CTIS supplier and the finalisation of the CTIS modernisation roadmap, which entered the implementation phase, setting out actions and deliverables through to 2028.
  - The Board was regularly updated on ACT EU initiatives in 2025. Key developments included the establishment of a new metrics framework and key performance indicators to monitor the EU clinical trials environment, the publication of the CTIS master sponsor handbook, and the establishment of a public health emergency ethics advisory group. The Board also noted the launch of the HMA-led FAST-EU initiative, with a pilot expected to start in January 2026.
- **International collaboration:**
  - The Board was updated on the activities of the International Coalition of Medicines Regulatory Authorities (ICMRA), chaired by EMA since 2019. EMA's chairmanship concluded with the ICMRA Summit and plenary meeting held at EMA's premises in Amsterdam from 21–24 October, bringing together global heads of agencies. The Board welcomed the positive results of the ICMRA Pharmaceutical Quality Knowledge Management (PQKM) initiative, which achieved around 90% harmonised outcomes and considerably reduced approval timelines in collaborative pilots.
  - The Board endorsed expanding the scope of EMA's OPEN Framework to include all medicines targeting unmet medical needs and advanced therapy medicinal products (ATMPs), and to allow its use for post-authorisation changes. The OPEN initiative was originally endorsed in December 2020 to allow regulators from outside the EU and WHO to participate in EMA's scientific evaluations.
  - The Board was also updated on EMA's support to the African Medicines Agency (AMA) and the African Medicines Regulatory Harmonisation (AMRH) Initiative, which completed the assessment and listing of the first five medicinal products at continental level.
- **Activities of the Network Data Steering Group:**

- At its October meeting, the Board endorsed the first data strategy for the European medicines regulatory network. The strategy sets out principles and goals to ensure the network's data assets are managed optimally and are easy to share and use for regulatory decision making. It is a key deliverable of the Network Data Steering Group workplan 2025–2028 and supports the EMANS to 2028 goal of leveraging data, digitalisation and artificial intelligence.
- At its June meeting, the Board endorsed recommendations for human Product Master Data implementation and data management principles. The Product Management System (PMS) is recognised as the central source of product master data for all EU medicinal products, aiming to provide a unified, EU-level repository supporting the full product data lifecycle. A feasibility study on data qualification for nationally authorised products is underway, with results expected in early 2026.
- At its October meeting, the Board was updated on the development of the EU Network Roadmap on Artificial Intelligence, including joint EMA–US FDA work on Guiding Principles for Artificial Intelligence in Medicine Regulation.
- At its December meeting, the Board was updated on plans to extend DARWIN EU from 2027 to 2032. Since its inception in 2022, more than 100 studies have been initiated and 32 data partners have joined, enabling the use of health data from 188 million patients across 16 European countries. Data training including modules on artificial intelligence will be rolled out to the network starting in Q1 2026.

- **Involvement of external experts to support EU regulatory network activities:**
  - At its June meeting, the Board was updated on proposals to expand the involvement of external experts in support of the European medicines regulatory network, as part of broader discussions on resourcing at the level of the HMA/EMA Strategic Resource Oversight Group (SROG). At its October meeting, the Board endorsed expanding the scope of activities for the involvement of external experts based on an EMA public call, and agreed to allow the engagement of suitably qualified experts from outside the EU/EEA, with the decision on use and remuneration remaining under NCA responsibility. The success of these activities will be reviewed within a two-year period.
- **Periodic reports from Chairs of Scientific Committees and Working Parties to the MB:**
  - The Chair of EMA's Committee for Medicinal Products for Human Use (CHMP), Bruno Sepodes, was invited to the Board at its June meeting to present an overview of recent achievements and challenges in the work of the CHMP. He outlined the Committee's preparation for expanded responsibilities under the new EU pharmaceutical legislation, its commitment to upholding the highest scientific standards, and ongoing efforts to improve efficiency in the assessment and approval of new medicines.
  - The Chair of EMA's Paediatric Committee (PDCO), Dr Sabine Scherer, was invited to the Board at its December meeting to provide an update on key activities in 2025. She highlighted that while the 2007 EU Paediatric Regulation has delivered nearly 600 new indications in children, significant unmet needs remain, particularly in younger age groups. The Board noted the importance of strengthening patient and healthcare professional engagement in paediatric drug development and the opportunities the new pharmaceutical legislation may bring for paediatric medicines.

Significant additional items adopted or decided by the Management Board in 2025 included:

- **Activities required by the EMA's founding and financial regulations:**

The Board's operational tasks include reporting on the use of the EU contributions for the Agency's activities. In 2025, these activities involved:

- adopting the 2026–2028 Programming document, including the 2026 budget;
- adopting the Board's assessment of the Executive Director's Annual activity report for 2024;
- adopting EMA's annual report for 2024;
- delivering an opinion on the Agency's final accounts for 2024; and
- noting the Executive Director's mid-year report for the first half of 2025.

- **Internal audit and advisory activities at the European Medicines Agency:**
  - At its March meeting, the Board adopted an updated Internal Audit Charter and updated the decision establishing the Management Board Audits and Risks Group (MBARG);
  - At its June meeting, the Board adopted the annual report of internal audit and advisory activities at the European Medicines Agency 2024 and the revised 2025 Audit Plan;
  - At its December meeting, the Board adopted the 2026 risk-based audit plan and the 2026–2028 strategic audit plan and the revised composition of the MBARG.
- **Independence and ethics:**
  - At its March meeting, the Board endorsed the annual report on EMA's independence policies and adopted a decision on the handling of declared interests of staff members and candidates before recruitment.
  - At its June meeting, the Board endorsed an update to EMA's code of conduct.
  - At its December meeting, the Board adopted revised breach of trust procedures for scientific committee members and experts and for Management Board members.
  - At its December meeting, the Board noted EMA's report on data protection activities.
- **Anti-Fraud Strategy:**
  - At its June meeting, the Board endorsed EMA's Anti-Fraud Strategy and Action Plan for 2025–2028.
  - The Board noted the 2024 EMA Annual Report on the implementation of the Anti-Fraud Strategy at its June meeting and the 2025 Annual Report at its December meeting.
- **Fee Regulation, financial matters and cooperation agreement:**
  - At its June meeting, the Board adopted revised working arrangements and financial arrangements on remuneration for (co-)rapporteur services under the new Fee Regulation.
  - At its October meeting, the Board adopted Addendum 1 to the Cooperation Agreement between EMA and the National Competent Authorities (NCAs), including amendments to the

remuneration of NCA staff for priority training services and provisions to allow the engagement of external experts from outside the EU/EEA.

- **Emergency Task Force:**
  - At its March meeting, the Board adopted a revised composition of EMA's Emergency Task Force (ETF) and agreed to revised Rules of Procedure. A further revised composition was endorsed at the December meeting.

- **Technology capability investment plan to 2028:**
  - At its December meeting, the Board noted EMA's updated technology capability investment plan to 2028, supporting the development of a fully digital, efficient and data-driven network.

2.2. Major Developments 2025

Revision of the EU Pharmaceutical legislation

The landmark political agreement reached by the European Commission, the European Parliament and the Council of the European Union on the comprehensive reform of the EU pharmaceutical legislation represents the most significant overhaul of the regulatory framework in over two decades. The new pharmaceutical legislation will bring significant changes across multiple areas of EMA's work.

EMA's Management Board adopted a governance structure to guide and oversee the implementation of the pharmaceutical legislation. A new group that includes representatives from EMA, its Management Board and the European Commission will oversee this work.

During the legislative process, EMA provided technical support, working closely with the European Commission and network partners to assess the implications of the evolving text. Early engagement has now started with scientific committees to explore future ways of working in line with the proposed committee reform, aiming to ensure continuity and a smooth transition.

Other pieces of new legislation

The new regulation on health technology assessment (HTAR) (Regulation (EU) 2021/2282) became applicable in January 2025. EMA has been supporting the preparation for the implementation of the regulation by working closely with the European Commission, EU Member States, and stakeholders representing the pharmaceutical industry, healthcare professionals, patients and academia. The new rules will initially apply to new active substances to treat cancer and to all advanced therapy medicinal products (ATMPs). They will be expanded to orphan medicinal products in January 2028, and to all centrally authorised medicinal products as of 2030. Selected high-risk medical devices will also be assessed under the HTAR as of 2026.

In June 2025, negotiators of the European Parliament and Council of the EU reached an agreement on the 'one substance, one assessment' (OSOA) legislative package. The proposals aims to: 1. strengthen cooperation and consolidate scientific and technical work on chemicals in the European Chemicals Agency, the European Food Safety Authority, the European Environment Agency and the European Medicines Agency, 2. Establish a Common Data Platform and introduce a 'one-stop shop' access to data on chemicals held by the EU agencies and the Commission, compiled under EU legislation. 3. Establish systematic collection of human biomonitoring data generated in the EU to inform policy makers about the levels of chemicals found in people 4. Set up a monitoring and outlook framework to enable early detection of chemical risks 5. Empower the European Chemicals Agency to generate data when needed. 6. Ensure transparency of scientific studies on chemicals.

The proposals for a revision of the Medical Device Regulation ((EU) 2017/745) and the In Vitro Diagnostic Medical Device Regulation ((EU) 2017/746) assign new responsibilities to EMA regarding the management of medical device expert panels, to work with the Commission to set up and manage an IT system for reporting and sharing information on supply interruptions or discontinuation of critical medical devices, and to provide support to the national competent authorities for medical devices to facilitate the exchange of experience, cooperation and coordination in certain areas. The Commission's proposed Biotech Act is designed to further boost biotech innovation and research in the EU and includes several amendments to the EU Clinical Trials Regulation.

EU medicines agencies network strategy to 2028

The new EU medicines agencies' network strategy to 2028 (EMANS), published in March 2025, takes into account the ongoing revision of the EU's pharmaceutical legislation, laying the groundwork for its implementation.

The strategy, titled 'Seizing opportunities in a changing medicines landscape', is a comprehensive review and update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). The Strategy draws on the extensive experience gained from tackling COVID-19. It will guide the European medicines regulatory network over the next few years as it meets the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

2.3. Budgetary and financial management

Budget overview

The initially authorised appropriations of EUR 600,230,000, represented an increase of 22.0% over the 2024 budget (EUR 491,862,000).

The unusually high increase compared to the previous year is due to the higher level of fees introduced by the new Fee Regulation, which entered into force in January 2025. Most of the increase relates to the higher share of remuneration to National Competent Authorities for the scientific service provided as established by the legislators in the new fee regulation.

The financial outturn for 2025, a surplus of EUR 19,585.23, represents 0.003% (EUR 4,594,984.37, represents 0.93% in 2024) of the approved budget of EUR 600,230,000, cf. the draft budget outturn for fund sources (C1, C11).

Revenue (income from evaluation activities and EU contribution)

As stipulated in the Financial Regulation, budget revenue is based on cash received in terms of fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, contributions from the European Union, as well as for various administrative activities.

Total cash revenue (C1 & C11) entered in the accounts as of 31 December 2025 amounted to EUR 590,489,880.94 (2024: EUR 492,127,783.68).

Out of the total C1 income, 91.4% (2024: 89.8%) derived from the evaluation of medicines and other business-related activities, 8.3% (2024: 9.4%) from the European Union budget to fund various public health and harmonisation activities, and 0.3% (2024: 0.8%) from various sources.

Expenditure (commitments and payments)

Total amount committed on fund source C1 was EUR 590,579,430.43, which represents 98.4% of the final appropriations of EUR 600,230,000 (2024: EUR 490,485,350.54, or 99.7%). Taking into account the non-automatic carry forward of EUR 2,450,000 for the building projects approved by the Management board in February 2026, the total amount committed (C1 & C2) would be EUR 593,029,430.43, which is 98.8% of the final appropriation.

Payments totalled EUR 517,862,913.37, or 87.7% of the total commitments (2024: EUR 411,317,623.40, or 83.9%).

Appropriations carried forward from 2024 to 2025

Automatic carry-forward

Automatic carry-forward to financial year 2026, C1 to C8, totalled EUR 72,716,517.06, or 12.3% of the total commitments (2024: 79,167,727.14, or 16.2%).

Non-automatic carry-forward

In February 2026 the Management Board approved a non-automatic carry-forward to 2026 of EUR 2,450,000 to cover the cost related to a fitting-out projects. The contracting of such works was planned for 2025 as most of the preparatory stages of the commitment procedure had been concluded by 31 December 2025, but for reasons outside the Agency's control the conclusion of the contract was

delayed. Therefore, in accordance with Article 12 (2)(a) Financial Regulation a non-automatic carry forward of appropriation is proposed to the Management Board.

Implementation of appropriations carried forward automatically from 2024 to 2025
Automatic carry-forward from financial year 2024 to 2025, i.e., fund source C8, totalled EUR 79,317,727.14 (2024: EUR 95,426,655.69), out of which EUR 76,589,864.97, or 96.6% were paid (2024: EUR 92,644,527.02, or 97.1%) and EUR 2,727,862.17 were cancelled (2024: EUR 2,782,128.67).

Appropriations from external and internal assigned revenue

The Agency's available appropriations in 2025 included external and internal assigned revenue. In accordance with the revised Financial Regulation which came into effect on 1 July 2019, this revenue, matched by expenditure appropriations, is managed outside the adopted budget and under separate fund sources, i.e. R0 for external assigned revenue, and CL for internal assigned revenue.

Externally assigned revenues derive from inducements related to the Agency's headquarters in Amsterdam, the planning and execution of an electronic Product Information pilot, to support regulatory systems at national and regional level in Africa, and in particular for the setting up of the African Medicines Agency (AMA) and various programmes related to the Instrument for Pre-accession Assistance (IPA) and the Innovative Health Initiative (IHI).

In 2025, a total of EUR 8,314,996.05 in new R0-funds were received, and expenditure amounting to EUR 3,638,416.00 incurred (payments).

Internally assigned revenues derive from rent, service and other charges received from the sub-tenant of the Agency's former headquarters in London. This revenue matches the payments made to the Agency's landlord in London. In 2025, EUR 8.8 million were received and EUR 2.2 million were carried forward to next year, and expenditure amounting to EUR 9.1 million incurred.

While R0 and CL appropriations do not expire, the revenue and expenditure must balance over time.

Budget transfers

In line with Art. 26 of the Financial Regulation, the Executive Director may make unlimited transfers within a title and of up to 10% of appropriations from one title to another. Transfers *per se* are not an indication of deficiencies in budget management but are a necessary tool to adjust the budget in a changing environment, e.g. resigning staff members receiving allowances related to their departure rather than their salaries, inflation impact on utilities, adjusting activities to evolving business environment, increased expenditure due to exchange rate fluctuation, etc.

In 2025, the Agency processed 7 transfers of appropriation and they were all related to expenditure budget lines.

The total value of transfers was 2.7% of the final commitment (3.2% in 2024). The transfers of expenditure appropriations were primarily needed to cover additional expenditure related to statutory staff due to the higher-than-expected salary adjustments and pension contribution, to recruit additional short-term staff and to cover their higher costs in line with the salary adjustment as per Dutch labour law, to accelerate IT portfolio investments, and to invest in building improvements.

Other transfers included higher translation expenditure due to the price increase of translations charged by the Centre de traduction, which was unknown at the time of budget planning, and the higher number of European public assessment reports modifications (EPAR) and Referral procedures,

to cover for the increase in canteen expenditure due to higher number of staff/ visitors in the office and change in cost of food.

Cancellation of appropriations

Expenditure appropriations should be understood as estimates of requirements, and not as an entitlement to create the corresponding commitments. Being reliant on fee income, as the agency is, this means that the level of cancelled expenditure appropriations does not indicate delays in the implementation of the work programme, but it is a result of rigorous monitoring of actual revenue and adjustments to the expenditure.

At the end of the year, expenditure appropriations totalling EUR 7,200,570.6[34] remained unused, which corresponds to 1.2% of final appropriations of EUR 600.2 million (2024: EUR 1,376,649.46, 0.3%).

The level of cancellation is well within the KPIs of 5%:

- title I (staff expenditure) — cancelled appropriation of 0.4%, (2024: 0.4%)
- title II (infrastructure and operating expenditure) — cancelled appropriation of 0.8% (2024: 0.3%)
- title III (operational expenditure) – cancellation of appropriation of 1.8% (2024: 0.2%).

Payment of interest on late payments

In line with the Agency's standard contract, the payment terms, set in accordance with Art. 77 of the Financial Regulation, require settlement within 30 days of receipt of a valid invoice. If the payment terms are not respected, default interest accrues from day 31 until the actual payment date, at the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, increased by 8%. Default interest is paid automatically to the supplier only when the accumulated amount exceeds EUR 200 at the time the valid invoice is paid.

In 2025, 3,039 payments out of a total of 48,703 (representing 6.24%) were processed beyond the time limits foreseen by Article 77 of the Financial Regulation (2024: 2.8%). This resulted in default interest of EUR 5,636.81 being paid to suppliers (2023: EUR 13,949).

[34] Excluding €2,450,000 non-automatic carry forward approved by the Management Board in February 2026, which were committed in 2026.

Procurement

Procedure type	Closed 2025		Closed 2024	
Open procedure (GFR 167 (1)(a))	2	6%	8	20%
Restricted procedure (GFR 167 (1)(b))	1	3%	0	0%
Competitive procedure with negotiation (Annex 1 – Point 12.1)	0	0%	1	3%
Negotiated procedure, middle value (Annex 1 – Point 14.2)	1	3%	3	8%
Negotiated procedure, low value (Annex 1 – Point 14.3)	2	6%	0	0%
Negotiated procedure, very low value (Annex 1 – Point 14.4)	3	8%	3	8%
Negotiated procedure, without prior publication (Annex 1 – Point 11.1)	0	0%	2	5%
Re-opening of competition	27	75%	23	58%
Total EMA-only procedures	**36**		**40**	
Interinstitutional EMA-led	0	0%	2	14%
Interinstitutional Non-EMA-led	15	100%	12	86%
Total interinstitutional procedures	**15**		**14**	

Summary of the information on grant, contribution and service level agreements provided in Annex VI

Grants received: The Agency participates in four grant agreements concluded with the Innovative Medicines Initiative Joint Undertaking, covering scientific projects in the areas of medication safety in pregnancy (ConcePTION), environmental risk evaluation of medicines (PREMIER), and patient-reported outcomes standardisation (SISAQOL). The amount of the grants received range from EUR 43,000 in 2024 to EUR 313,500 in 2025, to EUR 303,500 and EUR 300,000 in 2026 and 2027 respectively, with the IHI RealiseD grant constituting the predominant source from 2025 onwards.

Contribution Agreements: EMA has entered into four contribution agreements with an additional one being planned with various DGs of the European Commission, encompassing IPA candidate country participation in EMA trainings and activities, the electronic Product Information (ePI) initiative, and the NDICI AFRICA programme supporting local manufacturing and access to health technologies in Africa. Total amounts receivable stand at EUR 3.7 million in 2024, declining to approximately EUR 2.7 million annually in 2025 and 2026, and EUR 2.5 million in 2027.

Service-Level Agreements: The Agency does not provide services to other EU entities and therefore holds no service-level agreements during the period concerned.

Grants provided: EMA disburses funding to external beneficiaries through three agreements, all directed at strengthening African medicines regulatory capacity in the framework of the African Medicines Agency (AMA). These comprise the AMA AUDA-NEPAD grant (EUR 450,000 over 15 months), the AMA EMRN grant (EUR 1,045,998), and the AMA EDQM grant (up to EUR 1.5 million over 34 months).

Cost and benefits of controls

In 2025, EMA allocated approximately **13.69 FTEs** for control activities (amounting to **EUR 1.5M** or **0.26%** of the Agency's 2025 final budget). These activities were centred on the following areas: integrated quality management, audit, anti-fraud, finance and verification processes, corporate risk management and self-assessment activities. Considering the positive result of the ex-ante and ex-post control verifications, the opinion of the Head of Internal Audit Capability, the well-established

framework to manage exceptions and the regularity of operations, the overall balance between effectiveness, efficiency and economy of controls is reasonably satisfactory.

2.4. Delegation and sub-delegation of powers of budget implementation

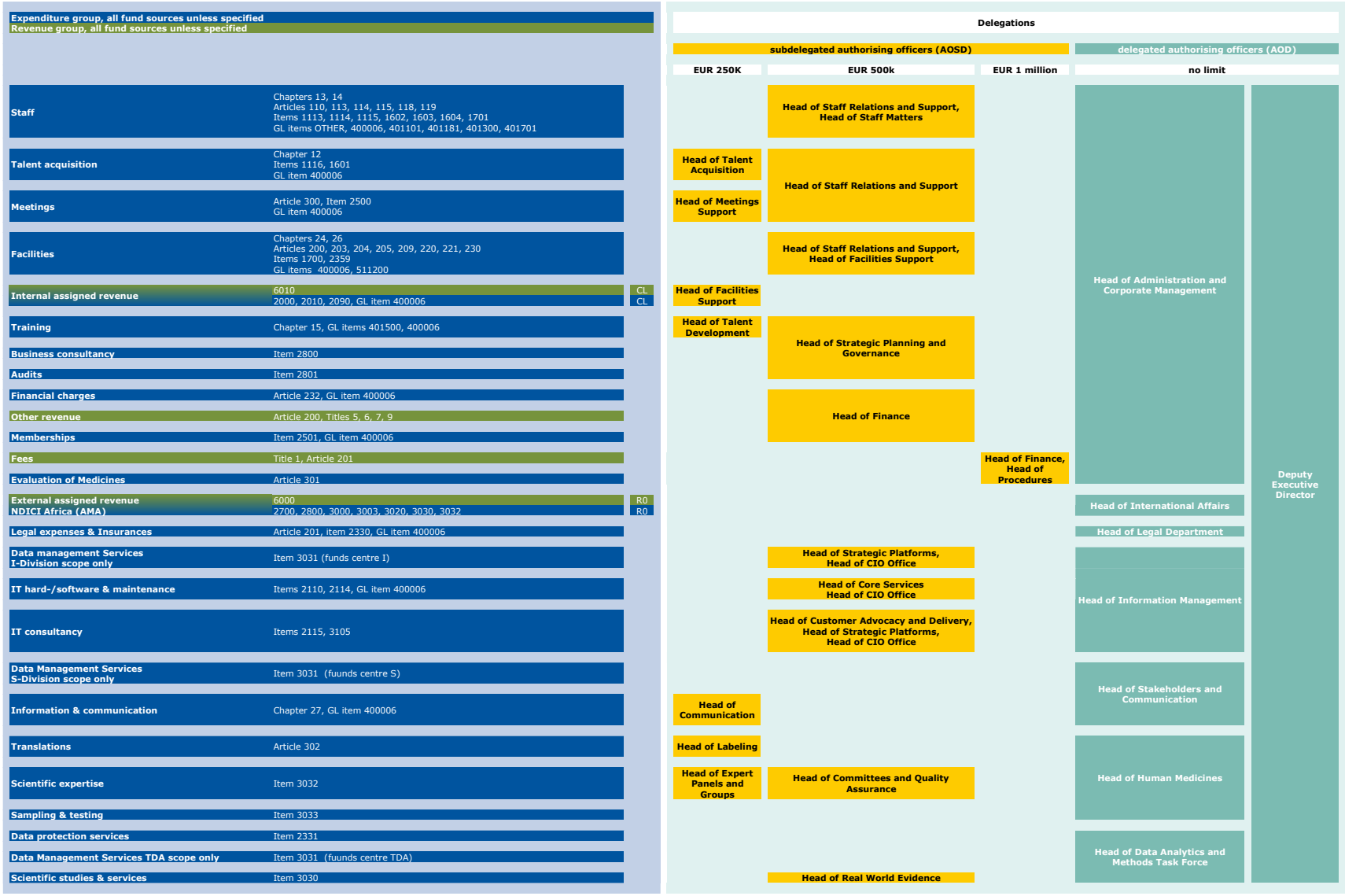
To enact the most effective management of the Agency, responsibilities are dispersed across various management levels to ensure proportionality and effective decision-making at the lowest possible level corresponding to the associated risks. To this effect, financial, operational and staff-related delegations have been put in place at the Agency, without prejudice to the Executive Director's power. These delegations are updated as required and to reflect any relevant organisational or staff changes.

The general principles for financial delegation and sub-delegation are set out in the Executive Decision on internal rules on the implementation of the budget of the European Medicines Agency and the Executive Decision on the charter of tasks and responsibilities of the Authorising Officer by delegation. The latter defines the conditions of delegations and sub-delegations, including reporting requirements and controls. The delegations and sub-delegations are linked to an organisational function and as such are issued by default for an unlimited time.

The authorising officer by delegation is required to sign a declaration of assurance, drawn up based on the assessment of the functioning of the management and internal control systems conducted for his/her area of responsibility. The declaration may contain reservations designed to highlight issues or weaknesses in the management and control systems associated with the operations and actions managed by the authorising officer by delegation. The declaration is an instrument of management accountability within the Agency and constitutes the basis on which the authorising officer takes responsibility for the management of resources by reference to the objectives set in the work plan and the efficiency and effectiveness of internal control systems, including an overall assessment of the costs and benefits of controls.

For the list of budget lines delegated by business area and subsequent sub-delegation, see table below:

Summary of the Executive Director's decisions to delegate powers of budget implementation and on financial circuits



2.5. Human resources management

Staffing

During 2025, the Agency recruited 88 statutory members of staff (42 TA and 46 CA).

12 national experts were seconded to the Agency, 62 trainees and 77 new interim assignments provided services to the Agency.

The total number of joiners therefore amounted to 239.

During the same year, 36 statutory staff members (24 TA, 12 CA) and 9 SNEs left the Agency.

49 interim assignments were terminated, and 36 trainees ended their contract in 2025. The total number of leavers was 130.

Turnover for TA and CA was at the rate of 3.90%.

The occupancy rate amongst temporary agent staff was 99.60%.

Human Resources Strategy

During 2025, the HR Strategy portfolio continued to deliver a range of initiatives supporting organisational resilience, talent development, wellbeing and the strengthening of HR as a strategic partner to the business.

Under the ambition of building a sustainable organisation, work progressed on the development of talent reviews and improved strategic resource planning and allocation processes. Pilot activities in A-Division contributed to shaping future approaches to skills mapping, succession planning and data-driven workforce planning.

In the area of talent management, the Agency further consolidated its development ecosystem. Following the successful launch of the first Development Day in 2024, preparations continued for its establishment as a recurring cross-Agency learning event. Development mobility opportunities were also expanded through the exchange and rotation programme, including job shadowing, fellowships and secondments with EU institutions and agencies. In addition, 2025 marked the groundwork for two new inter-institutional development initiatives: the Inter-Institutional Job Shadowing Programme led by EuSA, with EMA among the first five EU agencies to join the initiative as it expanded beyond its initial pilot phase within the European Commission, and the Inter-Institutional Staff Exchange Programme led by the European Commission. Both initiatives are expected to be launched in 2026.

To support an optimised work environment, the managers' community remained a key platform for peer learning and leadership development, with consistently high participation. The Agency also implemented its first Gender Equality Plan in 2025, strengthening compliance with Horizon Europe requirements and reinforcing commitments to diversity and inclusion. The Staff Values Awards continued to promote a culture of recognition aligned with EMA's organisational values.

In line with the ambition to enhance employee wellbeing, the Wellbeing @EMA learning programme engaged a significant proportion of staff and contributed positively to staff engagement results. In parallel, a third-party support service of social & employee assistance (COMPASS) was introduced in 2025 to provide confidential support to staff and their households on social and administrative matters.

Finally, under the ambition of One Agile HR, progress was made in strengthening HR's strategic capability. The portfolio led inter-agency collaboration on HR strategy through the EU Agencies Network (EUAN), including the coordination of the EUAN HR Strategy report and conference. The

portfolio coordinated and developed the first EUAN HR Strategy report providing insights into the state of HR strategies across the network, hosting the first EUAN HR Strategy Conference, which will continue on an annual basis. In total, 20 agencies were involved in the development of the EUAN HR Strategy report. 45 agencies participated in the inaugural EUAN HR Strategy conference, with the 2026 conference due to be hosted by ENISA. Internally, a data management framework was established to support evidence-based decision-making, while the HR process review significantly simplified and standardised HR processes, enabling future automation and efficiency gains.

Overall, these achievements contributed to reinforcing EMA's capacity to attract, develop and support its workforce while enhancing organisational effectiveness and preparedness for future challenges.

Recruitment and selection

In 2025 recruitment and selection saw a steady flow of vacant positions to be filled. Talent Acquisition successfully also conducted selection procedures for some key roles within the Agency, e.g. Head of the Public Health Threats Department, Head of Digital Workspace, Head of Veterinary Surveillance and Regulatory Support Department, Head of Service — Media and Public Relations, Head of Service: Digital Communication, and Head of Service: Stakeholder Engagement. In addition, Talent Acquisition continued to support the Agency with recruitment of Seconded National Experts, Collaborating Experts and Interims.

The focus was also on diversifying the candidate's pool. Talent Acquisition more actively engaged with a recruitment marketing agency, to target those less represented nations, and also performed major revision of the Diversity and Inclusion part of careers website. In addition, Talent Acquisition also increased the accessibility of the website by implementing the accessibility widget for candidates with visual impairments.

In 2025, EMA opened 54 traineeship opportunities, which once again proved highly popular: 4,327 candidates applied, demonstrating the EMA Traineeship Programme's strong reputation and continued appeal among young professionals. The programme provides hands-on experience, real responsibility, and a unique insight into the Agency's work and its role in safeguarding public health across the EU.

Talent Acquisition continued to digitalise its services to make them more efficient for its users. Following implementation of Fieldglass in September 2024, in 2025, the Agency focused on further trainings and improvements of this platform that allows one stop management for interim workforce in the Agency. In Q3 2025, Talent Acquisition also started work on candidate matching app, so that managers as well as HR have higher success rate when searching for candidates who are best qualified for vacant posts. The Talent Acquisition team also worked on the implementation of Employee Central-system that will help manage EMA workforce in a more efficient manner.

Implementing rules adopted

The list of implementing rules adopted in 2025 can be found in Annex 4.

2.6. Strategy for efficiency gains

During 2025, EMA continued the implementation of its strategy to achieve efficiency gains, maintaining the focus on two specific dimensions: a) process improvement and b) digitalisation. In the digitalisation domain the Agency specifically focused on harvesting the potential of AI and explored how AI can be leveraged to increase productivity and efficiency.

Organisational Change Management

Significant effort was put into supporting the fulfilment of the AI Literacy requirements of the AI Act. EMA's Digital Academy developed a bespoke curriculum for staff supported by an engagement campaign to drive EMA staff's AI literacy. This was a collaboration between EMA's Digital Academy, EMA's AI Risk Management Group, IT and Change Management Centre of Expertise.

The 2025 Staff Engagement Survey indicated several pain points relating to making the change load of the organisation more manageable. The Change Management Centre of Expertise performed follow up analysis of these results and contributed to the EMA wide effort lead by EMA's Internal Corporate Relations team to identify clear problem statements and explore countermeasures. One of the early countermeasures was to launch a first change impact map reflecting the density of change initiatives that impact the organisation every quarter. This map will be monitored and its use expanded as needed.

Finally EMA has consistently grown and improved it's change management capability through an active community of change managers, continuous improvement of tools and techniques and exploring new ways to enable teams to adopt change, for example through in house team development workshops.

User experience and User Interface in Digital Services

As part of the digitalisation dimension, in 2025 the European Medicines Agency formally launched the UX Hub and focused on embedding a more consistent, user-centred approach to digital product development. Following its endorsement, the UX Hub Core Team prioritised establishing the necessary governance while advancing its multi-annual goals: promoting a user-focused mindset across EMA, acting as guardian of UX standards and guidance, and supporting teams in increasing UX maturity.

Within a short timeframe, the UX Hub achieved most of its annual objectives, including adopting its terms of reference, strengthening internal UX capabilities, identifying pilot projects, and developing reusable UI components that underpin a centralised EMA Component Library. Initial updates to UX guidance were also delivered and scheduled for further completion in 2026.

These efforts contributed to a tangible improvement in EMA's UX maturity, which advanced from a limited to an emergent level by the end of 2025. Building on this progress, draft objectives for 2026 aim to consolidate and scale the UX Hub's impact through a clear customer experience strategy, expanded guidance and tooling, a formal UX Community of Practice, and stronger evidence of the value and return on investment of UX activities.

AI Implementation

During 2025 a series of workshops with national competent authorities (across human and veterinary domains) was organised to collect AI use cases and explore existing or potential solutions for their implementation. Several AI uses cases were identified, spanning 4 main AI areas:

- drafting and summarization of information,
- validation and quality assurance,

- knowledge mining and retrieving of information,
- and other divers use cases

The first two areas will be supported through a collection of validated and reusable prompts, focusing on AI solutions, allowing harmonisation and standardisation of AI use across the Network. To further strengthen Network-wide expertise in prompting and generative AI practices, it was agreed to establish an EMRN Prompt Community, starting as a pilot, and aiming at enabling the effective delivery and use of AI assistants.

At EU level EMA is chairing the EU Agencies Network Working Group on AI (EUAN WG on AI). It aims to support the Agencies and Joint Undertakings at the EU agencies network on the implementation of AI, fostering knowledge sharing and increasing the AI maturity level to provide guidance and common approaches. In 2025, the annual plenary meeting took place in June at the EMA premises, with participation of thirty-three EU Agencies and Joint Undertakings. The working group shared expertise, showcased agencies Proof of Concepts (PoC) and use cases, discussed topics including AI systems procurement, the EUAN staff exchange programme, AI factories and the development of the AI maturity assessment to inform 2026 priorities. It also contributed to assessing needs related to the EU AI Act implementation and discussed the GPT@EC pilot plans, including survey insights on IT and security, data protection, AI Act compliance and intellectual property considerations.

Other Digitalisation activities

DigiLab/Experimentation runway

- Establishment of the Digital Innovation Lab (DigiLab) and expansion of the Analytics Centre of Excellence (ACE) within EMA, as a set of activities to discover, experiment and develop digital solutions that have the potential to support core business and support functions across the Agency.
- In June 2025 DigiLab has led on the set up of an Experimentation Runway, to bridge experimentation efforts to the Network Portfolio, and foster innovation and transparency of the work of decentralised innovation teams. Within first 6 months: 7 decentralized innovation teams have been onboarded, and the work of 17 prototypes and pilots in the areas of Analytics, AI and Robotics Process Automations have been coordinated
- In Nov 2025, DigiLab also delivered the first successful experimentation to scale up through the Network Portfolio MTA VS, the Early Notification System (ENS). This is a secure and user-friendly portal that supports exchange of safety notifications within the EU Regulatory Network.
- EMA's first virtual reality powered training was launched to raise cybersecurity awareness using innovative and engaging approaches.
- Efficiencies gained through the launch of new automation and Analytical tools from the ACE team across a number of business areas where activities are performed manually, such as;
- the new Certificate Processing System (CPS) which enables the submission, prepayment and generation of medicine certificates faster using a process that is fully digital.
- Name review process: the Phonetic and Orthographic Name Similarity Algorithm (PONSA) is a pilot tool available to EMA and NCAs with potential high value for the Network and Industry that increases consistency, accuracy, and reliability in the similarity screening of reviewing proposed invented names for human medicinal products following the centralized procedure

- PSUR submission process: the European Union reference dates (EURD list) tool for EMA significantly increases operational efficiency, reduces data management challenges by consolidating the list of active substances and submission of periodic safety update reports (PSURs) and provides automated reporting
- Automating financial data processing and repetitive tasks: most notable being the PDF Vendor Invoicing that reduces manual work by automating the processing of 200 invoices and 300 emails per month
- Translation Automation of Annex I (TAXI). Designed to save time and reduce costs, TAXI internal application streamlines the translation process for Annex I referral documents.
- Controlled experiments with AI Technologies including AI Agents were conducted to explore where these technologies could be used at EMA for further efficiency and productivity gains and to support strategic goals.
- Development of Eureka to facilitate Signal detection. It includes comparing new adverse event reports of a medicine (already standardized in MedDRA/VedDRA terminology), against known reactions listed in the Summary of Product Characteristics (SmPC)

Agile Governance

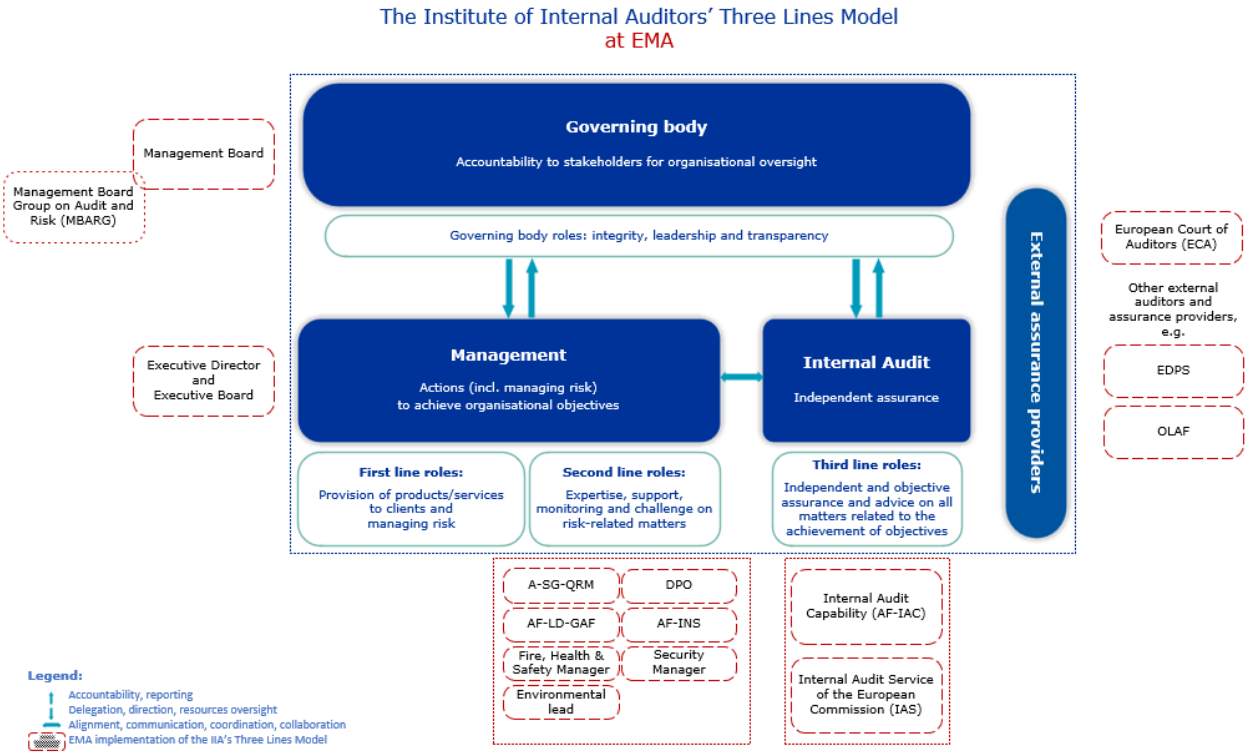
In 2025, the Agency continued to strengthen its Agile way of working. Agile Governance became fully operational, and the relevant governance bodies began preparing for the implementation of the New Pharma Legislation to ensure it is effectively embedded. This led to increased transparency with the Network and Industry, as well as enhanced collaboration among the various governance bodies through Agile ceremonies.

Agile Transformation

In 2025, the Agency continued maturing Agile ways of working within the Network Portfolio, strengthening capability, key roles and iterative delivery practices. Building on this experience, the Agency also assessed organisational readiness, stakeholder needs and opportunities for broader adoption of agile, customer-centric and cross-functional ways of working beyond the Network Portfolio, including through targeted pilots in selected business areas. These activities laid the foundations for a wider organisational transformation focused on user-centric design, adaptability and continuous improvement.

2.7. Assessment of audit and ex-post evaluation results during the reporting year

The European Medicines Agency applies the Three Lines Model developed by the Institute of Internal Auditors. With the aim to achieve organisational goals through effective risk management and accountability, the Three Lines Model separates roles into three lines. The first line refers to operational management, the second to risk and compliance monitoring, while the third line and beyond encompasses independent internal audit and external audit.



Three Lines Model (Copyright by The Institute of Internal Auditors, incl. all rights reserved.) at EMA

Internal audits carried at EMA in 2025 by the Internal Audit Service (IAS)

In accordance with its '2024 – 2026 strategic internal audit plan in EMA', the Internal Audit Service of the European Commission (IAS), supported by the Internal Audit Capability for effective coordination, initiated in 2025 their internal audit of Clinical Trials Information System. This audit is scheduled to be finalised in 2026 when its results will be made available through the final audit report. The implementation of all improvement actions will be monitored quarterly with EMA Management.

Internal audits carried at EMA in 2025 by Internal Audit Capability (AF-IAC)

In accordance with the '*EMA 2025 risk-based audit plan and 2025-2027 strategic audit plan*' approved by the EMA Management Board in December 2024, the Internal Audit Capability (AF-IAC) initiated and carried out in 2025 the following internal audit engagements:

Management of metadata at EMA

The main objective of this engagement, carried out by IAC supported by co-sourced auditors and experts, was to evaluate the design, effectiveness, and efficiency of the management and control

processes implemented for the governance of metadata at the EMA. The audit covered the activities undertaken in 2024. Whilst the audit fieldwork was conducted in 2024, the final audit report together with the improvement action plan were issued in 2025.

The audit engagement team concluded that the design of the internal control systems in place at the Agency for Metadata Management and Governance is adequate but can be further improved to achieve the Agency's intended objectives and issued 1 very important recommendation.

The implementation of all improvement actions is monitored quarterly with EMA Management.

Exchanges of data and information with EMA's international partners

The objectives of this audit were to review the governance, risks and controls in place at EMA to effectively manage exchange of data, documents and information with its international partners. The audit covered the period from 01/01/2024 and 31/03/2025.

The audit engagement team concluded that the internal control system established by the Agency provides limited assurance regarding the adequacy of the information and data exchange system with international partners in achieving its intended purpose and issued in 1 critical and 7 very important recommendations.

The implementation of all improvement actions is monitored quarterly with EMA Management.

Annual environmental audit

Since January 2025, an external verifier certified EMA as compliant with the requirements of the EU Eco-Management and Audit Scheme (EMAS) described in Regulation (EC) 1221/2009. EMAS is a voluntary, premium management tool for organisations to evaluate, report on, and improve their environmental performance. It promotes sustainable practices, requiring legal compliance, employee involvement, and regular environmental reporting.

The Agency's Internal Audit Capability carried out this internal audit in accordance with Article 9 of Regulation (EC) 1221/2009 which states that internal audits are required to be conducted at least on an annual basis, to provide additional assurance and demonstrate to the environmental verifier that EMA is in control of its significant environmental aspects. This internal audit covered the following legal requirements covered in Regulation (EC) 1221/2009:

- A.6.1. Actions to address risks and opportunities
- B.4.: Demonstrate that they have identified, and know the implications to the organisation of all applicable legal requirements relating to the environment.

Because the above requirements cross-referred to the following requirements, the scope of this audit also included:

- A.6.2: Environmental objectives and planning to achieve them
- A.7.: Support
- A.8.: Operation
- A.9.1: Monitoring, measurement, analysis and evaluation

While reviewing these requirements, this internal audit focused on any non-conformity, observation and/or opportunity for improvement for a period covering 01/01/2024 to 28/02/2025.

The audit engagement team concluded that the Environmental Management System is managed effectively since no non-conformity was observed. The auditor concluded however that the maturity of the EMA's Environmental Management System would benefit from implementing 7 opportunities for improvement.

The implementation of all improvement actions is monitored quarterly with EMA Management.

Variations for human medicines

The audit engagement team examined the governance framework, operational management, risk management and internal control mechanisms established at the Agency to ensure the effective management of variation procedures of Type IA, Type IB, Type II for human medicine, in compliance with applicable legal and policy requirements.

This internal audit is to be finalised in 2026 when its results will be made available through the final audit report.

The implementation of all improvement actions will be monitored quarterly with EMA Management.

Management of Periodic Safety Update Reports

The audit engagement team examined the governance, risks and controls in place at the Agency to ensure the effective and most efficient management of Periodic Safety Update Reports, in compliance with applicable legal and policy requirements.

This internal audit is to be finalised in 2026 when its results will be made available through the final audit report. The implementation of all improvement actions will be monitored quarterly with EMA Management.

Overall, relying on the results of the internal audits carried out at EMA in 2025 by IAS, AF-IAC and other assurance providers whose work has been coordinated by AF-IAC, including follow-up activities, quarterly monitoring with EMA senior management and independent analyses, the Head of Internal Audit Capability believes the internal control systems in place at the Agency provide reasonable assurance regarding the achievement of set business objectives.

This opinion is issued with due consideration to the findings (including major recommendations) outlined in the audit engagement reports issued in 2025, for which EMA management has prepared adequate improvement action plans and continuously monitors the implementation.

European Court of Auditors

Non-financial external audits

The European Court of Auditors, supported by IAC for effective coordination, carried out the following non-financial performance audit engagements at EMA in 2025:

Critical shortages of medicines (EU measures were of added value, but structural problems remain) Special report 19/2025: Critical shortages of medicines

The objective of this audit was to assess whether EU measures to ensure medicine availability were effective. ECA audit team examined whether the Commission and EMA had:

1) established and implemented an effective framework to prevent and mitigate critical shortages;

2) identified and addressed the root causes of shortages;

3) addressed market barriers to ensure a functioning single market for medicines.

The auditors concluded that there is not yet an effective framework for critical shortages of medicines. While EMA has provided valuable support to member states, and the Commission has taken initial

steps by proposing legislative changes, efforts to tackle the underlying causes of these shortages remain at an early stage. In addition, fragmentation within the single market continues to hinder the availability of medicines across the EU.

EMA has agreed an improvement action plan to address, where applicable, the recommendations issued by ECA.

Financial audits

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2024[35] on 23 September 2025.

In ECA's opinion the Agency's accounts for the year ended 31 December 2024 are reliable and present fairly, in all material respects, EMA's financial position as at 31 December 2024 and the revenue and payments underlying the accounts are legal and regular in all material respect.

The report includes an emphasis of matter drawing attention to the uncertainty with the lease agreement for the Agency's previous premises in London and one observation on the legality and regularity of payments made by the Agency under certain framework contracts for IT development. These payments were linked to exceptional circumstances, which were duly documented in the Agency's register of exceptions. At the time of writing, no additional payments are expected to be made under these framework contracts.

Observation on the legality and regularity of transactions[36]	
Observation number	**Description**
3.19.9	On 17 November 2020 EMA signed five framework contracts in cascade for IT software development, configuration and maintenance services for an initial amount of €12 million. The ceiling for these contracts was increased three times, up to €26.9 million, i.e. cumulatively by 124%. This contravenes Article 172(3)(a)(iii) of the EU Financial Regulation), which only allows an increase of up to 50%. EMA duly recorded this non-compliance in its register of exceptions, emphasising that the ceiling increases were all linked to exceptional developments, including unforeseen legislative changes related to EMA's public health mandate. In 2024 EMA paid €7.6 million under these contracts, in addition to €13.5 million it had paid by the end of 2023. The two amounts together exceed the maximum permitted increase of the contract ceiling of up to €18 million. Therefore, despite the exceptional circumstances invoked by EMA, we consider €3.1 million of what EMA paid under these contracts in 2024 as irregular.
3.19.10	A similar situation occurred with three other framework contracts in cascade signed on 10 September 2020 for IT software development, implementation and maintenance services for an initial amount of €44 million. The ceiling for these framework contracts was increased twice, up to €78 million, i.e. cumulatively by 77%, although Article 172(3)(a)(iii) of the EU Financial Regulation only allowed an increase of up to €66 million. Also in this case, EMA duly recorded the non-compliance in its register of exceptions, emphasising that the ceiling increases were all linked to exceptional

[35] Annual report on EU agencies for the 2024 financial year
[36] Ibid, page 152

Observation on the legality and regularity of transactions[36]	
	developments, including unforeseen legislative changes related to EMA's public health mandate. By the end of 2024, the cumulative payments under these contracts amounted to €62.3 million. Despite the exceptional circumstances invoked by EMA, we will consider as irregular any future payments under these contracts exceeding €66 million.

2.8. (a) Follow-up of recommendations and action plans for audits and evaluations

In 2025, several assurance providers including: the internal auditor Internal Audit Service of the European Commission (IAS), EMA's Internal Audit Capability (AF-IAC) and European Court of Auditors (non-financial) (ECA), carried out audit engagements at EMA, resulting in issuing 1 critical and 8 very important recommendations.

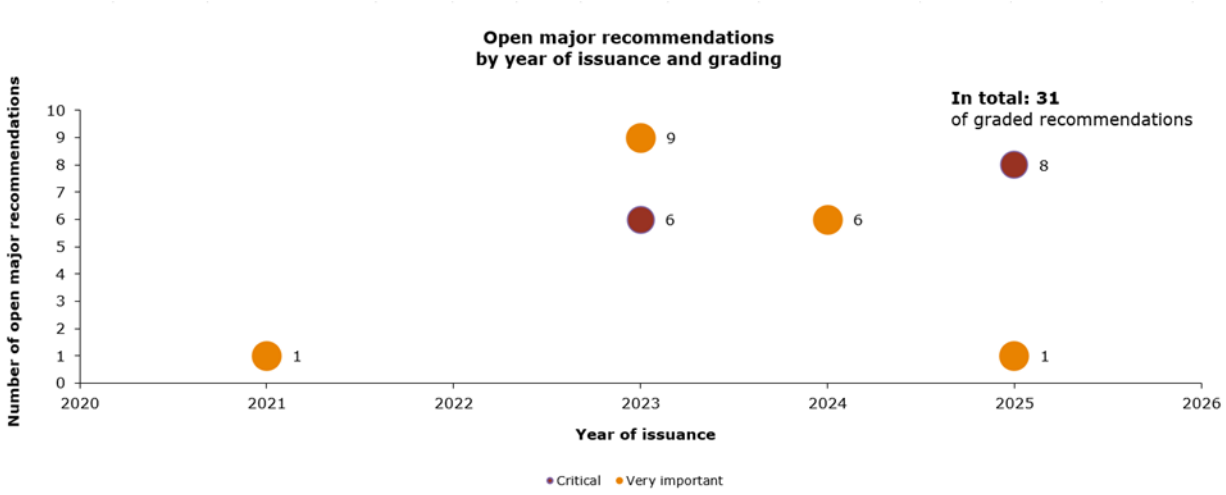
At the end of 2025, AF-IAC holds a record of and monitors with EMA's management the implementation of **31 major (i.e. critical and very important) open** (non-financial) **recommendations**, in addition to two unclassified recommendations issued by ECA in the context of a performance/non-financial audit. The following table breaks down the number of major recommendations issued by various assurance providers:

	Number of major recommendations currently under implementation		
Issued by	**Very important**	**Critical**	**Total**
IAC	23	7	**30**
IAS	1	0	**1**
ECA (non-fin)		*N/A*	***2***[37]

These major recommendations are due to be implemented in accordance with the actions and timelines set by EMA management in the Improvement Actions Plans finalised once the audit reports are completed, closely monitored and revised as necessary thereafter. The table below outlines the implementation status vis-à-vis the established completion dates.

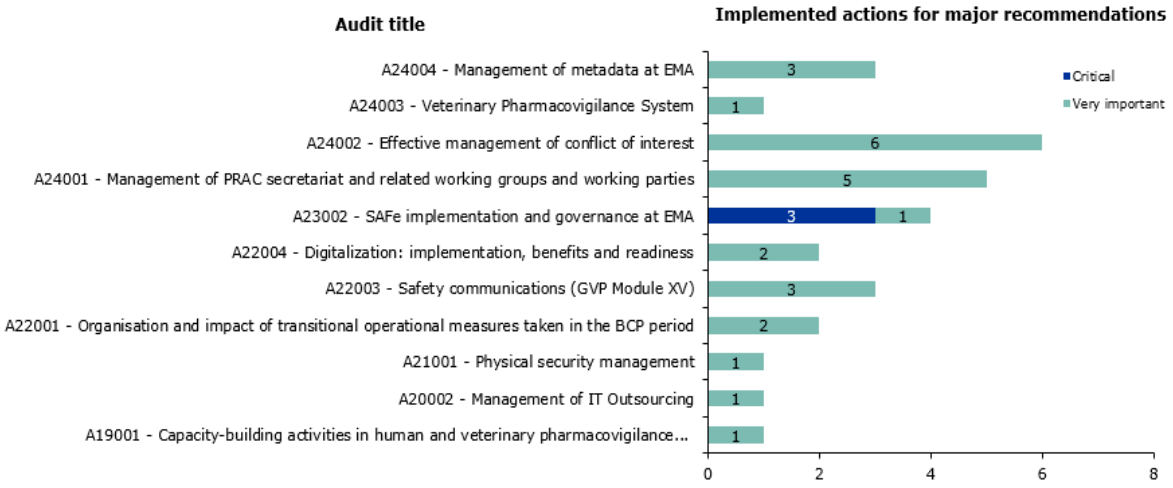
Recommendations implementation ongoing			
Grading	On time	With some delays (deadline extended)	Subtotal
Critical	1	6	*7*
Very important	7	17	*24*
Total	*8*	*23*	*31*

[37] No grading is provided in ECA Special report. The improvement action plan to address the ECA recommendation is pending adoption.



AF-IAC's recommendations implemented in 2025

In 2025, EMA's management implemented in total 61 improvement actions, 29 of which linked to major recommendations issued in the context of internal audits as per the chart below, leading to closure of 15 major recommendations (3 critical and 12 very important), and improvement of the governance, risk management and internal control system across the Agency.



IAS' recommendations implemented in 2025

In liaison with IAS and under close monitoring by AF-IAC, EMA-management continued implementing with some delays and subsequent extension requests, the improvement actions related to the IAS' internal audit on 'Information security management at EMA' finalised in 2025.

European Court of Auditors

Financial audits

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2024 on 23 September 2025[38].

The report includes a follow up of two previous years' observations for which corrective actions have been put in place by the Agency, leading to the closure of both observations.

Follow-up of previous years' observations[39]

Year	Summary of Court's observations	Summary of corrective action taken and other relevant developments	Status of the observation (Open/Closed)
2022	We found that EMA had not assigned clear identification to some of its assets since its relocation to Amsterdam in 2019. We also found some discrepancies between the list of assets donated by the Dutch government, EMA's assets register, and the assets found on the premises.	EMA labelled 11 000 items with a QR code and recorded them in a newly established management inventory database.	Closed
2023	After a data migration to a new corporate system for veterinary inspections (IRIS), EMA did not respect the legal deadlines for 48 veterinary inspections carried out at a cost of €1.3 million, and had issued the corresponding invoices with significant delays. The related revenue was wrongly booked in 2023, instead of 2022. These delays were not reported in the register of exceptions.	EMA revised its procedures, setting a 5-day deadline for validating the receipt of inspection reports and requiring that exceptions be documented when they are identified. We have not come across similar incidents in 2024.	Closed

[38] Annual report on EU agencies for the 2024 financial year
[39] Ibid, page 153

2.9. (b) Follow-up of recommendations issued following investigations by OLAF

OLAF issued one recommendation to the Agency on 24 June 2024 following an investigation opened in 2022.

On 26 May 2025, the Executive Director adopted a disciplinary penalty following the disciplinary proceedings initiated against the staff member concerned, which included the investigation conducted by OLAF and the subsequent reasoned opinion received from the EMA Disciplinary Board.

2.10. Follow-up of observations from the discharge authority

As a follow-up to the discharge decision for 2023, in August 2025 EMA reported on the measures taken in light of the observations made by the Discharge Authority. These measures are described in an annual report prepared by the Executive Director of EMA under Article 268 of the EU Financial Regulation and Article 107(2) of the EMA Financial Regulation. Many of the recommendations made by the European Parliament have been or are being implemented. The Agency is not experiencing any significant delay in the implementation of the observations.

The full report describing the observations made by the Discharge Authority as well as the responses and measures taken by all EU decentralised agencies, including by EMA, is publicly available on the website of the European Parliament. The following paragraphs of the European Parliament's discharge resolution include follow-up actions by EMA: 11, 31, 48, 50, 58, 96, 103, 105, 106, 112, 113, 114, 116, 118, 120, 121, 125, 130, 139, 144, 148, 149, 151, 153, 154.

2.11. Environment management

In January 2025, the Agency became registered to EMAS following the EMAS audit performed in September 2024. Following registration, EMA published its first Environmental Statement on the EMA website in February 2025. To maintain compliance an Internal Environmental Audit was performed in May to June 2025 resulting in seven observations for improvement and confirmed the EMA EMS to be effectively managed. In October a validation of the 2024 Environmental Statement was performed by an external EMAS verifier confirming the EMA EMS compliant with the EMAS regulation The 2024 Environmental Statement was published on 26 January 2026.

During the year a new Environmental Management Roadmap for the period 2025 to 2028 was endorsed by the EMA Executive Board, dated 12 August 2025. The aim of the roadmap is to identify areas where carbon emissions can be reduced, for continuous improvements towards the target of 55% reduction of carbon emissions by 2030, by using 2015 as base year. The focus areas for improvements are calculating the greenhouse gas emissions from direct and indirect activities of occupying the EMA building, duty travel by staff, travel arrangements by delegates and monitoring emissions from commuting and staff teleworking. The Agency will align its approach to carbon removals with that of other EU Institutions and Agencies in line with EU Directives and regulations. Actions include implementation of updated EU guidelines and steering documents with increased focus on the environmental impact, such as for example the new EC Guideline for Missions and Authorised Travel, implemented as of 1 January 2026. Other actions include reviewing the building set-points to implement improvements where suitable and possible, update of rules for reimbursement of delegates and experts to align with the new mission guidelines and increased focus on planning, monitoring and reporting during the year.

2.12. Assessment by Management

Based on the information provided in the previous sub-sections of this report, EMA Executive Director is of the opinion that overall, suitable controls are in place and working as intended, risks and opportunities are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented and that no significant weaknesses that may have a potential impact on the declaration of assurance of the authorising officer were identified.

2. (b) External evaluations

An external evaluation of the EMA's operation is mandated at least every 10 years by Article 86 of the EMA's founding regulation (Regulation EC 726/2004). The latest external evaluation of the EMA was published on 31 August 2021 and is available in the form of a Report from the Commission to the European Parliament and the Council (COM/2021/497 final). The Commission engaged an external contractor to provide a supporting study for this report. The study assessed the extent to which the current marketing-authorisation system for medicines met its objectives in the period 2010-2017, including aspects of effectiveness, efficiency, coherence, relevance and EU added value.

The recommendations of the evaluation report, such as addressing medicine shortages, streamlining regulatory procedures, increasing cooperation between relevant parties along the life cycle of medicines, and ensuring the availability of relevant expertise in the network have been fully taken up in the context of the reform of the EU pharmaceutical legislation, which was proposed by the European Commission in 2023 and provisionally agreed by co-legislators in December 2025 (Council press release). Other recommendations have been included in the subsequent work programmes and strategy documents of the EMA, including the European Medicines Regulatory Network Strategy to 2028.

The new legislation is expected to become applicable late 2028. In the coming years EMA will implement the new legislation by developing guidance for applicants and marketing authorisation holders in cooperation with the EU regulatory network and the European Commission. A dedicated group established by EMA's Management Board will oversee the implementation. More information about the implementation process is available on the Agency's website at: https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation

3. Assessment of the effectiveness of internal control systems

3.1. Effectiveness of internal control systems

The internal control framework is composed of 17 principles structured around five core components: control environment, risk assessment, control activities, information and communication, and monitoring activities. The framework is principle-based, allowing managers the flexibility to tailor controls to their specific operational context while ensuring a robust and consistent internal control approach across the Agency. The overall assessment confirms that the internal control system, its components and principles are in place and functioning reasonably well. The results indicate that the Agency operates from a position of strength, supported by a mature, reliable and well-functioning control environment. This is reflected in effective governance arrangements, a well-embedded risk culture, structured and largely effective control activities, sound information and communication practices, and consistently applied monitoring and assurance mechanisms across the organisation. Within this positive overall picture, the assessment also identified a limited number of areas where further consolidation and refinement would enhance consistency, efficiency and future readiness. Some principles would benefit from minor clarifications, additional documentation or targeted adjustments to improve their effectiveness. These observations do not point to weaknesses in the design or functioning of the internal control framework. Rather, they represent natural next steps in deepening integration, strengthening coherence and aligning processes with the Agency's evolving operational context. Addressing these areas will enable the Agency to sustain its strong control foundations while further enhancing resilience, transparency and long-term effectiveness.

Ex-ante financial control system and register of exceptions

Ex-ante verifications

The day-to-day ex-ante verification is the financial control, based on the subjective evaluation of risks where sound judgment applies. The Agency has decentralised the verification for fee revenue and expenditure, as these are standardised transactions requiring either an operational expertise or specific controls. The aim of the financial ex-ante verification is to assure the Authorising Officer that the budget implementation does respect the budgetary principles, focused on legality and regularity including sound financial management and transparency.

The financial verifying agents, as a general policy, perform checks focusing on medium/high-value commitments, sensitive contracts or complex procurement procedures where higher risks have been identified. Transactions are checked by applying appropriate checklists in line with the EMA's internal control framework, the Financial Regulation and the Charter of the Verifying Officer.

EMA's internal control system also relies on the segregation of duties and the corresponding mapping in the underlying IT system (SAP). Two segregated teams are responsible for initiation and verification.

Comparison between verified and rejected transactions	2023	2024	2025
Number of transactions verified	37,874	31,054	31,319
Number of transactions rejected	422	377	183

Comparison between verified and rejected transactions	2023	2024	2025
Rejections triggered by formal considerations or technical malfunctioning	164 (39%)	129 (34%)	111 (61%)
Rejections triggered by errors in the transaction (incorrect data, insufficient justification)	258 (61%)	248 (66%)	72 (39%)
Overall rejection rate	1.1%	1.2%	0.6%

Register of exceptions

As per the Agency's Internal Control Framework as well as internal procedures, exception and non-compliance reporting is one of the management tools used to draw conclusions about the effectiveness of internal control and/or the changes needed in the internal control system. In 2025 altogether 40 events were registered in total.

Exceptions: 11

Non-compliance events: 29

The exceptions related to marketing authorisation and inspection procedures, procurement, delegate reimbursement, and the staff, fee and financial regulations. The non-compliance events related to budgetary commitments a posteriori, procurement rules and the fee and financial regulations.

An annual report with more details on the exception requests and reported non-compliance events is prepared and submitted to the Executive Director and all Authorising Officers by Delegation, describing the status of the implementation of the mitigating actions stemming from these events.

Ex-post control system

Ex-post controls are part of the management and internal control procedures; they are required under Article 45 of the Financial Regulation. The purpose of ex-post controls is to detect and correct errors and irregularities of operations after they have been authorized. Such controls may be organized on a sample basis according to risk and shall take in account the results of prior controls as well as cost effectiveness and performance considerations.

Agency-wide ex-post controls are conducted once a year on three types of activities:

- Financial non-fee related;
- Financial fee related;
- Non-financial procedures and processes.

Financial, non-fee related

Financial, non-fee related ex-post controls are performed on transactions that did not undergo an ex-ante verification, in line with the Executive Decision on financial circuits as well as the internal guidance on methodology for conducting ex-post controls for financial transactions.

The ex-post control in 2025 was performed on budget lines 1300, 1420, 1601, 3000, 3003, 3020, 3021 and 3032 and led to no major findings. More specifically, across the 1,147 samples drawn, 4

errors were identified on budget lines 3000 and 3003 related to delegate reimbursement. For the remaining budget lines subject to ex-post control, no observations were reported.

Financial, Fee related

Following a calculation of comparative risk, EMA selected Transfer of a Marketing Authorisation, Initial Marketing Authorisation Application, Extension of a Marketing Authorisation (Veterinary) and Annual Fee Pharmacovigilance for the ex-post controls. No errors were identified within the selected samples, resulting in a 0% error rate.

Non-financial procedures and processes

Agency-wide ex-post controls on non-financial areas are conducted once a year on selected procedures and processes. The areas to be subjected to ex-post controls are proposed by the divisions and a delegated group of senior managers decides on the specific ex-post controls to be carried out, based on the risk assessment and the results of previous controls of these proposed areas.

The following areas were assessed in 2025:

- Contract management — SLA with Business Travel Partner;
- Declarations of Interests — Staff Members;
- Declarations of Interests — Members and Experts;
- Validation and Compliance checks for PCO and HCPO eligibility;
- Configuration Management process that operates Configuration Management Database (CMDB);
- Paediatric Procedures;
- Change Management Operating Model;
- Change Management in Network Portfolio.

Conclusion on ex post controls in non-financial areas:

In non-financial areas, several minor findings were observed highlighting the need for improvements in processes and documentation. No major findings were reported demonstrating overall compliance with established procedures.

Annual review of sensitive functions

As in any organisation, certain Agency staff members are required to carry out functions involving a considerable amount of autonomy or executive power, implying a risk that such powers or influence may be misused for personal gain (financial or otherwise). Consequently, the identification and management of such functions, defined as sensitive, form an important part of the EMA internal control system as they aim at preventing fraud and corruption, as well as at protecting the Agency's interests.

In line with the EMA 'Guidance on sensitive functions', a risk assessment to identify the Agency's sensitive functions was carried out in 2025. In total, 48 posts were identified as sensitive in 2025, compared to the number of sensitive functions in 2024 (47).

Advisory Committee on Procurement and Contract (ACPC) and procurement management

The ACPC has been set up as part of the internal control system of the Agency and provides an opinion, in an advisory capacity, on the compliance with the Financial Rules regarding procurements and contracts.

In 2025, the committee was requested to provide an opinion on 6 procurement procedures and expressed 3 favourable opinions, and 3 favourable opinions with recommendations.

Reconciliation of information in financial systems

Most of the Agency's operational systems are interfaced with the SAP system. During 2025, reconciliations for 100% of the data between the product- and procedure-tracking systems and SAP were carried out on a regular basis, including data from IRIS system.

Data protection

EMA processes personal data in accordance with the rules laid down in Regulation (EU) 2018/1725, the European Union Data Protection Regulation (EUDPR) (applicable as of 11 December 2018) and is subject to the supervision of the European Data Protection Supervisor (EDPS). National Competent Authorities in Member States and EMA's other stakeholders in the EEA are subject to Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR).

The Data Protection Officer (DPO) played a central role in consolidating EMA's data protection compliance framework by supporting internal controllers and Data Protection Coordinators (DPCs) and promoting consistent implementation across the Agency. Regular coordination meetings facilitated alignment on priorities, discussion of operational topics, and the timely integration of guidance and recommendations issued by the EDPS and the European Data Protection Board (EDPB).

Clear governance and accountability arrangements for data protection were maintained and further strengthened. In April 2025, the Internal guidance on personal data protection was updated, including topic-specific annexes, addressing key areas such as data protection principles, personal data retention, international data transfers, personal data breach management, and the use of artificial intelligence (AI). In addition, data protection quick guides were published internally to provide staff with practical, easy-to-use reference material. These resources reflect recent regulatory and supervisory guidance and support the consistent application of data protection rules in daily operations.

Oversight and transparency were reinforced through structured reporting. The DPO delivered quarterly updates to the Executive Director and internal controllers and presented the annual data protection report to the EMA Management Board in December 2025, ensuring senior management awareness and accountability.

Staff awareness and operational capacity continued to be strengthened through targeted training. A structured training programme was expanded with specialised modules, primarily for DPCs, as well as tailored sessions for specific divisions and task forces.

Prevention, detection and correction of fraud

EMA is committed to ensuring that its staff, members of committees and all external contractors pursue the highest ethical standards of honesty and integrity in the exercise of their duties. EMA has a 'zero tolerance' approach to fraud.

To improve the life-cycle management of fraud including prevention, detection, investigation and reparation including proportionate and dissuasive sanctions, the Agency adopted its first Anti-Fraud Strategy (AFS) in December 2014. The AFS is accompanied by a 3-year action plan. Both the strategy and the action plan are reviewed and updated every three years. The AFS and action plan address specific risks that have emerged at the Agency's level, as also reflected in the annual fraud risk assessments.

Prevention via communication and awareness-raising activities and training has been the most relevant objective since the adoption of AFS in 2014. New staff members are required to take a mandatory anti-fraud e-learning training that was updated in 2021. New staff members are also required to take a mandatory ethics e-learning training, which includes relevant information on the Agency's code of conduct and conflict of interest.

EMA's Management Board adopted a new AFS in June 2025. The AFS was designed following the methodology adopted by OLAF in May 2024 for Anti-Fraud strategies for decentralised agencies and joint undertakings. Following the identification of the most significant fraud risks in the fraud risk assessment of 2022, the AFS includes activities in its action plan to address them and thus address effectively the residual fraud risk. Among the activities included in the action plan, training and awareness-raising have been significantly scaled up, with mandatory training for all EMA staff to be completed within 18 months; a new methodology for the conduct of general and targeted fraud risk assessments will be adopted, following OLAF's methodology. Furthermore, EMA will continue cooperating with other EU agencies and sharing best practices and knowledge to improve the fight against fraud.

Handling of information from external reporting persons

The Agency's main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. EMA is strongly committed to carry out all of its responsibilities and to adhere to the highest standards of professional and personal integrity. In this regard, receiving and considering information provided by external persons reporting concerns about EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities is essential in safeguarding the public interest and in promoting a culture of public accountability and integrity.

A policy to handle allegations of breaches communicated by any external reporting persons is in place since March 2017, complementing the policy on whistleblowing which applies to the Agency's staff. The goal of the policy is to create an environment where individuals from outside the Agency feel confident to raise their concerns.

This policy outlines EMA's approach to the handling of any reporting by external persons which contain allegations of breaches relevant to EMA's sphere of competence. 'Breaches' are defined as acts or omissions that are unlawful or defeat the object of the purpose of the authorisation, supervision and maintenance of human and veterinary medicinal products and which are within the competence of EMA, i.e., any conduct or omission amounting to a violation of any legal provision governing the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use, or any other EMA activities.

The policy sets out the key principles underlying the handling of the information received from external reporting persons and helps EMA assess these reports and coordinate any further investigation in a structured way, while also protecting the identity of the reporter. The key principles relate to the confidentiality of the information received (including the management and processing of any personal data), the acknowledgement of receipt, the treatment of the information, the interaction (if any) with

the EMA Anti-Fraud Strategy, analysis of the competence, the transfer of information to other authorities and the notification to the external reporting persons. A dedicated inbox has been created for external reporting persons to report breaches to the Agency (reporting@ema.europa.eu).

The standard operating procedure (SOP) on handling information submitted by external reporting persons is effective as of 1 August 2017 and establishes a procedure providing for uniform, structured and confidential handling of information from external reporting persons disclosing allegations of breaches reported to the Agency. The procedure can be divided into six main sub-processes: receipt of information, triage of the information, initial evaluation of the information, assessment of the allegations, closure of the case and information to the external reporting person, and archiving.

Both the Policy and the SOP have been revised in 2022, taking into account the Regulation (EU) No 1725/2018 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, offices and agencies and the Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law.

EMA received 66 (sixty-six) external whistleblowing reports in 2025 and followed up on each of these cases in accordance with the Policy and SOP.

49 (forty-nine) cases have been closed, in 17 (seventeen) cases the assessment is ongoing. For 47 (forty-seven) cases, EMA was not competent on the matter (e.g. manufacturing sites not involved in centrally authorised products, supervision of ongoing clinical trials, medical devices) and handed the case over to the concerned NCAs as applicable. Ten cases were not assessed further as no sufficient information was provided by the reporter.

For the reports in EMA remit, there were 9 (nine) cases concerning manufacturing practice, 5 (five) cases concerning clinical practice, one case concerning pharmacovigilance practice, one case concerning market surveillance, and three cases of procedural breaches.

Management of competing interests

In order to preserve impartiality and objectivity in every aspect of the Agency's work, a number of policies and rules on management of competing interests have been put in place, covering the different groups of people involved in and contributing to the Agency's work.

Management Board

The policy on the handling of competing interests of Management Board members (Policy 0058) was last revised and approved by the Management Board in December 2024 and entered into force on 1 May 2025. The policy had been revised to align with the revised 'Policy 0044' (see further details below) including the introduction of rules to handle interests from Management Board members related to involvement or affiliation in a research organisation. …

EMA requires Management Board members to sign a declaration of interests (DoI) and submit a curriculum vitae (CV) when they join the Management Board. Members have to re-submit these documents at least on an annual basis, or when a change in their interests occurs.

In line with the Policy, EMA ensures that all members have a valid DoI before participation to any Board-related activities, including attendance at meetings and receipt of correspondence.

The Management Board secretariat reviews the DoIs of all meeting participants prior to the meeting. An interest level is assigned to the DoI based on whether the member has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Involvement

in Management Board activities takes into account several factors: the nature of the declared interest, the timeframe of the interest, the type of Management Board activity, the likelihood of impact on the industry, and the action requested from the Management Board member. Where a direct or indirect interest is declared by the Management Board member and creates a competing interest for an agenda item, the individual Management Board member will be restricted from participating and voting, if applicable, regarding that agenda point. Such restrictions are announced for each individual affected with the agenda points indicated at the outset of the meeting and the persons affected and the agenda points restricted are reflected in the meeting minutes.

Declarations of interests of all Management Board members are published on the Agency's website. No breach of trust procedure had to be initiated for a Management Board member in 2025.

The Agency publishes each year an Annual Report on Independence that is submitted to the Management board and which sets out how its policies on completing interests are implemented, monitored and any new activities undertaken during the year.

Scientific committee members and experts

The policy on the handling of competing interests of scientific committees' members and experts (policy 0044) was last revised in December 2024, with effect from 1 May 2025.

This latest revision aimed to align with the findings in the rulings of the Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P.

The main changes were the following:

- Increased and aligned restrictions across roles and groups for experts with a current interest on a product, including exclusion from procedures related to the product concerned and also products in the same declared condition. Experts with an interest as principal investigator and investigator will be subject to the same restrictions.
- Aligned restrictions across roles and groups, including a unified 3-year cooling-off period for past employment in a pharmaceutical company, consultancy / strategic advisory role, and past activity as (principal) investigator. The same rules will apply to experts involved on an ad-hoc basis that apply to Committee members.
- Strengthened handling of competing interests in the medical device industry.
- New rules to handle certain interests in research organisations.
- Clarification on the use of expert witnesses for providing specialist advice on specific issues.

The Agency continues to take a proactive approach to identifying cases where the potential involvement of an expert as a member of a committee, working party, body or other group, or in any other Agency activity in the context of the evaluation, supervision and maintenance of medicinal products for human or veterinary use, procedures regarding medical devices, public health emergencies on medicinal products or medical devices or shortages of medicinal products and medical devices, needs to be restricted or excluded, due to interests in a pharmaceutical company or a medical device company (or the biotechnology sector for CAT members and alternates) and also to certain interests in research organisations.

The Agency requires experts to provide a declaration of interests (DoI) every year, or when a change in their interests occurs, to ensure that they do not have any financial or other interests in the pharmaceutical/medical device industry or in research organisations that could affect their impartiality. The Agency also requires the experts to submit an up-to-date curriculum vitae (CV).

For the handling of DoIs submitted by members and experts of scientific committees' and the Agency's other bodies, a 2-step procedure applies: firstly, an interest level is automatically assigned to the DoI

based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Subsequently the level of participation in the Agency's activities is determined by active screening of the DoI by the Agency's secretariat for each procedure or activity where the relevant expert would be involved.

Involvement of an individual member or expert in the Agency's activities is determined taking into account 3 factors:

- the nature of the declared interests;
- the timeframe during which such interest occurred;
- the type of activity that the expert will be undertaking.

The policy reflects a balanced approach and aims to effectively restrict the involvement of experts with possible competing interests in the Agency's work, while maintaining EMA's ability to access the best available expertise. It includes a number of measures to take into account, including the nature of the declared interest, before determining the length of time for which any restrictions may apply.

A procedural guidance is made available to scientific committees' members and experts on completing the EMA DoI in the Experts Management tool (EMT). This guidance also supports EMA staff in the evaluation of DoIs.

The Agency has a Declaration of Interest/Conflict of Interest community composed of EMA staff members with experience in handling of competing interest, who can provide advice on the evaluation of DoIs of members and experts.

All members proposed for the Agency's scientific committees, ETF, MSSG and MDSSG have their DoI screened before their formal appointment to the committee or body. In cases where the nominating authority appoints a member or alternate to a scientific committee, body or other forum, or an expert for participation in an Agency's activity where the expert has declared interests incompatible with involvement in Agency's activities in accordance with the policy, the Agency would not allow this expert to participate and will inform the nominating authority accordingly. Pre-meeting, meeting, and post-meeting arrangements are applied to ensure application of the policy, and to provide documented evidence. The outcomes of the evaluation of DoIs, and restrictions applicable to meeting participation, are included in the meeting minutes. The meeting minutes of all scientific committees are published on the Agency's website.

DoIs, their interest levels, and the CVs of scientific committees' members and experts, are published on the Agency's external website for transparency purposes. The European experts' list on the Agency's website includes only those experts who have a valid DoI and CV. The Agency removes from the list the experts whose DoI is older than a year, until they submit an updated DoI.

EMA has a breach of trust (BoT) procedure, which sets out how it deals with incorrect or incomplete DoIs by scientific committees and other bodies' members and experts, as well with disclosure of confidential information. The BoT procedure was last revised in December 2025 (EMA/154320/2012 Rev 4) to align it to the latest changes to policy 0044, to bring further clarity in particular between the 'investigation' and actual 'initiation' and conduct of the procedure and on the factors triggering the initiation of the procedure, focusing on cases with apparent intention or gross negligence.

In 2025, the Agency conducted two investigations following information or knowledge of possible omission to declare an interest. In these cases, experts omitted to declare interests that were not compatible with their participation in EMA activities (financial interests and current consultancy for a pharmaceutical company, respectively). Following clarifications and exchanges with the experts concerned, relevant remedial actions were undertaken resulting in the disposal of the interest in one

case and cessation of the expert's participation in EMA activities while the interest remains in the other case. In both cases, the Agency concluded that breach of trust procedures were not warranted as the omissions to declare were not intentional or done through gross negligence.

The Agency immediately restricts scientific committee members, as well as any other experts, from any further involvement in the Agency's activities, from the date they inform the Agency that they intend to take up employment in a pharmaceutical company. In 2025, 1 PRAC member and 1 MWP member informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the Guidance on handling EMA scientific committee, Management Board or other group member's declared intention to engage in occupational activities (EMA/267183/2015 Rev 2), the members were immediately fully restricted from further involvement in any Agency activity. The imminent employment in a company did not constitute a conflict for any of the ongoing assessment procedures. The Guidance has last been updated in November 2025 to align it to the latest changes to policy 0044, to include also Management Board members and to clarify the process steps.

In 2025, 934 new experts registered in the Experts Management Tool and their DoI were checked. An error was noted in 46 DoIs (4.9%). The errors were related to:

- omission by the expert to declare in their DoI their recent employment, consultancy or (principal) investigator interests (in the past 3-year period) for a pharmaceutical or medical device company mentioned in their CV (15);
- omission to declare in their DoI their current affiliation to a research organisation mentioned in their CV as required by the latest version of Policy 0044 (14);
- declaration of an interest which was not required to be declared in accordance with the policy or procedure guidance (10);
- inaccuracies in the completion of the DoI (e.g. incorrect section or dates) (7).

EMA asked the experts to correct their DoI, resulting in a higher or same interest level being assigned to their DoI. This EMA *ex ante*/preventive check of each new expert registering in the EMT is important and is maintained to ensure a low number error on the DoIs of new experts and to ensure that the necessary restrictions will be imposed on the expert.

The Agency publishes each year an Annual Report on Independence that sets out how its policies on independence are implemented, monitored and any new activities undertaken during the year.

Expert panels in the field of medical devices (EXPAMED) Policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices (Expamed document D 4.3)

According to Article 106 and Article 107 of the MDR, expert panel members shall perform their tasks with impartiality and shall not have financial or other interests in the medical device industry which could affect their impartiality. To this effect the European Commission adopted a Policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices (EXPAMED document D4.3).

Interests from members of the expert panels are declared and evaluated by EMA in accordance with this policy: a DoI needs to be completed by all candidates applying to the call for expression of interest for expert panels on medical devices and in vitro diagnostic medical devices. Moreover, a DoI needs to be completed and regularly updated by all advisors appointed as expert panel members. The DoI should be updated without delay if there is a change of interests or new interests declared during the course of the term.

The handling of declared interests is based on a two-step procedure. Following receipt of the DoI an interest level is assigned based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Subsequently, the level of participation in the expert panel activities is determined taking into account the assigned interest level, the task at hand, the envisaged role of the expert as well as the relevant interest and resulting restrictions.

The restrictions applicable in the event that direct or indirect interests are declared, are set out in Annex 1 of the Policy. Some interests result in an exclusion of the expert from any involvement in the expert panel, other interests result in a restricted involved, e.g. no involvement in procedures on the declared medical device or any medical device from the declared company, while membership in the panel is allowed.

Of a total of 186 advisors that were screened as of 31 December 2025, 112 had no interest declared, 23 declared indirect interests and 51 declared direct interests according to the policy.

The DoIs and the CVs of all expert panel members are published on the European Commission's website.

Agency Staff

The Staff Regulations (Article 11, 11a and 13) and in addition, Agency's Code of Conduct extends the requirements for impartiality and the submission of annual declarations of interests to all staff members working at the Agency, including temporary agents, contract agents, seconded national experts, interims, visiting experts, collaborating experts and trainees. Staff must therefore complete a

declaration of interest prior to the start of their contract, at the start of their contract and update their declaration annually. Equally, staff members must update their declaration if their circumstances change. Following the completion of a declaration of interests, and depending on the nature of the declared interests, if any, an interest level (1-3) is assigned to the staff member and/or candidate by the reporting officer evaluating the declaration. Staff members and/or candidates with interest level 2 or 3 are subject to a documented risk-based assessment, which includes mitigating actions, where required, to reduce the risk. The decision is based on:

- the nature of the declared interests;
- the timeframe during which such interest occurred;
- the staff member's specific role and responsibilities.

Staff declarations are available internally in the HR tool and for consultation by external persons upon a justified request. CVs and DoIs of the Executive Director and all EMA managers are published on the Agency's corporate website.

Following the revision of the policy on the handling of competing interests of scientific committee's members and experts (policy 0044) adopted in December 2024, the rules for handling declared interests of staff and candidates before recruitment were revised at the beginning of 2025 to align, where required, to the revision of policy 0044. The revised rules for staff were implemented as of 1 May 2025. The main changes included an update to definitions; a unified cooling-off period of 3 years; the prohibition of financial interests in medical device companies and the introduction of new rules for interests in research organisations.

With regards to selection procedures and procurement, any competing interests must be declared by selection committee members and procurement evaluation committee members, and action taken accordingly.

Staff must request prior authorisation for outside activities during active service, in accordance with the Commission rules on outside activities and assignments of 2018, applicable to the Agency by analogy. In 2025, the Agency received 19 requests for an outside activity during active service. All requests except for one were granted.

Post-employment

Staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. National experts are also required to seek permission, although the period is restricted to the equivalent duration of the secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, based on an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

It is important to note that in accordance with the current rules on outside activities and assignments and on occupational activities after leaving the service, taking up employment at a European Union institution does not trigger the obligation to inform the Agency as working for another EU institution does not lead to leaving the service of the Union for the purpose of applying Article 16 of the Staff Regulations. Therefore, any staff member leaving the European Medicines Agency to take up employment with another EU institution is not required to seek prior authorisation.

In 2025, EMA staff members made a total of 13 applications, which were finalised within the year. These resulted in 1 application not falling within the remit of Article 16 of the Staff Regulations, 8 authorisations without restrictions, and 4 authorisations with restrictions.

Restrictions (that are grade and role related) imposed include a distance clause, whereby the former staff member may not contact individual Agency staff for a certain period of time, e.g. 6 — 24 months.

External consultants and contractors

Competing interests for external consultants and contractors are covered by the standard framework contract provisions (section II.7), specifically:

The contractor shall take all necessary measures to prevent any conflict of interest or professional conflicting interest, i.e. any situation that could compromise the impartial and objective implementation of the contract. Such conflicts of interest or professional conflicting interest could arise, in particular, as a result of family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the contracting authority or any third party related to the subject matter of the contract.

In the event of any such conflict, the contractor must notify the contracting authority in writing as soon as possible of any situation that could constitute a conflict of interest or a professional conflicting interest during the implementation of the contract. The contractor must immediately take action to rectify the situation.

The Agency may do any of the following: verify that the contractor's action is appropriate; require the contractor to take further action within a specified deadline; decide not to award a specific contract to the contractor.

The contractor must pass on all the relevant obligations in writing to its personnel, any natural person with the power to represent it or take decisions on its behalf, third parties involved in the

implementation contract, including subcontractors. The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

Furthermore, in compliance with section II.8 of the standard framework contract (provisions regulating confidentiality), the contractor has the obligation to treat with confidentiality any information or documents, in any format, disclosed in writing or orally, relating to the implementation of the contract and identified as confidential. In particular:

The contractor shall not use confidential information or documents for any purpose other than to perform its obligations under the contract without the prior written agreement of the other party;

The contractor shall ensure the protection of such confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence;

The contractor shall not disclose, directly or indirectly, confidential information or documents to third parties without the prior written agreement of the other party.

3.2. Conclusions of assessment of internal control systems

Detailed assessment of the internal control system is carried out at the beginning of each calendar year, with the results included in the Annual activity report. Based on the assessment of internal controls 2025, the Agency concluded that the internal control systems in place, both in terms of the individual elements, and the system as a whole, are effective overall, with some improvements needed to further enhance the effectiveness of specific elements of the system. Nonetheless, the internal control systems in place are considered to provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

3.3. Statement of the Manager in charge of risk management and internal control

I, the undersigned, Mario Benetti, Head of Quality and Risk Management Service within the European Medicines Agency, in my capacity as Manager in charge of risk management and internal control, declare that in accordance with the European Medicines Agency's Internal Control Framework, I have reported my advice and recommendations on the overall state of internal control in the Agency to the Executive Director.

I hereby certify that the information provided in the present Annual activity report and in its annexes is, to the best of my knowledge, accurate, reliable and complete.

[signature on file]

Amsterdam, 20 May 2026

Head of Quality and Risk Management Service

4. Management assurance

4.1. Review of the element supporting assurance

Taking into account the review of the elements supporting assurance, the Executive Director is of the opinion that the management and control systems in place at the Agency are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

4.1.1. Assurance from the authorising officers by delegation

In accordance with the charter of tasks and responsibilities of authorising officer by delegation, and in support of the Annual activity report, all authorising officers by delegation were asked to confirm their reasonable assurance for their areas of responsibility.

The authorising officers by delegation confirmed their reasonable assurance that, overall, suitable controls have been in place and have been working as intended; identified risks have been appropriately monitored and mitigated, and necessary improvements have been implemented.

4.1.2. Conclusions

Given the review of the elements supporting assurance, the Executive Director confirms that the management and control systems in place at the Agency are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

4.2. Reservations

Based on the assurance provided by the control system results, the Executive Director sees no reason that would justify or require a reservation.

4.2.1. Materiality criteria used

In line with the suggestion of the guidelines on the preparation of the Annual activity report, the Agency used the qualitative and quantitative materiality criteria described below to assess if issues identified merit a reservation.

4.2.2. Qualitative criteria used

The Agency would consider as significant the weaknesses in the internal control system that fall under the following qualitative criteria:

- significant errors detected during the control or supervision exercises;
- significant weakness in one of the control systems;
- situations where the Agency does not have sufficient evidence from internal control systems or audit coverage to be confident of providing the necessary assurance;
- situations where a major issue has been outlined by the European Court of Auditors or the Internal Audit Service of the Commission (critical or very important audit recommendations for underlying weaknesses relevant to the area covered by the declaration of assurance that are not adequately addressed by other internal controls and where the materiality threshold is exceeded); situations revealed through own control work or audits where significant risks remain unmitigated;

- significant reputational risk.

4.2.3. Quantitative criterion used

According to the Commission guideline on preparation of Annual activity reports, the Court of Auditors uses a 2% materiality threshold. The Agency has therefore set the quantitative criterion of materiality at 2% of its total budget, as the Agency's tasks can be considered a policy area. This enables the Agency to apply the materiality criteria to the data and results of various control activities.

5. Declaration of Assurance

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the Court of Auditors on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Agency can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

EMPHASIS OF MATTER

Without calling into question the overall conclusions on assurance, I would like to draw your attention to the following important matter: The issue of the Agency's London premises arose following the United Kingdom's (UK) unilateral decision to leave the European Union. The Agency's premises in the UK were not included in the EU-UK political negotiations on the Withdrawal Agreement. Further to the ruling of the High Court of Justice of England and Wales of February 2019, stating that Brexit is not a cause for frustrating the lease agreement, the Agency sought an alternative solution to mitigate the financial burden on the EU budget by subletting its former office premises to a subtenant from July 2019, under conditions that are consistent with the terms of the head lease. The sublease term lasts until the expiry of EMA's lease in June 2039.

In 2023, the situation regarding EMA's premises in London became increasingly challenging due to global macroeconomic changes, following the pandemic, and changing work habits of the population that had significant negative consequences in the UK office real estate sub-market, i.e. the business of the current Agency's subtenant. The parent company's liquidity situation and macroeconomic factors directly affected the subtenant, who approached EMA to renegotiate the sublease agreement to be able to remain in the premises. The negotiations were concluded in March 2024 enabling the subtenant to remain in the premises, paying the agreed rent, and all other building charges. The revised lease agreement has been approved by the Budgetary Authority in April 2024.

The subtenant has met its contractual obligations with rental payments and service charges covering the period up to 30 June 2026. The EMA's Management Board remains regularly updated on the situation.

It must be noted, however, that since EMA remains a party to the head lease, the Agency remains liable vis-à-vis its landlord in the UK. This long-term liability forces the Agency to continuously divert some of its resources away from its public and animal health remit to manage a commercial property in a third country (an activity not foreseen in the Agency's founding regulation), for which neither the Agency nor the EU have business use. Furthermore, the Agency is liable for the entire remaining amount payable under the contractual obligations of the head lease if the subtenant fails to meet its obligations. Considering that the contractual obligation of the head lease is denominated in Pounds Sterling, currency fluctuations between Pound Sterling and Euro may impact the actual cost of the obligation, with the risk of increasing the financial burden on the Agency. As of 31 December 2025, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by EMA up to the end of the lease term is €328 million.[40]

The EMA Management Board has stressed on numerous occasions the unsustainability of this situation and urged EU institutions to resolve this matter at the highest political level. The persistent volatility of

[40] Corresponding to £ 287 million as the total estimated outstanding rent, associated service charges and landlord insurance to be paid by EMA up to the end of the lease term, converted in Euro at the exchange rate in force on 31 December 2025 (0.8726).

global — and UK — economies, exacerbated by geopolitical and economic tensions, underlines the need for a political resolution of this issue, to allow the Agency to fully focus its resources on the implementation of its recently expanded mandate and on the Union's commitments to public and animal health.

Declaration of assurance

I, the undersigned Emer Cooke, Executive Director of the European Medicines Agency, in my capacity as authorising officer,

- Declare that the information contained in this report gives a true and fair view.
- State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.
- This reasonable assurance is based on my own judgement and on the information at my disposal such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service, the work of the Internal Audit Capability and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.
- Confirm that I am not aware of anything not reported here which could harm the interests of the Agency.

Amsterdam, 22 May 2026

[signature on file]

Emer Cooke

Executive Director

Annexes

Annex 1. Core business statistics

Business statistics can be found in Part 1.

2025 key figures

Human Medicines

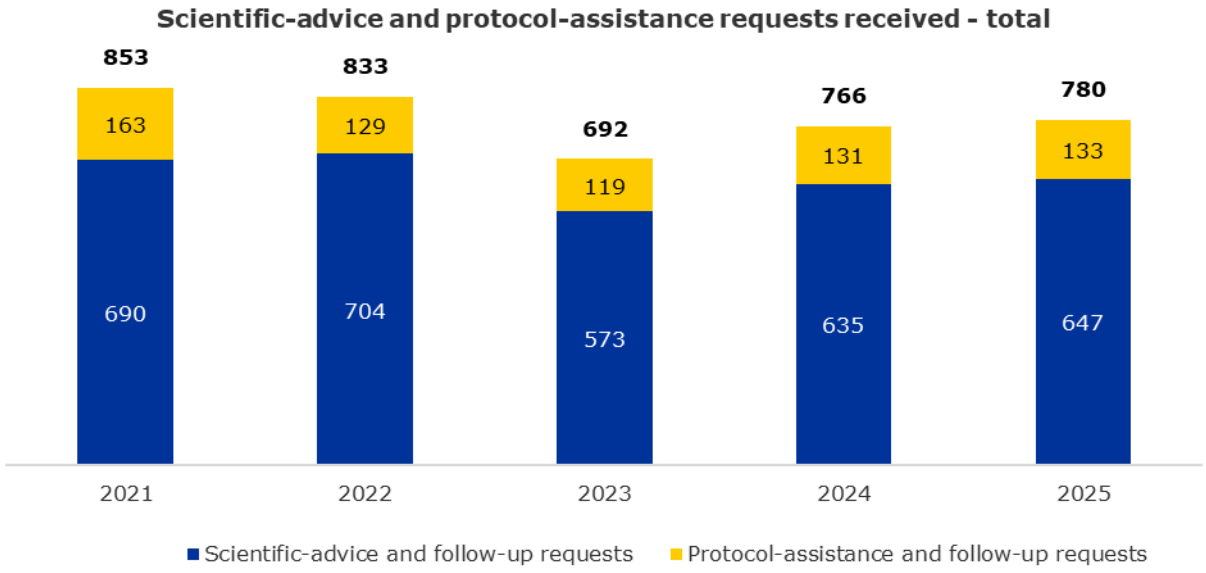
Supporting research and development

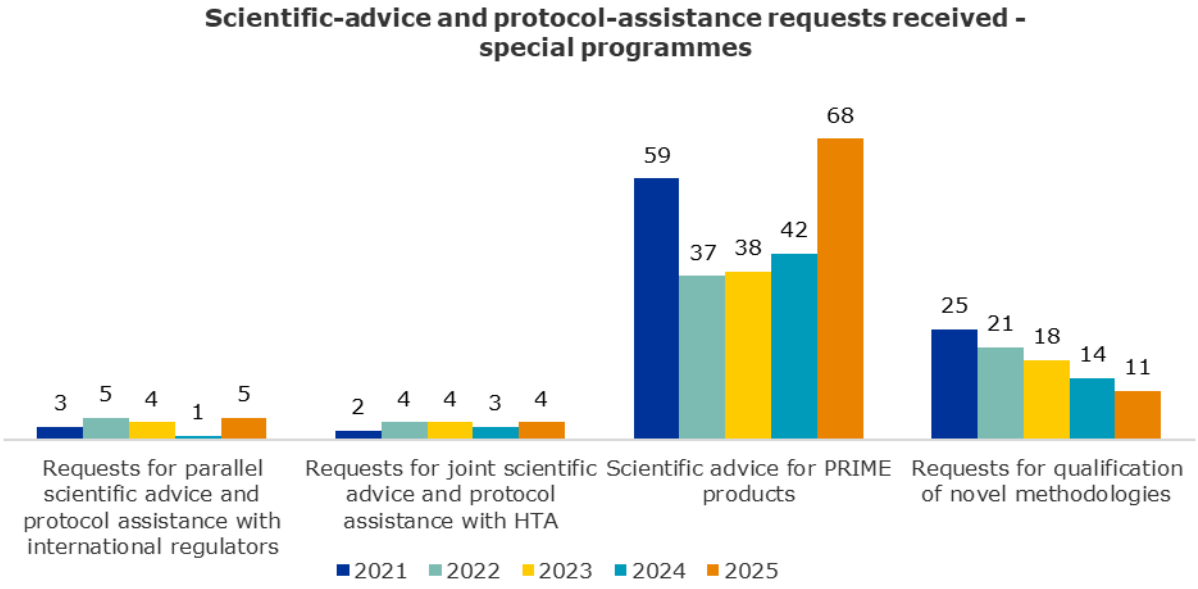
Scientific advice

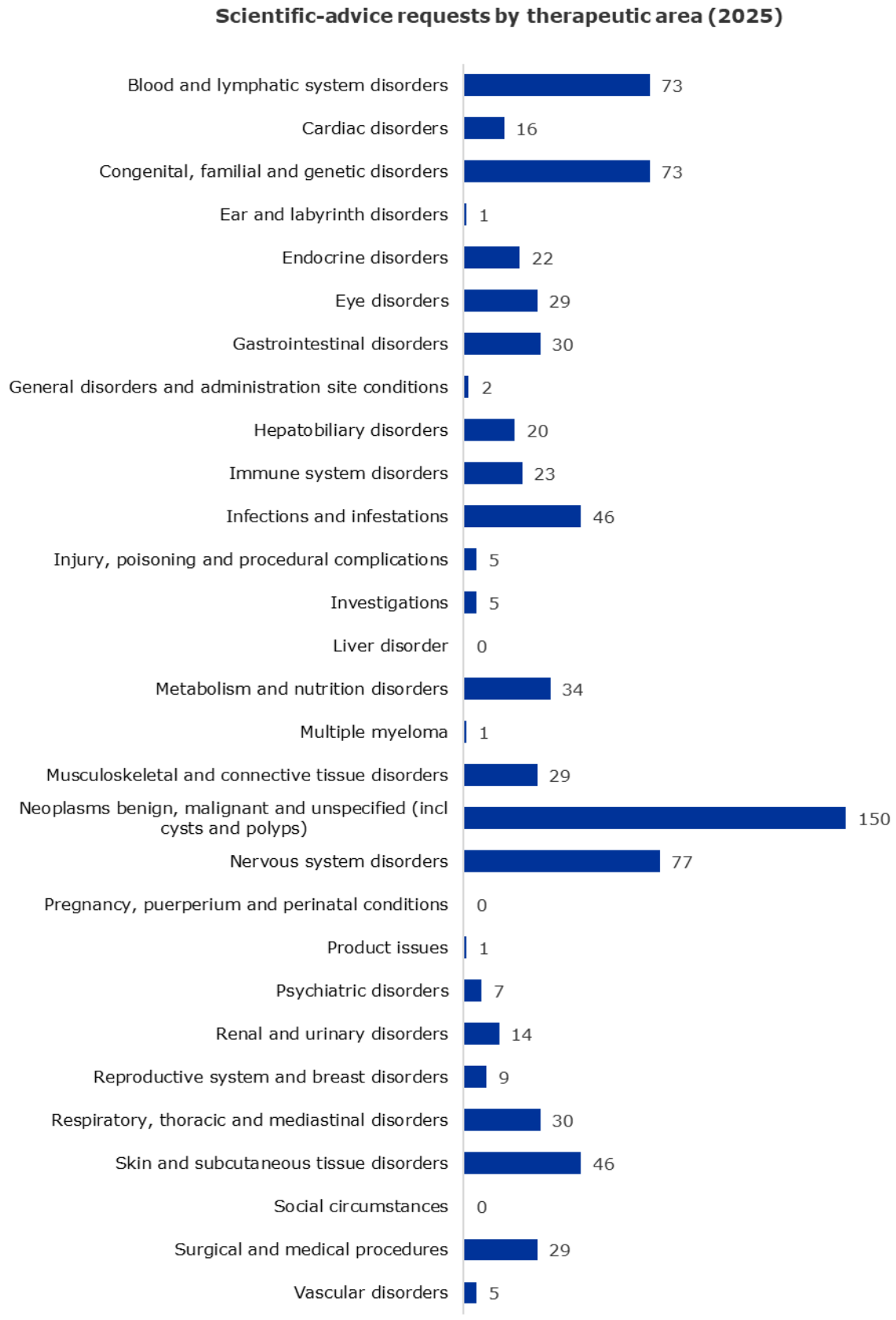
During a medicine's development, a developer can request guidance and direction from EMA on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. This is known as scientific advice.

Scientific advice is one of the Agency's key instruments for supporting the development of high-quality, effective and safe medicines, for the benefit of patients. Early dialogue and scientific advice lead to better development plans, promote the collection of high-quality data and, most importantly, help to ensure that patients only take part in those clinical trials that are likely to be robust enough to generate data that are relevant to support the evaluation of a marketing authorisation application or extension of indication.

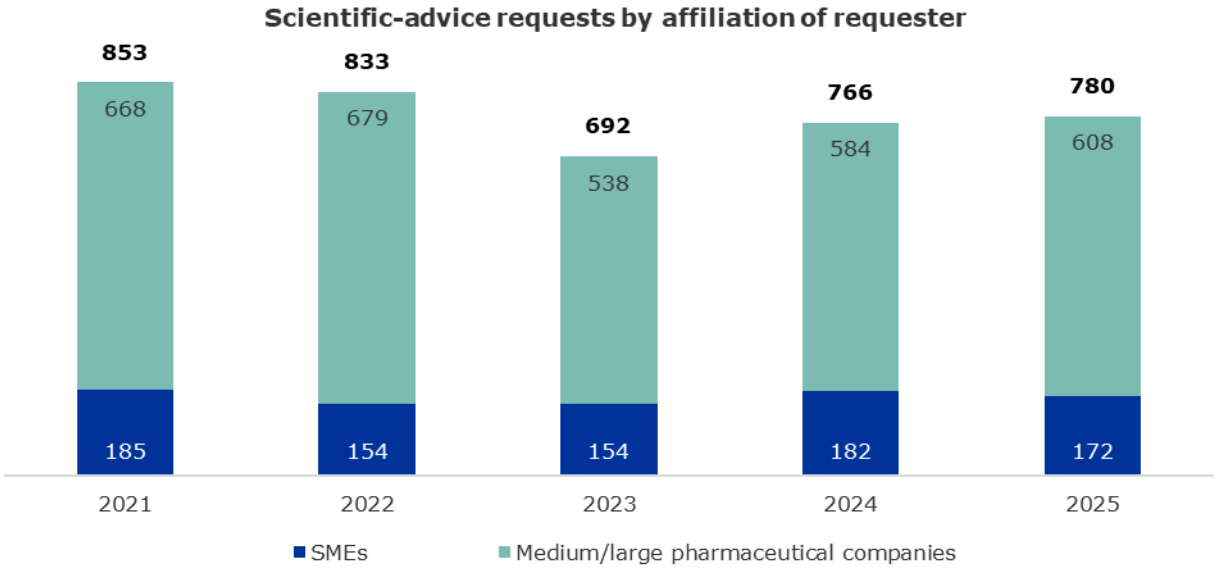
Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases.




Scientific-advice and protocol-assistance requests received - special programmes
3
5
4
1
5
2
4
4
3
4
59
37
38
42
68
25
21
18
14
11
Requests for parallel scientific advice and protocol assistance with international regulators
Requests for joint scientific advice and protocol assistance with HTA
Scientific advice for PRIME products
Requests for qualification of novel methodologies
2021
2022
2023
2024
2025



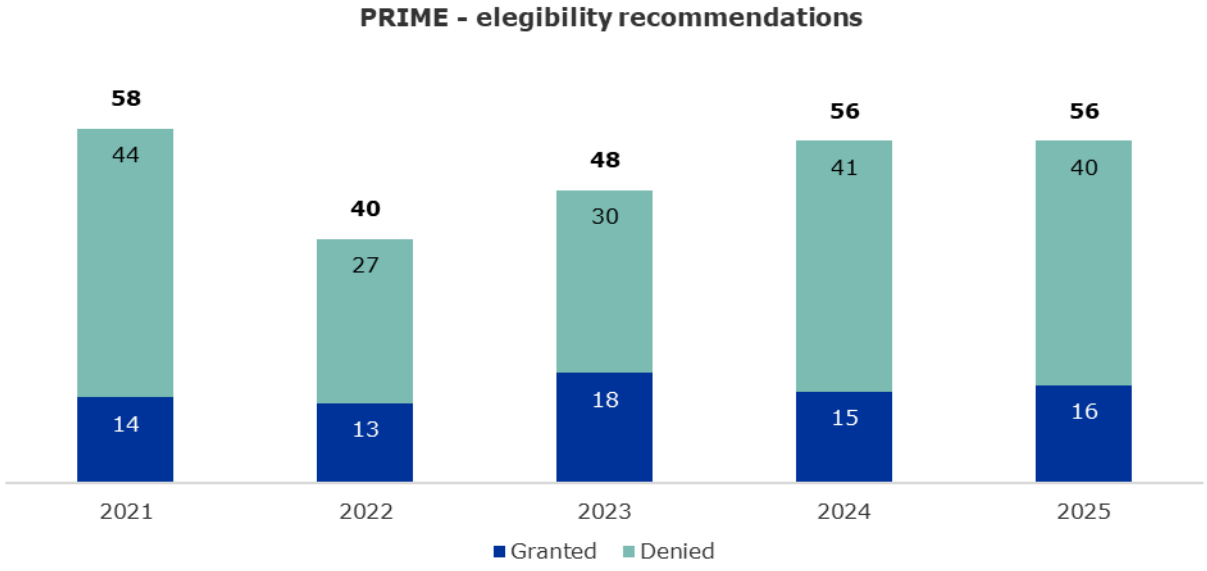
(excludes biomarkers)



PRIority Medicines (PRIME) programme

PRIME aims to support and optimise medicine development so that patients who have no or only unsatisfactory treatments for their disease have access to new medicines that have the potential to make a difference and enable them to live healthier lives.

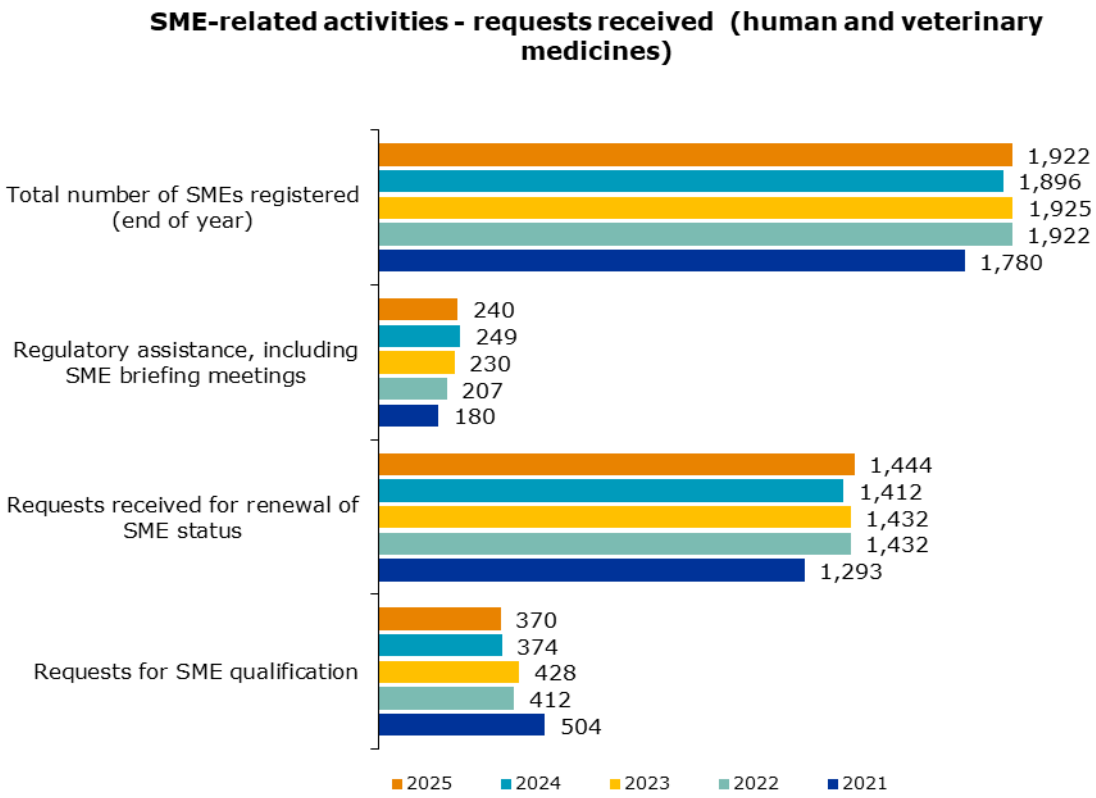
PRIME is meant for the most promising medicines and EMA focuses its attention on medicines that have the potential to bring a major therapeutic advantage. That is why only a limited number of applications are accepted into the scheme.



Support for small and medium-sized enterprises (SMEs)

SMEs are recognised as a driver of innovation in the EU. The Agency promotes innovation and the development of medicines by SMEs through regulatory and administrative support to these companies.

The Agency's SME office provides advice and guidance, organises topical workshops and produces a dedicated newsletter for SMEs registered with EMA. These companies also have access to various fee incentives to enable access to regulatory procedures and advice.



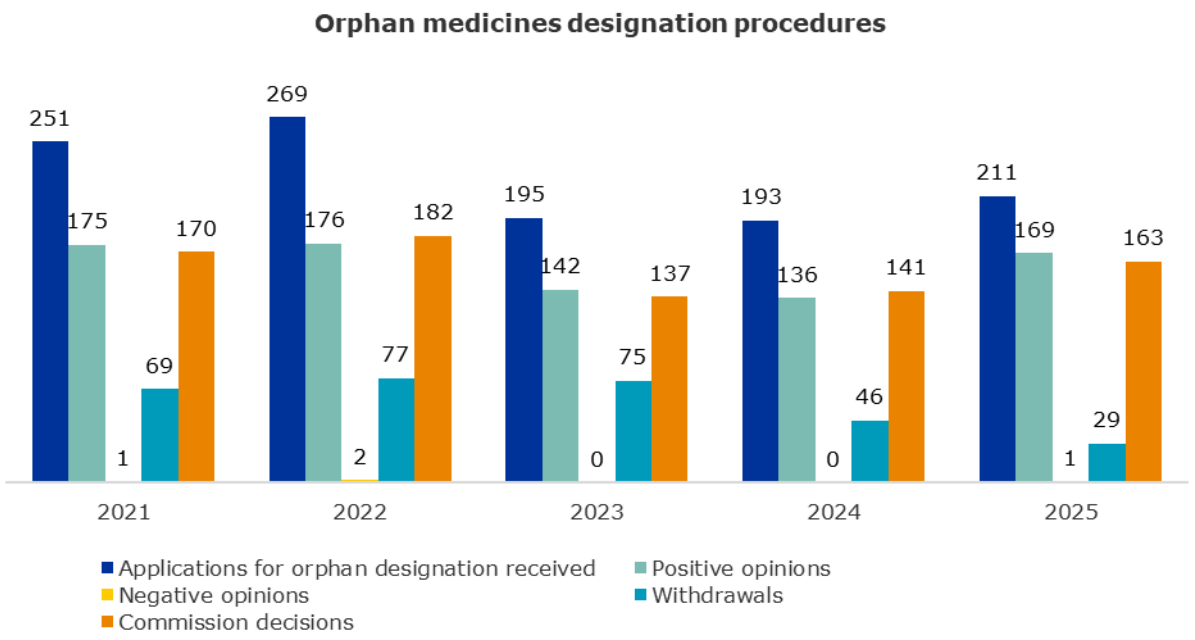
SMEs and initial MAAs (human medicines)					
	2021	**2022**	**2023**	**2024**	**2025**
Initial MAAs submitted by SMEs	10	13	10	10	17
of which orphan medicines MAAs	4	5	4	5	7
Positive opinions	11	5	9	7	7
of which new active substances	8	1	3	2	3
of which orphan medicines	4	2	3	1	3
Negative opinions	0	4	1	1	1
Withdrawals	4	3	2	0	6

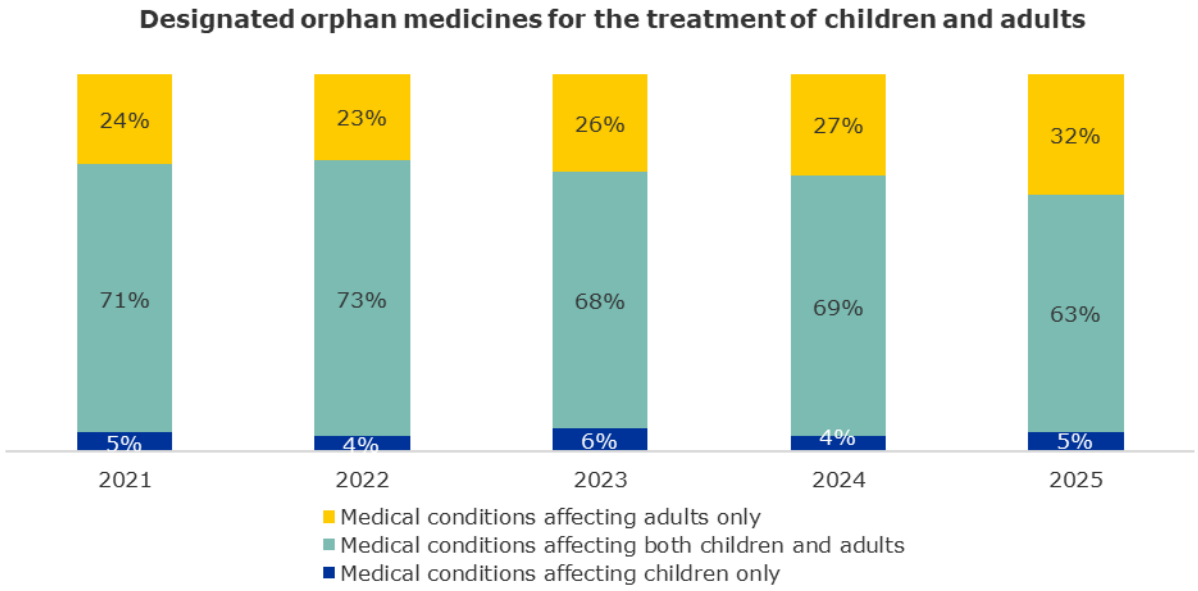
Orphan medicine designation

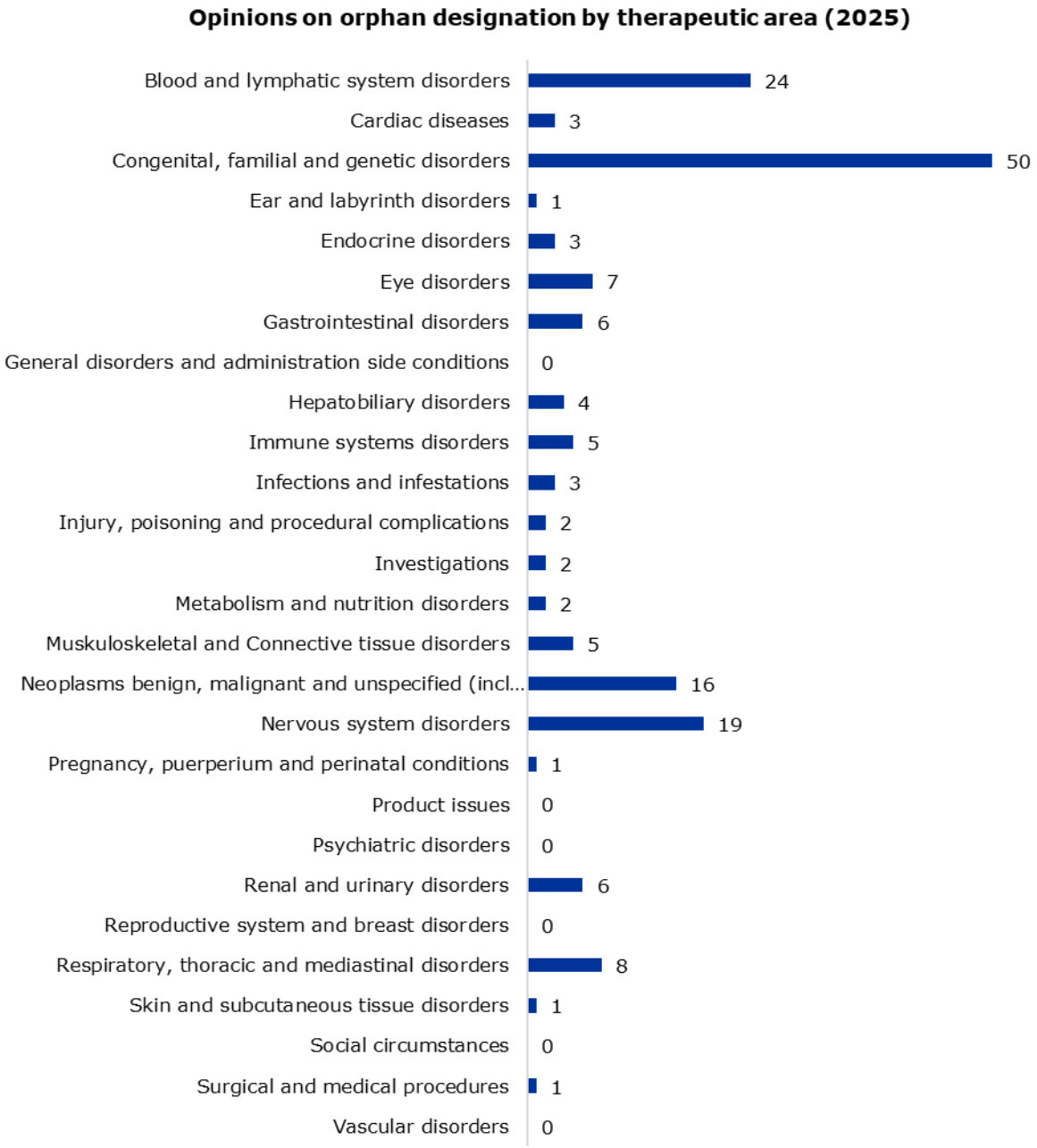
The EU framework for orphan medicines aims to encourage the development and marketing of medicines for patients with rare diseases by providing incentives for developers.

Medicines with an EU orphan designation benefit from ten years of market exclusivity if they are granted a marketing authorisation and continue to fulfil the criteria for orphan designation.

During the development of an orphan medicine, other incentives such as a fee reduction for scientific advice (protocol assistance, see above) are also available for medicine developers. EMA's Committee for Orphan Medicines (COMP) is responsible for assessing orphan designation applications.


Orphan medicines designation procedures
251
175
1
69
170
269
176
2
77
182
195
142
0
75
137
193
136
0
46
141
211
169
1
29
163
2021
2022
2023
2024
2025
Applications for orphan designation received
Positive opinions
Negative opinions
Withdrawals
Commission decisions


Designated orphan medicines for the treatment of children and adults
24%
71%
5%
23%
73%
4%
26%
68%
6%
27%
69%
4%
32%
63%
5%
2021
2022
2023
2024
2025
Medical conditions affecting adults only
Medical conditions affecting both children and adults
Medical conditions affecting children only



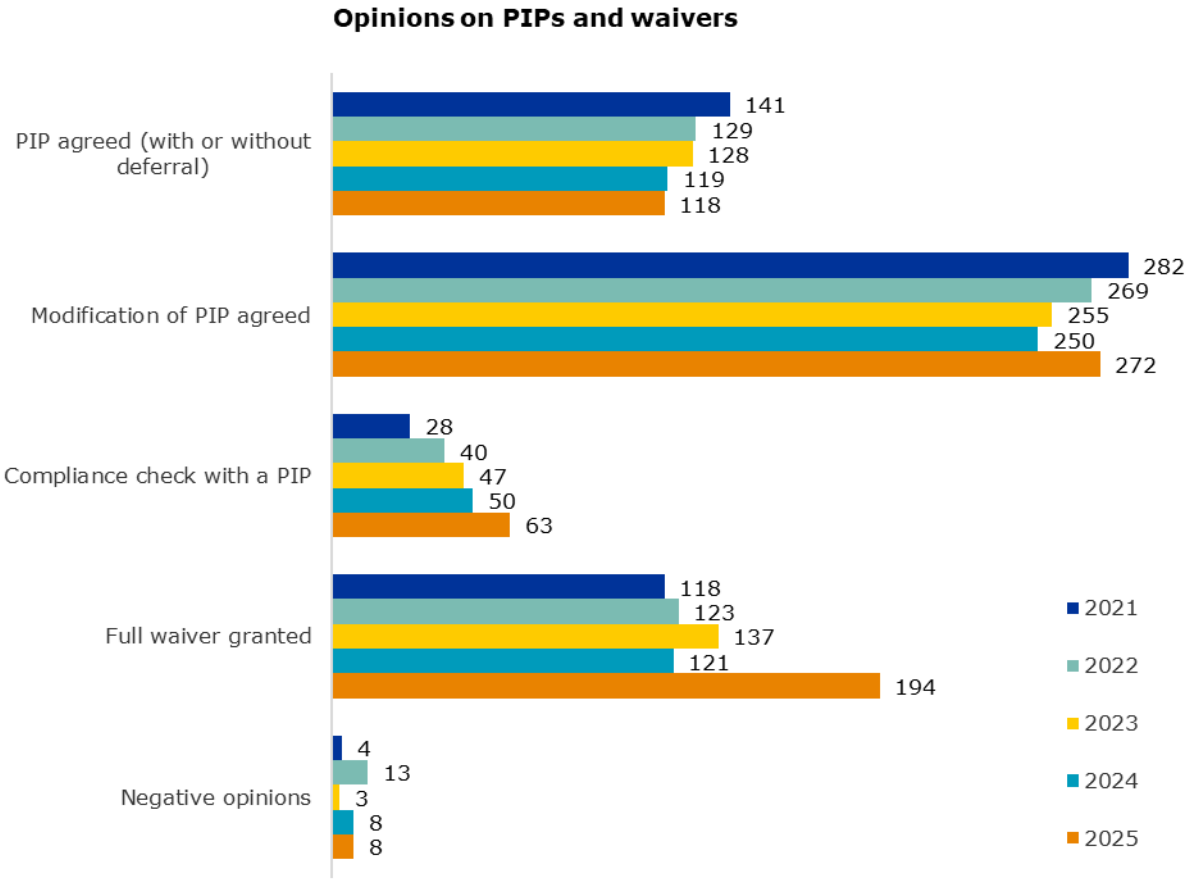
Total 2025: 169

Medicines for children

The Agency also promotes the development of medicines for children. EMA's Paediatric Committee (PDCO) assesses and agrees paediatric investigation plans (PIPs) as well as PIP waivers for medicines that are unlikely to benefit children. The committee also checks compliance with a PIP at the time of the submission of a marketing authorisation. To support research and development of medicines for children, EMA provides the secretariat for the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA).

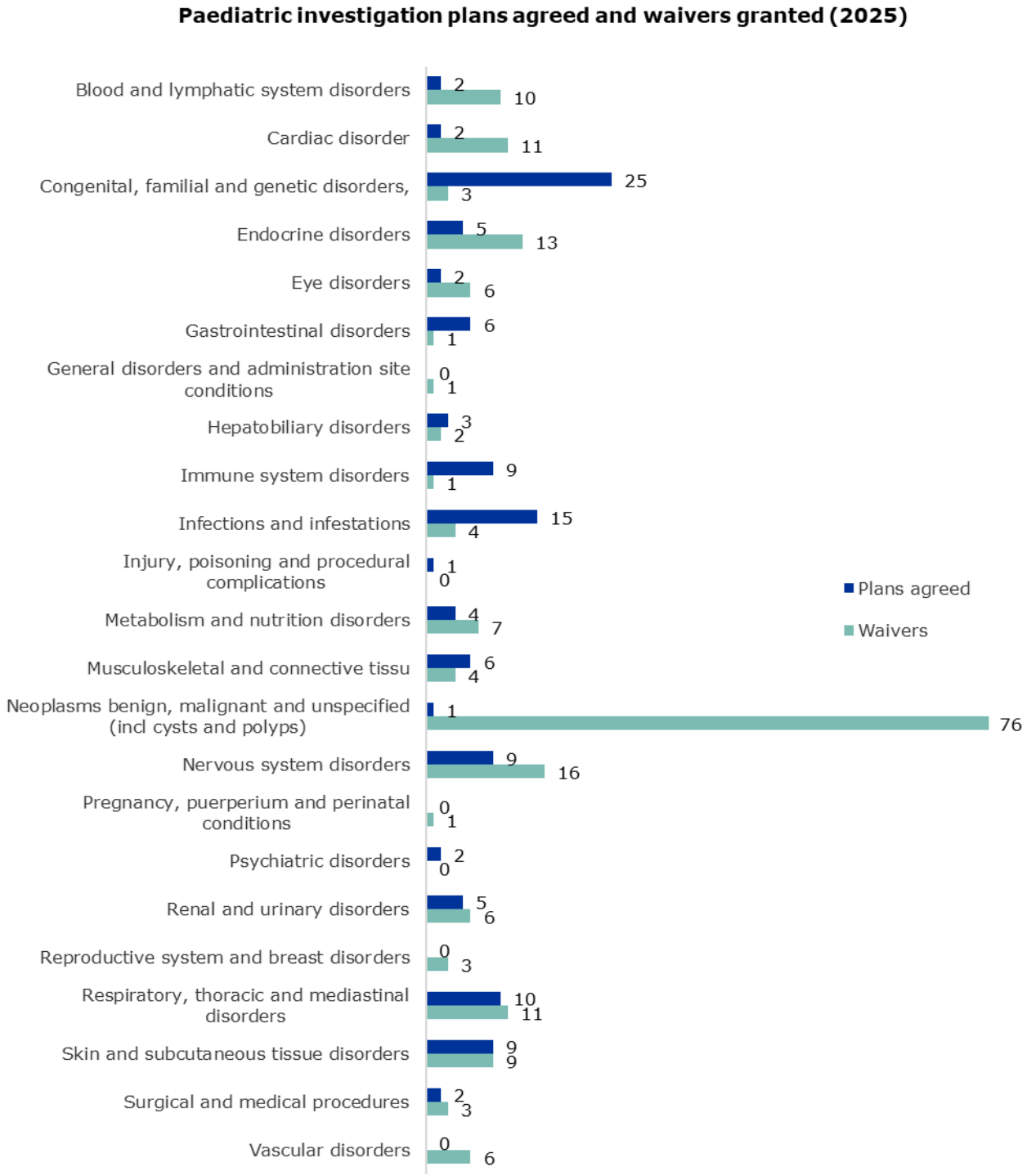
A PIP is a development plan aimed at ensuring that the necessary data are obtained through studies in children to support the authorisation of a medicine for children. Where studies in children are inappropriate or unnecessary, a waiver may be granted.

Drug developers can request a deferral so that some or all studies in a paediatric investigation plan (PIP) can be conducted at a later stage, ensuring that they are scientifically appropriate and do not hinder the approval process in adults. Deferrals are typically granted by the Paediatric Committee (PDCO) when the medicine is first being developed in adults, and studies in children are not immediately feasible or more data from adult studies is needed, before paediatric studies can be conducted in a safe and ethical way.



Total 2025: 655

Article 46 of the Paediatric Regulation requires marketing authorisation holders to submit studies on the use of already authorised medicines in children to regulatory authorities. This ensures that all paediatric studies are assessed by the relevant competent authorities. These studies are available to the public through the EU Clinical Trials Register.



Total 2025: 118 plans agreed, 194 waivers

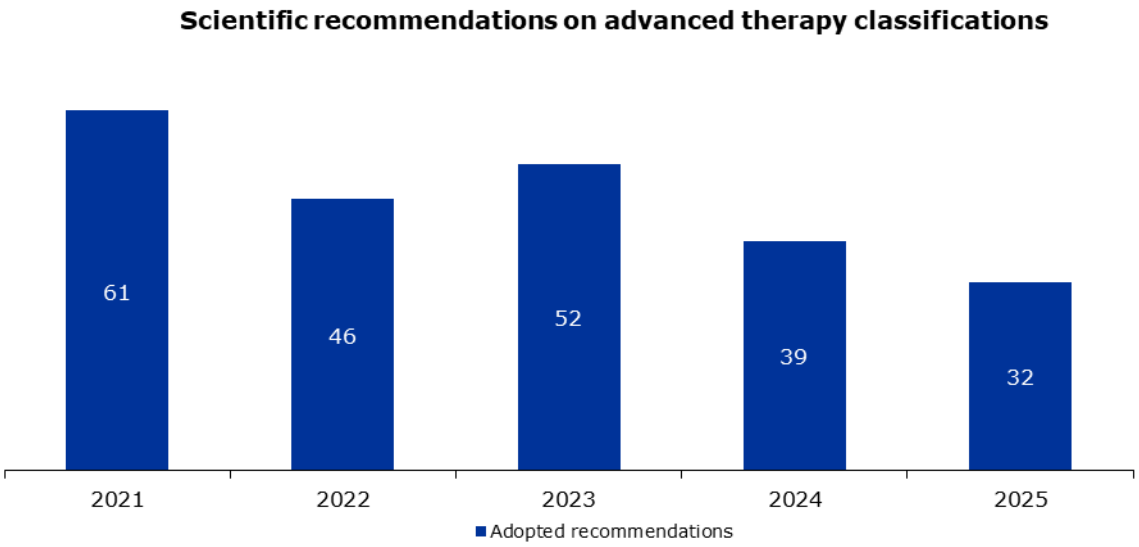
* Graph based on initial PIPs only. One opinion can cover several areas, therefore the total of areas is higher than the number of the opinions adopted.

Advanced-therapy medicinal products

Advanced-therapy medicinal products (ATMPs) are medicines based on genes, cells and tissue-engineered products. that have the potential for ground-breaking new treatments. They are particularly

important for severe, untreatable or chronic diseases for which conventional approaches have proven to be inadequate.

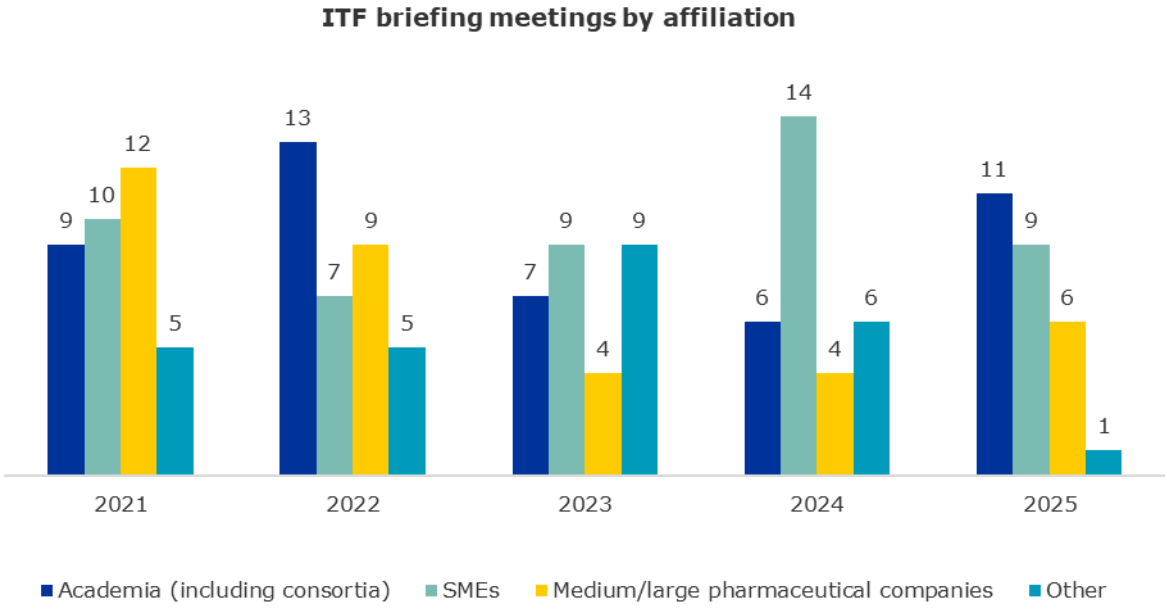
The Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety and efficacy of ATMPs. It prepares a draft opinion on each ATMP application before the CHMP adopts a final opinion for the medicine concerned. The CAT also reviews requests for the certification of quality and non-clinical data for SMEs developing ATMPs and provides scientific recommendations on the classification of a medicine as an ATMP.



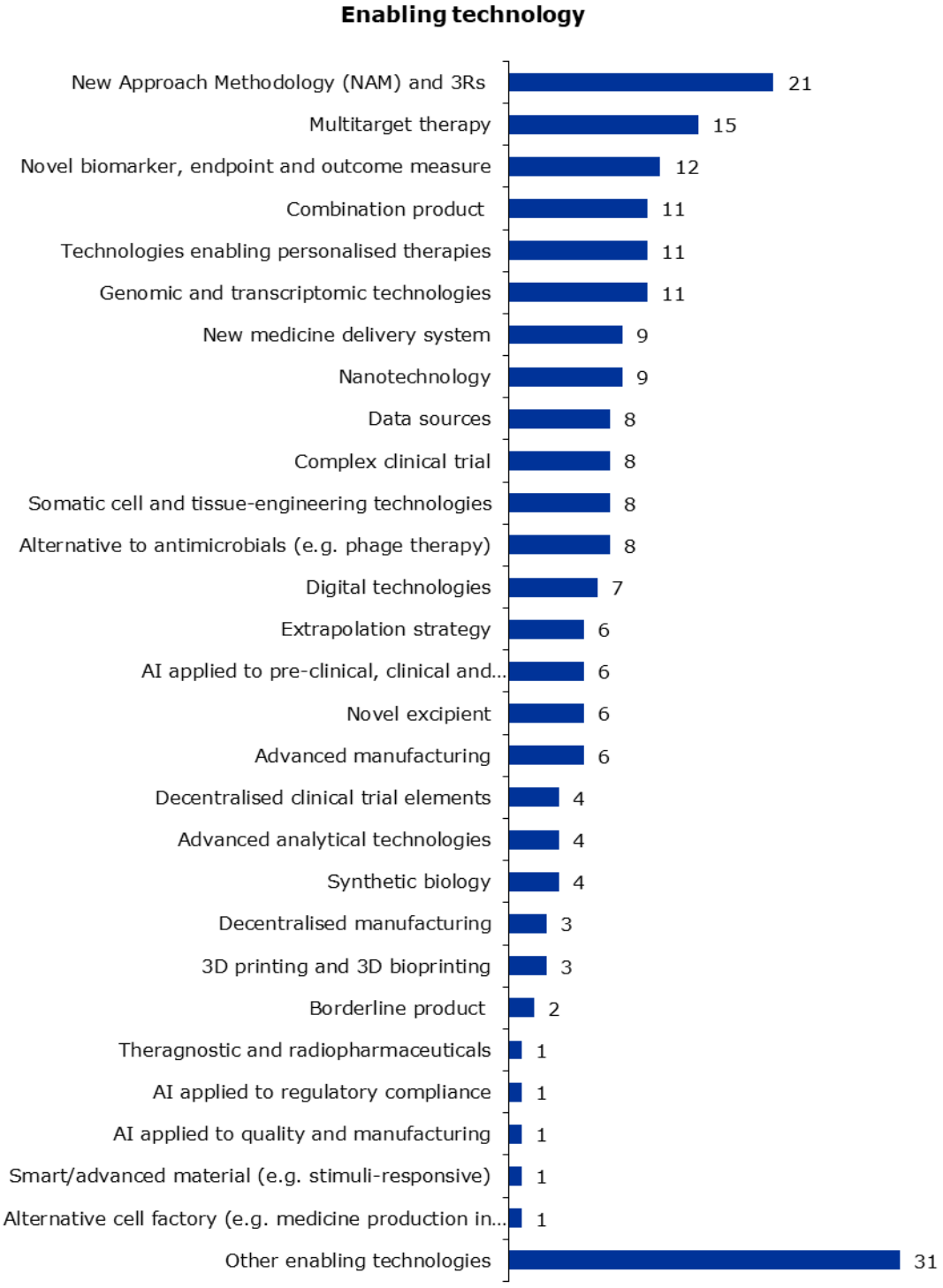
Innovation Task Force

The Innovation Task Force (ITF) is a multidisciplinary group that includes scientific, regulatory and legal competences. It provides a forum for early dialogue with applicants, in particular SMEs and academic sponsors, to proactively identify scientific, legal and regulatory issues linked to innovative

therapies and technologies.



Each request could be associated with up to three of the categories in the table:

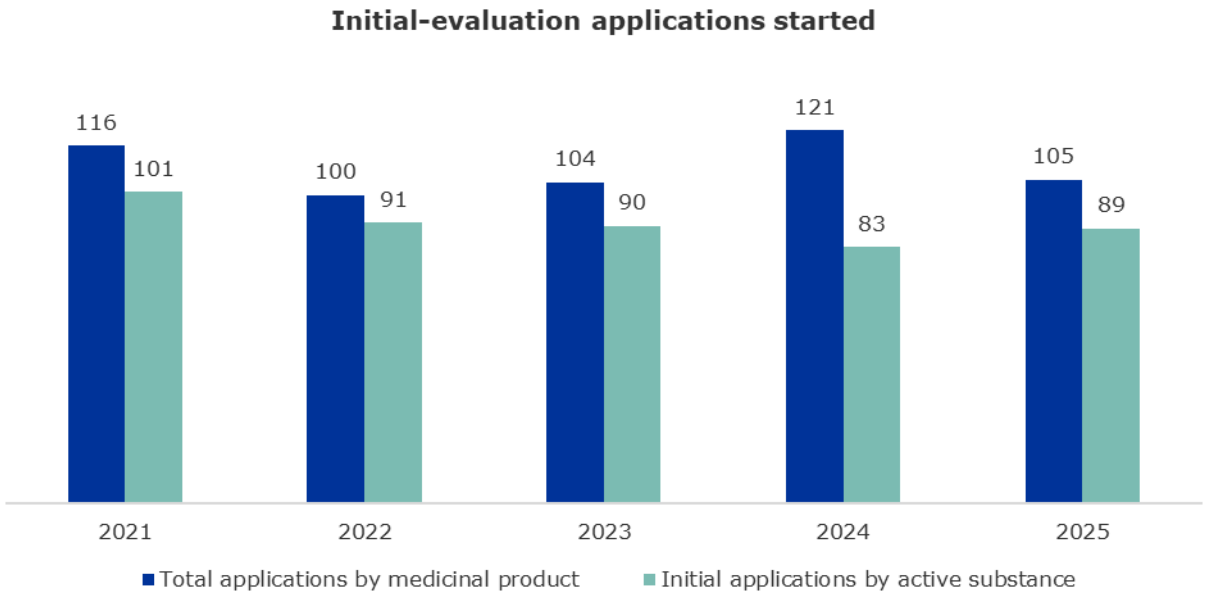


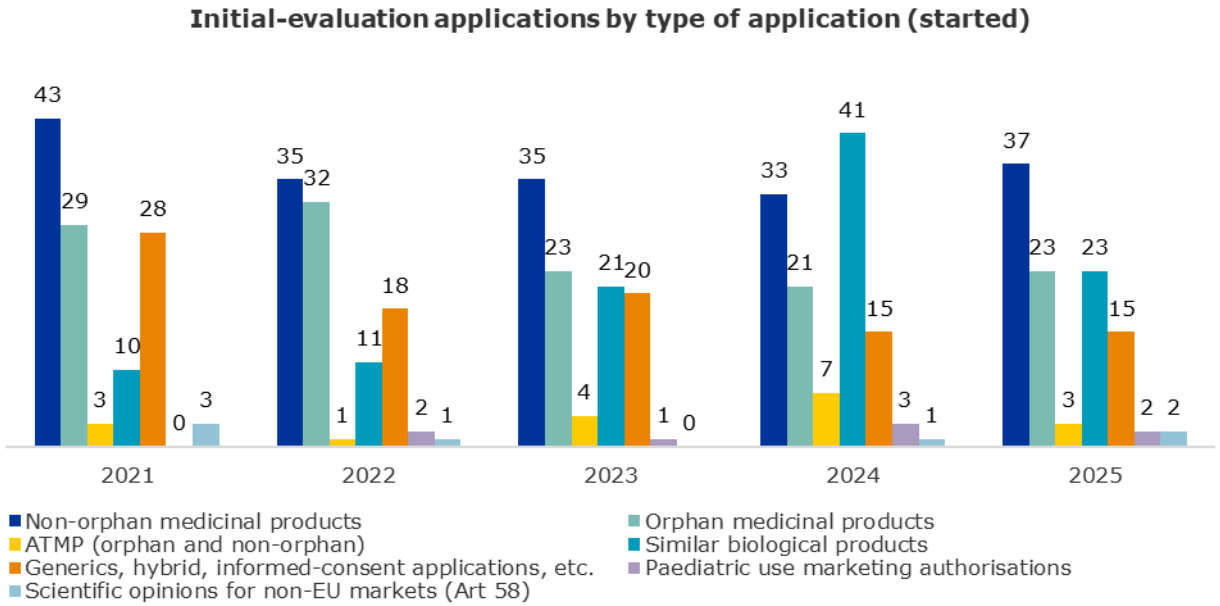
Recommendations for marketing authorisation

Applications for initial evaluation

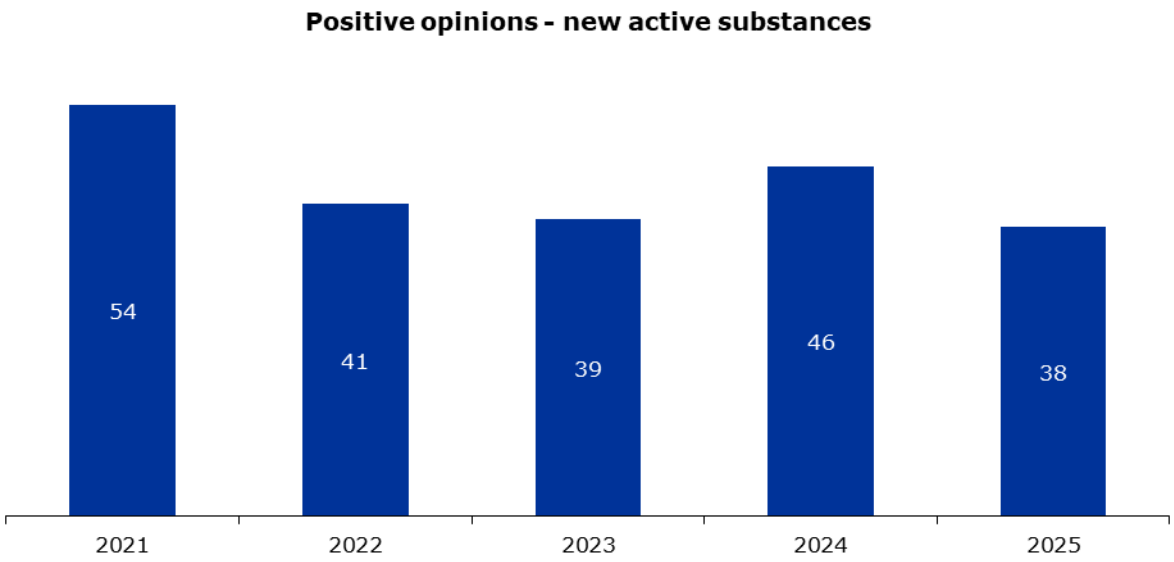
EMA's committee for human medicines, the CHMP, carries out robust scientific evaluations of medicines and issues recommendations for the European Commission, which ultimately decides whether or not to authorise a medicine for marketing throughout the EU.

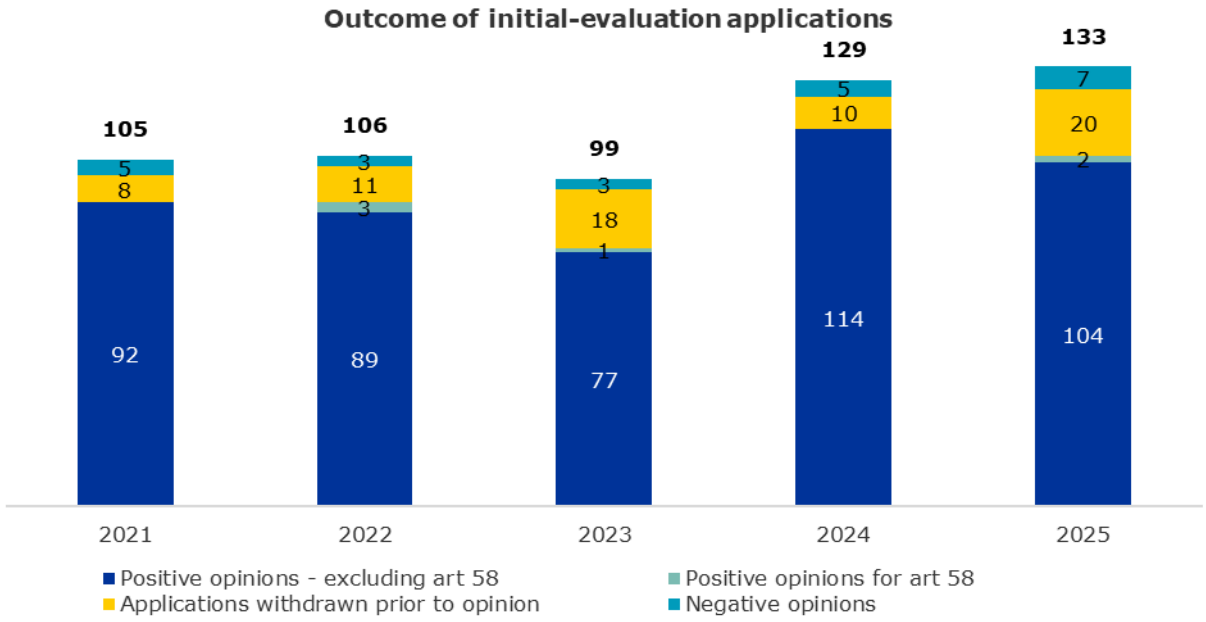
Activities in the initial evaluation phase of human medicines range from pre-submission discussion with future applicants, through the evaluation by the CHMP to the granting of marketing authorisation by the European Commission.





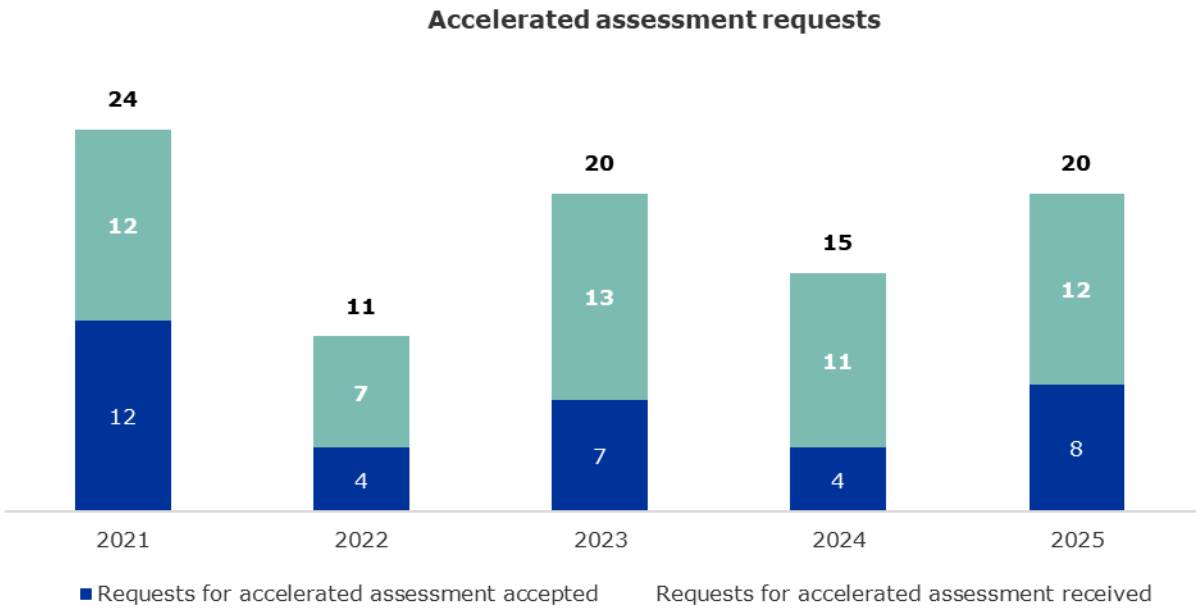
Outcome of initial evaluation





Accelerated assessment

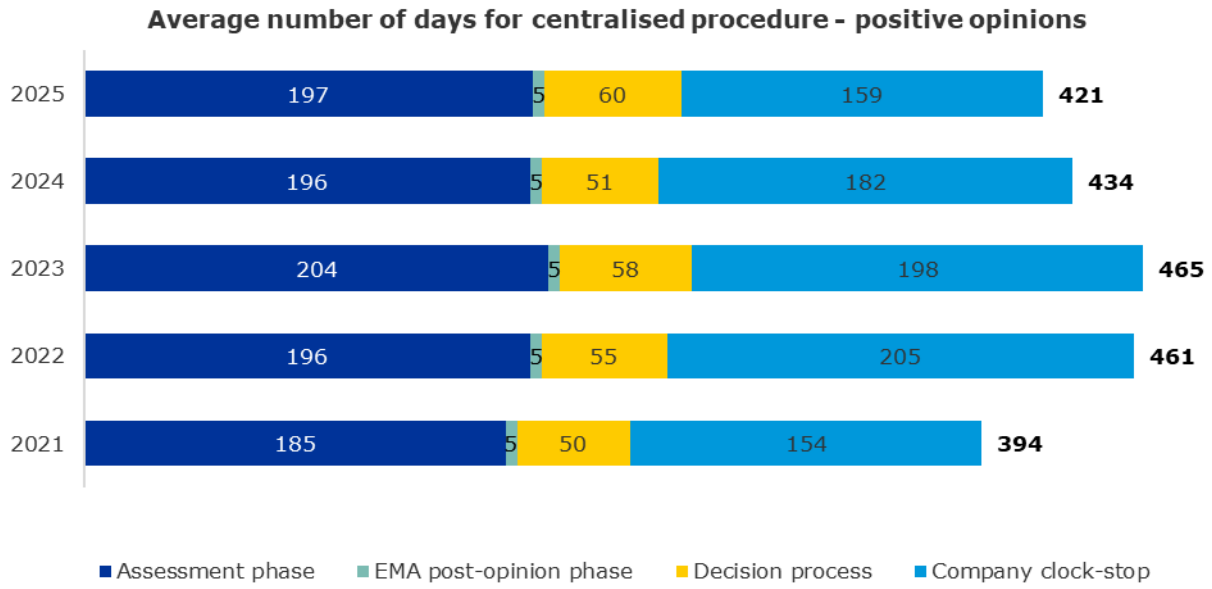
This mechanism is reserved for medicines that can address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees.



Average assessment time

EMA has a maximum of 210 active days[41] to carry out its assessment. Within this time frame, the CHMP must issue a scientific opinion on whether the medicine under evaluation should be authorised. During the assessment, questions or concerns with the application may be raised, requiring further information or clarification from the company. In this case, the clock is stopped to give the company time to reply to the Agency. Once the reply is received, active assessment timetable resumes.

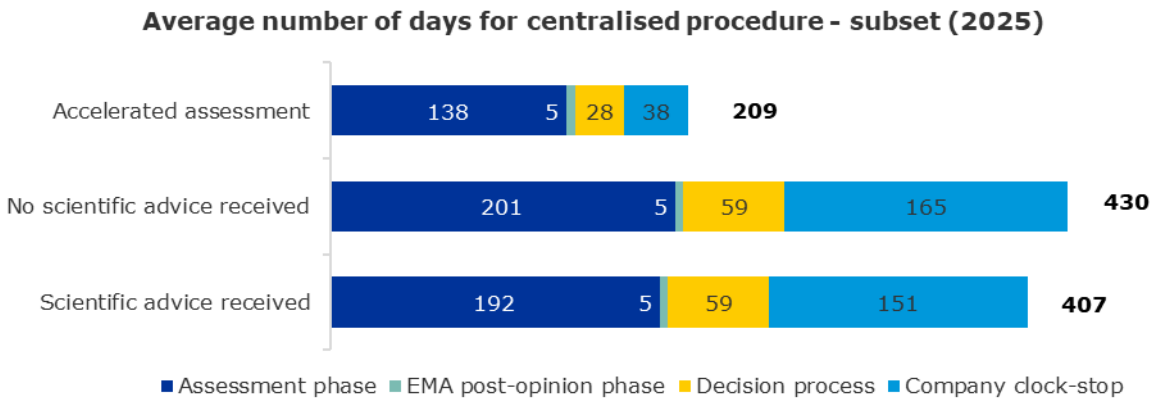
Once issued, the CHMP opinion is transmitted to the European Commission, which has the ultimate authority to grant a marketing authorisation and will take a decision within 67 days of receipt of the CHMP opinion.



[41] This active evaluation time is the time spent by EMA experts to evaluate the evidence provided by the applicant in support of a marketing authorisation application.

Note: The average time for the decision process includes, in the case of orphan medicinal products, the time for the finalisation of the review of orphan designations carried out by EMA's COMP.

The statistics of 2025 include two approved products, for which a long clock stop was agreed before the CHMP systematically started scrutinising the clock stop durations (September 2024 onwards, GIREX project). Without these applications, the average clock-stop time for 2025 would have been 147 days.



Post-authorisation activities

In 2025, EMA started the evaluation of:

- 3,831 type-IA variations;
- 3,490 type IB variations;
- 1,284 type-II variations;
- 35 extensions of marketing authorisations.

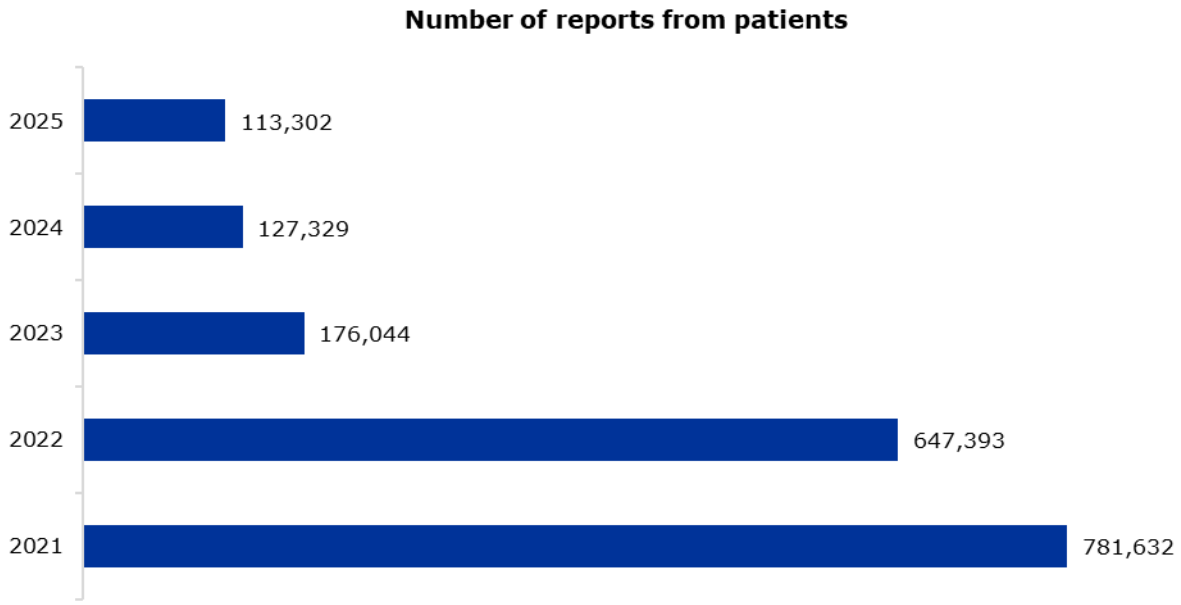
Safety monitoring of medicines

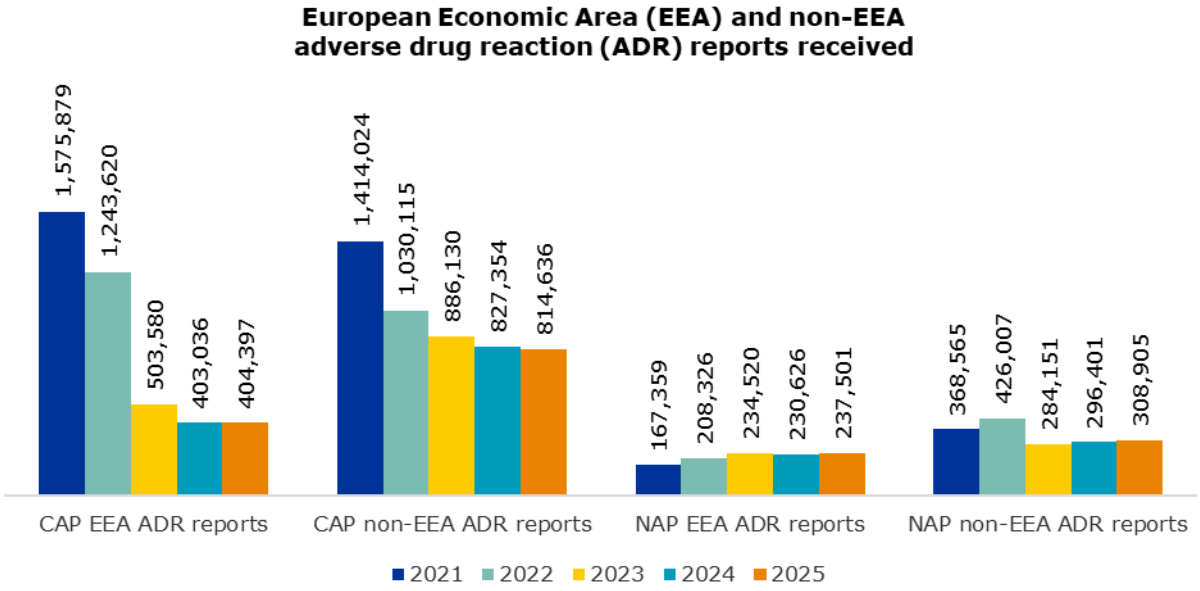
EMA and EU Member States are responsible for coordinating the EU's safety monitoring of medicines, also known as pharmacovigilance. Regulatory authorities constantly monitor the safety of medicines and can take action if there is plausible evidence that a medicine's safety profile or benefit-risk balance has changed since it was authorised. EMA's safety committee, the PRAC, plays a key role in overseeing the safety of medicines in the EU, covering all aspects of safety monitoring and risk management.

The Agency's main responsibilities in relation to the safety-monitoring of medicines include coordination of the European pharmacovigilance system, setting standards and guidelines for pharmacovigilance, provision of information on the safe and effective use of medicines, detecting new safety issues for centrally authorised products (CAPs), managing assessment procedures, e.g. for periodic safety update reports (PSURs), and the operation and maintenance of the EudraVigilance system.

EudraVigilance

Both EMA and the NCAs are legally required to continuously monitor the adverse drug reaction (ADR) data reported to EudraVigilance to determine whether new or changed risks have been identified and whether these risks have an impact on a medicine's overall benefit-risk balance.





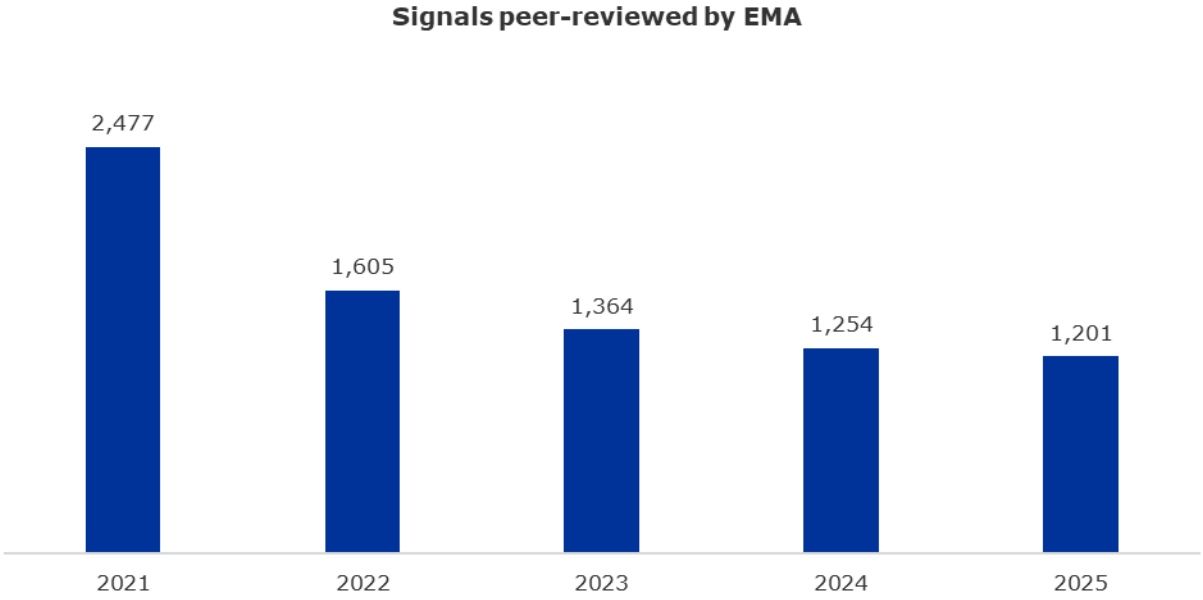
Total 2025: 1,765,439

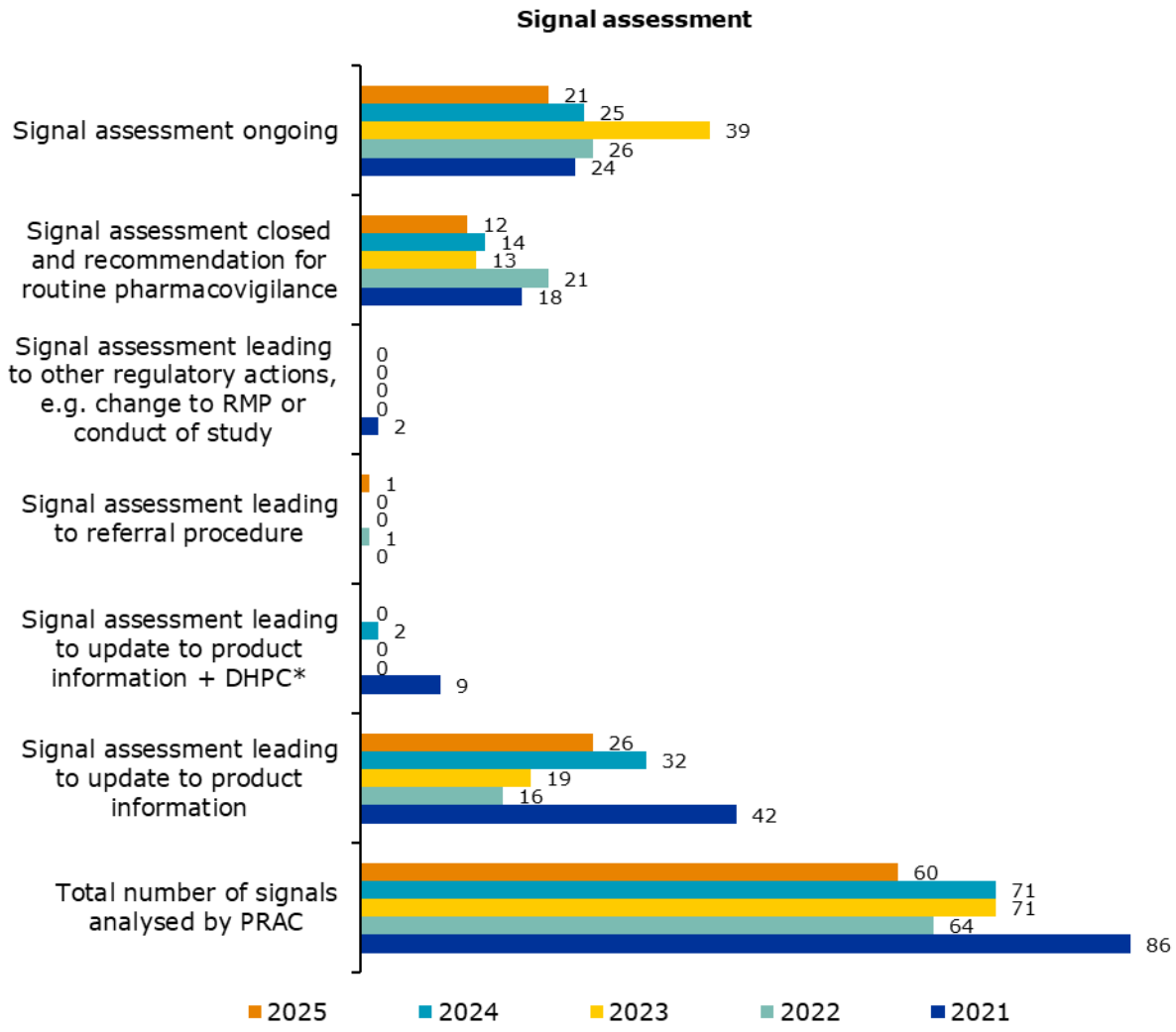
Notes: CAP: centrally authorised products. NAP: nationally authorised products.

Signal detection

A safety signal is information on a new or known adverse event that is potentially caused by a medicine and warrants further investigation. Signals are generated from several sources, such as spontaneous reports of suspected adverse reactions, clinical studies and the scientific literature. The evaluation of a safety signal is a routine pharmacovigilance activity to establish whether there is a causal relationship between a medicine and a reported adverse event.

In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary. This mainly comprises changes in the information on medicines available for patients (in the package leaflet) and prescribers (in the summary of product characteristics).


Signals peer-reviewed by EMA
2,477
1,605
1,364
1,254
1,201
2021
2022
2023
2024
2025


Signal assessment
Signal assessment ongoing
21
25
39
26
24
Signal assessment closed and recommendation for routine pharmacovigilance
12
14
13
21
18
Signal assessment leading to other regulatory actions, e.g. change to RMP or conduct of study
0
0
0
0
2
Signal assessment leading to referral procedure
1
0
0
1
0
Signal assessment leading to update to product information + DHPC*
0
2
0
0
9
Signal assessment leading to update to product information
26
32
19
16
42
Total number of signals analysed by PRAC
60
71
71
64
86
2025
2024
2023
2022
2021

Notes:

Signal assessment ongoing — Data from previous years (2021-2024) are all related to the situation at data cut by the end of each calendar year.

* Direct Healthcare Professional Communication (DHPC) is a communication intervention by which important information is delivered directly to individual healthcare professionals by a marketing authorisation holder or by a competent authority, to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product.

Outcome of signal assessment	2025
Signals peer-reviewed by EMA	1,201
Signals assessed by PRAC (validated by EMA)	33
Signals assessed by PRAC (validated by Member States)	27
Signal assessment leading to update to product information	26
Signal assessment leading to referral procedure	1
Signal assessment closed and recommendation for routine pharmacovigilance	12
Signal assessment ongoing	21

Periodic safety update reports (PSURs)

Marketing authorisation holders are required to submit an evaluation of the benefit-risk balance of a medicinal product to the regulatory authorities at regular, predefined intervals following the authorisation of a medicine. These reports summarise data on the benefits and risks of a medicine and take into consideration new or emerging safety information in the context of cumulative information on risks and benefits, both in authorised and unauthorised indications.

The Agency is responsible for procedures supporting the analysis of these reports for both CAPs and for nationally authorised medicines (NAPs) that are authorised in more than one Member State. These reports are called PSURs. When the assessment procedure involves more than one medicinal product with the same active substance, the procedures are referred to as periodic safety update single assessments or PSUSAs.

PSURs and PSUSAs finalised	2021	2022	2023	2024*	2025
PSURs standalone (CAPs only) finalised	575	542	570	618	604
PSURs single assessment (CAPs with NAPs) finalised	49	46	37	51	45
PSURs single assessment (NAPs only) finalised	287	272	239	244	257

*2024 result corrected.

Post-authorisation safety studies and post-authorisation efficacy studies

A post-authorisation safety study (PASS) can be carried out after a medicine has been authorised to obtain further information on its safety, or to determine the effectiveness of risk-management measures. A PASS can be imposed on MAHs as part of their post-authorisation obligations. The PRAC is responsible for assessing the protocols of imposed PASS and their results. The PRAC also reviews protocols of large numbers of voluntarily submitted PASS in the context of RMP assessments.

Post-authorisation efficacy studies (PAES) are also conducted after a medicine has been granted a marketing authorisation to collect data on aspects of the benefits in its approved indication that can only be explored once the medicine is marketed.

Post authorisation safety studies	2021	2022	2023	2024	2025
Imposed PASS protocol procedures started	22 (7 PASS protocol + 15 PASS protocol follow up)	17 (5 PASS protocol + 12 PASS protocol follow up)	14 (2 PASS protocol + 12 PASS protocol follow up)	12 (5 PASS protocol + 7 PASS protocol follow up)	20 (8 PASS protocol + 12 PASS protocol amendment)
Imposed PASS result procedures started	11	2	7	5	7
PASS scientific advice through SAWP	1	1	1	1	2

Withdrawals

Companies are required to report the cessation of the marketing of a medicine in any Member State for reasons affecting patient safety so that regulatory authorities can ensure that the same action is taken across all Member States. For CAPs, companies also need to notify EMA of withdrawals for commercial reasons. The Agency is responsible for coordinating these actions across the EU. These notifications are forwarded to all NCAs in the EEA. The list of withdrawn products is also published on the EMA website.

Other pharmacovigilance activities

Additional monitoring aims primarily to enhance ADR reporting for certain types of medicines. The list of medicines under additional monitoring is reviewed every month by the PRAC and is available on EMA's website and also published by the NCAs.

These medicines are identified by an inverted black triangle on their packaging. The EU incident management plan is coordinated by EMA and aims to ensure that concerned bodies in the EU take appropriate action whenever new events or information (known in this context as incidents) arise concerning human medicines. It covers medicines authorised centrally, nationally and through the decentralised and mutual-recognition procedures. The plan's operation involves representatives from EMA, the European Commission and regulatory authorities in the Member States.

The European pharmacovigilance issues tracking tool (EPITT) is a database developed by EMA to promote the discussion of pharmacovigilance and risk-management issues between the Agency and Member States. It provides access to documents related to the safety of medicinal products/substances authorised in the EEA. EPITT helps medicines regulatory authorities in the EEA and EMA to track signals at EU level.

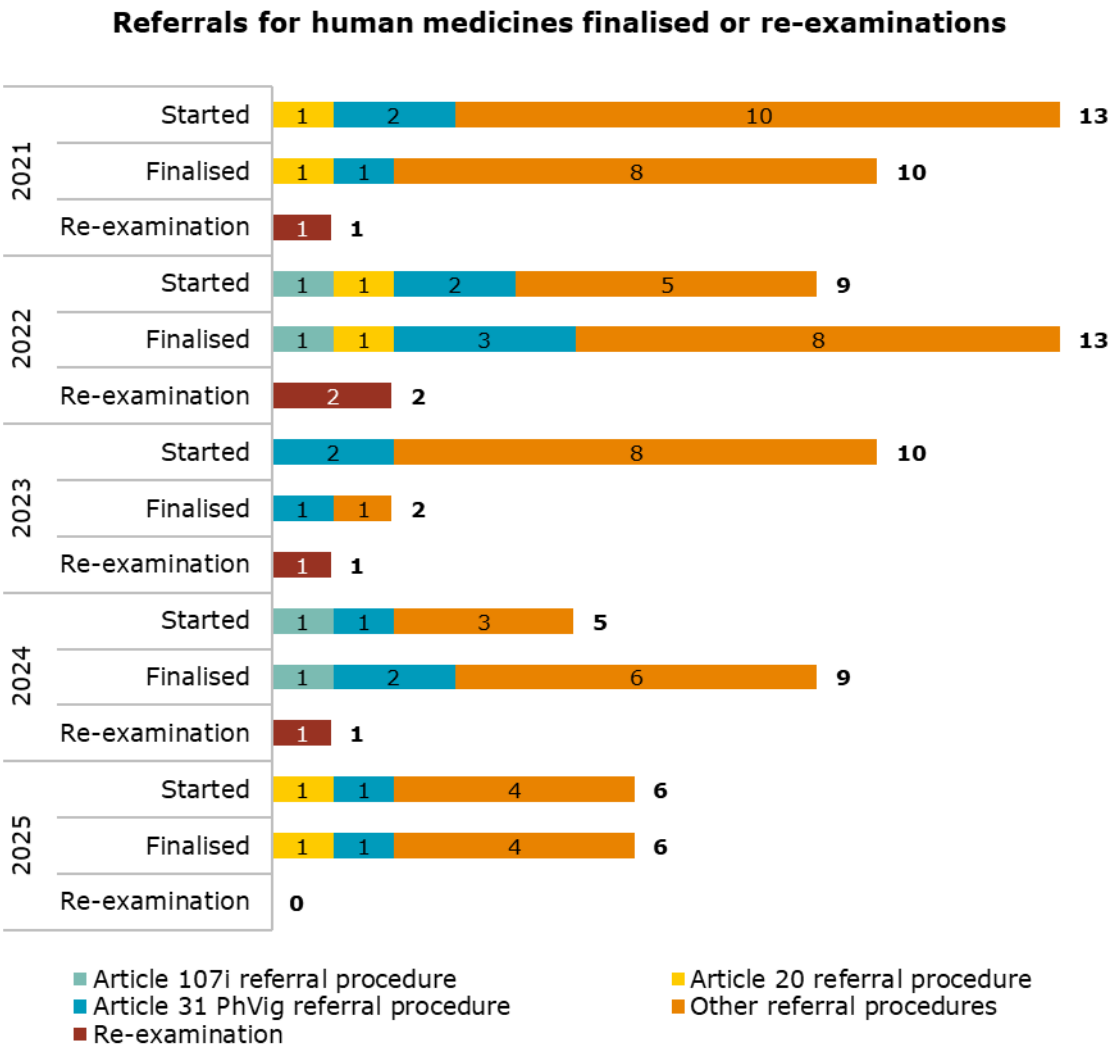
Scientific and medical literature is an important source of information to identify suspected adverse reactions with medicines authorised in the EU. EMA is responsible for monitoring a number of substances and selected medical literature to identify suspected adverse reactions with such medicines, and for entering the relevant information into the EudraVigilance database.

Other pharmacovigilance activities	2021	2022	2023	2024	2025
Cumulative number of products on the list of products to be subject to additional monitoring	372	365	351	361	396
Number of Incident management plans triggered	4	2	0	1	1
Number of non-urgent information or rapid alert notifications submitted through EPITT	20	30	24	20	19

Other pharmacovigilance activities	2021	2022	2023	2024	2025
Number of external requests for EV analyses	30	16	14	20	18
Number of MLM ICSRs created	9,193	8,278	9,698	11,411	14,203

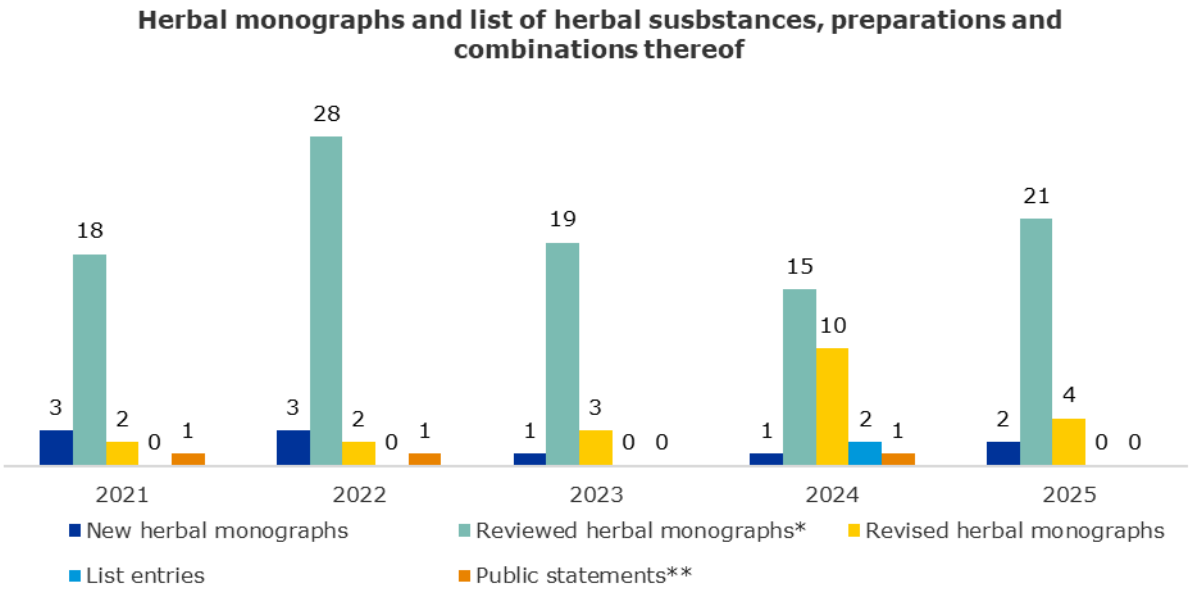
Referral procedures

Referral procedures are initiated to address concerns over the safety or benefit-risk balance of a medicine, as well as to deal with disagreement among Member States on the use of a medicine. In a referral, EMA is requested, on behalf of the EU, to conduct a scientific assessment of a particular medicine or class of medicines and issue a recommendation. Following the recommendation, the European Commission will issue a legally binding decision for the EU. Less often, in cases where only NAPs are concerned, the decision is taken by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). In cases where the CMDh position is agreed by majority, rather than by consensus of all CMDh members, the European Commission will issue a final decision applicable throughout the EU.



Herbal medicines

The Agency's Committee on Herbal Medicinal Products (HMPC) is responsible for preparing opinions on herbal medicines with the aim of promoting an increasingly harmonised process for licensing and information on herbal substances across the EU. The HMPC establishes EU monographs for traditional and well-established herbal medicines, as well as draft entries to the European Commission's list of herbal substances, preparations and combinations thereof for use in traditional medicines.

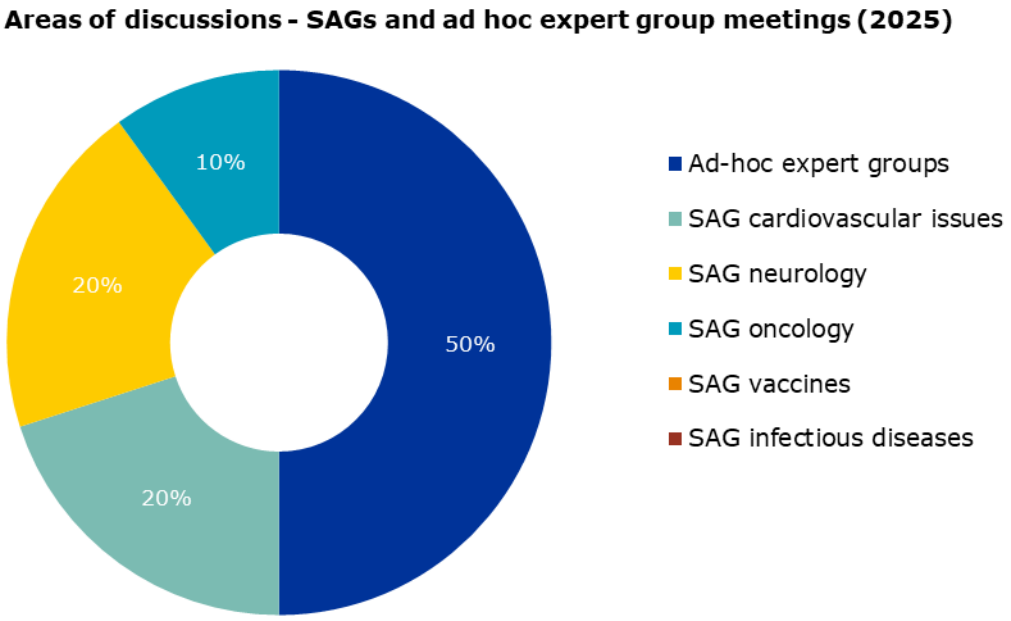


* When, after the review of new data, no change is required in the monograph, an addendum to the previous assessment report is prepared (otherwise start of revision procedure leading to a revised monograph).

** When the assessment does not lead to a monograph, a public statement is prepared.

Contribution of experts, patients and healthcare professionals to scientific assessments

EMA's scientific committees can consult additional experts, patients and healthcare professionals to enrich their scientific assessment of medicines. These external parties may be involved in scientific advisory groups (SAGs) or ad hoc expert groups.



Note: There were no meetings of SAG vaccines and SAG infectious diseases.

Procedures with scientific advisory group or ad hoc expert group involvement (number of consultations)	2021	2022	2023	2024	2025
Marketing authorisation (new MAA, new MAA re-examination, Art 58)	11	10	9	9	8
Extension of indication (including line extensions)	2	7	1	3	1
Referral (including re-examination)	1	2	3	3	1
Guideline	0	0	0	0	0
Other topics (renewal, orphan designation, PSUR, signal, class review)	1	0	5	2	0
Total	15	19	18	17	10

Involvement of patients and healthcare professionals

Patients and healthcare professionals are involved in a wide range of EMA activities. They bring a valuable real-life perspective to scientific discussions on medicines, which is expected to lead to better outcomes of the regulatory process. Patients and healthcare professionals participate by:

- contributing as members of scientific committees and the Management Board;
- being consulted on disease-specific requests by the scientific committees and working parties;
- taking part in discussions on the development and authorisation of medicines;
- reviewing written information on medicines prepared by the Agency;
- being involved in the preparation of guidelines;
- taking part in the Agency's conferences and workshops.

Patient engagement in EMA activities	2021	2022	2023	2024	2025
Patient membership in MB, committees, working parties	56	57	60	62	66
EMA Management Board	2	2	2	2	2
Scientific committees	13	12	15	15	15

Patient engagement in EMA activities	2021	2022	2023	2024	2025
Patients' and Consumers' Working Party	41	43	43	45	49
Active patient experts nominated by EMA		80	163	186	219
Number of patients and consumers eligible organisations		42	43	41	42
Number of patients experts contracted	NA	NA	NA	NA	28

Healthcare-professional involvement in EMA activities	2021	2022	2023	2024	2025
HCP membership in MB, committees, working parties	57	56	56	60	62
EMA Management Board	2	2	2	1	1
Scientific committees	12	12	12	12	11
Healthcare Professionals' Working Party	43	42	42	46	50
Active healthcare professionals experts nominated by EMA		140	87	84	101
Number of healthcare professionals eligible organisations		39	40	41	45
Number of healthcare professionals experts contracted	NA	NA	NA	NA	47

Mutual-recognition and decentralised procedures

90% of the medicines entering the EU market are nationally authorised. These are mainly generics which reach the market through the mutual recognition procedure (MRP) and the decentralised procedure (DCP), the primary authorisation routes for generic applications within the EU. The CMDh, a separate body from EMA which represents the EU Member States plus Iceland, Liechtenstein and Norway, plays a key role, together with its working parties, in the authorisation and maintenance of these medicines. EMA provides secretarial support to the CMDh in accordance with the approved rules of procedure.

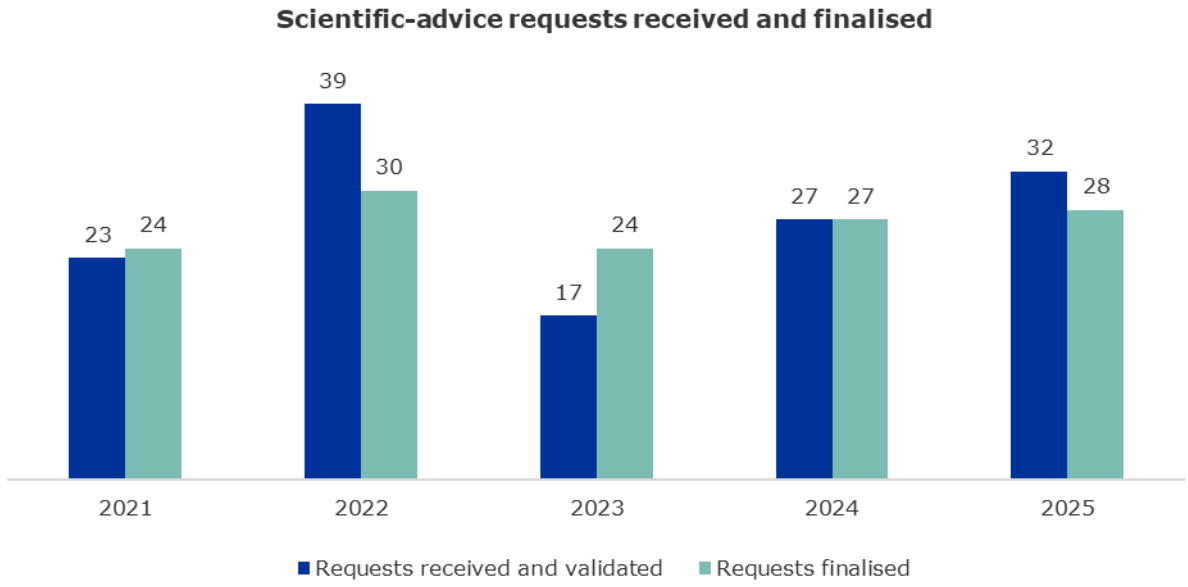
Detailed information about the work of the CMDh in 2025 in relation to pharmacovigilance and referrals can be found on the HMA website.

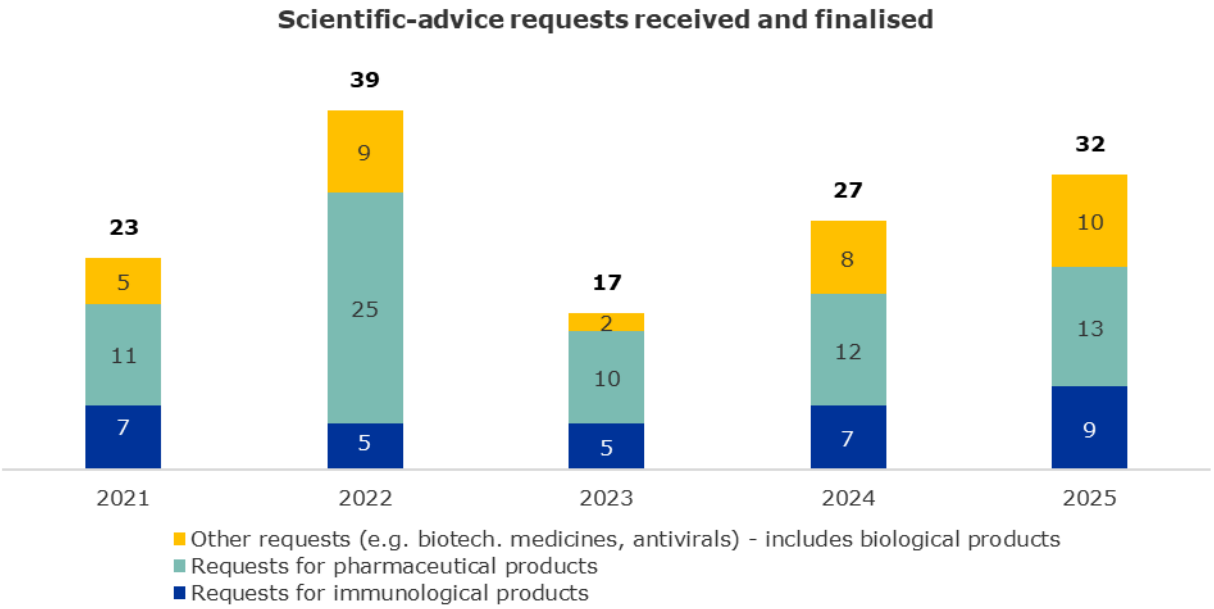
Veterinary medicines

Activities supporting research and development

Scientific advice

EMA offers scientific advice to companies on the appropriate tests and studies in the development of a veterinary medicine to facilitate the availability of high-quality, effective and acceptably safe medicines.

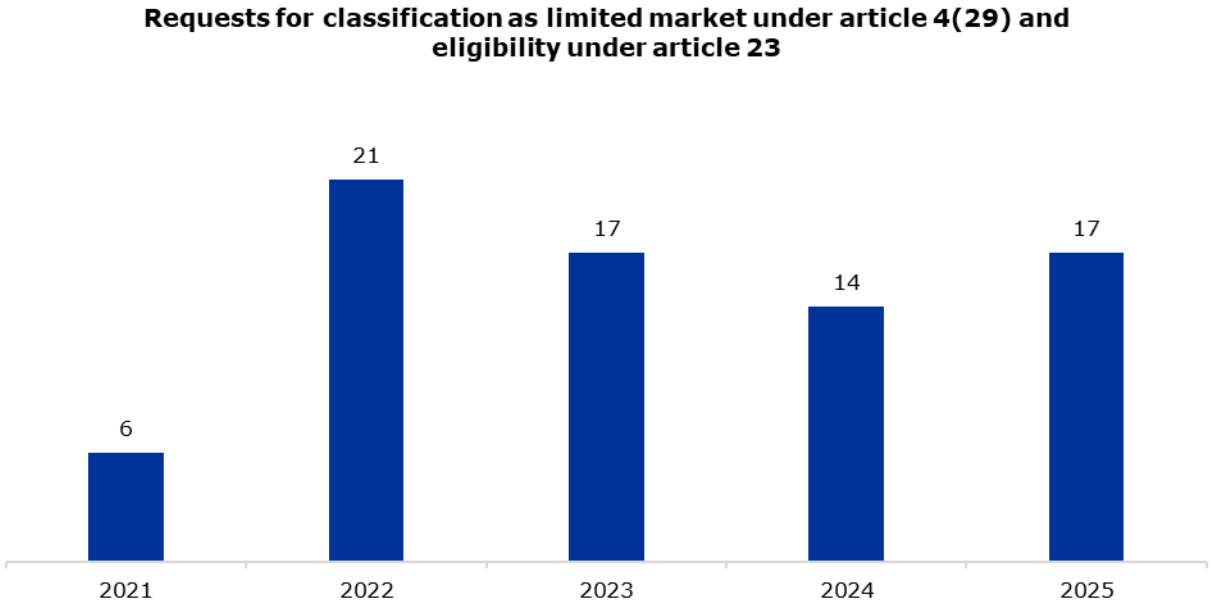




Veterinary limited markets

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) has established a specific authorisation route for medicines intended for veterinary limited markets in the EU. It enables the CVMP to recommend marketing authorisations on less comprehensive data than normally required, provided the benefit for animal or public health of placing such medicines on the market is greater than the inherent risk of a reduced data package. The Regulation aims to further stimulate the development

of veterinary medicines for small markets, to increase the availability of treatments for serious or life-threatening animal diseases and unmet veterinary medical needs.

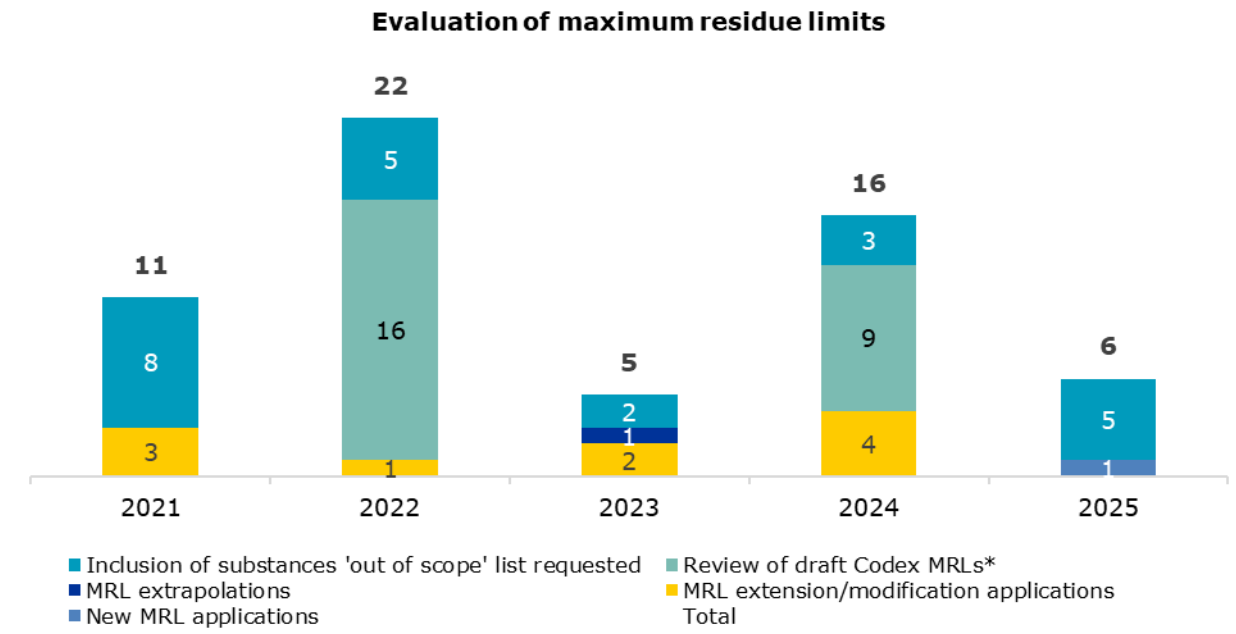


Innovation Task Force

The ITF is a multidisciplinary group that includes scientific, regulatory and legal expertise from across the EU. It provides a forum for early dialogue with applicants, in particular SMEs, to proactively identify scientific, legal and regulatory issues related to emerging therapies and technologies. In 2025, 9 meetings requests were received and 4 meetings were held with applicants.

Maximum residue limits (MRL)

The use of veterinary medicines in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. The Agency assesses and recommends MRLs for pharmacologically active substances in veterinary medicinal products used to treat food producing animals. The objective is to ensure the safety of foodstuffs of animal origin, such as meat, fish, milk, eggs and honey. EMA has a parallel responsibility for recommending MRLs for pharmacologically active substances in biocidal products used in animal husbandry. MRLs are formally established by the European Commission on the basis of a recommendation from the CVMP.

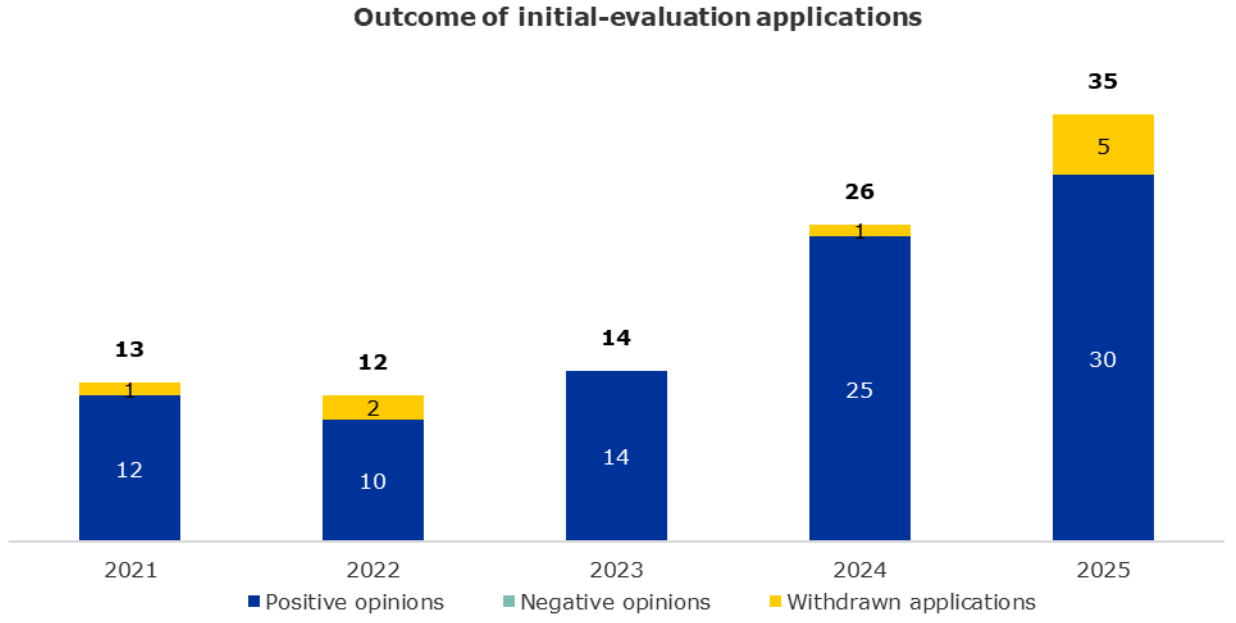


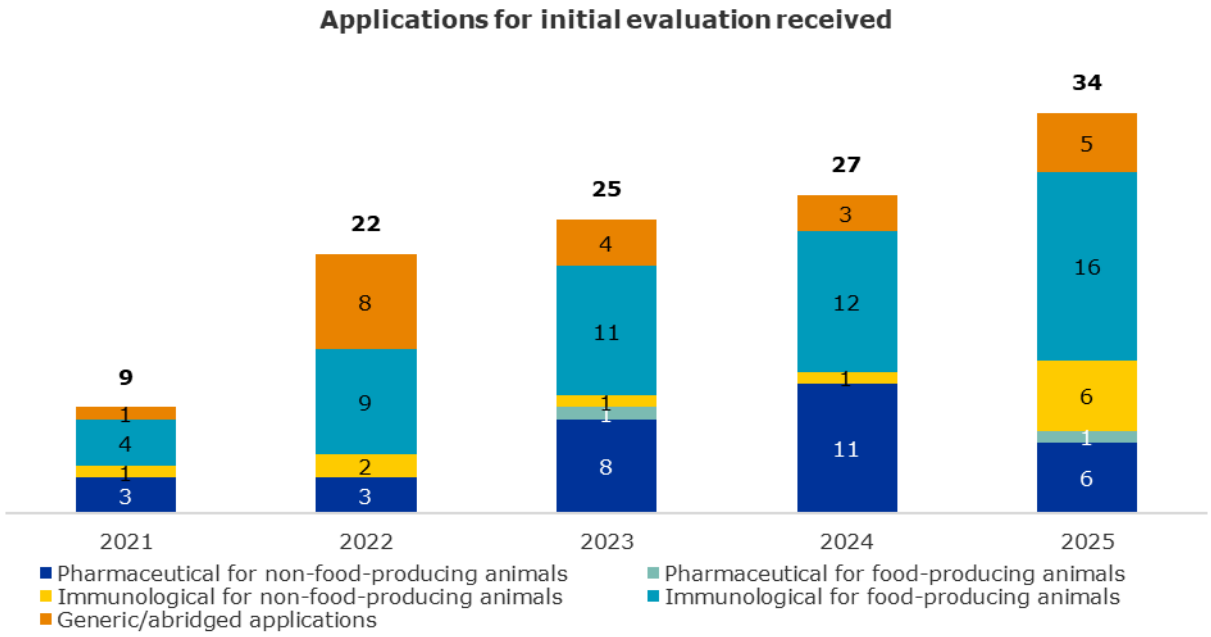
*From 2022, it also includes extrapolations

Recommendations for marketing authorisation

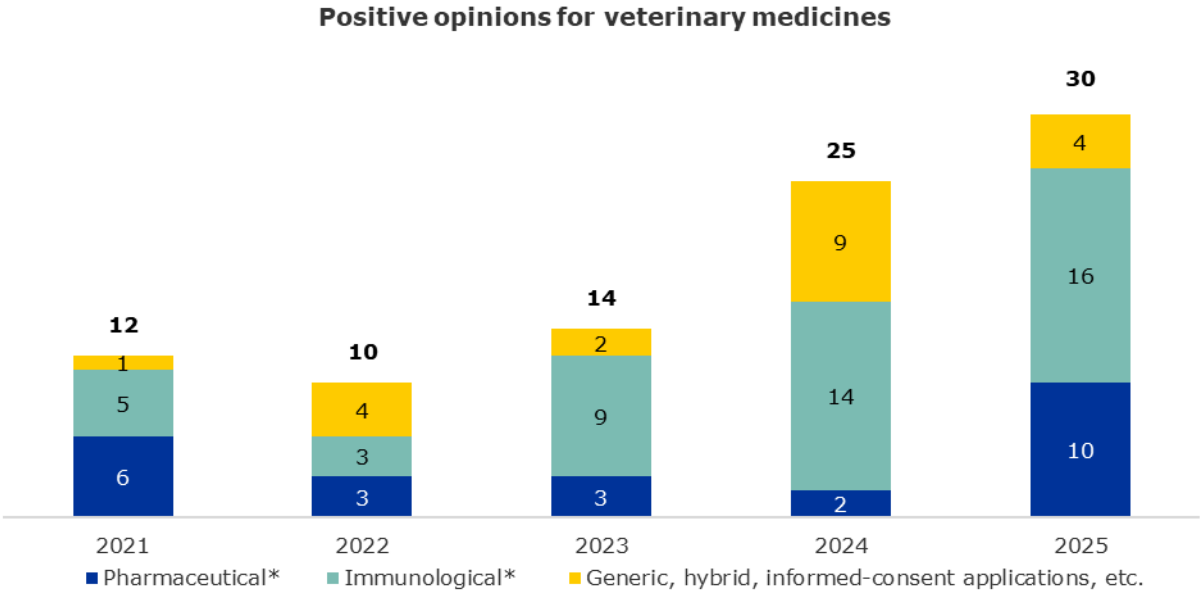
Applications for initial evaluation

Activities in the initial evaluation phase of veterinary medicines include pre-submission meetings with future applicants, evaluation by the CVMP, and the decision on the granting of marketing authorisation by the European Commission.

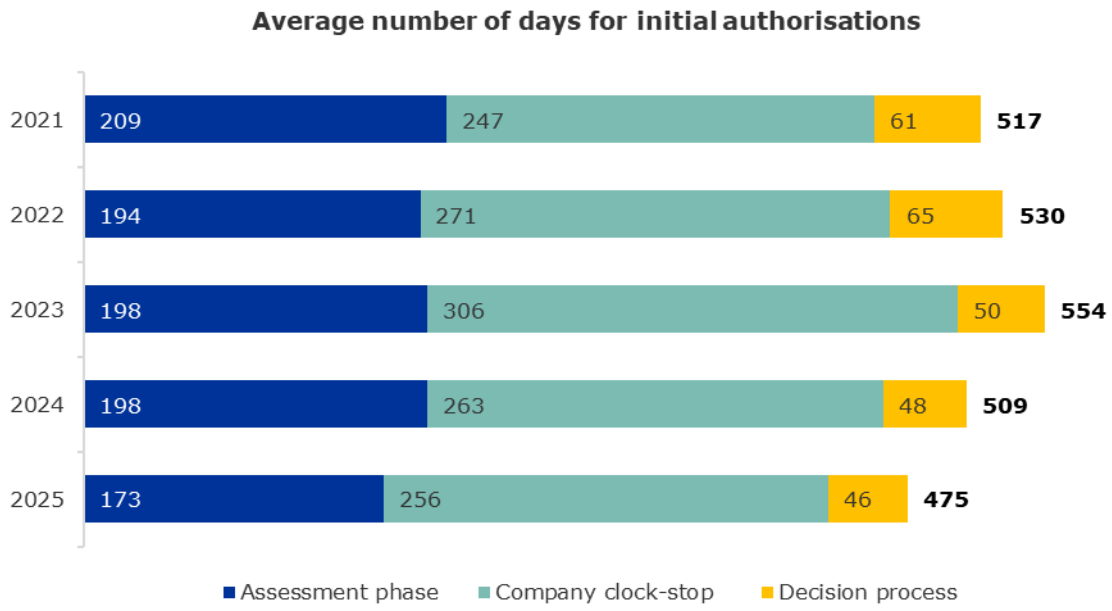




Recommendations for authorisation



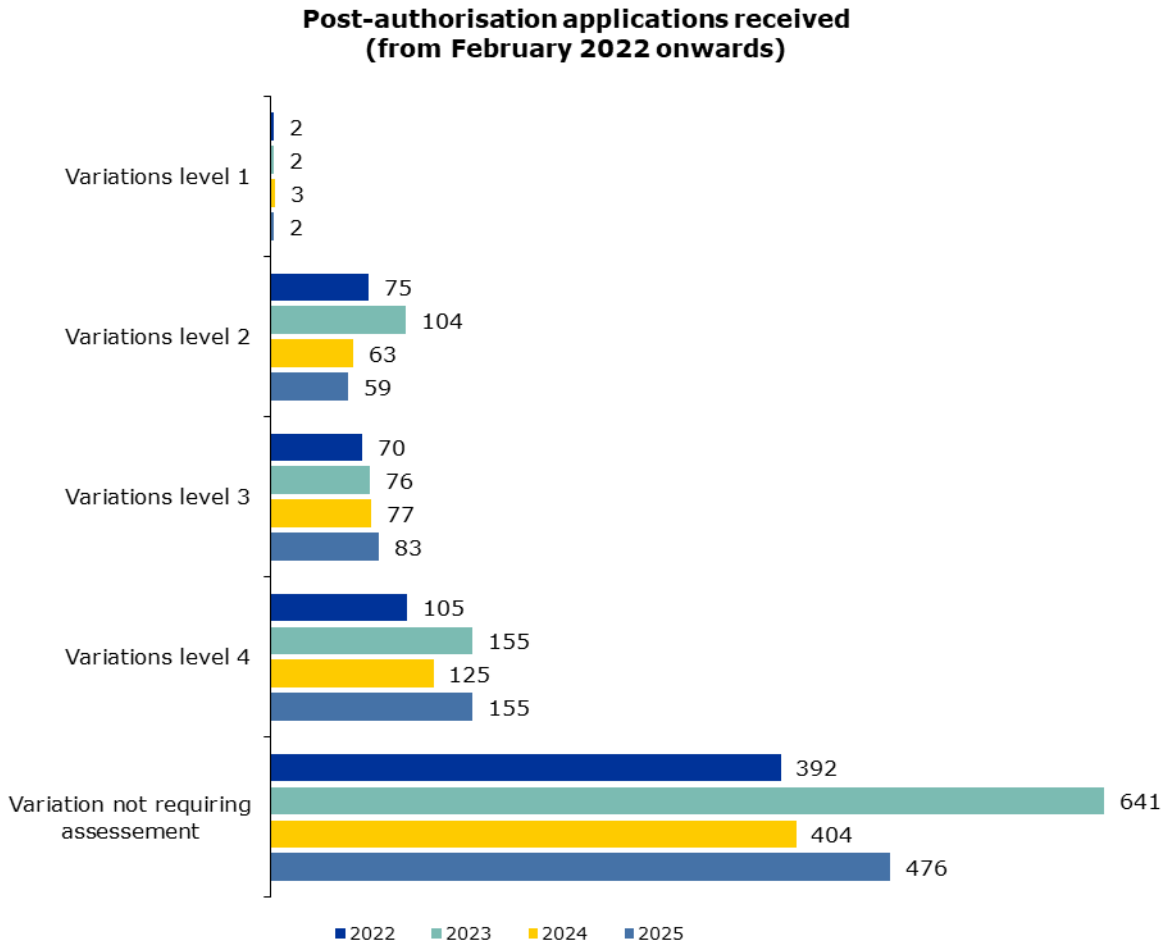
* if a product is generic/hybrid/informed consent this overruns any other feature (e.g. an immunological hybrid will be counted as 'hybrid' only)



Post-authorisation activities

Post-authorisation activities relate to activities such as variations and transfers of marketing authorisations. The use of an already-authorised medicine in a new species or the addition of a new indication offers new treatment opportunities.

Under the Veterinary Medicinal Products Regulation there are two types of variations (i.e. changes to the terms of a marketing authorisation): variations not requiring assessment (VNRA), which have minimal or no impact on the quality, safety or efficacy of the medicine, and variations requiring assessment (VRA), including different levels of complexity.



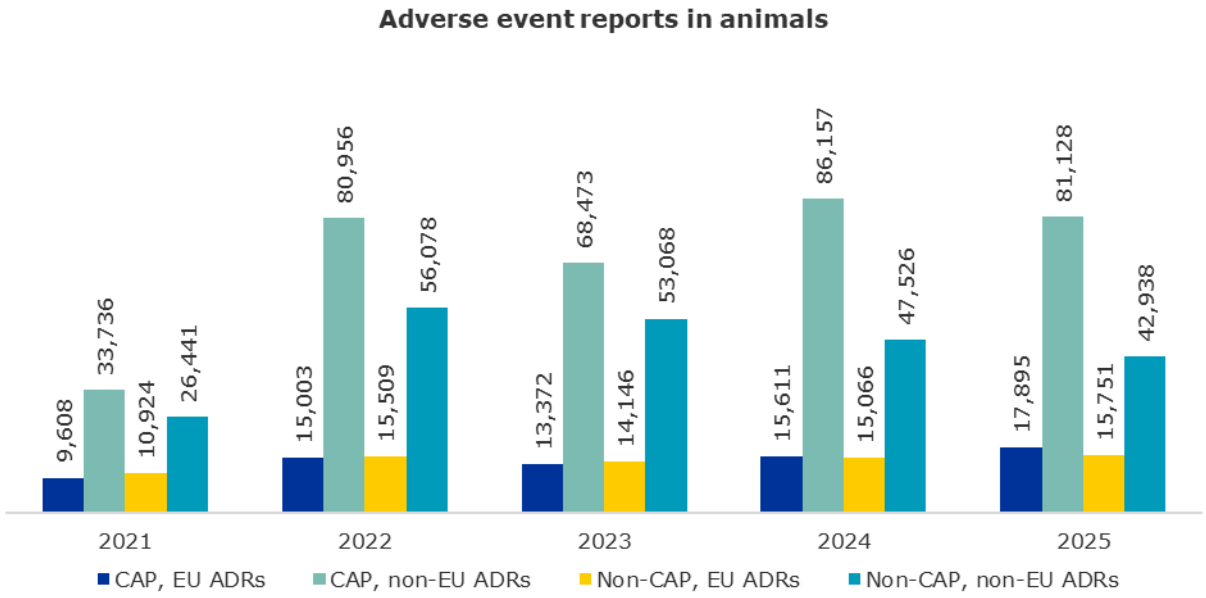
Total 2025: 299

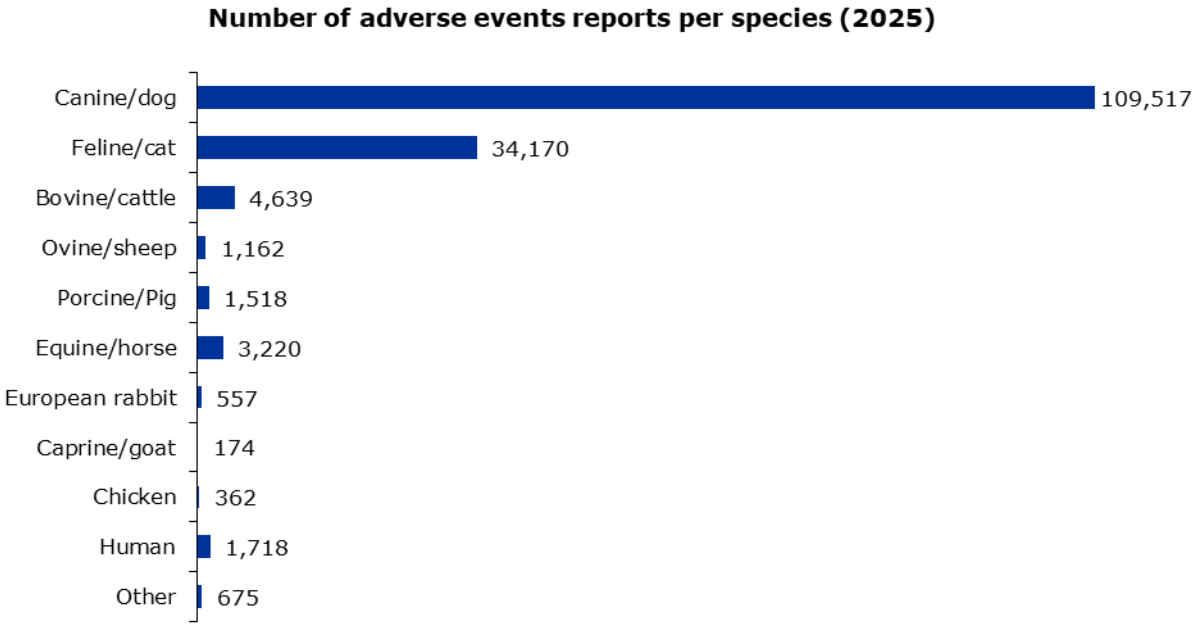
Safety monitoring of medicines

Pharmacovigilance covers activities related to the detection, reporting, assessment, understanding and prevention of adverse events following the administration of veterinary medicines. It aims to ensure the monitoring of the safety of veterinary medicines and the effective management of risks throughout the EU.

EudraVigilance

The Veterinary Medicinal Products Regulation requires reporting of adverse events as so-called Adverse Drug Reaction Reports (ADRs).

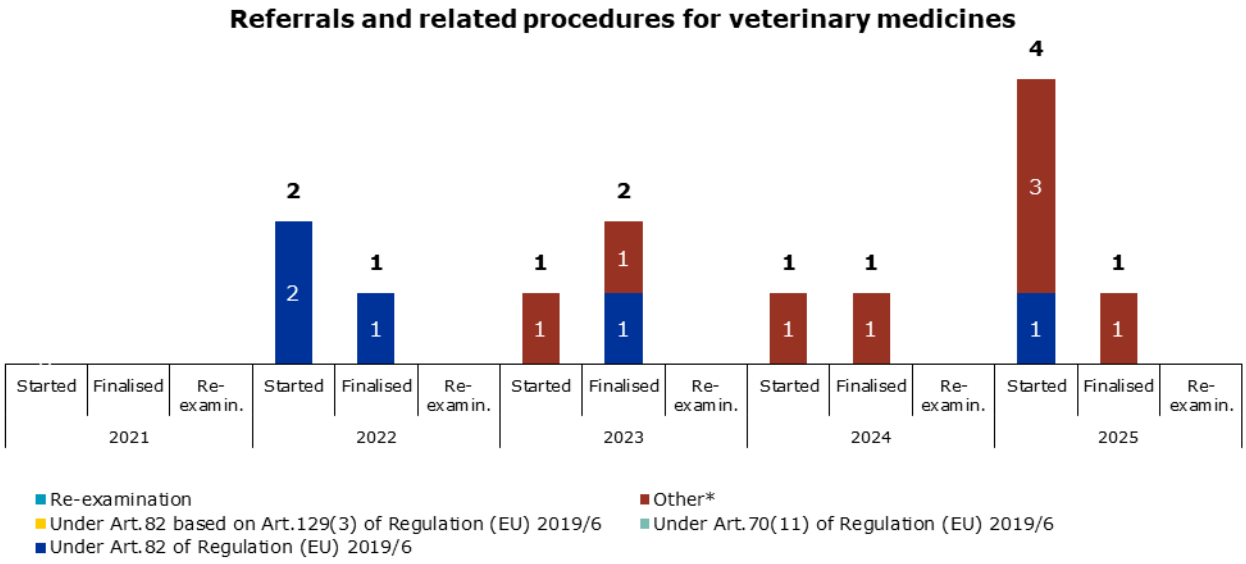




Total 2025: 157,712

Referral procedures

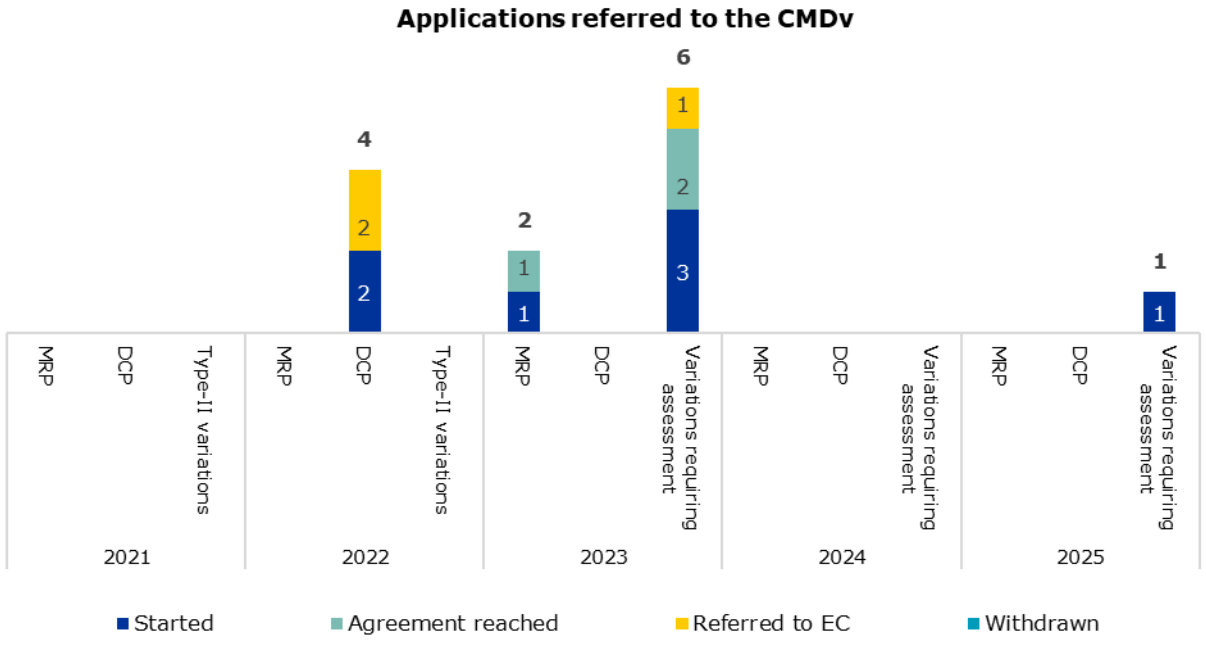
Referral procedures are used to address concerns over the quality, safety, efficacy or benefit-risk balance of a veterinary medicine, or disagreement among Member States on the use of a veterinary medicine. In a referral, the Agency is requested, on behalf of the EU, to conduct a scientific assessment of a particular veterinary medicine or class of veterinary medicines, and issues a cross-EU recommendation. The recommendation subsequently results in a legally binding decision throughout the EU issued by the European Commission.



*Including Art.13 of Regulation 1234/2008; Art.78 of Directive 2001/82/EC; Articles 30 or 45 of Regulation 726/2004 and Art.54(8), Art.130(4) and Art .141(1)(c) and (e) of Regulation (EU) 2019/6

Mutual-recognition and decentralised procedures

The Agency provides secretarial support to the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) and its working groups, in accordance with the approved rules of procedure. The work of the CMDv is essential for the effective authorisation and maintenance of veterinary medicines entering the EU market via the MRP and the DCP, which constitute the primary routes for veterinary medicines entering the EU market.



Inspections and compliance

In the European medicines regulatory network, the responsibility for carrying out inspections rests with EU NCAs. EMA plays an important role in coordinating the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP), good pharmacovigilance practices (GVP) and certain aspects of the supervision of authorised medicinal products in the EU. The main verification tool is inspections. Some are carried out routinely, while others are triggered upon request from the CHMP or the CVMP during the context of the assessment of the marketing authorisation applications and/or matters referred to these committees in accordance with EU legislation.

The inspection programme at the EU level that EMA coordinates to verify compliance with the principles of GMP, GCP and pharmacovigilance includes:

- a programme of risk-based GMP inspections based on the results of inspections of pharmaceutical manufacturing sites by trusted authorities;
- a programme of risk-based routine GCP inspections at sites of clinical research organisations (CROs) most often used in the conduct of bioequivalence trials included in a marketing authorisation application in the mutual-recognition and decentralised procedures (in collaboration with NCAs// the Coordination Group for Mutual Recognition and Decentralised Procedures — Human (CMDh));
- a programme of risk-based routine inspections of the pharmacovigilance systems in place for CAPs (in collaboration with NCAs); and
- a two-year programme of routine GCP inspections based on risk factors and a random element, to ensure that a diverse range of applications, trials and sites and geographical locations are covered.

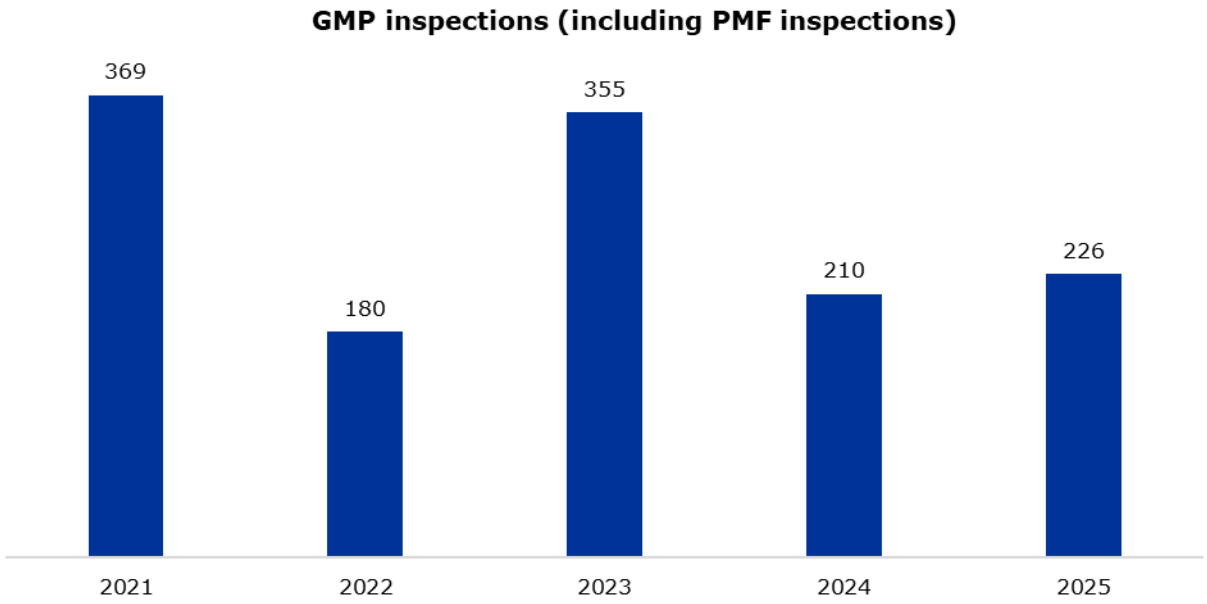
EMA promotes mutual reliance and work-sharing with other international authorities to ensure the best use of resources. There are several mutual recognition agreements in place for GMP inspections.

Through its inspectors' working groups, the Agency coordinates the development and setting of standards for GMP, GCP, GLP and GVP. This helps to harmonise standards within the EU and internationally, to strengthen global supply chains and improve access to authorised medicines. The delivery of training and capacity building on inspection-related activities for inspectors and assessors, including non-EU regulators, is one focus area for EMA. The Agency is the primary contact point for the notification of suspected quality defects for CAPs and coordinates their investigation, evaluation and follow-up. It also operates a sampling-and-testing programme to supervise the quality of CAPs placed on the market and to check compliance of these products with their authorised specifications.

Inspections

The CHMP and the CVMP can request GMP, GCP, GLP and pharmacovigilance inspections for medicines that are subject to centralised authorisation procedures. These inspections take place worldwide. Overall, non-EU inspections only represent a small part of the total number of inspections performed by the EU/EEA inspectors, who also carry out inspections as part of their national programmes.

GMP inspections

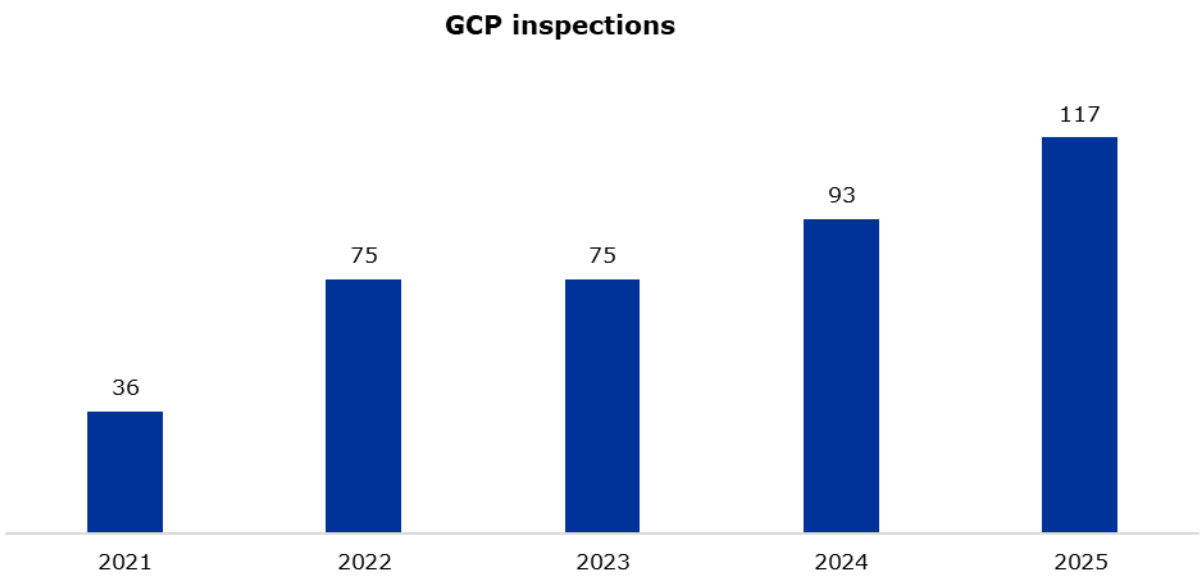


GMP certificates and non-compliance statements issued by EEA authorities

	2021		2022		2023		2024		2025	
	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement
EEA/ EU	1,825	5	1,730	2	1,857	2	1,634	4	2,003	7
China	24	0	15	0	44		53	1	49	1
India	29	0	81	2	101	4	105	5	135	4
USA	52	0	118	0	155		165	0	160	0
Rest of the world	52	0	187	2	231	1	153	0	89	5
Total	**1,982**	**5**	**2,131**	**6**	**2,388**	**7**	**2,110**	**10**	**2,436**	**17**

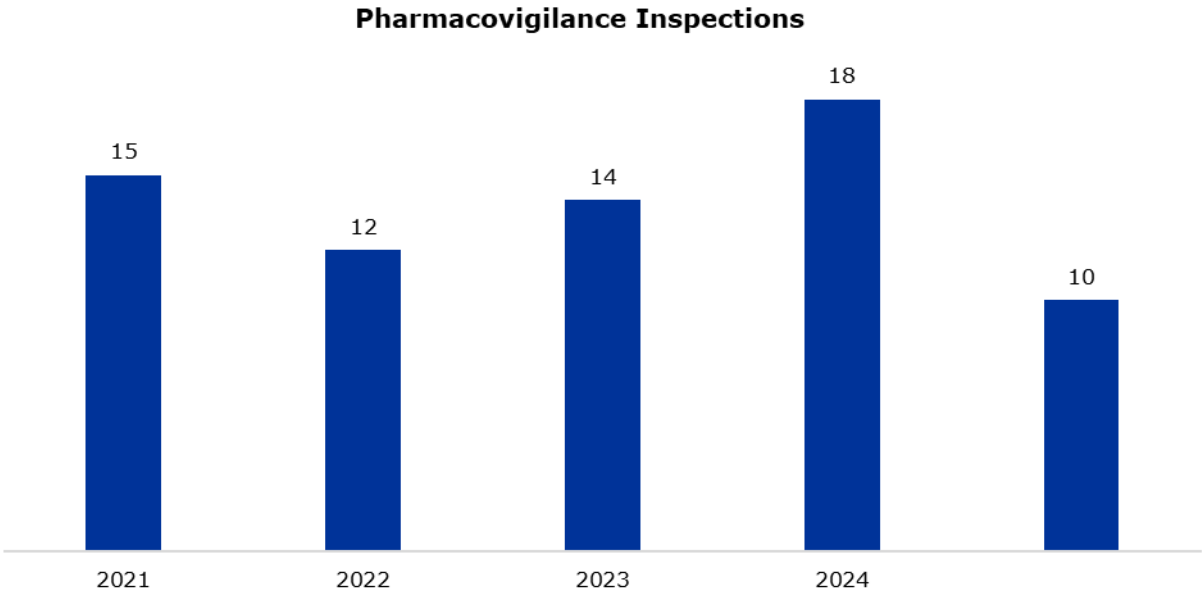
Note: This table shows the number of GMP certificates and non-compliance statements issued by EEA authorities as an outcome of GMP inspections conducted between 2021 and 2025. It includes GMP inspections requested by the CHMP or the CVMP.

GCP inspections



Pharmacovigilance inspections

EMA, in cooperation with competent authorities in Member States, maintains a risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders of CAPs and ensures its implementation. It also plays a key role in the coordination of pharmacovigilance inspections specifically triggered by the CHMP or the CVMP and in inspection follow-up.



Market surveillance and quality defects

Manufacturers are required to inform the authorities of quality defects in a manufactured product. This can lead to a recall of batches from the market or a prevention of their release by the manufacturer. Where a defect is considered to be a risk to public or animal health, the marketing authorisation holder

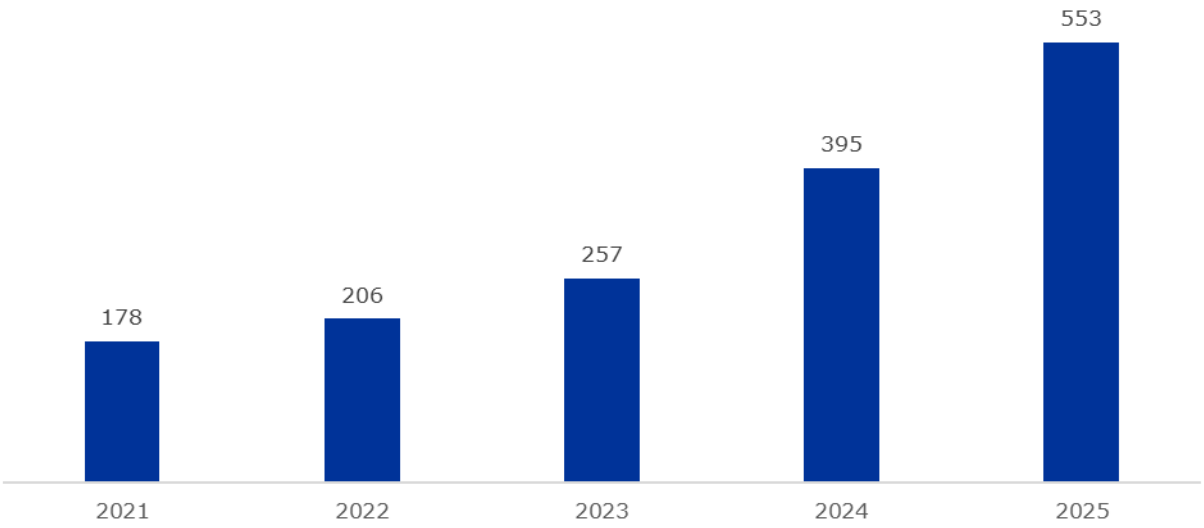
is requested to withdraw the affected batches of the CAP from the EU market and the supervisory authority issues a rapid alert. The alert is classified from 1 to 3, depending on the expected risk to public or animal health posed by the defective product:

Class 1 recall: the defect presents a life-threatening or serious risk to health;

Class 2 recall: the defect may cause mistreatment or harm to the patient or animal, but is not life-threatening or serious; and

Class 3 recall: the defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

Number of quality defect notifications received



Quality defects reported	2021	2022	2023	2024	2025
Quality defects confirmed cases	164	185	188	221	167
Recalls	10	11	9*	9	11**
Class 1	1	2	0	0	0
Class 2	7	5	6	5	6
Class 3	2	4	2	4	3

* 1 recall not classified

** 2 recalls not classified

Parallel distribution

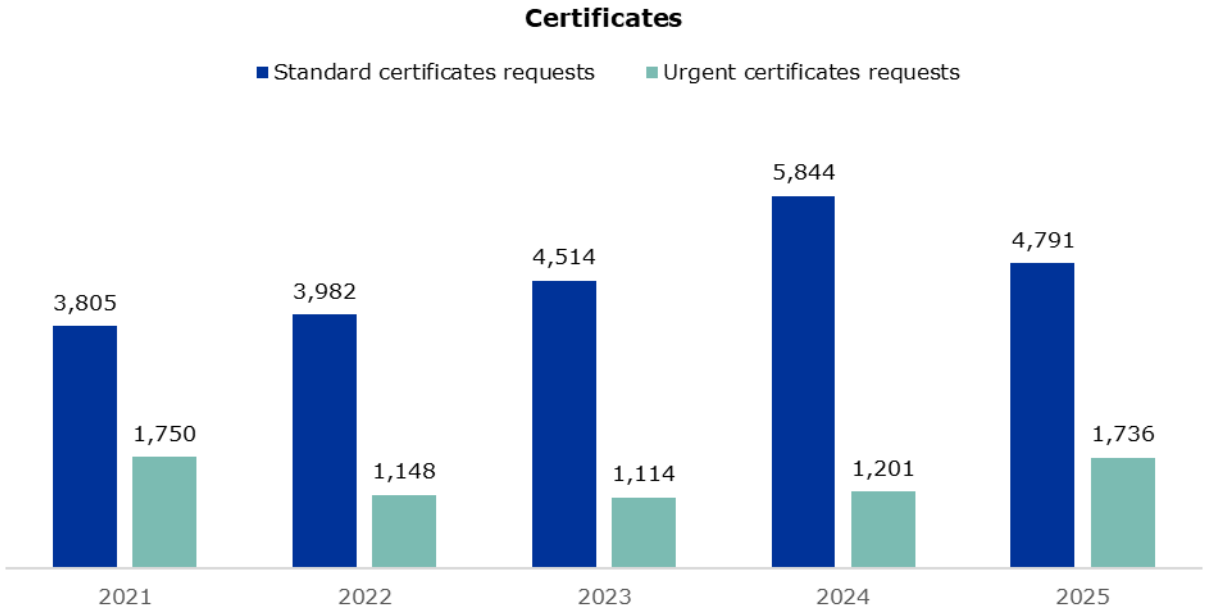
EMA checks that the parallel distribution of CAPs from one Member State to another by a company independent of the marketing authorisation holder is compliant with the rules.

Parallel distribution notifications received

Parallel distribution notifications received	2021	2022	2023	2024	2025
Initial notifications	2,555	1,816	2,092	2,656	2,926
Notifications of change	0	0	0	0	0
Notifications of bulk change	19	32	21	18	17
Annual updates	4,816	5,509	5,477	5,691	7,132
Total	7,390	7,357	7,590	8,365	10,075

Certificates

EMA also issues electronic-only certificates to confirm the marketing authorisation status of medicines that have either been authorised, or for which an application for marketing authorisation has been submitted to the Agency.



Medical devices

In the EU, medical devices must undergo assessments to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. They are regulated by notified bodies at EU Member State level, but EU legislation requires that expert panels coordinated by EMA are consulted before issuing a CE certificate for certain high-risk medical devices. These include:

Class III implantable devices and class IIb active devices that are intended to administer or remove medicinal products from the body; and

Class D in vitro diagnostic medical devices. The expert panels can provide:

opinions on the notified body's assessment of the manufacturer's clinical file of class III and class IIb medical devices, known as the clinical evaluation consultation procedure (CECP); and

views on the manufacturer's performance evaluation report of class D in vitro diagnostic medical devices, known as the performance evaluation consultation procedure (PECP).

CECP dossiers are first reviewed by the screening experts, who decide whether or not an opinion needs to be provided on the clinical evaluation assessment report. Their decision is based on the novelty of the device, any significant health concerns, including device components and the health impact of the failure of the device, and increased rates of reported serious incidents.

Figures on opinions/views/advice by expert panels on high risk Medical Devices	2021	2022	2023	2024	2025
Number of finalised screened applications for CECP	9	29	48	73	118
Number of finalised scientific opinions for Clinical Evaluation Consultation Procedures CECP	3	7	1	6	15
Number of finalised Performance Evaluation Consultations PECP	15	1	2	4	0
Number of finalised advice procedures to Medical Device Coordination Group MDCG			3	2	0
Number of finalised Scientific Advice Pilot procedures			3	17	9
Number of finalised Orphan Device Designation Pilot procedures					5
Number of finalised Orphan Device Clinical Advice Pilot procedures					2

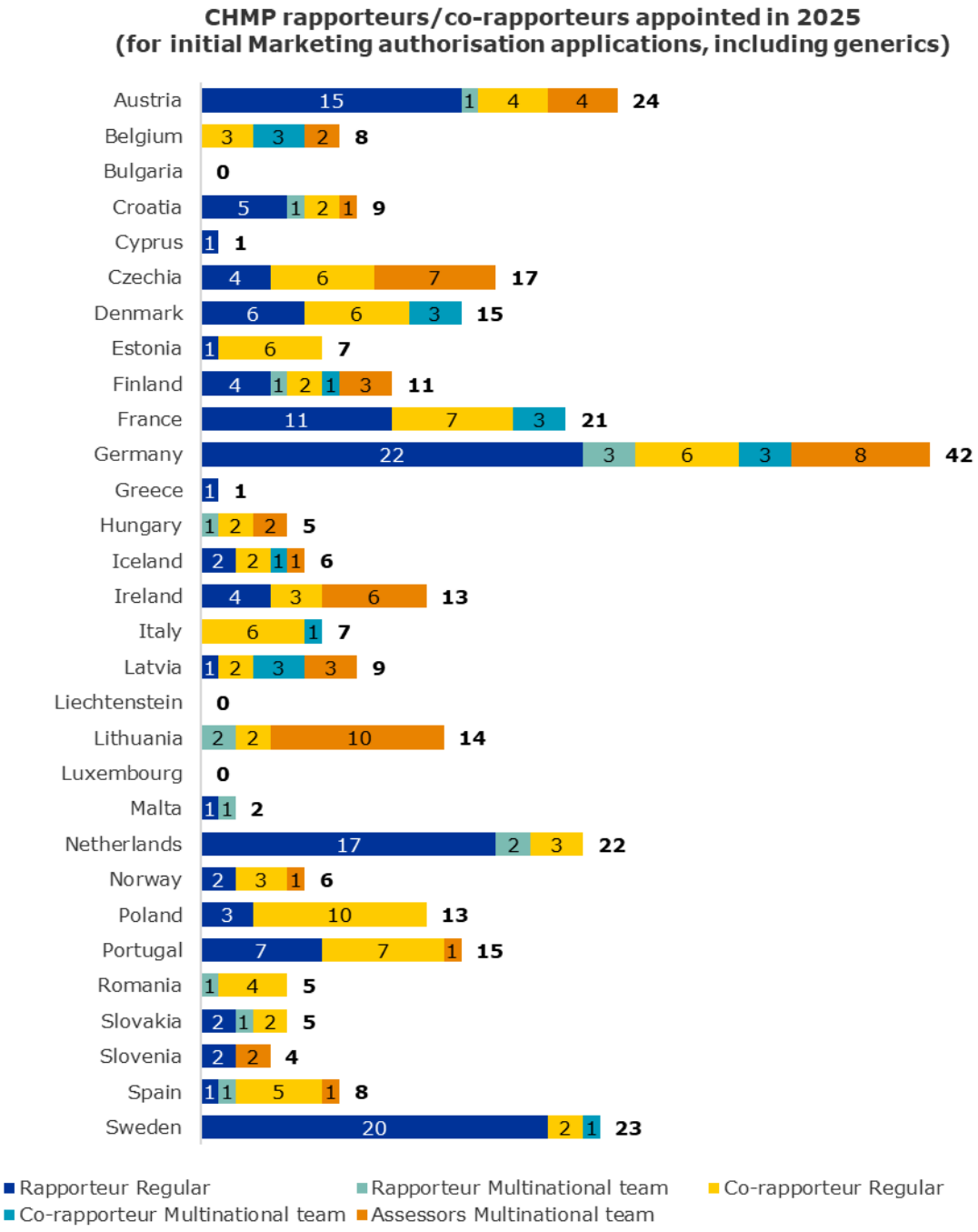
European medicines regulatory network

The European medicines regulatory network is the cornerstone of EMA's work and success. EMA plays a central role in this network, coordinating and facilitating collaboration between more than 50 national competent authorities across the EU and EEA for both human and veterinary medicines.

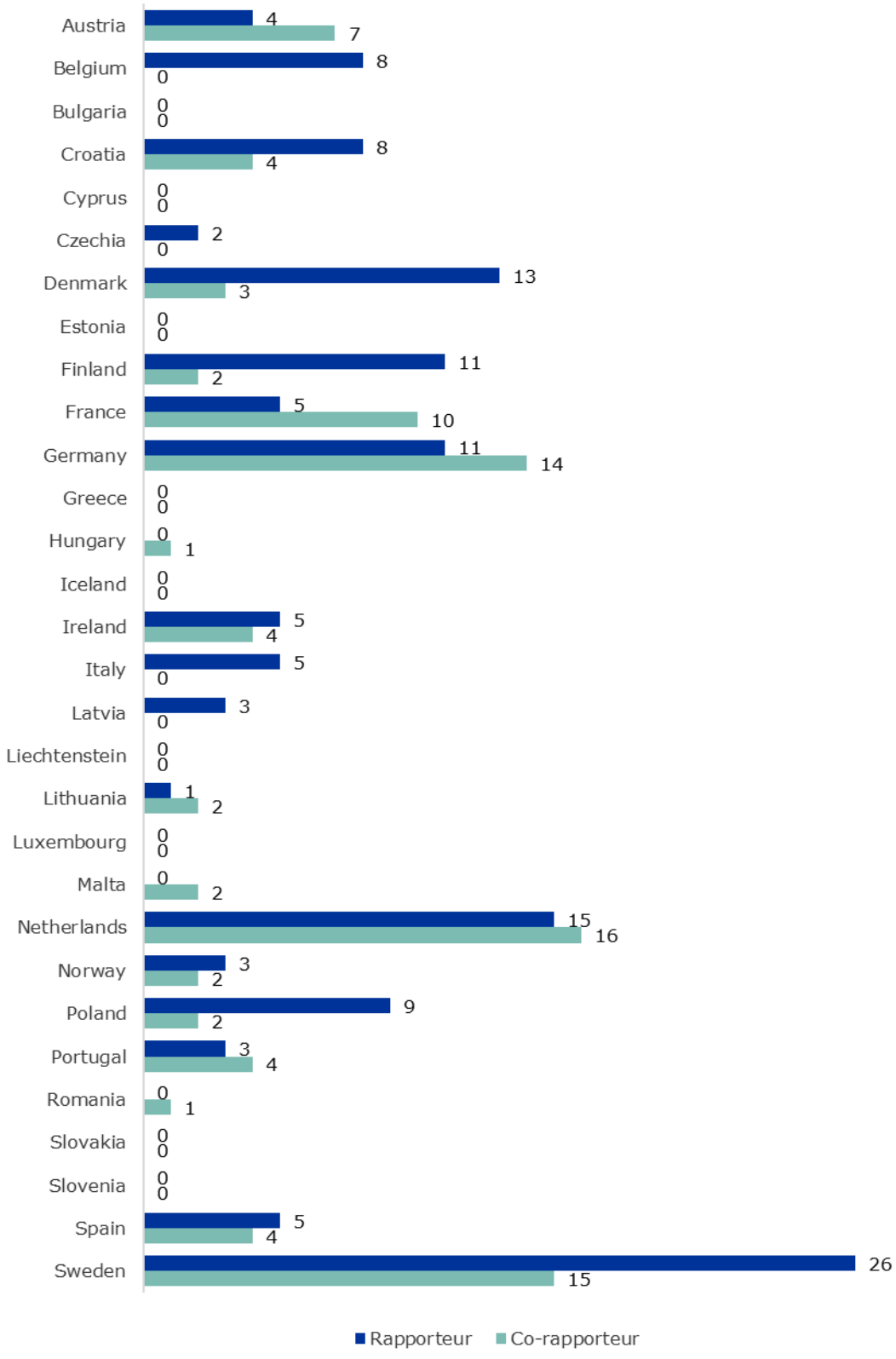
Through the network, EMA can draw from a pool of over 5,000 experts, who provide the highest level of scientific expertise to the regulation of medicines in the EU. These experts contribute to EMA's scientific committees, working groups, and other bodies, and are also involved in the evaluation teams that carry out the evaluation of medicines.

Rapporteurships and co-rapporteurships

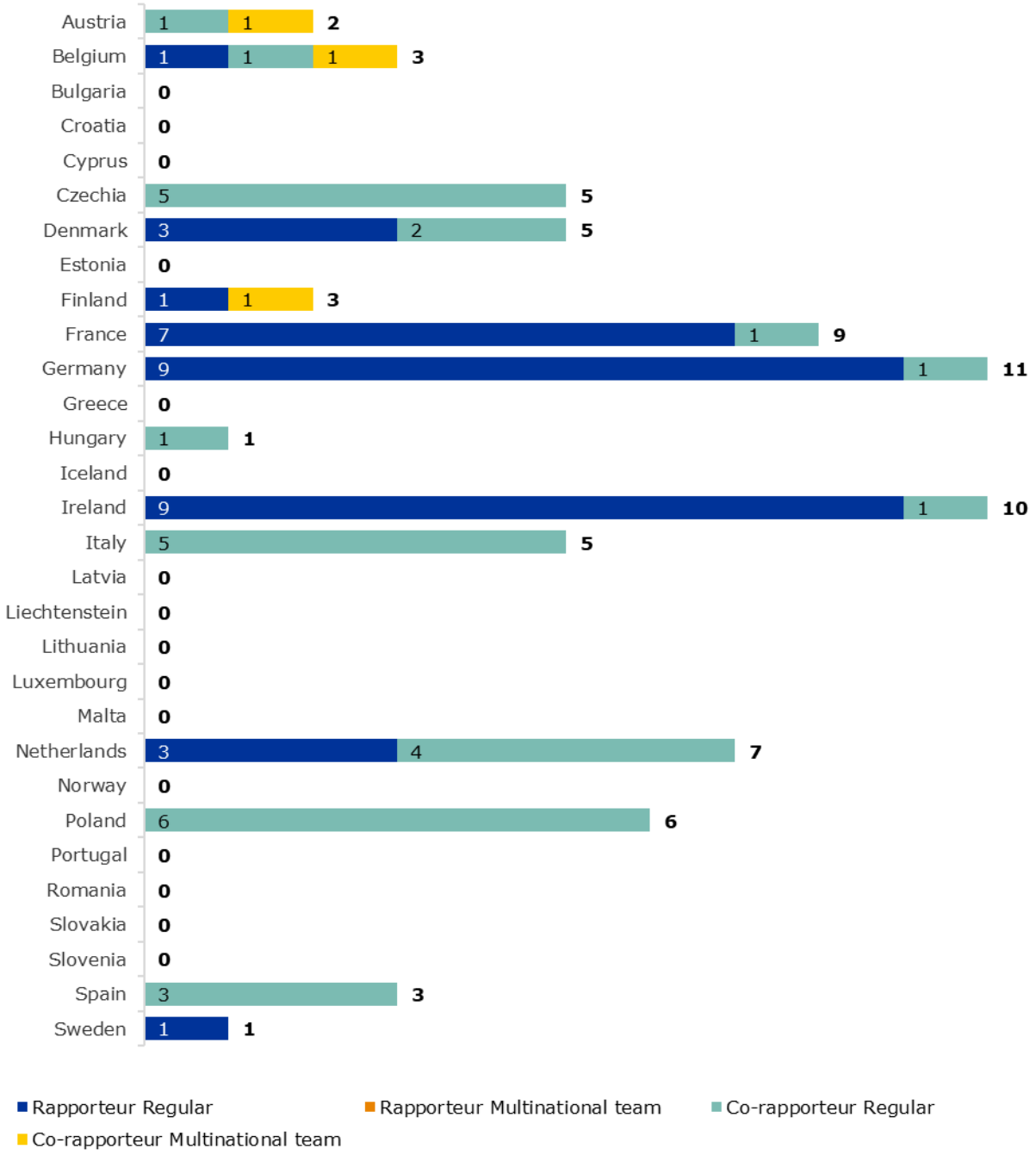
The assessment of a medicine by EMA's scientific committees is carried out by a rapporteur and a co-rapporteur, who prepare the assessment reports and lead discussions in the committees. The appointment is made on the basis of the best possible expertise for the particular product. Rapporteurs work through assessment procedures and take the lead in evaluating any new information on the medicine that may become available. EMA and its regulatory network partners run a scheme to enable multinational teams to assess applications for human and veterinary medicines. The aim is to mobilise the best expertise for medicines evaluation, regardless of where experts are based. The concept enables rapporteurs and co-rapporteurs for EMA's scientific committees to include experts from other Member States in their assessment teams. This helps to optimise resource use across the regulatory network and encourage cross-border fertilisation of scientific expertise.


CHMP rapporteurs/co-rapporteurs appointed in 2025
(for initial Marketing authorisation applications, including generics)
Austria 15 1 4 4 24
Belgium 3 3 2 8
Bulgaria 0
Croatia 5 1 2 1 9
Cyprus 1 1
Czechia 4 6 7 17
Denmark 6 6 3 15
Estonia 1 6 7
Finland 4 1 2 1 3 11
France 11 7 3 21
Germany 22 3 6 3 8 42
Greece 1 1
Hungary 1 2 2 5
Iceland 2 2 1 1 6
Ireland 4 3 6 13
Italy 6 1 7
Latvia 1 2 3 3 9
Liechtenstein 0
Lithuania 2 2 10 14
Luxembourg 0
Malta 1 1 2
Netherlands 17 2 3 22
Norway 2 3 1 6
Poland 3 10 13
Portugal 7 7 1 15
Romania 1 4 5
Slovakia 2 1 2 5
Slovenia 2 2 4
Spain 1 1 5 1 8
Sweden 20 2 1 23
Rapporteur Regular
Rapporteur Multinational team
Co-rapporteur Regular
Co-rapporteur Multinational team
Assessors Multinational team

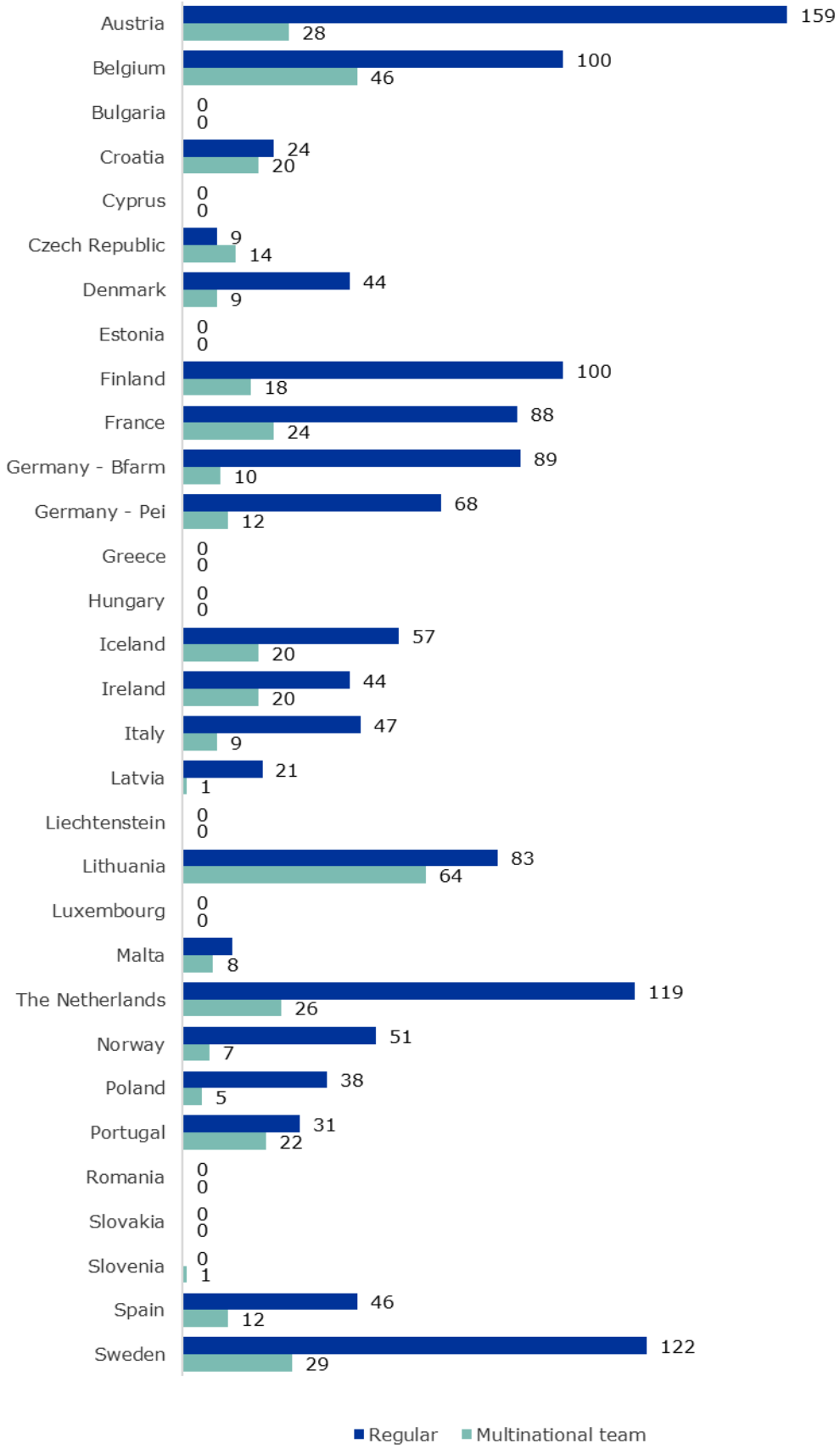
PRAC rapporteurs/co-rapporteurs appointed in 2025 (for initial Marketing authorisation applications)



CVMP rapporteurs/co-rapporteurs appointed in 2025
(for initial Marketing authorisation applications, including generics)



SAWP coordinators appointed in 2025



EU network training centre

The EU Network Training Centre (EU NTC) is a joint initiative of EMA and the national competent authorities. It enables the entire European medicines regulatory network (EMRN) to access and build subject matter expertise through a shared learning ecosystem covering both, human and veterinary medicines. By providing a central resource and platform for scientific and regulatory training, the EU NTC supports the quality and efficiency of operations by addressing the training needs of the EMRN and making best use of available resources. The EU NTC provides tools to drive didactic quality and foster knowledge sharing. The table below highlights its key activities from when it was established in 2015 to 2025.

EU Network training centre	2021	2022	2023	2024	2025
New scientific, regulatory and network portfolio curricula developed	1	1	0	1	5
Number of training events advertised to the EU Network	77	76	79	158	121
Number of reimbursed training events to the EU Network	0	4	3	4	12
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	15	11	13	9	11
Number of users registered to the EU NTC Learning Management System	5,916	6,610	7,036	7,776	9133
Number of NCA experts registered to the EU NTC Learning Management System	4,872	5,485	5,832	6,452	1,065

Communication and stakeholders

External communication

Providing clear, accurate information about medicines to our audiences and stakeholders—patients, healthcare professionals, researchers, academics, industry representatives and the general public is a key aspect of EMA's public health mission.

EMA works closely with regulatory partners and stakeholders both within the EU and globally. The Agency also uses many different channels to disseminate this information, by contributing to articles to relevant scientific journals, maintaining regular communication with media and engaging with diverse audiences across different social media platforms.

EMA's website is a comprehensive source of information and guidance on centrally authorised medicines and medicine regulation in the EU.

The EMA website remains the primary communication platform, offering a thorough source of information and guidance on centrally authorized medicines and EU medicine regulation. In 2025, 3,382 webpages were added and updated and 8,882 documents were published on the site.

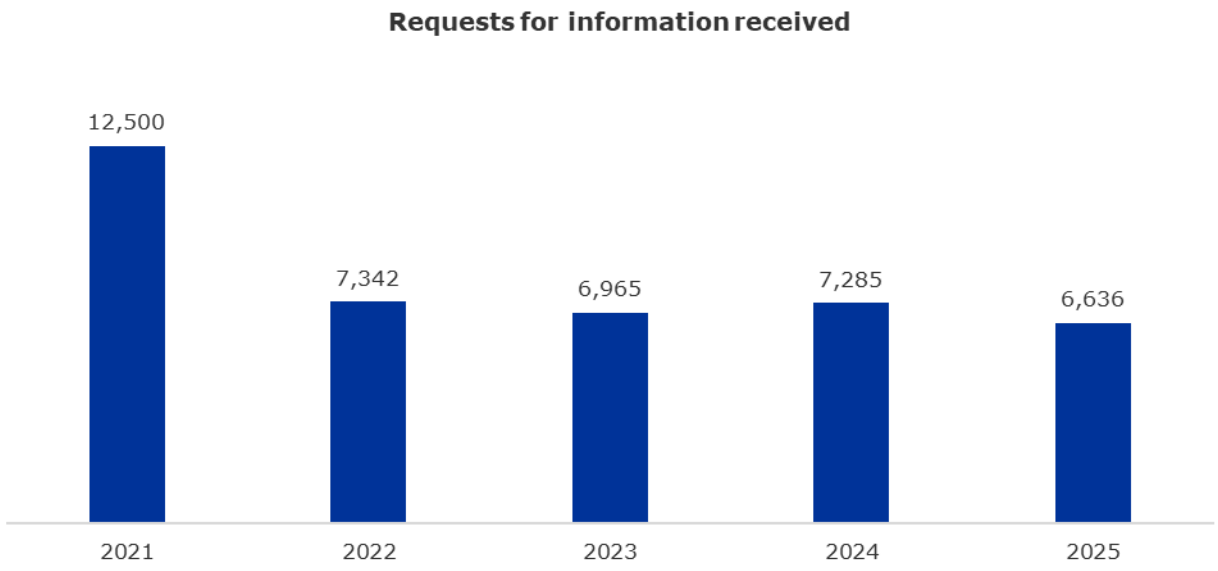
EMA staff and experts contributed to 127 articles on scientific and regulatory subjects to international journals in 2025.

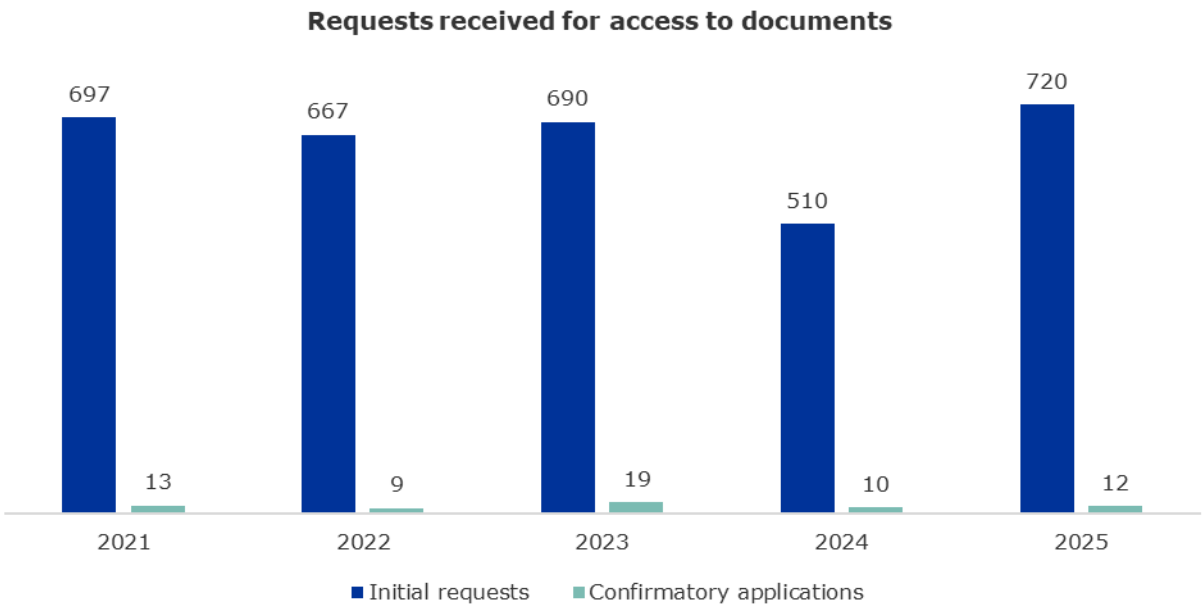
Requests for information and access to documents

Providing citizens with clear, transparent information about its activities is a fundamental aspect of EMA's work.

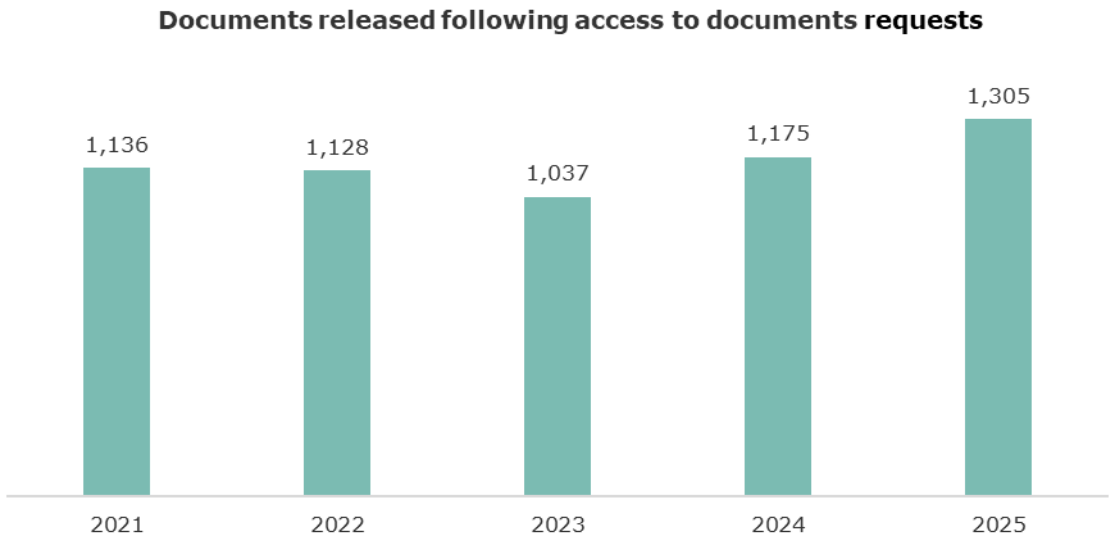
Access to Documents requests
EU citizens have the right to access documents held by EU institutions, bodies, offices and agencies. EMA facilitates this access in accordance with the principles and conditions outlined in by Regulation (EC) No 1049/2001 and the Agency's policy on document access.

Requests for information

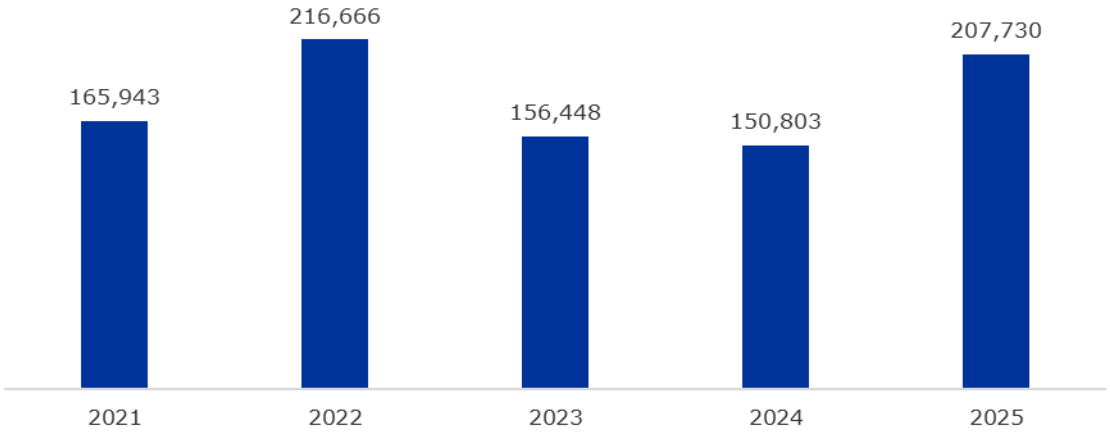




Total 2025: 732



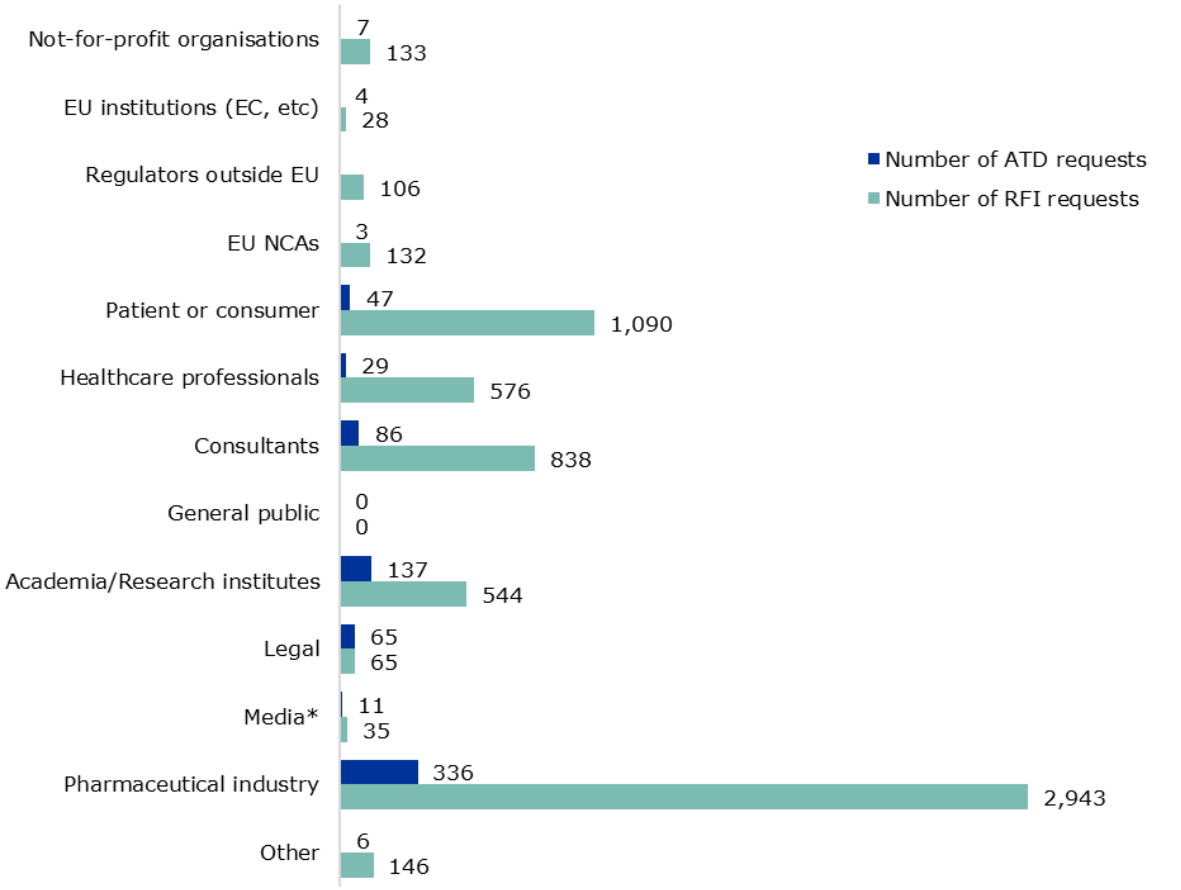
Pages released following access to documents requests



Access to documents by type of document (2025)

Note: More than one type of document can be requested per ATD.

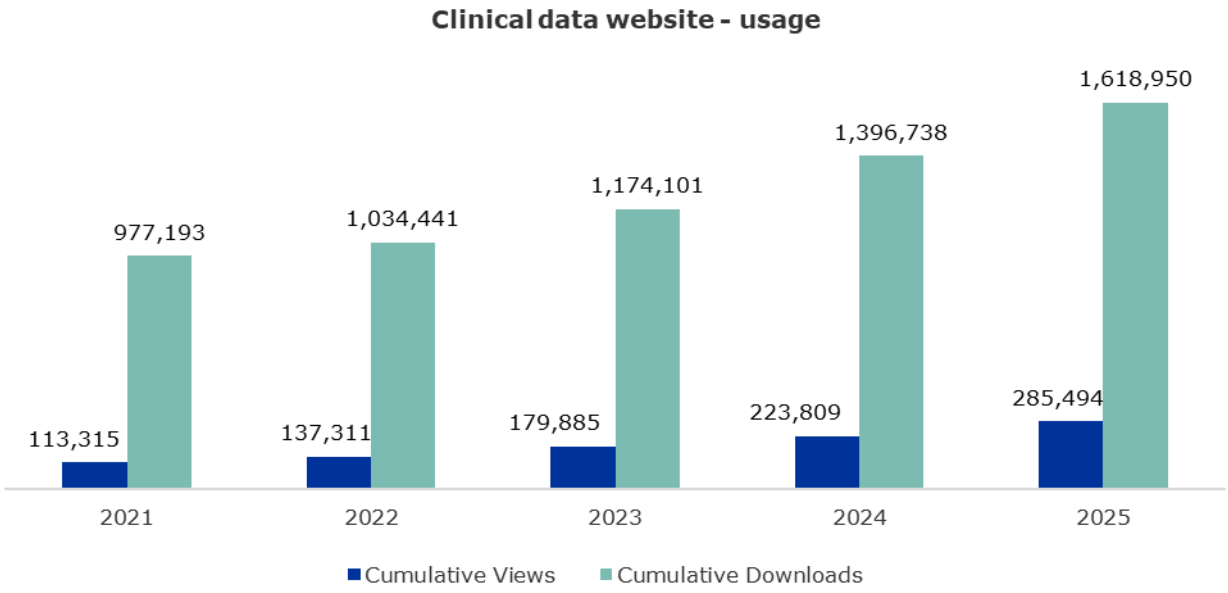
Affiliation of requestors of access to documents and access to information (2025)

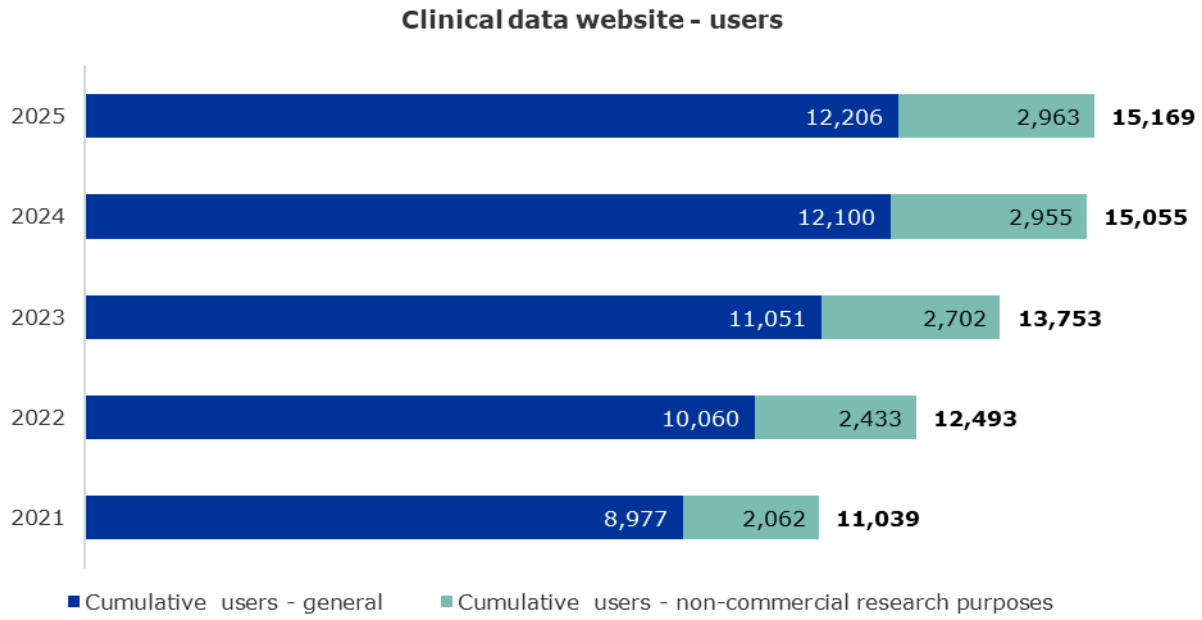


* Requests from the media submitted via the online form do not include requests sent directly to the press email inbox.

Publication of clinical data

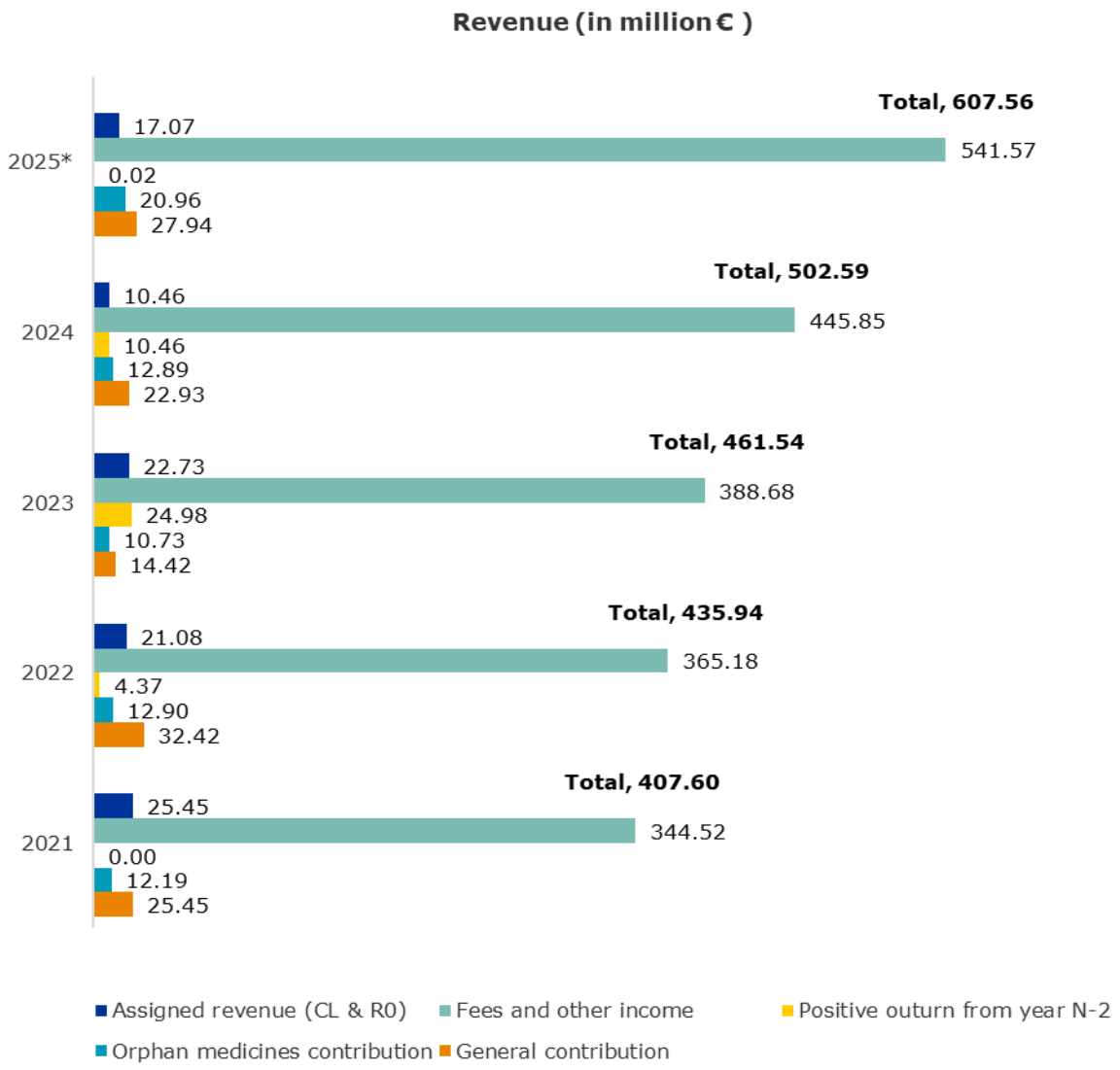
EMA releases clinical data provided by pharmaceutical companies to support their regulatory submissions for human medicines under the centralised procedure. This follows the agency's flagship policy on the publication of clinical data.





Administrative aspects

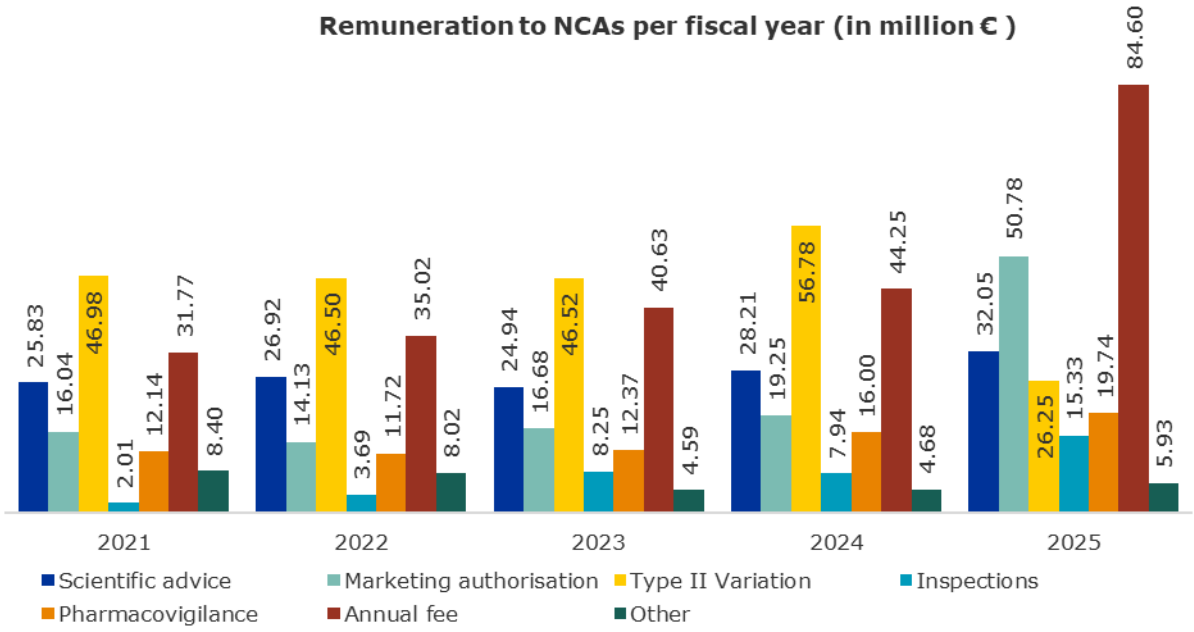
Financial information



* Includes non-automatic carry forward
R0 — external assigned revenue
CL — internal assigned revenue

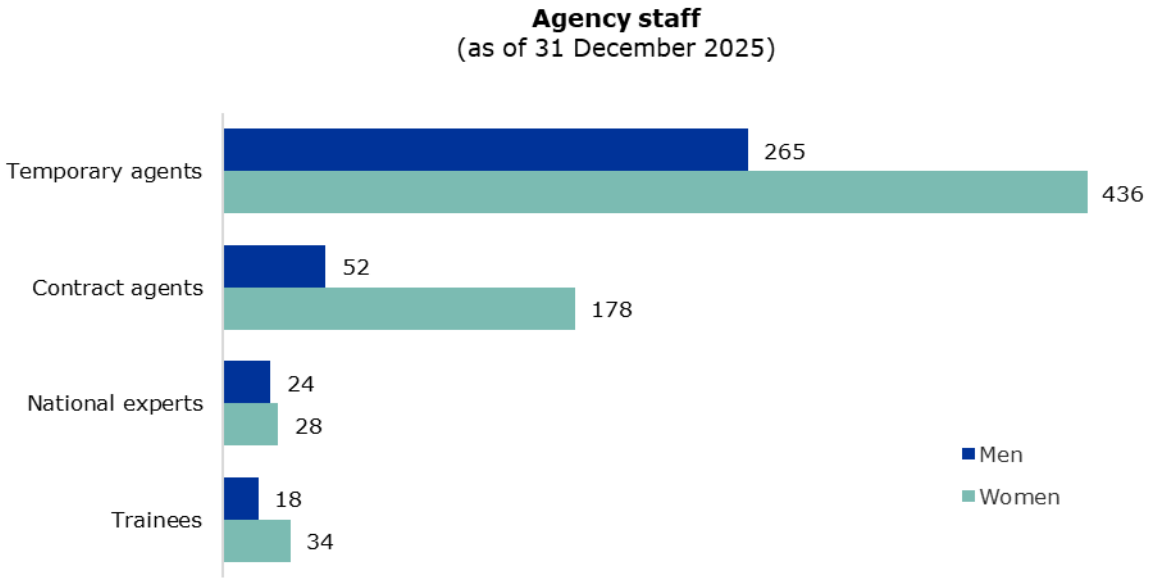
Remuneration to national competent authorities

NCAs in the EU Member States receive a share of EMA's revenue from fees for the assessments they carry out on behalf of the Agency. This figure includes payments for pharmacovigilance procedures, including the assessment of PSURs, PASS protocols and study results, and of pharmacovigilance-related referrals.

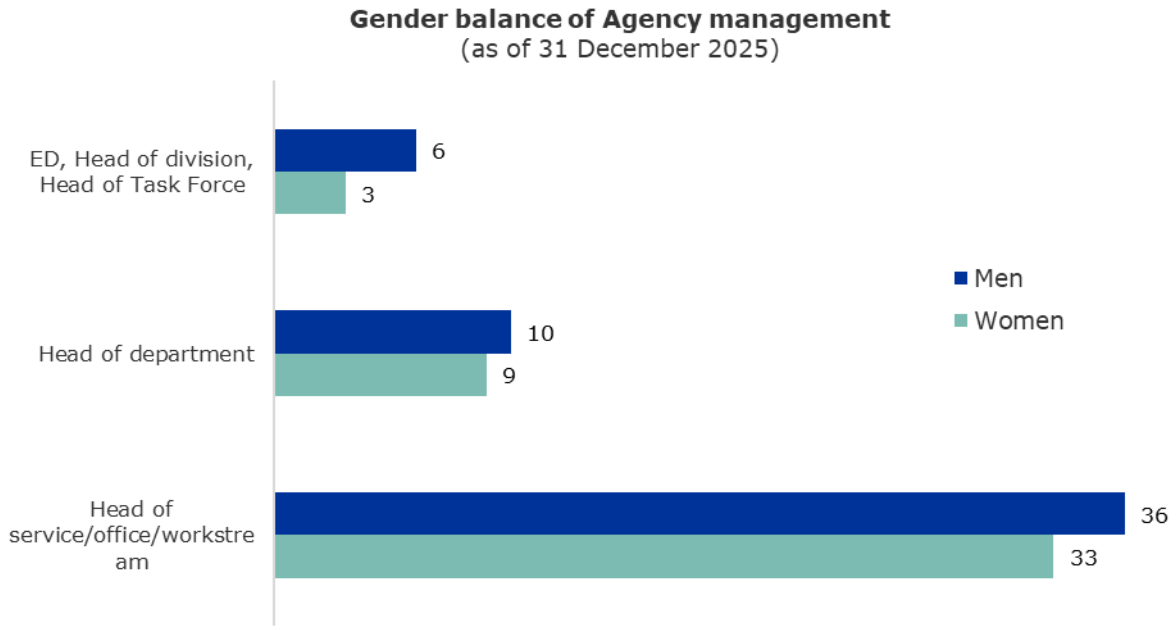


Total 2025: 234.67

Agency staff



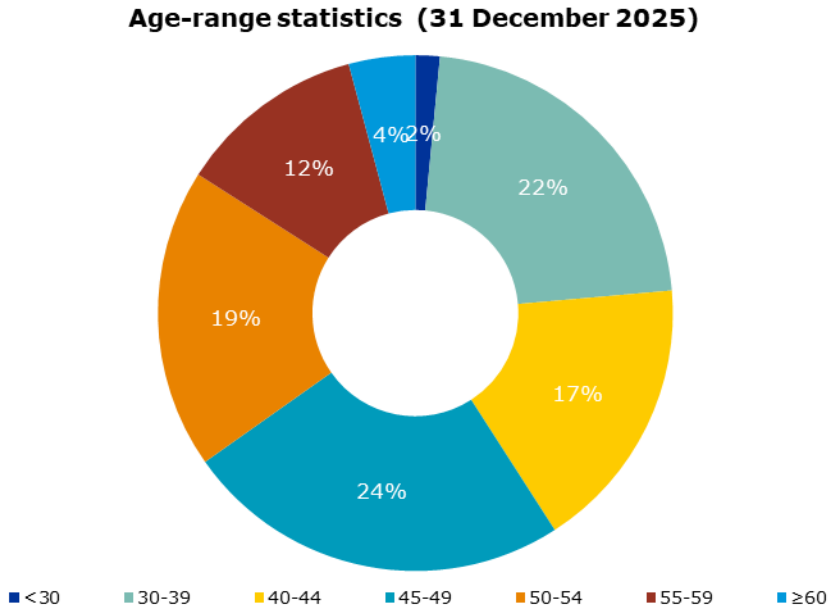
Total 2025: 1,035

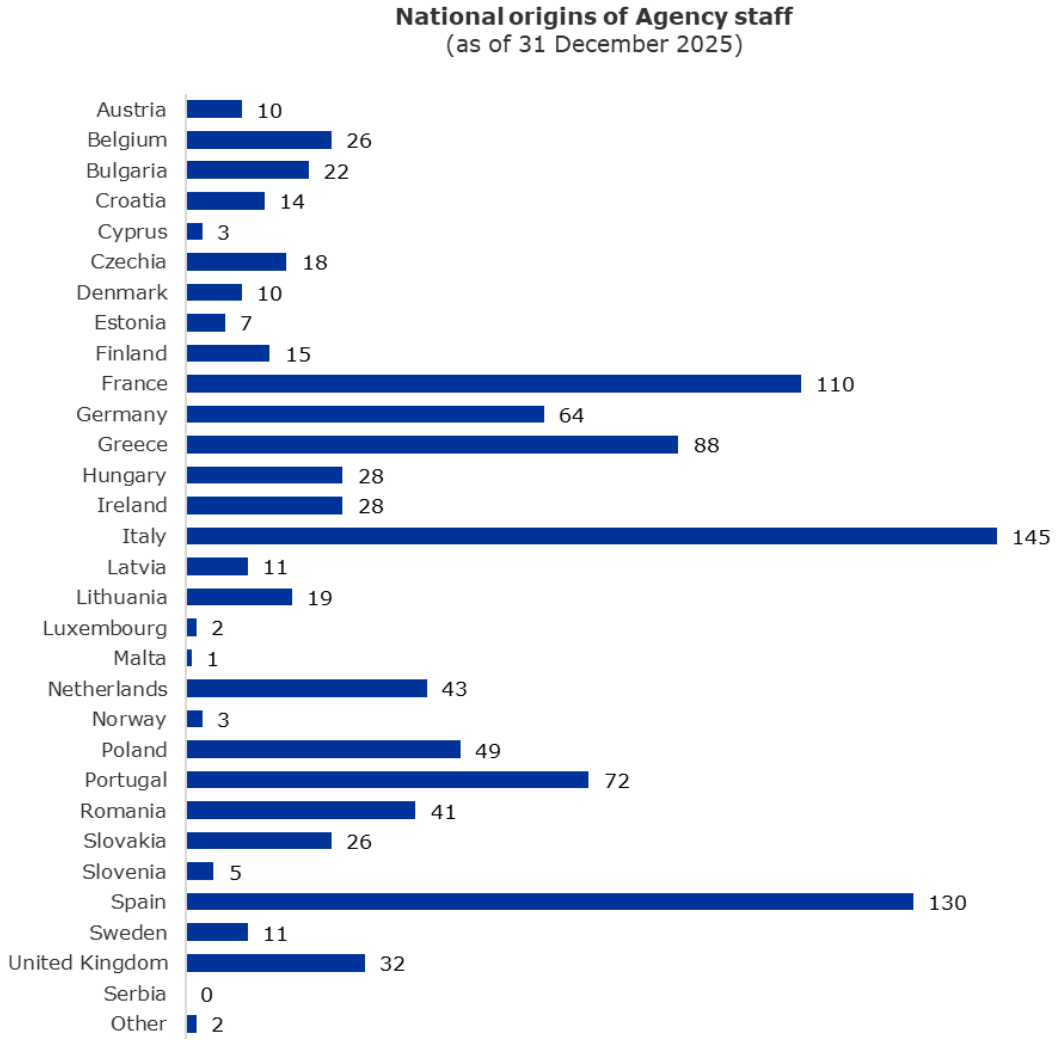


Total 2025: 97

Gender balance 2025

Status	Category AD (administrators) and FGIV				Category AST (assistants) and FGIII				TA/CA — all grades			
	Men		Women		Men		Women		Men		Women	
Temporary agents	229		242		36		194		265		436	
Contract agents	37		93		15		85		52		178	
Total	**266**	**44%**	**335**	**56%**	**51**	**15%**	**279**	**85%**	**317**	**34%**	**614**	**66%**





Includes Temporary Agents, Contract Agents, Seconded national experts and trainees

Annex 2. Statistics on financial management

Calculation budget outturn	2023	2024	2025
Revenue actually received (+)	€438,811,276.00	€492,127,783.68	€590,489,880.94
Payments made (-)	-€347,820,472.27	-€411,317,623.40	-€517,862,913.37
Carryover of appropriations (-)	-€96,226,655.69	-€79,167,727.14	-€75,166,517.06
Cancellation of appropriations carried over (+)	€5,174,935.87	€2,782,128.67	€2,727,862.17
Adjustment for carryover of assigned revenue appropriations from previous year (+)	-€0.01	€0.00	€0.00
Exchange rate differences (+/-)	€81,854.69	€170,422.56	-€168,727.45
Adjustment for negative balance from previous year (-)	€0.00	€0.00	€0.00
TOTAL	**€20,938.59**	**€4,594,984.37**	**€19,585.23**

The financial outturn for 2025, a surplus of EUR 19,585.23, represents 0.003% (EUR 4,594,984.37, represents 0.93% in 2024) of the approved budget of EUR 600,230,000, cf. the draft budget outturn for fund sources (C1, C11).

The Agency's adopted budget consists of non-differentiated appropriations only, so no distinction is made between commitment and payment appropriations.

Budget implementation per title reflects a similar level in 2025 as achieved in 2024:

- Title I — Staff expenditure — final implementation was 99.6% (99.6% in 2024), which is considered a good result
- Title II — infrastructure and operating expenditure — final implementation[42] was 99.2% (99.7% in 2024), which is considered a good result
- Title III — operational expenditure — final was 98.2% (99.8% in 2024), which is considered a good result.

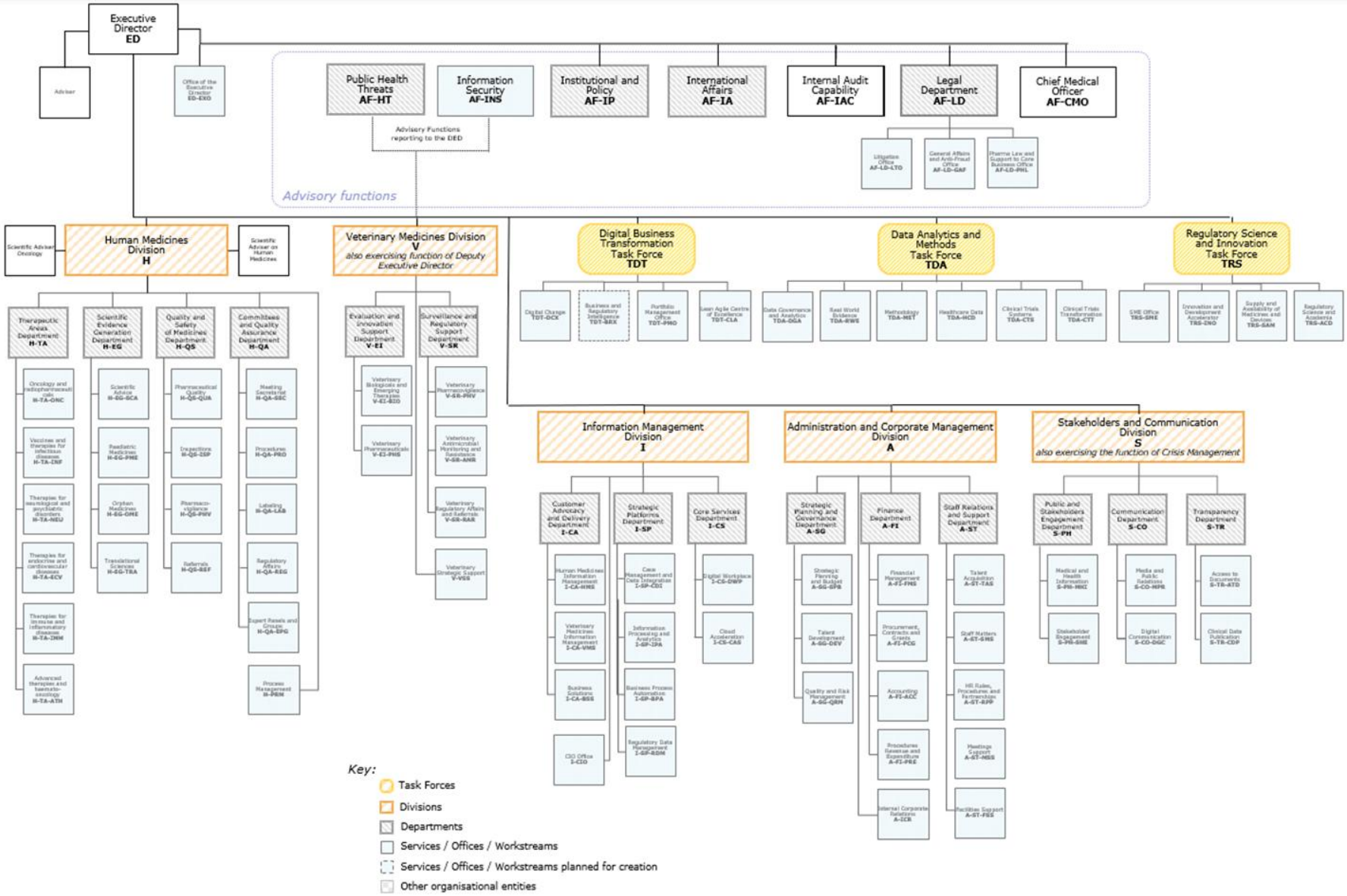
In 2025, all the KPIs related to the amounts carried forward from 2025 to 2026 (C1 to C8):

- title I — Staff expenditure: actual 3.1% (3.1% in 2024) versus KPI of 10%
- title II — infrastructure and operating expenditure: actual 16.3% (13.3% in 2024) versus KPI of 20%
- title III — operational expenditure: actual 16.8% (26.0% in 2024) versus KPI of 30%.

The of overall amount carried forward from 2025 to 2026 of 12.3% (16.1% in 2024) was also within the KPI of 15%.

[42] Including non-automatic carry forward of €2,450,000 as approved by the Management Board in February 2026

Annex 3. Organisation chart as of 31 December 2025


Executive Director
ED
Adviser
Office of the Executive Director
ED-EXD
Public Health Threats
AF-HT
Information Security
AF-INS
Institutional and Policy
AF-IP
International Affairs
AF-IA
Internal Audit Capability
AF-IAC
Legal Department
AF-LD
Chief Medical Officer
AF-CMO
Advisory Functions reporting to the DED
Litigation Office
AF-LD-LTO
General Affairs and Anti-Fraud Office
AF-LD-GAF
Pharma Law and Support to Core Business Office
AF-LD-PHL
Advisory functions
Scientific Adviser Oncology
Human Medicines Division
H
Scientific Adviser on Human Medicines
Veterinary Medicines Division
V
also exercising function of Deputy Executive Director
Digital Business Transformation Task Force
TDT
Data Analytics and Methods Task Force
TDA
Regulatory Science and Innovation Task Force
TRS
Digital Change
TDT-DCX
Business and Regulatory Intelligence
TDT-BRX
Portfolio Management Office
TDT-PMO
Lean Agile Centre of Excellence
TDT-CLA
Data Governance and Analytics
TDA-DGA
Real World Evidence
TDA-RWE
Methodology
TDA-MET
Healthcare Data
TDA-HCD
Clinical Trials Systems
TDA-CTS
Clinical Trials Transformation
TDA-CTT
SME Office
TRS-SME
Innovation and Development Accelerator
TRS-INO
Supply and Availability of Medicines and Devices
TRS-SAM
Regulatory Science and Academia
TRS-ACD
Therapeutic Areas Department
H-TA
Scientific Evidence Generation Department
H-EG
Quality and Safety of Medicines Department
H-QS
Committees and Quality Assurance Department
H-QA
Evaluation and Innovation Support Department
V-EI
Surveillance and Regulatory Support Department
V-SR
Oncology and radiopharmaceuticals
H-TA-ONC
Vaccines and therapies for infectious diseases
H-TA-INF
Therapies for neurological and psychiatric disorders
H-TA-NEU
Therapies for endocrine and cardiovascular diseases
H-TA-ECV
Therapies for immune and inflammatory diseases
H-TA-IMM
Advanced therapies and haemato-oncology
H-TA-ATH
Scientific Advice
H-EG-SCA
Paediatric Medicines
H-EG-PME
Orphan Medicines
H-EG-OME
Translational Sciences
H-EG-TRA
Pharmaceutical Quality
H-QS-QUA
Inspections
H-QS-INS
Pharmacovigilance
H-QS-PHV
Referrals
H-QS-REF
Meeting Secretariat
H-QA-SEC
Procedures
H-QA-PRO
Labelling
H-QA-LAB
Regulatory Affairs
H-QA-REG
Expert Panels and Groups
H-QA-EPG
Process Management
H-PRM
Veterinary Biologicals and Emerging Therapies
V-EI-BIO
Veterinary Pharmaceuticals
V-EI-PHS
Veterinary Pharmacovigilance
V-SR-PHV
Veterinary Antimicrobial Monitoring and Resistance
V-SR-ANR
Veterinary Regulatory Affairs and Referrals
V-SR-RAR
Veterinary Strategic Support
V-VSS
Information Management Division
I
Administration and Corporate Management Division
A
Stakeholders and Communication Division
S
also exercising the function of Crisis Management
Customer Advocacy and Delivery Department
I-CA
Strategic Platforms Department
I-SP
Core Services Department
I-CS
Strategic Planning and Governance Department
A-SG
Finance Department
A-FI
Staff Relations and Support Department
A-ST
Public and Stakeholders Engagement Department
S-PH
Communication Department
S-CO
Transparency Department
S-TR
Human Medicines Information Management
I-CA-HMI
Veterinary Medicines Information Management
I-CA-VMI
Business Solutions
I-CA-BSS
CIO Office
I-CIO
Case Management and Data Integration
I-SP-CDI
Information Processing and Analytics
I-SP-IPA
Business Process Automation
I-SP-BPA
Regulatory Data Management
I-SP-RDM
Digital Workplace
I-CS-DWP
Cloud Acceleration
I-CS-CAS
Strategic Planning and Budget
A-SG-SPB
Talent Development
A-SG-DEV
Quality and Risk Management
A-SG-QRM
Financial Management
A-FI-FMS
Procurement, Contracts and Grants
A-FI-PCG
Accounting
A-FI-ACC
Procedures Revenue and Expenditure
A-FI-PRE
Internal Corporate Relations
A-ICR
Talent Acquisition
A-ST-TAS
Staff Matters
A-ST-SMS
HR Rules, Procedures and Partnerships
A-ST-RPP
Meetings Support
A-ST-MSS
Facilities Support
A-ST-FES
Medical and Health Information
S-PH-MHI
Stakeholder Engagement
S-PH-SHE
Media and Public Relations
S-CO-MPR
Digital Communication
S-CO-DGC
Access to Documents
S-TR-ATD
Clinical Data Publication
S-TR-CDP
Key:
Task Forces
Divisions
Departments
Services / Offices / Workstreams
Services / Offices / Workstreams planned for creation
Other organisational entities

Annex 4. Establishment plan and additional information on HR management

Annex 4.1. Establishment plan

Function group and grade	2024				2025				2026	
	Authorised budget		Actually filled as of 31/12/2024		Authorised budget		Actually filled as of 31/12/2025		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16		0		0		0		0		0
AD 15		3		3		3		1		3
AD 14		12		12		12		11		13
AD 13		12		12		15		15		18
AD 12		61		61		64		64		64
AD 11		50		50		49		49		51
AD 10		57		57		59		59		60
AD 9		82		82		94		94		109
AD 8		78		78		81		81		76
AD 7		90		90		85		85		93
AD 6		55		55		43		43		29
AD 5		0		0		0		0		0
AD TOTAL	**0**	**500**		**500**	**0**	**505**		**502**		**516**
AST 11		3		3		3		3		3
AST 10		7		7		7		7		7
AST 9		10		10		13		13		15
AST 8		15		15		19		19		23
AST 7		29		29		38		38		41
AST 6		35		35		26		26		40
AST 5		49		49		56		56		42
AST 4		32		32		22		22		16
AST 3		11		11		15		15		16
AST 2		0		0		0		0		0
AST 1		0		0		0		0		0
AST TOTAL	**0**	**191**		**191**	**0**	**199**		**199**		**203**
AST/SC1										
AST/SC2										
AST/SC3										
AST/SC4										
AST/SC5										
AST/SC6										
AST/SC TOTAL	**0**	**0**			**0**	**0**		**0**	**0**	**0**
GRAND TOTAL	**0**	**691**		**691**	**0**	**704**		**701**	**0**	**719**

Contract agents	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025 (1)	Headcount as of 31/12/2025	FTE corresponding to the authorised budget 2026
Function Group IV	125	111	119	128	111	123	131
Function Group III	78	100	99	75	93	99	72
Function Group II	0	0	0	0	0	0	0
Function Group I	0	0	0	0	0	0	0
Additional CA	0	0	0	0	0	0	0
TOTAL	**203**	**211**	**218**	**203**	**204**	**222**	**203**

(1) In 2025 the Agency applied a significant effort optimize utilization of the authorized CA ceiling, which is set in terms of FTEs rather than posts. The FTE numbers therefore may fluctuate up or down but generally are balanced by small vacancy rates occurring in other types of contracts predominantly in TAs. Any budgetary impact from these minor fluctuations is managed through a regular budget monitoring process and funded through industry fees without placing any additional burden on the EU budget.

Seconded National Experts	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025	Headcount as of 31/12/2025	FTE corresponding to authorised budget 2026
Total	45	48	53	45	45	52	45

Interims

	Total FTEs in year 2025
Number	120

Other Human Resources | Structural service providers

	Actually in place as of 31/12/2025
Security	23
IT service desk	48
IT maintenance and support 'time & means' contracts only	2
Reception	14
Building maintenance[1]	n/a
Cleaning	26
Catering	27
Reprographics and mail services	7
1) Building maintenance: included in the rental package	

4.2. Information on the entry level for each type of post

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment	Indication whether the function is dedicated to administrative support or operations
Head of Division/Task Force (Level 2)	TA	AD12 AD10	Depending on function: operational or administrative
Head of Department (Level 3)	TA	AD09 (int.), AD10 (ext.)	Depending on function: operational or administrative
Head of Service/Office/Workstream (Level 4)	TA	AD06 (int.), AD08 (ext.)	Depending on function: operational or administrative
Adviser, Senior Expert	TA	AD13	Operational or administrative
Senior Specialist, Architect, Lead (e.g. scientific, information technology management, communication)	TA	AD08	Depending on function: operational or administrative
Specialist, Lead, Partner, Architect (e.g. scientific, information technology management, communication)	TA	AD06	Depending on function: operational or administrative
Senior Assistant, Technical adviser	TA	AST10	Depending on function: operational or administrative
Coordinator (e.g. scientific support, HR, communication, legal, facilities)	TA	AST03	Administrative / Operational
Executive Assistant (senior management support)	TA	AST03	Administrative
Officer (e.g. core and support functions)	CA	FGIV	Depending on function: operational or administrative
Analyst (information technology management)	CA	FGIV	Operational
Assistant (e.g. scientific support, HR, communication, department management support)	CA	FGIII	Administrative / Operational

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment	Indication whether the function is dedicated to administrative support or operations
Special functions			
Head of Audit	TA	AD09	Administrative/Operational
Head of Accounting and Agency's Accounting Officer (Level 4)	TA	AD09	Operational
Data Protection Officer	TA	AD06	Administration

4.3. Results of the screening/benchmarking exercise as of December 2025

	2024 (%)	2025 (%)
Job Type (sub) category		
Administrative support and Coordination	**18%**	**18%**
Administrative Support	16%	17%
Coordination	2%	2%
Operational	**76%**	**75%**
Top level Operational Coordination	1%	1%
Programme management and Implementation	28%	27%
Evaluation & Impact assessment	33%	33%
General operational	14%	14%
Neutral	**6%**	**7%**
Finance/ Control	6%	7%
Linguistics	**0%**	0%
Total	**100%**	**100%**

4.4. HR implementing rules adopted in 2025

Implementing rule	Adopted	Effective date
Revised Decision of the European Medicines Agency on rules relating to Articles 11,11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members and candidates before recruitment	20 March 2025	1 May 2025
Decision of the European Medicines Agency on the adoption by analogy of Commission decision C(2025) 2495 of 13 May 2025 on the general provisions for implementing Articles 11,12 and 13 of Annex VII to the Staff Regulations of Officials and on authorised travel	3 October 2025	1 January 2026

Annex 5. Human and financial resources by activity

Activities	Temporary Agents	Contract Agents & Seconded National Experts (FTEs)	Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	TOTAL
			€'000	€'000	€'000	€'000	€'000	€'000
1 Evaluation activities for human medicines	**274**	**101**	**69,083**	**25,500**	**6,780**	**203,095**	**14,091**	**318,550**
1.1 Pre-authorisation activities	57	22	16,347	3,355	3,986	37,048	16	60,752
1.2 Initial evaluation activities	54	14	13,340	2,646	0	47,200	1,745	64,931
1.3 Post-authorisation activities	74	25	16,331	11,843	0	103,348	4,414	135,936
1.4 Referrals	6	1	1,504	306	0	250	264	2,324
1.5 Pharmacovigilance activities	47	22	11,843	3,460	1,810	15,018	5,950	38,080
1.6 Other specialized areas and activities	31	13	8,557	3,599	985	0	1,446	14,586
1.7 Medical Devices	5	2	1,162	291	0	231	257	1,941
2 Evaluation activities for veterinary medicines	**26**	**10**	**7,073**	**2,852**	**368**	**16,483**	**474**	**27,250**
2.1 Pre-authorisation activities	1	0	350	72	52	295	0	769
2.2 Initial evaluation activities	9	3	2,368	510	17	3,616	249	6,760
2.3 Post-authorisation activities	8	3	1,868	595	0	1,104	221	3,788
2.4 Arbitrations and referrals	1	0	174	41	0	131	0	346
2.5 Pharmacovigilance activities	4	2	1,164	1,312	256	11,337	4	14,074
2.6 Other specialized areas and activities	4	1	1,148	323	43	0	0	1,514
3 Horizontal activities and other areas	**261**	**106**	**69,611**	**63,988**	**8,615**	**16,117**	**15,803**	**174,135**
3.1 Committee coordination	61	19	12,882	3,287	5,979	0	24	22,172
3.2 Inspection and Compliance	31	19	6,610	2,711	65	16,117	6	25,509
3.3 Partners and Stakeholders	48	11	13,933	2,649	1,688	0	726	18,997
3.3a Transparency and access to documents	17	8	3,754	1,036	0	0	0	4,789
3.3b Information	55	30	16,315	13,375	460	0	2,337	32,488
3.4 International activities	16	9	5,599	593	156	0	0	6,347
3.5 Information Management (incl. EU Telematics)	34	11	10,518	40,337	267	0	12,710	63,832
4 Corporate Governance and Support activities	**139**	**32**	**41,568**	**14,018**	**340**	**0**	**1,065**	**56,992**
4.1 Governance, Quality Management and Internal Audit	19	4	7,077	1,119	340	0	904	9,441
4.2 Finance	24	11	7,204	5,972	0	0	107	13,282
4.3 Information technology	36	8	11,996	2,141	0	0	0	14,136
4.4 Human resources	47	8	12,397	4,146	0	0	55	16,598
4.5 Infrastructure services	13	0	2,895	641	0	0	0	3,535
Total	**701**	**249**	**187,335**	**106,359**	**16,104**	**235,695**	**31,434**	**576,927**

Less - Earmarked fund from Ministry of Foreign affairs as contribution for rent and building maintenance cost (R0)	495
Plus - exceptional expenditure related to London premises	14,148
Current year (C1) net of exceptional expenditure for London premises	**590,579**

Annex 6. Contribution, grant and service level agreements. Financial Framework Partnership Agreements

Grants received

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**		**2025**	
Grant agreements										
SISAQOL 945052	09/11/2020	€78,756	31/12/2025	Innovative Health Initiative Joint Undertaking	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life endpoints	Amount	CA	PA	CA	PA
							€17,953	€17,953	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
PREMIER 875508	24/06/2020	€47,000	31/08/2026	Innovative Health Initiative Joint Undertaking	Prioritisation and Risk Evaluation of Medicines in the Environment	Amount	CA	PA	CA	PA
							€1,045	€1,045	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
BRIDGE 101219311	07/11/2025	€197,595	31/10/2028	Innovative Health Initiative Joint Undertaking	Breakthrough Regulatory Innovation and Development through sandbox Environments	Amount	CA	PA	CA	PA
							€0	€0	€95,504	€95,504
						Number of CA	0		0	
						Number of SNEs	0		0	
RealiseD 101165912	12/12/2024	€554,459	31/12/2029	Innovative Health Initiative Joint Undertaking	Comprehensive methodological and operational approach to clinical trials in rare and ultra-rare diseases	Amount	CA	PA	CA	PA
							€0	€0	€194,061	€194,061
						Number of CA	0		0	
						Number of SNEs	0		0	
Total grant agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€18,997	**€18,997**	**€289,565**	**€289,565**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Contribution agreements										
IPA III 700001692	11/12/2023	€600,000.00	31/12/2026	European Commission DG NEAR	Participation of candidate countries and potential candidates in	Amount	CA	PA	CA	PA
							€570,000	€570,000	€0	€0
						Number of CA	1		1	
						Number of SNEs	0		0	

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**		**2025**	
					EMA trainings and activities					
NDICI AFRICA 2023/448-916	20/12/2023	€10,000,000.00	30/11/2027	European Commission DG INTPA	Local Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa	Amount	CA	PA	CA	PA
							€0	€0	€5,128,848	€5,128,848
						Number of CA	6		7	
						Number of SNEs	0		0	
ePI II SI.919030-4500063793	31/05/2024	€3,900,000.00	31/12/2028	European Commission DG SANTE/EU4Health	Implementation of the action 'electronic Product Information (ePI) for medicinal products'	Amount	CA	PA	CA	PA
							€1,500,000	€1,500,000	€2,400,000	€2,400,000
						Number of CA	0		0	
						Number of SNEs	0		0	
Total contribution agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€2,070,000	**€2,070,000**	**€7,528,848**	**€7,528,848**
						Number of CA	**7**		**8**	
						Number of SNEs	**0**		**0**	
Service-level agreements										
n/a	n/a	n/a	n/a	n/a	n/a	Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
Total service-level agreements:						Amount	**CA**	**PA**	**CA**	**PA**
							€0	**€0**	**€0**	**€0**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
GRAND TOTAL						**Amount**	**CA**	**PA**	**CA**	**PA**
							€2,088,997	**€2,088,997**	**€7,818,413**	**€7,818,413**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	

Grants given

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**		**2025**	
Grant agreements										
EMA/GRANT/2024/01/IA	17/07/2024	€450,000	15 months from date of signature, extended until 22 October 2025	African Union Development Agency New Partnership for Africa's Development	AUDA-NEPAD launched a pilot to test joint continental evaluation procedures	Amount	CA	PA	CA	PA
							€450,000	€450,000	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-01	19/12/2024	€95,200	Max 33 months from signature (19 September 2027)	Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. (INFARMED)	Capacity building in Mozambique and Cape Verde related to quality, clinical, reliance, GMP inspections, PhV	Amount	CA	PA	CA	PA
							€95,200	€95,200	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-02	19/12/2024	€26,300	Max 33 months from signature (19 September 2027)	Malta Medicines Authority	Capacity building in Zimbabwe related to PhV	Amount	CA	PA	CA	PA
							€26,300	€26,300	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-03	19/12/2024	€44,400	Max 33 months from signature (19 September 2027)	Health Products Regulatory Authority (An tÚdarás Rialála Táirgí Sláinte)	Capacity building for African Medicines Agency GMP/GDP inspectors	Amount	CA	PA	CA	PA
							€44,400	€44,400	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-04	19/12/2024	€97,000	Max 33 months from signature (19 September 2027)	Swedish Medical Products Agency (Läkemedelsverket)	Capacity building for EAC countries related to antimicrobial resistance	Amount	CA	PA	CA	PA
							€97,000	€97,000	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-05	19/12/2024	€94,150	Max 33 months from signature (19 September 2027)	Office for Registration of Medical Products, Medical Devices and Biocidal Products (Urząd Rejestracji Produktów	Capacity building in Botswana related to quality, clinical and non-clinical trials	Amount	CA	PA	CA	PA
							€94,150	€94,150	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**		**2025**	
				Leczniczych, Wyrobów Medycznych i Produktów Biobójczych)						
EMA/GRANT/2024/02/IA-06	19/12/2024	€54,450	Max 33 months from signature (19 September 2027)	Paul-Ehrlich Institute (Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel)	Capacity building in Botswana related to PhV	Amount	CA	PA	CA	PA
							€54,450	€54,450	€0	€0
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-07	26/05/2025	€132,200	Max 29 months from signature (26 October 2027)	Office for Registration of Medical Products, Medical Devices and Biocidal Products (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych)	Capacity building in Ethiopia related to quality, clinical and non-clinical trials and PhV	Amount	CA	PA	CA	PA
							€0	€0	€132,200	€132,200
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-08	23/04/2025	€54,450	Max 31 months from signature (23 November 2027)	Paul-Ehrlich Institute (Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel)	Capacity building in Uganda related to PhV	Amount	CA	PA	CA	PA
							€0	€0	€54,450	€54,450
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-09	23/04/2025	€54,450	Max 31 months from signature (23 November 2027)	Paul-Ehrlich Institute (Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel)	Capacity building in Lesotho related to PhV	Amount	CA	PA	CA	PA
							€0	€0	€54,450	€54,450
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2024/02/IA-10	23/04/2025	€162,500	Max 31 months from signature (23 November 2027)	Agencia Española De Medicamentos Y Productos Sanitarios	Capacity building in Ghana related to clinical assessment of biological medicines, GMP and GDP inspections	Amount	CA	PA	CA	PA
							€0	€0	€162,500	€162,500
						Number of CA	0		0	
						Number of SNEs	0		0	
	23/04/2025	€169,200				Amount	CA	PA	CA	PA

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**		**2025**	
EMA/GRANT/2024/02/IA-11			Max 31 months from signature (23 November 2027)	Agenzia Italiana del Farmaco (AIFA)	Capacity building for EAC countries related to quality		€0	€0	€169,200	€169,200
						Number of CA	0		0	
						Number of SNEs	0		0	
EMA/GRANT/2025/03/IA	02/09/2025	€899,247	Max 26 months from signature (2 November 2027)	European Directorate for the Quality of Medicines and Healthcare (EDQM)	Medicines regulatory systems strengthening in Sub-Saharan Africa	Amount	CA	PA	CA	PA
							€0	€0	€899,247	€899,247
						Number of CA	0		0	
						Number of SNEs	0		0	
Total grant agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€861,500	**€861,500**	**€1,472,047**	**€1,472,047**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Contribution agreements										
n/a	n/a	n/a	n/a	n/a	n/a	Amount	CA	PA	CA	PA
						Number of CA	0		0	
						Number of SNEs	0		0	
Total contribution agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€0	**€0**	**€0**	**€0**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Service-level agreements										
n/a	n/a	n/a	n/a	n/a	n/a	Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
Total service-level agreements:						Amount	**CA**	**PA**	**CA**	**PA**
							€0	**€0**	**€0**	**€0**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
GRAND TOTAL						**Amount**	**CA**	**PA**	**CA**	**PA**
							€861,500	**€861,500**	**€1,472,047**	**€1,472,047**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	

Annex 7. Environment management

Aspect	Environmental objectives	Key Performance Indicator	Target 2025 — 2028	Reporting
Energy	Energy efficiency: "EMA drives energy efficiency in line with good practices"	Total annual consumption of energy (heating, cooling, electricity) per FTE Total share of energy from sustainable sources.	To establish a reduction trend over the programming period. Continue to use 100% renewable electricity	During 2025 investments were made in the building management system software, allowing for adjustments of temperature set-points to optimise efficiency. Over the last year, EMA has maintained its continuous replacement scheme of laptops to support recovery of raw materials. When technically and financially justifiable other electric equipment and small electrical devices, products and appliances are replaced with a focus on further energy efficiency. An awareness campaign was running throughout 2025 encouraging staff and contractors to switch off their IT equipment over night and during weekends to reduce energy consumption. Energy baseline year 2024 Electricity consumption – 2328,9 kWh/FTE/per year — ↓4,3% decrease Heating consumption – 1608,7 kWh/FTE/per year — ↑20,5% increase Cooling consumption – 1321,9 kWh/FTE/per year — ↑38,4% increase While electricity consumption shows a downward trend, both heating and cooling consumption have increased in comparison with 2024. Electricity continues to be sourced from 100% Dutch wind power Heating provided over the district heating system had a renewable factor of 0,19

Aspect	Environmental objectives	Key Performance Indicator	Target 2025 — 2028	Reporting
				(19%) and cooling had 87% renewable sources.
Material efficiency	Material efficiency: "EMA drives material efficiency in line with good practices"	Consumption of sheets of office paper per FTE per working day	Monitor consumption	The total number of printed copies continues to be at low levels despite the stabilised occupancy of the offices in 2025. Paper use: 3 sheets per FTE per working day
Material sustainability	Material sustainability: "EMA implements green criteria in its procurements for conscious selection of sustainable materials"	Choice of materials used for the environmental impact and reduction of hazards	Green criteria to be used in all procurements where it is relevant and possible given the type of service or supply	Implementation of green criteria in procurements where it was relevant and possible to promote sustainable materials and products such as eco-labels or equivalent, and sustainable/fair-trade and seasonal produce continued throughout the year.
Water	Water – not relevant due to the water efficiency at the EMA building	Total annual consumption of water per FTE and per occupancy of the building	Monitor consumption	9.1 m3/FTE/per year
Waste	Waste: "EMA drives waste reduction in line with good practices"	Total annual generation of waste per FTE	To monitor all waste streams generation.	The total generation of waste per FTE was 66.5 kg/FTE/per year
Soil	Land contamination – not relevant (no further land to be used)	N/A	N/A	N/A
Air	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] through office occupancy; Emissions of greenhouse gases [t] from meetings with external participants, reimbursed by the Agency Emissions from staff duty travel	Target to reduce emissions from delegates travel with 40% compared with 2015, i.e. carbon budget of 1600 TCO2e Target of 5% annual reduction of emissions from staff travel, during the programming period	EMA generated 271.5 TCO2e emission from office occupancy Monitor and report travel by staff and delegates towards the agreed targets on a regular basis, with consideration and for alignment to rules in place, for a balanced approach between face-to-face and virtual participation in meetings and other events. In 2025 the emission-factors for air travel were adjusted reducing the carbon impact from short and medium haul flights and increasing the impact slightly for long haul flights. These updates had a positive impact on the carbon emissions from both delegate's travel and staff missions.

Aspect	Environmental objectives	Key Performance Indicator	Target 2025 — 2028	Reporting
		Emissions from staff commuting and teleworking	Emissions from staff commuting and teleworking will be monitored over the programming period	Emissions from meetings with external participants reimbursed by the agency generated 1,473.5 TCO^2e, a reduction of 4.75% compared with 2024 and of 44,75% compared with 2015. Emissions from staff duty travel generated 254.6 TCO2e, a reduction of 8% compared with 2024. In 2025 a staff survey was used to gather information regarding commuting and teleworking on an annual basis for data gathering, with a response rate of 57%. Emissions from staff commuting generated 202.4 TCO2e, and from heating, cooling and use of electrical equipment of 198.5 TCO2e
Air **Soil** **Water**	Environmental effects of medicines for human and veterinary use (ERA)	As included in the Single programming document (SPD) 2025-2028		Actions as included in the operational reporting in the AAR 2025

Annex 8. Draft annual accounts

The Agency's annual accounts are published yearly on the Agency's website Financial management and budgetary reporting | European Medicines Agency (europa.eu) on or around the 1st July.

Annex 9. 2025 report on staff engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

Individual decisions of senior EMA staff leaving the agency, are published on the Art 16/CoI webpage: Handling competing interests | European Medicines Agency (europa.eu)

Engaging in an occupational activity within two years of leaving the service — restrictions applied to applications in 2025:

No	Job title/Function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
1	Data science officer and specialist	2 years 10 months	23 June 2025	22 July 2025	During a period of six months, to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during the last three years of service. This distance clause is without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders	25 July 2025
2	Senior statistician	11 years 9 months	16 June 2025	14 July 2025	During a period of twelve months, to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during the last three years of service. This distance clause is without prejudice to the possibility to liaise or attend meetings	16 July 2025

No	Job title/Function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
					through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders	
3	Medicines and medical devices shortages specialist	6 years 7 months	13 June 2025	14 July 2025	During a period of six months, to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during the last three years of service. This distance clause is without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders	16 July 2025
4	Head of Litigation	7 years 6 months	12 May 2025	11 June 2025	During a period of twelve months, to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during the last three years of service. This distance clause is	13 June 2025

No	Job title/Function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
					without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders. In the course of their professional activities and as of the date of leaving service, they may not engage in any activity, whether gainful or not, which concerns any legal case involving or connected to the Agency in which they were previously involved directly or indirectly. This restriction shall apply indefinitely	

Annex 10. Administrative appropriations – Building policy

The Agency has a lease agreement with the host Member State for its premises at Domenico Scarlatti Laan, Amsterdam, NL.

In addition, the Agency also has a lease agreement for its previous premises at 30 Churchill Place, London, UK as during the Brexit discussions between the EU and the UK government, the matter of EMA's London premises was removed from the negotiation package. This resulted in the Agency having to maintain its contract for its former headquarters in London following the EU decision to relocate the Agency to a new host Member State.

The Agency agreed on a sub-underlet of its London premises in 2019. Respective building dossiers were EMA/104158/2019 of 21/02/2019, EMA/119300/2019 of 28/02/2019 and for a subsequent change pre-information note EMA/546071/2023 and building dossier EMA/122997/2024.

#	Building name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	Non-office space	Total	Rent (€/year)	Contract duration	Type	Break — out clause Y/N	Conditions attached to breakout clause	
1	EMA premises Amsterdam	Domenico Scarlattilaan 6 Amsterdam, 1083 HS	22,574	10,837	33,411	11,385,790 (for 2025; yearly indexation)	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (Central Government, Real Estate Agency of The Netherlands)	Y (condition to terminate)	The Lease can be terminated • At any time by mutual consent of the parties • At any moment by the Lessee/EMA with a notice period of 6 months if a decision is made to transfer EMA headquarters to another EU location • By either party after a consecutive period of 6 months of force majeure events which make the performance of the aggrieved Party impossible.	EUR 18 million inducement of which EUR 15 million were for enhancements to fitting out the premises and EUR 3 million are for rent reductions over the term of the lease.
2	Previous EMA premises, London **– sub-let**	30 Churchill Place, Canary Wharf, London E14 5EU	26,213	4,127	30,340	Funding through sub-lease and specific EU contribution	25 years from 01/07/2014 to 30/06/2039	Lease agreement with Canary Wharf Limited	N	No break-clause	None
		Total	**40,520**	**23,231**	**63,751**	**11,385,790** (for building in NL) *plus* specific EU contribution for previous premises in London					

Financial Regulation, Article 110 (GFR Article 272 (2)) Evolution of surface area and locations and building projects in planning phase

The Agency does not have any further building projects in planning phase.

Financial Regulation, Article 110 (GFR Article 272 (3)) Building projects submitted to the European Parliament and the Council

The Agency does not have any further building projects submitted to the European Parliament and the Council.

Annex 11. Annual report 2025

Please see the Agency's Annual report 2025, publicly available on the EMA corporate website.

Annex 12. Regulation (EU) 2024/568

Context

The Fees and charges regulation (Regulation (EU) No 2024/568) was adopted on 07 February 2024 and entered into force on 01 January 2025.

The general objective of the Regulation is to contribute to providing a sound financial basis for the operations of the Agency, thus contributing to ensuring a high level of protection of public and animal health. It should establish cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks. There should be a single Union remuneration amount per type of fee, where relevant, regardless of the Member State of origin of the competent authority. Cost-based fees should take into account an evaluation of costs of the Agency's activities and of the contributions of competent authorities of the Member States to its work. In addition, this Regulation aims to establish a single framework for a streamlined fee system for the Agency and to introduce regulatory flexibility for adjustment to that fee system in the future.

Section 4 of Article 6 states that on a reasoned proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable fee or charge, in accordance with Article 8. The Agency shall make information on such reductions publicly available on its website, after deletion of all information of a commercially confidential nature

Article 10 states that the Agency shall monitor its costs and the Executive Director of the Agency shall provide, in a timely manner as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of the Regulation. That information shall include the performance information set out in Annex VI.

Sections below show the indicators for the calendar year 2025.

1. Performance information 1

The overall cost and breakdown of Agency staff and non-staff costs[43] relating to the fees and charges referred to in Article 3[44] of Regulation (EU) No 2024/568 (Annex IV (1)). Number of Agency staff involved and the overall costs for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency (annex IV (2)).

Reference to annex of Fee Regulation	Reference to article of Fee Regulation	Staff	Staff costs	Non-staff costs	Total cost
Annex I	Art. 1 - Scientific advice provided by the Agency in accordance with Article 57(1), point (n), of Regulation (EC) No 726/2004	42	10,636,477	39,063,444	49,699,922
	Art. 10 - Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by SMEs in accordance with Regulation (EC) No 1394/2007	2	527,745	1,113,326	1,641,070
	Art. 2 - Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004 & Scientific opinions on the evaluation of medicinal products intended exclusively for markets outside the Union	92	20,562,425	57,960,196	78,522,621
	Art. 5 - Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008	74	15,423,100	37,463,115	52,886,215
	Art. 4 - Extension of a marketing authorisation within the meaning of Annex I to Regulation (EC) No 1234/2008	14	2,976,389	5,589,977	8,566,366
	Art. 8 & 9 - Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I to Directive 2001/83/EC & Certification of compliance with Union legislation for a vaccine antigen master file (VAMF)	2	612,241	315,625	927,866
	Art. 6 - Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004	13	2,935,574	1,885,398	4,820,972
	Art. 14 - Periodic safety update reports	19	4,121,330	18,715,456	22,836,785
	Art. 15 - Post-authorisation safety studies	2	410,512	567,586	978,098
	Art. 12 - Orphan designation in accordance with Regulation (EC) No 141/2000	13	2,910,218	2,536,897	5,447,116
	Art. 11 - Paediatric applications in accordance with Regulation (EC) No 1901/2006	31	6,451,638	9,506,335	15,957,973
Annex I Total		**304**	**67,567,649**	**174,717,354**	**242,285,004**
Annex II	Art. 1 - Scientific advice provided by the Agency in accordance with Article 57(1), point (n), of Regulation (EC) No 726/2004	2	453,263	606,490	1,059,753
	Art. 2 - Request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation	1	160,152	118,302	278,455
	Art. 4 - Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6 and Scientific opinions in the context of cooperation with international organisations for animal health for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union	17	4,296,204	5,976,207	10,272,411
	Art. 3 - Establishment, modification or extension of an MRL in accordance with the procedure laid down in Regulation (EC) No 470/2009	-	-	34,698	34,698
	Art. 6 - Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6	12	2,827,389	2,727,440	5,554,829
	Art. 8 - Certification of compliance with Union legislation for vaccine antigen master files (VAMF) and Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)	0	50,288	50,709	100,997
	Art. 7 - Referrals and arbitration procedures	1	336,627	413,873	750,500
Annex II Total		**34**	**8,123,923**	**9,927,720**	**18,051,643**
Annex III	Art. 1 - Art. 1 - Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004	30	5,575,535	82,551,882	88,127,417
	Art. 1 - Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004	132	31,949,334	58,799,532	90,748,866
	Art. 2 - Annual fee for veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6	7	1,850,392	13,344,961	15,195,353
	Art. 3 - Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6	22	6,059,310	17,405,382	23,464,692
	Public Health activities: eg Antimicrobial Resistance, Influenza pandemic, Innovation and emerging therapies technology, Regulatory science and registries, stakeholders, PRIME(Priority Medicines) , Health Technology Assessment, transparency, SME etc.	182	44,639,844	21,262,270	65,902,115
Annex III Total		**373**	**90,074,416**	**193,364,026**	**283,438,442**
Annex IV	Art. 1 - Inspections pursuant to Article 8(2), Article 19 and Article 57(1), point (i), of Regulation (EC) No 726/2004 and Article 126(2) of Regulation (EU) 2019/6	36	7,143,598	19,734,860	26,878,459
	Art. 2 - Transfer of a marketing authorisation	1	204,932	214,600	419,533
	Art. 3 - Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure & Late payments	5	826,337	1,112,875	1,939,212
	Art. 6.3 - Notification of parallel distribution in accordance with Article 57(1), point (o), of Regulation (EC) No 726/2004	9	1,246,407	758,135	2,004,542
	Art. 6.2 - Certificates of medicinal products as referred to in Article 127 of Directive 2001/83/EC and in Article 98 of Regulation (EU) 2019/6	7	779,227	531,697	1,310,924
	Art. 6.1 - Administrative charge	0	68,545	79,813	148,358
	Art. 7 - Consultation on medical devices	0	117,556	332,846	450,402
Annex IV Total		**58**	**10,386,603**	**22,764,826**	**33,151,429**
Grand Total		**769**	**176,152,592**	**400,773,927**	**576,926,518**

[43] The costs exclude the expenditure related to the previous EMA premises in London

[44] Procedures assessed in 2025 include also applications submitted under previous fee regulations (Regulation (EC) no 297/95 and (EU) no 658/2014)

2. Performance information 2

Number of procedures for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary products and for other services (Article 10 (3)).

Reference to Fee Regulation	Fee type	NFR Procedure Description	Quantities / Pharmacogivilance Chargeable units	Net Amount EUR
Annex I	1H 01.01	SA request - level I	401	25,524,960
	1H 01.02	SA request - level II	305	14,480,705
	1H 01.03	SA request - level III	131	4,831,890
	1H 02.01	Initial - New active substance Art. 8(3)	51	36,857,520
	1H 02.02	Initial-Known active substance Art. 8(3)	10	6,837,930
	1H 02.03	Initial - Fixed combination Art. 10(b)	1	285,550
	1H 02.04	Initial - Biosimilar Art. 10(4)	21	14,648,000
	1H 02.05	Initial - Well established use Art. 10a	1	780,900
	1H 02.06	Init-Abridged,Generics,Ess App Art.10(1)	7	1,245,300
	1H 02.08	Initial - Hybrid Art. 10(3)	6	2,343,550
	1H 02.09	Initial - patent	1	33,300
	1H 04.01	Extension of MA - no data submission	7	1,179,500
	1H 04.02	Extension of MA - data submission	37	7,124,160
	1H 05.01	Type II MAJOR-ADD CHANGE THERAPEUTIC IND	99	16,091,520
	1H 05.02	TYPE II MAJOR - OTHER	1,153	25,069,000
	1H 05.04	WORK-SHARING - 2ND SUBSEQUENT	103	89,100
	1H 06.03	Referral - Article 29(4) -	1	-
	1H 06.05	Referral -Article 31 -	30	274,883
	1H 06.06	Referral -Article 20 -	29	206,600
	1H 06.71	Phv Referrals level 1	29	219,900
	1H 06.73	Phv Referrals level 3	4	377,100
	1H 08.03	PMF - Re-certification TII variation	1	12,800
	1H 08.04	PMF - Annual re-certification	12	244,800
	1H 10.01	ATMP Cert - Quality & non clinical data	2	-
	1H 11.01	PIP - Agreement	178	-
	1H 11.02	PIP - Modification	316	-
	1H 11.03	PIP - Waiver	226	-
	1H 11.04	PIP - Compliance check	137	-
	1H 12.00	Orphan designation	241	-
	1H 14.00	PHV PSUR	855	28,257,446
	1H 15.20	Phv PASS - draft protocol	5	246,100
	1H 15.21	Phv PASS - final study	64	374,131
Annex I Total			38,647	187,636,645
Annex II	2V 01.01	SA request - level I	8	150,930
	2V 01.02	SA request - level II	15	254,430
	2V 01.03	SA request - level III	7	83,620
	2V 02.00	Limited Market classification Art.23	17	71,500
	2V 03.01	MRL Establishment	1	89,700
	2V 04.01	Initial- New active substance	14	2,347,500
	2V 04.02	Initial- known active substance	9	1,559,800
	2V 04.03	INITIAL -ART18 ART19 ART21	5	724,500
	2V 06.01	VRA-Level 1 - I	2	93,000
	2V 06.02	VRA Level 2 -safety, efficacy or PhV	54	1,672,475
	2V 06.03	VRA Level 3 - quality	55	948,750
	2V 06.04	VRA - 3rd and subsequent grouped	29	196,850
	2V 06.05	VRA workshare	34	27,200
	2V 07.01	Referral - Article 54(8)	1	-
	2V 07.03	Referral - Article 141(1)(c,e,i)	2	-
	2V 07.04	Referral - Article 82 PhV	95	215,632
	2V 09.02	vPTMF certification –separate	1	17,550
Annex II Total			349	8,453,437
Annex III	3H 01.01	Annual Fee - Level I (10.1,10.3,10.c)	350	20,102,038
	3H 01.02	Annual Fee - Level II(10.4)	98	11,475,761
	3H 01.03	Annual Fee - Level III (8.3, 10.b, 10.a)	1,001	227,832,544
	3H 03.01	Phv Annual fee	148,088	27,956,937
	3V 02.01	Annual Fee - Level I Art 18, 19, 21	52	946,089
	3V 02.02	Annual fee - Level II	222	13,750,888
	3V 03.02	Annual Fee - PhV	42,158	3,353,738
Annex III Total			191,969	305,417,994
Annex IV	Re-examination	Initial - New active substance Art. 8(3)	7	1,038,240
	Re-examination	Initial-Known active substance Art. 8(3)	1	103,605
	Re-examination	Initial - Hybrid Art. 10(3)	1	-
	Re-examination	TYPE II MAJOR - OTHER	1	3,960
	4H 07.12	MD - Ancillary - Consultation known	1	57,200
	4H 07.13	MD - Ancillary - Change	12	55,500
	4H 07.30	Companion diagnostics - Initial	11	621,500
	4H 07.32	Companion diagnostics - Initial 2nd subs	7	67,200
	4I 01.03	PRE Inspection cancellations >30 days	5	2,300
	4I 01.12	GMP inspection - Outside EU	34	1,314,900
	4I 01.13	GCP inspection - Within EU	38	934,800
	4I 01.14	GCP inspection -Outside EU	57	1,402,200
	4I 01.15	PMF Inspection - Distinct	18	874,100
	4I 01.16	PMF Inspection - Consecutive	6	265,800
	4I 01.22	POST GMP INSPECTION - OUTSIDE EU	277	13,441,200
	4I 01.23	POST GCP INSPECTION - WITHIN EU	1	45,600
	4I 01.24	POST GCP INSPECTION -OUTSIDE EU	5	285,000
	4I 01.28	POST GVP INSPECTION	88	527,259
	4X 02.00	Transfer	51	224,400
	4X 03.10	Pre-submission activities	173	1,406,100
	4X 03.20	Change submission date >60 days	83	338,100
	4X 06.10	Admin charge (e.g.Withdraw +24h,neg val)	61	136,400
	4X 06.21	Export certificates - Standard procedure	10,402	2,074,400
	4X 06.22	Export certificates - Urgent procedure	2,814	1,392,500
	4X 06.31	Parallel Dist - Initial notification	2,926	4,096,400
	4X 06.32	Parallel Distribution - Bulk changes	17	6,800
	4X 06.33	Parallel Distribution - Annual Update	7,132	2,852,800
	INT 01.25	Late payment interests	1,149	204,367
Annex IV Total			25,378	33,772,631
Former Fee Regulation			1,896	9,135,291
Grand Total			**258,239**	**544,415,999**

3. Performance information 3

Number and amount of fee reductions or waivers granted per type of fee reduction or waiver under Union legislation and number of applicants or holders concerned (Annex IV (4)).

On a reasoned proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable fee or charge, in accordance with Article 8. The Agency shall make information on such reductions publicly available on its website, after deletion of all information of a commercially confidential nature (Art 6 (4)).

Basis for reduction	Fee reduction type	Procedure type	Quantities / Pharmacogivilance Chargeable units	Incentive amount EUR
Annex V Reg 2024/568	EEEA	Scientific advice	4	320,100
	Epizootic diseases	Annual fee	2	212,800
	Generic Product	Annual pharmacovigilance fee	79,967	4,124,955
	Herbal Product	Annual pharmacovigilance fee	1,472	84,640
	Homeopathic Product	Annual pharmacovigilance fee	2,145	118,508
	Immunological veterinary medicinal products	Annual fee	121	6,345,923
		Application for a marketing authorisation	17	2,572,300
		Certification of compliance for vPTMF	1	17,550
		Pre-submissions requests	22	83,600
		Request for classification	8	22,000
		Scientific advice	6	83,400
		Variations requiring assessment (VRA)	83	1,185,050
	Limited Market veterinary medicinal products	Application for a marketing authorisation	3	454,800
		Pre-submissions requests	2	8,600
		Scientific advice	3	50,950
	Pandemic Influenza	Annual fee	4	585,400
		Major variation of type II	1	22,000
		Worksharing application of type II	4	3,600
	PUMA	Annual fee	-	-
		Application for a marketing authorisation	1	192,150
		Re-examination of an application of MA	1	103,605
	Well Established Product	Annual pharmacovigilance fee	20,336	1,113,878
	Veterinary MP	Annual fee	135	2,663,498
	Paediatric	Major variation of type II	3	33,000
		Scientific advice	22	1,853,800
	Orphan Paediatric	Scientific advice	10	794,700
	SME	Administrative charge	24	105,600
		Annual fee	52	3,298,783
		Annual pharmacovigilance fee	12,128	1,099,724
		Certificates	61	20,880
		Consultation on medical devices	1	4,500
		Extension of a marketing authorisation	2	157,440
		Inspections	17	631,440
		Major variation of type II	22	263,280
		Periodic safety update reports (PSUR)	109	508,096
		Post-authorisation safety studies (PASS)	2	21,769
		Re-examination of a Type II variation	1	2,640
		Referrals	9	163,585
		Renewal	1	14,080
		Request for classification	1	12,060
		Scientific advice	125	9,048,600
		Scientific advice	5	418,500
		Annual fee	2	153,260
		Application for a marketing authorisation	1	306,450
	ATMP	Scientific advice	30	1,592,500
Annex V Reg 2024/568 total			**116,966**	**40,873,991**
Annex I / Annex II Reg 2024/568	NFR Fee waiver 100%	Certification of quality & non-clinical data for ATMPs	2	346,200
		Orphan designation	241	4,820,000
		Paediatric applications	857	18,082,200
		Re-examination of an application of MA	1	259,560
		Referrals	4	572,500
Annex I / Annex II Reg 2024/568 total			**1,105**	**24,080,460**
Art. 6.4 Reg 2024/568 (Working Arrangements)	Orphan & Orphan SME	Application for a marketing authorisation	17	1,330,870
		Inspections	35	1,862,300
		Scientific advice	72	4,265,325
		Application for a marketing authorisation	8	6,788,800
		Inspections	13	656,000
		Major variation of type II	1	22,000
		Re-examination of an application of MA	3	646,950
		Scientific advice	66	5,605,400
	Health Threat	Annual fee	3	348,600
		Major variation of type II	1	11,000
	VRA with scope GI18	Variations requiring assessment (VRA)	21	528,150
.4 Reg 2024/568 (Working Arrangements) total			**240**	**22,065,395**
Art. 6.5 Reg 2024/568	Executive Director Decision	Administrative charge	6	26,400
		Annual fee	1	79,800
		Application for a marketing authorisation	1	357,600
		Inspections	2	48,700
		Major variation of type II	1	11,000
		Scientific advice	3	224,200
		Variation of type I	2	4,000
		Variations requiring assessment (VRA)	1	37,725
Art. 6.5 Reg 2024/568 total			**17**	**789,425**
Grand Total			**118,328**	**87,809,271**

4. Performance information 4

Attribution of rapporteur, co-rapporteur or persons performing other role considered as equivalent for the purposes of the Regulation no. as referred to in its annexes per Member State and per procedure type (Art 10 (3)).

Reference to Fee Regulation	Procedure Description	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE
Annex I	Application for a marketing authorisation	3,467,060	1,384,707			1,237,566	6,437,202	2,060,375	691,680	1,422,270	627,984	4,011,960	103,800	2,062,110	837,486	1,175,880
	Certification of compliance for PMF	2,400	2,400				16,800			6,800	7,200					2,400
	Certification of quality & non-clinical data for ATMPs															
	Extension of a marketing authorisation	86,625	69,300				190,575	295,000		69,300	138,600	69,300		156,400	56,700	667,800
	Major variation of type II	1,395,000	785,100			188,700	4,271,500	2,280,100	115,700	1,179,300	890,600	1,784,800		201,100	202,200	1,338,800
	Orphan designation	19,000	9,500		1,900	26,600	30,400	3,800	9,500	32,300	28,500	39,900	17,100	38,000	28,500	
	Paediatric applications	215,500	185,800			135,500	368,900	162,100	132,900	389,900	58,000	445,800	25,300		2,300	
	Periodic safety update reports (PSUR)	934,200	674,700	34,600		570,900	1,937,600	986,100	294,100	501,700	674,700	692,000		449,800	190,300	622,800
	Post-authorisation safety studies (PASS)					44,600	22,300	22,300	22,300	44,600	22,300					
	Referral Pharmacovigilance		28,600				28,600							40,100		
	Referrals						3,500					15,500				37,400
	Scientific advice	3,649,642	2,534,194			210,945	3,432,855	879,559		1,014,155	2,202,328	1,588,769		707,846		980,218
Annex I Total		**9,769,427**	**5,674,301**	**34,600**	**1,900**	**2,414,811**	**16,740,232**	**6,689,334**	**1,266,180**	**4,660,325**	**4,650,212**	**8,648,029**	**146,200**	**3,655,356**	**1,317,486**	**4,825,298**
Annex II	Application for a marketing authorisation	52,360	164,150			59,400	785,420	259,400		96,800	95,440	642,050			19,000	529,500
	Certification of compliance for vPTMF											5,300				
	Establishment, modification or extension of an MRL											10,900				
	Referrals						71,800			21,900	8,200	18,500				
	Scientific advice		33,900				55,250			33,400		10,700				91,600
	Variations requiring assessment (VRA)		29,900			14,200	180,500	157,300		62,200	8,100	116,200			26,600	268,900
Annex II Total		**52,360**	**227,950**			**73,600**	**1,092,970**	**416,700**		**214,300**	**111,740**	**803,650**			**45,600**	**890,000**
Annex III	Annual fee	3,086,005	4,110,742	15,000		1,244,200	10,430,095	6,575,551	1,208,000	6,377,392	3,021,838	7,503,827	555,200	659,500	1,731,700	5,739,734
Annex III Total		**3,086,005**	**4,110,742**	**15,000**		**1,244,200**	**10,430,095**	**6,575,551**	**1,208,000**	**6,377,392**	**3,021,838**	**7,503,827**	**555,200**	**659,500**	**1,731,700**	**5,739,734**
Annex IV	Consultation on medical devices	29,200					53,700			39,600		93,800				3,600
	Inspections	1,008,700	857,000	11,400		246,080	1,682,500	602,900	75,200	1,540,200	687,400	689,400	31,000	209,300	1,071,200	1,470,100
	Pre-submissions requests	31,200	19,200		1,600	18,400	55,200	32,000	12,000	20,800	19,200	40,800	800	10,400	4,800	24,800
Annex IV Total		**1,069,100**	**876,200**	**11,400**	**1,600**	**264,480**	**1,791,400**	**634,900**	**87,200**	**1,600,600**	**706,600**	**824,000**	**31,800**	**219,700**	**1,076,000**	**1,498,500**
Former Fee Regulation		**338,979**	**127,906**			**16,280**	**797,805**	**205,908**	**8,800**	**549,813**	**178,867**	**254,669**	**18,801**	**32,194**	**27,100**	**301,860**
Total		**14,315,872**	**11,017,098**	**61,000**	**3,500**	**4,013,371**	**30,852,502**	**14,522,393**	**2,570,180**	**13,402,430**	**8,669,256**	**18,034,175**	**752,001**	**4,566,750**	**4,197,886**	**13,255,392**

Reference to Fee Regulation	Procedure Description	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SK	SI	Total
Annex I	Application for a marketing authorisation	485,995	1,061,220	1,277,209		822,370	251,980	4,477,785	1,005,920	2,612,000	948,060	528,100	4,435,796	901,250	576,655	44,904,420
	Certification of compliance for PMF		4,800					6,800			4,800		7,200			61,600
	Certification of quality & non-clinical data for ATMPs							59,400					59,400			118,800
	Extension of a marketing authorisation		138,600			39,100		680,400		186,600	207,900		378,000			3,430,200
	Major variation of type II	14,600	826,700	365,000		14,600	258,400	3,538,200	463,900	431,400	448,200		2,891,080	14,600	43,800	23,943,380
	Orphan designation		17,100	1,900	7,600	5,700		53,200	7,600	9,500	38,000	3,800	28,500			457,900
	Paediatric applications		170,500		210,200	110,100	59,900	307,000	144,400	138,200	700,600	95,700	227,500	235,700	199,300	4,721,100
	Periodic safety update reports (PSUR)	51,900	795,800	363,300		173,000	155,700	1,799,200	138,400	570,900	519,000	34,600	1,159,100	207,600	51,900	14,583,900
	Post-authorisation safety studies (PASS)							44,600		22,300			22,300			267,600
	Referral Pharmacovigilance											40,100				137,400
	Referrals			21,900		15,500	15,500						3,500			112,800
	Scientific advice	1,726,164	1,036,045	2,356,457		394,000	302,826	2,767,448	1,153,445	848,120	1,016,284		2,656,060		22,140	31,479,500
Annex I Total		**2,278,659**	**4,050,765**	**4,385,766**	**217,800**	**1,574,370**	**1,044,306**	**13,734,033**	**2,913,665**	**4,819,020**	**3,882,844**	**702,300**	**11,868,436**	**1,359,150**	**893,795**	**124,218,600**
Annex II	Application for a marketing authorisation		193,000					399,400		146,480			87,000			3,529,400
	Certification of compliance for vPTMF							5,300								10,600
	Establishment, modification or extension of an MRL												22,700			33,600
	Referrals							10,200								130,600
	Scientific advice							17,200					52,450			294,500
	Variations requiring assessment (VRA)		37,000					94,900		18,500			43,600			1,057,900
Annex II Total			**230,000**					**527,000**		**164,980**			**205,750**			**5,056,600**
Annex III	Annual fee	355,800	3,422,450	721,785	216,071	444,556	461,358	9,510,074	2,102,787	2,157,138	2,954,370	254,500	9,183,306	251,100	302,300	84,596,378
Annex III Total		**355,800**	**3,422,450**	**721,785**	**216,071**	**444,556**	**461,358**	**9,510,074**	**2,102,787**	**2,157,138**	**2,954,370**	**254,500**	**9,183,306**	**251,100**	**302,300**	**84,596,378**
Annex IV	Consultation on medical devices		5,400										5,400			230,700
	Inspections		636,500	41,700				1,768,200	97,200	820,000	320,200	5,700	663,700	89,820	529,200	15,154,600
	Pre-submissions requests	7,200	13,600	4,800		4,800	3,200	61,600	8,000	34,400	21,600	5,600	37,600	8,000	5,600	507,200
Annex IV Total		**7,200**	**655,500**	**46,500**		**4,800**	**3,200**	**1,829,800**	**105,200**	**854,400**	**341,800**	**11,300**	**706,700**	**97,820**	**534,800**	**15,892,500**
Former Fee Regulation		**24,630**	**179,025**	**34,675**		**11,891**	**3,615**	**783,100**	**107,300**	**468,130**	**67,200**		**333,206**		**37,570**	**4,909,324**
Total		**2,666,289**	**8,537,740**	**5,188,726**	**433,871**	**2,035,618**	**1,512,478**	**26,384,007**	**5,228,952**	**8,463,668**	**7,246,214**	**968,100**	**22,297,398**	**1,708,070**	**1,768,465**	**234,673,401**

5. Performance information 5

Number of working hours[45] spent by the rapporteur, the co-rapporteurs or persons performing other roles considered as equivalent for the purposes of this Regulation as referred to in the Annexes to this Regulation, including hours spent by experts[46] and others employed by the competent authorities of the Member States to assist them, and number of working hours spent by experts contracted for the work of the expert panels on medical devices (Annex IV (6))

Reference to Annex and article of the Fee Regulation	Role	No. of appl.	Average number of hours per application
Major variation of type II (point 5.1 of Annex I)	Rapporteur	10	277
	Co-rapporteur	3	135
Variations to the terms of a marketing authorisation, requiring assessment - level 1 (point 6.1 of Annex II)	Rapporteur	1	67
	Co-rapporteur	1	11
Variations to the terms of a marketing authorisation, requiring assessment - level 2 (point 6.2 of Annex II)	Rapporteur	26	23
	Co-rapporteur	2	50
Variations to the terms of a marketing authorisation, requiring assessment - level 3 (point 6.3 of Annex II)	Rapporteur	8	34
Consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product (Point 7.3 of Annex IV)	Rapporteur	1	14

Procedure type	Role	No. of appl.	Average number of hours per application
Clinical Evaluation Consultation Procedure (CECP) - Screening	Rapporteur	30	6
	Co-rapporteur	29	5
Clinical Evaluation Consultation Procedure (CECP) - Opinion	Chair	6	13
	Rapporteur	6	21
	Co-Rapporteur	6	17
	Reviewing member 1	6	7
	Reviewing member 2	6	8

[45] The sample is based on a low level of data and it is deemed not fully representative of the average time needed to assess a procedure.
[46] Some actors involved in the Medical Devices CECP opinion procedure did not provide time data.

6. Performance information 6

In exceptional circumstances and for imperative reasons of public or animal health, the Executive Director of the Agency may grant[47], on a case-by-case basis, total or partial reductions of the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in Sections 6, 14 and 15 of Annex I, Sections 7 and 10 of Annex II and Section 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based. The Agency shall make information on such reductions, including the reasons for the reductions, publicly available on its website, after deletion of all information of a commercially confidential nature (Art. 6 (5)).

Therapeutic area	Therapeutic indication	Type of application	Type of applicant	ED decision date	ED decision on reduction (%)	Summary of the ED decision
Infectious disease	Tuberculosis	Scientific Advice	Research	06/10/2025	100%	Tuberculosis (TB)—including multidrug-resistant (MDR-TB) and extensively drug-resistant strains (XDR-TB)—has been classified by the European Centre for Disease Prevention and Control (ECDC) as a serious cross-border health threat. TB remains the leading cause of death from an infectious disease worldwide, with the highest burden falling on low- and middle-income countries, though parts of Europe continue to be affected as well. Progress in the development of new anti-tuberculosis drugs has been limited, and there is an urgent need for novel anti-TB products. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.
Infectious disease	Human African Trypanosomiasis (HAT)	iMAA	Non SME	26/08/2025	50%	Human African trypanosomiasis (HAT), also known as sleeping sickness, is a life-threatening disease caused by a single-celled, extracellular protozoan parasite that circulates freely in the bloodstream and other body fluids, including lymph and cerebrospinal fluid. This disease has been classified by the World Health Organisation (WHO) as a priority condition, and there is an urgent need for new medicinal products to address it. If ultimately authorised, the candidate medicinal product is expected to substantially improve patient care and diagnosis by significantly simplifying treatment administration. It would represent a major advance in public health by expanding access to treatment for all patients with gambiense HAT (g-HAT), including those living in remote rural areas or facing sociopolitical instability. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.

[47] The partial or total fee reduction granted by the Executive Director shall be applied upon submission of the application by the company.

Therapeutic area	Therapeutic indication	Type of application	Type of applicant	ED decision date	ED decision on reduction (%)	Summary of the ED decision
Genetic disease	Severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)	Post-authorisation variation	Not for profit	03/12/2025	50%	Adenosine deaminase deficiency (ADA-SCID) is an ultra-rare inherited condition, with only 3–4 new patients diagnosed each year. It results in severe disruption of the immune system and leads to early death if left untreated. The concerned product is an orphan gene therapy indicated for the treatment of this form of severe combined immunodeficiency. It is in the public health interest to maintain it on the market, ensuring that patients affected by this neglected disease—who have very limited therapeutic options—continue to have access to a potentially life-saving treatment and that the existing gap in available treatment options is addressed. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.
Genetic disease	Severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)	Post-authorisation Annual fee	Not for profit	03/12/2025	50%	Adenosine deaminase deficiency (ADA-SCID) is an ultra-rare inherited condition, with only 3–4 new patients diagnosed each year. It results in severe disruption of the immune system and leads to early death if left untreated. The concerned product is an orphan gene therapy indicated for the treatment of this form of severe combined immunodeficiency. It is in the public health interest to maintain it on the market, ensuring that patients affected by this neglected disease—who have very limited therapeutic options—continue to have access to a potentially life-saving treatment and that the existing gap in available treatment options is addressed. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.
Infectious disease	Antiretroviral therapy (ART)	Post-authorisation extension	Research	27/03/2025	100%	HIV remains a major global public health concern, with women bearing a disproportionate share of the burden. The concerned application for an extension of the marketing authorisation relates to the expansion of the overall access by extending the dosing interval from one month to three months, offering greater convenience and supporting improved adherence—an essential factor in mitigating this health threat among vulnerable patients, particularly in women in countries affected by sociopolitical instability. Ensuring that women, including pregnant and breastfeeding women, have access to a range of HIV prevention options is critical to addressing ongoing unmet needs and a World Health Organization (WHO)prioritised intervention. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.
Infectious disease	Active immunisation to reduce viraemia associated with infection by Schmallenberg virus (SBV)	Post-authorisation variation	Non SME	05/05/2025	25%	The Schmallenberg virus (SBV) causes stillbirths and congenital malformations in cattle and sheep, and no specific treatment is currently available, demonstrating a significant gap in available treatment options. Vaccination remains the only effective means to prevent or reduce the impact of this health threat during outbreaks. Because it is very difficult to predict the re-emergence and scale of future SBV outbreaks, it is essential to ensure that an authorised vaccine remains available on the EU market. This is critical to enable a rapid and efficient response to any potential (re-)emergence of the disease and to prevent a serious animal health emergency. The Executive Director of EMA considers that, in this case, there are imperative reasons of animal health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.

Therapeutic area	Therapeutic indication	Type of application	Type of applicant	ED decision date	ED decision on reduction (%)	Summary of the ED decision
Infectious disease	Malaria	Scientific Advice	Research	19/08/2025	100%	Malaria is a life-threatening, World Health Organization (WHO)-prioritised infectious disease with major global and regional health implications, including for paediatric populations. Development efforts for effective therapies remain limited for this neglected disease, as illustrated by the historically low number of scientific advice requests submitted to the EMA—only 18 on record overall, with just one in the past five years. Potentially, the proposed biomarker could support detection, diagnosis, and disease monitoring for malaria across medicinal product development efforts, thereby contributing to the prevention or mitigation of associated health threats. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.
Infectious disease	Mycobacterium tuberculosis	Scientific Advice	Research	18/12/2025	100%	Tuberculosis (TB)—including multidrug-resistant (MDR-TB) and extensively drug-resistant strains (XDR-TB)—has been classified by the European Centre for Disease Prevention and Control (ECDC) as a serious cross-border health threat. TB remains the leading cause of death from an infectious disease worldwide, with the highest burden falling on low- and middle-income countries, though parts of Europe continue to be affected as well. Progress in the development of new anti-tuberculosis drugs has been limited, and there is an urgent need for novel anti-TB products. The Executive Director of EMA considers that, in this case, there are imperative reasons of public health and exceptional circumstances, and, therefore, has decided to grant a fee reduction pursuant to Article 6(5) of Regulation (EU) 2024/568.

The reduction percentage represents the discount applied on the final price, following the application of any applicable incentives

Annex 13 Reporting on Waiver of Recoveries Art 101(5) GFR

(Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast))

Article 101 (2) of the general financial regulation stipulates that under certain circumstances the authorising officer may waive recovery of all or part of an established amount receivable.
In 2025 the authorising officer has waived recovery orders for a total of EUR 27,918.50 as the amount receivables could not be recovered due to the insolvency of the debtors.

Terms and abbreviations

Term/abbreviation	Definition
AAR	Annual activity report
ACPC	Advisory Committee on Procurement and Contracts
ACT	Accelerating Clinical Trials in the EU
AD	Administrator category post
ADR	Adverse Drug Reaction
ADRA	Dosage review and adjustment of selected veterinary antibiotics
AF	Advisory function
AFS	Anti-Fraud Strategy
AI	Artificial intelligence
AIFA	Agenzia Italiana del Farmaco
AM	Antimicrobials
AMA	African Medicines Agency
AMEG	EMA CHMP/CVMP Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonisation initiative
API	Active Pharmaceutical Ingredient
AR	Assessment Report
ASR	Annual Safety Reports
AST	Assistant category post
ASU	Antimicrobial sales and use
ATD	EMA Access to Documents
ATMP	Advanced Therapy Medicinal Product
AUDA	African Union Development Agency
AVAREF	African Vaccine Regulatory Forum
AWS	Amazon Web Services
BE	Bioequivalence
BI	Business Intelligence
BJCP	British Journal of Clinical Pharmacology
BMWP	EMA CHMP Biosimilar Medicinal Products Working Party
BRIDGE	Breakthrough Regulatory Innovation and Development through sandbox Environments
CA	Contract agent
CAP	Centrally Authorised Product
CAT	EMA Committee for Advanced Therapies

Term/abbreviation	Definition
CBRN	Chemical, Biological, Radiological and Nuclear
CCI	Commercially Confidential Information
CDDF	Cancer Drug Development Forum
CDP	EMA Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CE	Conformité Européenne
CECP	Clinical Evaluation Consultation Procedure
CeSHarP	Clinical electronic structured harmonised protocol
CGREA	Central Government Real Estate Agency of The Netherlands
CHMP	EMA Committee for Medicinal Products for Human Use
CJEU	Court of Justice of the European Union
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
CMDB	Configuration Management Database
COA	Certificate of Analysis
COMP	EMA Committee for Orphan Medicinal Products
CRM	Customer Relationship Management
CRO	Clinical research organisations
CRP	Collaborative registration procedure
CT	Clinical Trial
CTA	Clinical Trial Application
CTCG	Clinical Trial Coordination Group
CTD	Common Technical Document
CTIS	Clinical Trials Information System
CTR	Clinical Trial Regulation
CV	Curriculum vitae
CVMP	EMA Committee for Veterinary Medicinal Products
DALT	Digital Acceleration Leadership Team
DAP	Data Analytics Platform
DARWIN	Data Analytics and Real World Interrogation Network
DC	Data Centre
DCP	Decentralised Procedure
DG INTPA	European Commission Directorate-General for International Partnerships
DG NEAR	European Commission Directorate-General for Neighbourhood and Enlargement Negotiations
DG SANTE	European Commission Directorate-General for Health and Food Safety

Term/abbreviation	Definition
DHPC	Direct Healthcare Professional Communication
DIA	Drug Information Association
DPC	Data Protection Coordinator
DPIA	Data Protection Impact Assessments
DPN	Data Protection Notice
DPO	Data Protection Officer
DQ	Data Quality
DQF	Data quality framework
DREAM	Document Records Electronic Archive Management System
EA	Enterprise Architecture
EAB	EMA Architecture Board
EAC	East African Community Region
EAG	Ethics Advisory Group
EAP	European Academy of Paediatrics
EAWG	Enterprise Architecture Working Group
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission Priority
ED	Executive Director
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines
EEA	European Environment Agency
EFSA	European Food Safety Authority
EHDS	European Health Data Space
ELMs	Engineered living materials for in situ production of therapeutics
EMA	European Medicines Agency
EMANS	European Medicines Agencies Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMRN	European Medicines Regulatory Network
EMT	EMA Experts Management Tool
EMVS	European Medicines Verification System
EMWP	European Medicines Web Portal
END	Seconded national expert (Experts nationaux détachés)

Term/abbreviation	Definition
ENS	Early Notification System
EP	European Parliament
EPAR	European Public Assessment Report
EPITT	European Pharmacovigilance Issues Tracking Tool
ERA	Environmental Risk Assessment
ERATO	Enhanced Review of Abstracts with Transformer Models
ESEC	EMA European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESUAvet	European Sales and Use of Veterinary Antimicrobials Working Group
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	EMA Emergency Task Force
EU	European Union
EUAN	European Union Agencies Network
EUDPR	EU Data Protection Regulation
EUI	European University Institute
EUNTC	EU Network Training Centre
EUR	Euro
EurEKA	EU product information Entity Extraction and Knowledge Acquisition
EURS	European Review System for eCTDs
EV	EudraVigilance
EVV	Union Pharmacovigilance Database
EWG	ICH Expert Working Group
EWP	Efficacy Working Party
EXB	EMA Executive Board
EXPAMED	Expert Panels on Medical Devices
EXTM	Exceptional Transparency Measures
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FTE	Full-time equivalent
FVE	Federation of Veterinarians of Europe
FWC	Framework contract
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GDPR	General Data Protection Regulation
GFR	General Financial Regulation

Term/abbreviation	Definition
GIDWG	Global Identification Working Group
GIREX	Group for Internal Rules on Extensions of Clock Stops
GL	Guideline
GLP	Good Laboratory Practice
GMDP	Good manufacturing and distribution practice
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practices
HCIN	Heads of Communication and Information Network
HCP	Healthcare Professional
HERA	Health Emergency Preparedness and Response Authority
HEvKA	Health Evidence Knowledge Accelerator
HL7 FHIR	Health Level 7 Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
HMPC	EMA Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority (Ireland)
HQ	Headquarters
HS	Herbal substance
HTA	Health Technology Assessment
HTACG	Member State Coordination Group on HTA
HTAR	Health Technology Assessment Regulation
IA	International Affairs
IAC	Internal audit capability
IAS	Commission's Internal audit service
ICH	International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	Individual Case Safety Report
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
IG	Implementation guide
IGAD	Intergovernmental Authority on Development
IHD	Instant Health Data
IHI	Innovation Health Initiative
INFARMED	Portuguese National Authority of Medicines and Healthcare Products
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme

Term/abbreviation	Definition
IRIS	Not an abbreviation. Refers to the regulatory & scientific information management platform between EMA and stakeholders
ISO	International Organisation for Standardisation
IT	Information technology
ITF	EMA Innovation Task Force
IVD	In vitro Diagnostics
IVDR	EU In vitro Diagnostic medical devices Regulation
IVMAB	ECDC/EMA Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JCA	Joint Clinical Assessment
JCASG	Joint Clinical Assessment subgroup
JIACRA	Joint Inter-agency Antimicrobial Consumption and Resistance Analysis
JSC	Joint Scientific Consultation
KPI	Key Performance Indicator
LACE	Lean-Agile Centre of Excellence
LLFG	EMA Listen and Learn Focus Group
LMS	Lead Member State
LTT	Lines to take
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MAWP	Multi-annual Work Plan
MB	EMA Management Board
MD	Medical Device
MDCG	EU Medical Device Coordination Group
MDR	EU Medical Devices Regulation
MDSSG	EMA Medical Devices Shortages Steering Group
MLM	Medical literature monitoring
MON	Monitoring
MP	Medicinal Products
MRA	Mutual Recognition Agreement
MRL	Maximum Residue Limit
MRP	Mutual Recognition Procedure
MS	Member State of the European Union
MSSG	EMA Medicines Shortages Steering Group
MTA	Managing the Agency
MUMS	Minor Use, Minor Species

Term/abbreviation	Definition
MVP	Minimum viable product
MWP	EMA CHMP Methodology Working Party
NAMs	New Approach Methodologies
NAMS	New Approach Methodologies
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDSG	Network Data Steering Group
NEPAD	New Partnership for Africa's Development
NFR	New Fee Regulation
NICTAC	Network ICT Advisory Committee
NIS	Non-Interventional Study
NITAG	National Immunisation Technical Advisory Group
NLP	Natural Language Processing
NPL	New pharmaceutical legislation
NRA	WHO National Regulatory Authority
NTC	EU Network training centre
OLAF	European Anti-Fraud Office, based on its name in French Office européen de lutte antifraude
OoNM	Qualification of Novel Methodologies
OPEN	Opening our Procedures at EMA to Non-EU authorities
OSOA	'One substance, one assessment'
OTC	Over-the-counter
PA	Protocol Assistance
PACMP	Post approval change management protocols
PAES	Post-Authorisation Efficacy Study
PASS	Post-Authorisation Safety Study
PCO	Patients' and Consumers' Organisations
PDCO	EMA Paediatric Committee
PECP	Performance Evaluation Consultation Procedure
PED	Patient Experience Data
PHE	Public Health Emergency
PI	Product Information
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric Investigation Plan
PLCM	Product Lifecycle Management
PLM	Product Lifecycle Management

Term/abbreviation	Definition
PMF	Plasma Master File
PMS	Post-Marketing Surveillance
PMSV	Post-market surveillance and vigilance
PQ	Pre-qualification
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	EMA Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure
Pre-SIG	Pre-submission Interaction Group
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PRIME	EMA Priority Medicines scheme
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PSUSA	PSUR Single Assessment
PUI	Product User Interface
QAT	Quality control, assurance and acceptance testing
QPPV	Qualified Person responsible for Pharmacovigilance
QRD	EMA Working Party on Quality Review of Documents
QSPR	Quarterly Strategic Portfolio Review
RAPS	Regulatory Affairs Professionals Society
RBA	Risk based approaches
RCD	Regulatory Capacity Development
RFI	EMA Request for Information
RMP	Risk Management Plan
RMS	Risk Management System
ROG	Regulatory Optimisation Group
RPM	Regulatory Procedure Management
RSS	EMA Regulatory Science Strategy
RWD	Real World Data
RWE	Real World Evidence
SA	Scientific Advice
SADC	Southern African Development Community
SAFE	Scaled Agile Framework
SAG	EMA Scientific Advisory Group
SAWP	EMA CHMP Scientific Advice Working Party
SC	Scientific committee

Term/abbreviation	Definition
SDO	Standards Development Organisations
SIA	Special Interest Area
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SISAQOL	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints in Cancer Clinical Trials
SLA	Service level agreement
SM	Signal Management
SME	Subject Matter Expert
SNE	Seconded national expert
SOC	Standard of care
SOP	Standard Operating Procedure
SPC	Supplementary Protection Certificate
SPD	Single programming document
SPMP	Shortage prevention and mitigation plan
SPOC	Single Point of Contact
SPOR	Substance, Product, Organisation and Referential
SRA	WHO Stringent Regulatory Authority
SSA	EMA Signal and Safety Analytics
SUMMA	Financial Platform of the European Commission
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TC	Technical Committee
TCIP	Technology Capability Implementation Plan
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TF	Task force
TFAAM	HMA-EMA Task Force on Availability of Medicines
TGA	Therapeutic Goods Administration
TIG	Technical Implementation Guide
TLM	Technology Lifecycle Management and Information Security Value Stream
TRS	EMA Regulatory Science and Innovation Task Force
UDP	Utilizing the Digital protocol
UI	User interface
UK	United Kingdom

Term/abbreviation	Definition
UP	Union Pharmacovigilance Database
UPD	Union Product Database
US	United States of America
UX	User experience
VE	Vaccine Effectiveness
VMC	VMware Cloud on AWS
VMP	ECDC/EMA Vaccine Monitoring Platform
VNRA	Variation Not Requiring Assessment
VOG	Vaccine Outreach Group
VRA	Variation Requiring Assessment
VS	Value Stream
VWP	EMA CHMP Vaccines Working Party
WG	Working Group
WGCP	Working Group of Communication Professionals
WHO	World Health Organization
WLA	WHO-Listed Authority
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary
XML	Extensible Markup Language