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Annual activity report 2024

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
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Management Board’s assessment report

Introduction

The consolidated Annual activity report provides an overview of the activities and achievements of the European Medicines Agency (hereinafter EMA or the Agency) in 2024. The EMA Annual activity report 2024 is a report of the EMA Executive Director. It is a key component of the strategic planning and programming cycle and the basis upon which the EMA Executive Director takes responsibility for the management of resources, and the achievement of objectives. It also allows the EMA Executive Director to decide on necessary measures in addressing any potential management and control weaknesses identified.

The Annual activity report 2024 comprises five main parts and annexes, as follows:

Part 1: Key achievements in 2024. This section provides information on achievements of objectives and performance indicators set in the EMA annual work programme. This section mirrors the structure of the annual work programme of EMA for the year 2024 and provides information on achievements of objectives set in the annual work programme.

Part 2: Management. This section provides an overview of the Agency's major achievements and includes information on EMA governance; information on budgetary, financial and human resources management; assessment of audit results during 2024; as well as the follow-up on recommendations and action plans resulting from audits. It also includes components of the follow-up on observations from the Discharge Authority.

Part 3: Assessment of the effectiveness of the internal control systems. This section includes the assessment of the effectiveness of the 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 report concludes with a declaration of assurance in which the EMA 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 the EMA 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 EMA Annual activity report 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 of medicines for human use, with respect to the authorisation, maintenance and supervision, for treatment of cancer, diabetes, neuro-degenerative dysfunctions, viral diseases, acquired immune deficiency syndrome, and auto-immune diseases and other immune dysfunctions and rare human diseases ('orphan' medicines). 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. For veterinary medicines, innovative and technologically advanced products, in particular those derived from biotechnology, must also be assessed by the Agency. To achieve this, EMA provides a single route for the evaluation of innovative medicines in the EU, thus avoiding the duplication of the evaluation in each of the Member States. This allows making highly needed medicines available to all EU citizens and 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 withdrawing a medicine from the EU market) within the shortest possible timeframe, where public or animal health is endangered.
Information to 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. This translates into 7 scientific committees[1] which evaluate medicines along their lifecycle, from early stages of development, through marketing authorisation, to safety monitoring once they are on the market. These scientific committees are supported by working parties and scientific advisory groups and can draw from a network of over 4000 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 coordinates inspections to verify compliance with the principles of good manufacturing, clinical, pharmacovigilance and laboratory practices.

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 Member States), the European Commission and EMA. In this context, EMA

[1] CHMP: Committee for Medicinal Products for Human Use CVMP: Committee for Medicinal Products for Veterinary Use
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.

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 — one of the largest databases in the world of adverse reactions reported for all medicines authorised in 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 in terms of 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 not only in a well-established and mature agency, but also an agency that covers a wide range of activities in the regulation 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 for medicines regulation.

2024 in brief

The main focus areas of the Agency for the year 2024 comprised enhancing the assessment of key medicines, translating innovation into medicines that reach and provide benefits to more patients based on better data and evidence generation, and preparing for the review of the EU pharmaceutical legislation to seize the opportunity to future-proof medicines regulation in the EU.

In terms of assessment of key medicines, the Agency continued to use haematology and oncology products as pathfinders to enhance assessments, provided regulatory training for oncologists, and strengthened international partnerships. Regarding translating innovation into medicines, achievements included the growth of the real-world data network DARWIN EU®, and the ACT EU initiative to

strengthen the generation of clinical evidence. In preparation for the revision of the Pharmaceutical Legislation, various activities and initiatives were undertaken by EMA and the Heads of Medicines Agencies (HMA). The new European medicines agencies network strategy (EMANS 2028) developed in the course of 2024, lays the groundwork for future implementation of the Legislation.

Collaboration with partners continued to be essential in the Agency's work in 2024. Together with EU Member States and the European Commission, the Agency continued efforts to support the transition of ongoing clinical trials to the Clinical Trials Regulation (CTR) through the Clinical Trials Information System (CTIS) and contributed to preparing for the implementation of the new regulation on health technology assessment (HTAR). In addition, EMA collaborated with other EU agencies on One Health to launch a joint framework for action to strengthen cooperation on the implementation of the One Health agenda in the EU. The Agency also played a significant role by working closely with Member States in addressing challenges related to the availability and security of supply for critical medicines, through initiatives such as the Medicines Shortages Steering Group and the European Shortages Monitoring Platform.

In the area of international cooperation, EMA supported the establishment of the African Medicines Agency, in close collaboration with African and European regulators. EMA continued fostering international regulatory cooperation, by leveraging its position as Chair of the International Coalition of Medicines Regulatory Authority (ICMRA) and by hosting and coordinating the 2024 Steering Committee and 7th conference of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

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

2024 at a glance

Human medicines

In 2024, the European Medicines Agency (EMA) recommended the authorisation of 114 new medicines for human use, of which 46 contain a new active substance. The Agency also recommended extensions of indication for 90 medicines already authorised in the EU, offering new treatment opportunities for patients.

Of the new medicines authorised, three received a recommendation for marketing authorisation following an accelerated assessment, a mechanism reserved for medicines that address unmet medical needs; eight medicines received a recommendation for a conditional marketing authorisation, designed to give patients early access to new medicines; and four medicines were authorised under exceptional circumstances, allowing patients to gain access to medicines when comprehensive data cannot be obtained.

In the context of the PRIME scheme, which aims to help patients benefit as early as possible from promising medicines targeting an unmet medical need, six PRIME-designated medicines were recommended for approval. In addition, the Agency confirmed 15 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.

Veterinary medicines

EMA also recommended 25 veterinary medicines for marketing authorisation, two of which contain a new active substance. The Agency also issued positive opinions for four authorised products to be used in a new species or for a new indication.

The Agency issued one opinion recommending maximum residual limits (MRLs). MRLs are limits placed on the levels of residues of medicines in food producing animals. MRL is established before a medicine for a food-producing animal is authorised in the EU and entered in the annex to Commission Regulation (EU) No 37/2010.

Main focus areas

The European Medicines Agency (EMA) made substantial progress in the three main focus areas identified in the Single Programming Document (SPD) 2024-2026, while continuing to deliver on its overall strategic priorities.

Focus area 1: Assessment of key medicines – enabling high-quality, robust and rapid assessments, using cancer medicines as a pathfinder

As envisaged in the SPD, the Agency has been using haematology and oncology products as pathfinders to enhance the assessment of key medicines, strengthen collaboration with stakeholders and improve communication on benefits and risks.

Activities in oncology

With respect to oncology, EMA and the Heads of Medicines Agencies (HMA) completed a pilot project providing regulatory training to oncologists through a series of webinars, which covered the basic concepts of medicines evaluation. The Agency, in collaboration with the Network, also launched a monthly newsletter on oncology-related news.

During the year, the Agency continued to strengthen its international partnerships. Following the agreement on EMA's participation in the US Food and Drug Administration's Project Orbis, the Agency participated as an observer in two procedures.

The Agency also extended the scope of its interactions with international partners in scientific advice as well as in transversal topics like patient engagement. Other stakeholder activities included consolidating collaboration with academia and establishing a focus group under the industry stakeholder platform on the operation of the centralised procedure for human medicines, to explore opportunities to further optimise the evaluation process. Regulatory science activities included discussions about evidentiary standards for rare cancers, patient reported outcomes, multiple myeloma and single-arm studies with external comparators based on real-world data.

Activities aimed at ensuring the sustainability of the network and accelerating approvals

EMA's Revamp Project carried out a pilot in which marketing authorisation applicants were requested to pre-fill the factual parts of Day 80 assessment reports. Seven applicants participated in the pilot, which aims to relieve assessors of the need to copy and paste information from Module 2 of the eCTD into the reports. In addition, the Revamp Project delivered a new Overview template that significantly improves the way assessment teams collaborate, eliminating many copy and paste steps and incorporating the PRAC Day 94 report directly into the Overview. The new Overview will be co-authored in SharePoint and evolve from D0 of the marketing authorisation application all the way to the EPAR.

The GIREX (Group for Internal Rules on Extensions of Clock Stops) project recommended a stricter application of the 2009 guideline on clock-stops. From July 2024, provisions of the 2009 guideline were applied more strictly. Early data from the 2024 submissions show that on average, clock stops for the whole-year were 16 days shorter than in 2023.

The Agency also started different activities to emphasize to industry the importance of submission predictability and the problems that the lack of it causes to the network. The Focus Group on Submission Predictability (which includes NCA and industry representatives) organised a multi-stakeholder workshop in September 2024, which was attended by 400 participants. A LinkedIn Live event was also organised on the topic. Almost 10,000 unique viewers watched the recording. The live sessions had a peak of around 350 viewers, and 85 comments and questions were received.

Focus area 2: translating innovation into medicines that reach and provide benefits to more patients, based on better data and evidence generation

The Agency continued its efforts to enhance the translation of innovation into medicines that reach patients using several initiatives, such as DARWIN EU® and Accelerating Clinical Trials in the EU (ACT EU), to strengthen the generation of clinical evidence.

Real-word data

DARWIN EU® continued to grow its real-world data (RWD) network throughout 2024. In total, 30 data partners are now providing access to 35 different data sources with the potential to access data from more than 160 million patients from 16 European countries. In 2024, 47 studies were completed or ongoing in DARWIN EU® and 10 data partners were onboarded. These data partners generate real-world evidence from sources such as hospitals, primary care providers, health insurers, registries and biobanks.

In February 2024, the new electronic catalogues were launched and have replaced the former European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resource Database and EU Post-Authorisation Study register (EU PAS Register). The catalogues help medicines regulators, researchers and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results. They aim to promote transparency, encourage the use of good practices and foster observational research based on real-world data. By the end of 2024, the catalogues had registered approximately 3,000 real-world data studies and 235 data sources.

Clinical trial and individual patient level data

ACT EU

As part of the ACT EU initiative, a multi-stakeholder platform (MSP) was established to foster collaboration and promote open dialogue on the challenges and opportunities represented by advances in clinical trial regulation, methodologies and technology. Feedback from the MSP was key in delivering the revised ACT EU workplan for 2025-2026.

Two new pilots to improve clinical trials in Europe were launched. The first pilot offers developers of medicinal products scientific advice on clinical trials and on requirements for marketing authorisation applications. The second pilot is coordinated by the Clinical Trials Coordination Group (CTCG) and provides technical and regulatory support for the preparation of the dossier for clinical trial applications (CTAs) prior to submission through the Clinical Trials Information System (CTIS).

ACT EU intensified efforts to provide dedicated support to non-commercial sponsors with the creation of a helpdesk for technical and regulatory advice on clinical trials and an interactive map of existing national support initiatives.

Clinical Trial Regulation (CTR)

Together with EU Member States and the European Commission, the Agency continued efforts to support the transition of all ongoing clinical trials to the Clinical Trials Regulation (CTR) through submission 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 three-year transition period ends on 30 January 2025.

In 2024, a new version of CTIS was launched introducing the revised transparency rules for CTIS to allow for earlier and more efficient access to information about clinical trials in the European Union for patients, healthcare professionals and other stakeholders. As a result of the new rules, by the 31 December 2024 information on more than 8,600 clinical trials with issued decisions are now publicly accessible. The updated rules strike a balance between transparency and the protection of commercially confidential information. They benefit patients, because key clinical trial information, that patients flagged as being most relevant for them, is published early. They also benefit clinical trial

sponsors because they introduce process simplifications. Finally, they benefit healthcare professionals because the resulting system is more user-friendly, facilitating access to information on clinical trials and enrolment in clinical trials, and also increasing awareness of possible treatment options.

Use of clinical study data in medicines evaluation

The interim report of the EMA/HMA proof-of-concept pilot on using individual patient level data from clinical studies in medicines evaluation was published in October 2024.

The report highlighted that access to clinical study data improves understanding of product dossiers, streamlines decision-making and fosters more efficient collaboration among regulators. These early results show that analyses of individual patient data could lead to faster assessment and earlier authorisation of products.

Artificial intelligence workplan to guide use of AI in medicines regulation

During 2024, significant progress was seen in implementing the multiannual Artificial Intelligence (AI) workplan. In March 2024 Scientific Explorer was launched. This is an AI enabled knowledge mining tool for EU regulators that facilitate easy, focused and precise searches of regulatory scientific information from network's sources. The first release was dedicated to scientific advice procedures for human medicines and the second release to veterinary medicines.

Guiding principles on the use of large language models (LLM) in regulatory science and for medicines regulatory activities were published and are available for the network. This document aims to promote the safe, responsible and effective use of this category of AI technology. The publication was supported by an information campaign that included the factsheet Four *principles for safe and responsible use of LLMs.*

Following a public consultation, the final *Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle* was published. This paper reflects on principles relevant to the application of AI and machine learning at every stage of a medicine’s lifecycle, from drug discovery to post-authorisation activities.

Quality Innovation Group

The Quality Innovation Group (QIG) is an operational expert group set up to support the translation of innovative approaches to the design, manufacture, and quality control of medicines. The aim is to help bring new therapies to patients and improve the supply of existing medicines. In line with the QIG workplan, which is developed using input from horizon scanning activities, pipeline information and surveys to Industry, the main areas of focus in 2024 were: Platform technologies; Process models; Digitalisation and automation of manufacturing and control; Decentralised manufacturing and continuous manufacturing.

In 2024, QIG held two Listen and Learn Focus Groups (LLFG) with industry, academia, and learned societies: one, on the use of process models and one on platforms. All meetings were attended by international partners. Meeting reports highlighting the key challenges as identified during the discussions and proposed solutions have been published on the Agency’s website.

In addition to engaging with stakeholders via LLFGs, QIG experts have continued to provide product support to developers through 4 Innovation Task Force meetings, 6 closed 1-1 meetings, 2 manufacturing site visits (one jointly with international partners) and contributing to the assessment of procedures that include these new technologies (2 scientific advices).

In terms of guidance, QIG published the Preliminary considerations on the use of pharmaceutical process models. Acknowledging the global dimension of medicine's development and manufacturing QIG holds regular meetings with international partners e.g. FDA (Center for Biologics Evaluation and Research Advanced Technologies Team (CATT) and Emerging Technology Team (ETT)) to exchange information and learning (6 meetings in 2024). QIG experts have also contributed in the International Coalition of Medicines Regulatory Authorities (ICMRA) workshop on Decentralized and Point of Care manufacturing that was held in December 2024.

QIG has been actively sharing the knowledge gained with the Network through regular (quarterly) updates to the relevant Working Parties and Inspectors Working Group. Network experts are participating in QIG led drafting groups (process models, 3D printing). The LLFGs and the closed 1-1 meetings are open to Network experts and there is active Network participation.

Focus area 3: Preparing for the review of the EU pharmaceutical legislation - seizing the opportunity to future-proof medicines regulation in the EU

With respect to preparations for the revision of the general pharmaceutical legislation, the Agency has been conducting a series of preparatory activities, exploring innovative ways to design more efficient and data-driven approaches and providing regular internal updates on the proposed legislation. Additionally, change management activities and preparations to engage with committees have also begun.

The EMA and HMA have also been working on a new European medicines agencies network strategy (EMANS 2028) which will lay the groundwork for the future implementation of this most significant reform of the EU medicines regulation in decades.

The draft EU medicines agencies network strategy to 2028 was endorsed by the HMA in September 2024 and by EMA's Management Board at its October 2024 meeting. EMA and HMA expect to adopt the final strategy by March 2025. The updated strategy replaces the current network strategy to 2025 and incorporates the strategic aspects of EMA's Regulatory Science Strategy. It takes into account progress made so far with the EMANS 2025 (as outlined in the mid-term report) and has been developed in collaboration with HMA, with input from experts from across the EU medicines regulatory network.

Contributing to EU priorities

In 2024, EMA continued to promote a functioning single market for human and veterinary medicines by acting as the hub of the European network of regulatory medicines authorities and implementing the EU pharmaceutical legislation.

EMA recommended the authorisation of numerous new cancer medicines (28 in total for 2024) to provide safe and effective treatment options for patients. In line with the objectives of the EU Beating Cancer Plan of ensuring access to medicines and innovation, and the new regulation on health technology assessment (HTAR), the EMA made significant contributions, including related to the exchange of information and regulatory science. The Agency also developed its 'pathfinder' initiative, exploring opportunities to further streamline the scientific assessment, strengthen collaboration with academia and other stakeholders, and improving communication on the benefits and risks of medicines (see also Focus area 1 above as regards the 'cancer medicines pathfinder' for more details).

Throughout 2024, EMA continued to provide support to the EU's COVID-19 response, recommending the authorisation of a new vaccine, Kostaive (zapomeran), as well as three adapted vaccines targeting the JN.1 variant, the KP.2 subvariant and the Omicron XBB.1.16 subvariant.

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. To achieve this objective, EMA increased its interactions with Directorate-General Health Emergency Preparedness and Response (DG HERA) as well as with various international organisations. The Agency also provided recommendations to marketing authorisation holders to facilitate the availability and supply of critical human medicines for which there are vulnerabilities in the supply chain.

Communication and engagement with stakeholders played an important role in EMA's overall approach to the management of shortages. This was demonstrated in relation to the shortages of GLP-1 receptor agonists. The Agency published information and organised a public meeting, a press conference and a wide range of social media activities to promote recommendations that prioritised availability of these important medicines for patients most in need.

As part of its overall outreach on shortages, the Agency organised a successful seminar with 26 journalists from across the EU to explain the processes and interactions in place to prevent and manage shortages.

The Medicines Shortages Steering Group (MSSG) published recommendations to address vulnerabilities in the production and supply of medicines in the Union list of critical medicines and to strengthen their supply chains. The Agency continued the management of requests in relation to the solidarity mechanism under the auspices of the MSSG to support Member States experiencing critical shortages of important medicines when all other options have been exhausted.

Furthermore, the European Shortages Monitoring Platform (ESMP) core set of functionalities was launched to enable quick and efficient exchange of information on shortages between regulators and pharmaceutical companies. This platform utilises harmonised medicinal product data from the Product Management Service (PMS). The launch of the full range of ESMP functionalities took place in early 2025.

In support of the EU Chemical Strategy for Sustainability and in accordance with the principles of 'one substance, one assessment', the Agency worked closely with other EU agencies such as the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). EMA focused on discussing hazard and risk assessments performed by ECHA and EFSA concerning chemicals also used in medicinal products. Furthermore, EMA began exploring with ECHA and EFSA opportunities for alignment of scientific methodologies for risk assessments of chemical across various legal frameworks.

In April 2024, the Agency hosted the first Inter-Agency Technology Innovation Workshop in collaboration with EU health agencies — ECHA, EFSA and the European Centre for Disease Prevention and Control (ECDC)) and the European Commission, facilitating the sharing of experiences and discussing opportunities in artificial intelligence, interoperability, and innovation.

Other key developments and activities

One Health and antimicrobial resistance

In 2024 EMA joined forces with the ECDC and EFSA in the area of antimicrobial resistance (AMR), publishing the fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals (JIACRA IV). Taking a One Health approach, the report presents data primarily collected between 2019 and 2021 on antibiotic consumption and AMR in Europe.

To support Member States in the crucial work of collecting data on the sale and use of antimicrobials in animals, EMA launched the new Antimicrobial Sales and Use (ASU) platform in January. All Member States submitted their data following the data call for the ESUAVet report to be published in March 2025. The new platform addresses the obligation for annual data submission which is one of the measures to fight antimicrobial resistance set out in the Veterinary Medicinal Products Regulation (Regulation (EU)2019/6). The platform streamlines the submission of data by Member States, strengthens the analysis and identification of trends in antimicrobial consumption in the EU and the wider European Economic Area (EEA), and provides insights for participating countries on the impact of their measures relating to the prudent use of antimicrobials in animals.

Furthermore, in the area of human medicines, the Agency recommended the authorisation of one new antibiotic against aerobic Gram-negative bacteria (Emblaveo) and continued to support discussions on international harmonisation and work on the implementation of the veterinary medicines' regulation, in particular on aspects related to AMR such as the mandatory collection of data on sales and use of veterinary antimicrobials in EU/EEA Member States.

In May 2024 EMA joined forces with four other EU agencies – the ECDC, ECHA, EFSA and the European Environment Agency (EEA) — and launched a joint framework for action to strengthen cooperation on the implementation of the One Health agenda in the EU. One Health is an integrated approach that recognises that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely linked.

The cross-agency task force was created, with the aim of ensuring that the scientific advice provided by the agencies is increasingly integrated, that the evidence base for One Health is strengthened and that the agencies are able to contribute with a common voice to the One Health agenda in the EU.

New regulation on health technology assessment

Regarding the new regulation on health technology assessment (HTAR), EMA made a significant contribution towards improving access to medicines by supporting the European Commission and the Member States in preparing for the implementation of the HTA regulation. In particular, EMA focused on new legal requirements at the intersection between regulatory activities and health technology assessment, including the exchange of information. This includes the new interface between the assessment of a marketing authorisation application by EMA and the joint clinical assessment by the EU HTA Coordination Group under the new HTA Regulation, for which a common notification process was established in June 2024 to ensure preparedness during the pre-submission phase.

Other key activities include the preparation for the launch of parallel joint scientific consultation under the regulation, as well as the exchange of pipeline and forecasting data. The activities covered both medicinal products and medical devices. They prepared the Agency for the implementation of the legislation from 12 January 2025.

International cooperation and stakeholder engagement

During the year, the Agency continued its support for the establishment of the African Medicines Agency, in close collaboration with African and European regulators. The African Medicines Agency is a specialised Agency of the African Union; its work will improve collaboration across Africa and help support patients access to medicines.

EMA provided technical support and funding for the first joint continental pilots to test procedures for joint evaluation of medicines and good manufacturing practice (GMP) inspections in Africa. In addition,

EMA awarded grants in 2024 to six competent authorities in the European medicines regulatory network aiming to strengthen the scientific and regulatory expertise of African national authorities.

On 20 May 2024, the whole European medicines regulatory network was designated as a WHO Listed Authority (WLA) by the World Health Organization (WHO). The announcement by WHO means that the network – including the European Commission, EMA and each of the 30 national authorities of the European Economic Area Member States – are recognised as meeting the highest international regulatory standards.

In the area of stakeholder engagement, the Agency published the biennial report on stakeholder engagement activities, covering activities involving the Agency's key stakeholder groups: patient and consumer organisations, healthcare professional organisations, academia and EU industry trade organisations. The report highlighted key topics, such as the EU clinical trial initiative ACT-EU, as well as targeted engagement activities with each stakeholder group.

Multistakeholder workshops on psychedelics and shortages of GLP-1 receptor agonists were held, bringing together the views of all parties involved and fostering consensus on how to address critical issues in these challenging areas.

On 13 and 14 November, EMA co-hosted the 7th International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) public conference in Amsterdam, under the theme "VICH and a New Era", bringing together regulators and industry leaders to discuss global challenges and strategies for enhancing access to veterinary medicines. Key discussions focused on regulatory convergence, international collaboration, and streamlining registration processes to address rising global demand and challenges. This public event was held in parallel with the 43rd VICH Steering Committee and the 17th VICH Forum (VF) meetings.

The Agency also opened a training catalogue in the EU Network Training Centre (EU NTC) Learning Management System (LMS) to candidate countries in the framework of the Instrument for Pre-accession Assistance (IPA) programme.

Legal developments

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law or procedural irregularities continues to remain high. In the course of the year, EMA has been involved in 12 court cases, without the assistance of any outside counsel.

Further, during the year, five judgments/orders were delivered by the Court of Justice of the European Union. In Case C-291/22 P, the Court of Justice set aside the first instance judgment in Case T-556/20 and annulled the Commission decision which had refused the grant of a conditional marketing authorisation for a medicinal product. In its judgment, the Court of Justice provided important guidance in relation to the organisation and impartiality of EMA's scientific advisory groups/ad hoc expert groups. In Case T-416/22, the General Court sided with the Commission and EMA by upholding the lawfulness of the recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC) to suspend several marketing authorisations due to risks related with off-label use. In Case C-237/22 P, the Court of Justice sided with the Commission and EMA, confirming their understanding of the notion of clinical superiority under the Regulation (EC) No 141/2000. In the separate Cases T-594/18 RENV and T-703/20, the General Court concluded the respective court proceedings with a declaration that they had become devoid of purpose.

New Fee Regulation

The adoption of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency is an important milestone in the strengthening of the financial sustainability of the European medicines regulatory network. Adopted in February 2024, the regulation came into effect on 1 January 2025, modernising the fee system that had been in place for nearly three decades by aligning fees with the actual costs of EMA and network's regulatory activities.

The transition to the new fee system required extensive collaboration across the Agency, with over 100 experts involved in optimising processes, integrating regulatory and fee systems and providing extensive stakeholder support.

New processes, such as the prepayment for services like scientific advice, parallel distribution and certificates, were introduced as part of the implementation. To support stakeholders through this transition, the agency led comprehensive change management activities, including webinars, communication campaigns, and updated guidance documents for both internal and external audiences. Moving forward into 2025, the Agency aspires to continue exploring the possibilities offered by the new systems to ensure the continued efficiency of EMA's services.

Information technology – cross cutting initiatives

In 2024, EMA decommissioned its physical data centres in Hamburg and is now fully operational from its cloud-based, software-defined data centres. This is a milestone, marking EMA as the one of the first EU Agencies to fully migrate to the cloud to increase its operational efficiency and foster innovation. The new software-defined data centres facilitate access to state-of-the-art technologies, including Artificial Intelligence (AI) and quantum computing, thereby allowing EMA to further transform its business and ways of working.

To enable data-driven operations and support the work of the human and veterinary medicines divisions, all centrally authorised products and nationally authorised products have been migrated to the central Product Management Service (PMS) and are now accessible to stakeholders, partners and the public through the Lifecycle Management Portal. PMS data supports key regulatory systems developed as part of the Network Portfolio e.g. the electronic product information (ePI), the regulatory procedure management (IRIS), the European Shortages Monitoring Platform (ESMP) and others.

In addition, a pivotal milestone in modernising procedure management is the introduction of the new digital application form for centrally authorised product variations and the transition of all post-authorisation regulatory procedures to IRIS, the regulatory and scientific information management platform between EMA and stakeholders. The platform uses identification of medicinal products (IDMP)-compliant product information from PMS.

Building on the post-authorisation processes introduced in 2023, the Agency successfully piloted generics and leveraged these insights to implement all post-authorisation procedures for both human and veterinary medicinal products. This rapid implementation was aligned with the new fee regulation (NFR), showcasing the Agency's commitment to efficiency and regulatory excellence.

A significant milestone was achieved in June 2024 when, with the onboarding of paediatric procedures onto IRIS, the entire development support offering from the Agency was brought onto this single application management platform. Starting from orphan designation, covering scientific advice, PRIME designation, paediatric investigation planning and engagement with the Innovation Task Force, all product development activities are now connected on IRIS through a single Research Product Identifier (RPI).

To enhance the human regulatory submission process with health authorities, the electronic product information initiative was successfully piloted, and the adoption of the Electronic Common Technical Document (eCTD4) standard is currently in the proof-of-concept stage.

The Union Product Database (UPD), which serves as a single source of information on all authorised veterinary medicines and their availability in the EU and the European Economic Area (EEA), continues to be enhanced and modernised.

Scaled Agile Framework (SAFe) implementation in the Network Portfolio

Since the end of 2021, the Agency has been implementing a new governance structure and ways of working, based on the Scaled Agile Framework (SAFe) methodology to better meet the IT software development needs of the European Medicines Regulatory Network. The flexibility of agile teams allowed the Network Portfolio to double the number of its products since 2022 without proportionally increasing the allocated budget. More value is being delivered, with at least monthly releases and many digital products in continuous delivery mode.

Due to highly focused portfolio-management practices, investment decisions are based on lean business cases that must demonstrate business value and are taken by a multidisciplinary Portfolio Board with executive strategic guidance.

Furthermore, network and industry involvement is structured around cadenced 'agile events' (e.g. System Demo and Quarterly Strategic Portfolio Review) for consistent and recurrent alignment. Stakeholder representatives take also an active part in product development as subject matter experts. This approach aims at a customer centric Portfolio delivery and high levels of transparency.

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 2024 forecast/target
	Results within +/- 10% (included) of the 2024 forecast/target
	Results 10%-25% below the 2024 forecast/target
	Results more than 25% below 2024 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 2024 forecast/target
	Results within +/- 10% (included) of the 2024 forecast/target
	Results 10%-25% above the 2024 forecast/target
	Results more than 25% above 2024 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

Pre-authorisation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Total scientific-advice and protocol-assistance requests	853	833	692	733	766
Parallel scientific advice with international regulators requests	3	5	4[2]	2	1
Joint scientific advice with HTA bodies requests	2	4	4	3	3
Scientific advice for PRIME designated products	59	37	38	34	42
Protocol assistance	163	129	119	130	131
Novel technologies qualification advice/opinions	25	21	18	14	14
PRIME eligibility requests received	52	45	52	60	58
Applications for orphan medicinal product designation	251	269	195	210	193
Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	778	755	713	718	771
Requests for classification of ATMPs	66	51	43	45	40
Additional indicator:					
Scientific advice by ETF	77	51	44	-	24

Initial evaluation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
New non-orphan medicinal products	43	35	35	51	33
New orphan medicinal products	29	32	23	29	21
Similar biological products	10	11	21	36	41
Generic products, hybrid and abridged products	28	18	20	17	15
Scientific opinions for non-EU markets (Art. 58)	3	1	0	1	1
Paediatric-use marketing authorisations	0	2	1	3	3
Number of granted requests for accelerated assessment	12	4	7	12	4
ATMP marketing application authorisation requests received	3	1	4	11	7
COVID-19 related product applications received	14[3]	2	2	4	1
Companion diagnostics opinions[4]	-	-	9	30	10

[2] Corrected value.
[3] 2 applications were withdrawn during evaluation.
[4] Finalised.

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Average assessment time for new active substances and biosimilars (days) (reversal of traffic lights)	183	189.8	200.56	205	198.45
Average clock-stop for new active substances and biosimilars (days) (reversal of traffic lights)	149	182.1	178.29	180	169.80
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	27%	31.30%	75.00%	50%	75.00%

Post-authorisation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Type IA variations	3,809	3,586	3,864	3,624	3,931
Type IB variations	3,102	3,354	3,332	3,305	3,323
Type II variations	1,390	1,388	1,201	1,261	1,333
Line extensions of marketing authorisations	27	31	43	25	33
Renewal applications	123	132	101	64	107
Annual reassessment applications	27	27	33	31	35
Transfer of marketing authorisation applications	95	74	41	53	70
Article 61(3) applications	396	236	270	200	342
Post-authorisation measure data submissions	1,272	1,278	1,146	925	1,079
Plasma master file annual update and variation applications	20	17	18	25	20

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Average assessment time for variations that include an extension of indication (reversal of traffic lights)	177	175.19	175.5	180	184.92

Referrals

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Pharmacovigilance referrals started	3	4	2	3	2
Non-pharmacovigilance referrals started	10	5	8	6	3

Pharmacovigilance

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Number of signals peer-reviewed by EMA	2,477	1,605	1,364	1,300	1,254
Number of ICSRs for CAPs (reports received)	2,989,903	2,273,735	1,389,710	1,300,000	1,230,390
Number of signals assessed by PRAC (validated by EMA)	55	39	39	40	39
PSUSAs (CAPs only) started[5]	568	-	584	622	627
PSUSAs (mix CAP/NAP) started[6]	49	-	38	48	49
PSUSAs (NAPs only) started[7]	287	-	237	285	234
Number of imposed PASS protocol procedures started	7	5	2	4	5
Number of imposed PASS result procedures started	11	2	7	4	5

Inspections and compliance

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
GMP inspections	247	96	209	327	134
GLP inspections	0	1	2	1	1
GCP inspections	36	75	75	78	93
Pharmacovigilance inspections	15	12	14	17	18
PMF inspections	122	84	146	134	76
Notifications of suspected quality defects	178	206	257	250	395
Medicinal products included in the sampling and testing programme	75	85	88	66	83
Standard certificate requests received	3,753	3,849	4,817	5,367	4,845
Urgent certificate requests received	1,659	1,147	1,117	1,125	985
Parallel distribution initial notifications received	2,555	1,816	2,092	2,200	2,656
Parallel distribution annual updates received	4,816	5,509	5,477	5,430	5,691

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Standard certificates issued within established timelines (30 working days)	99%	100%	100.00%	90%	100.00%
Average days to issue standard certificate (reversal of traffic lights)	12.81	3.90	4.4	15	6.0
Urgent certificates issued within established timelines (2 working days)	99%	100%	99.00%	98%	99.00%
Parallel distribution initial notifications checked for compliance within the established timeline	99%	99%	99.00%	98%	98.00%

[5] New indicator introduced in 2023 work programme.
[6] New indicator introduced in 2023 work programme.
[7] New indicator introduced in 2023 work programme.

Committees and working parties

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Number of reimbursed meetings	2	106	264	323	257
Committee meetings[8]	78	76	76	76	76[9]
Working Parties[10]	-	-	78	44	60
Workshops, Forum, Seminars, Infoday[11]	-	-	87	38	46
Other meetings[12]	-	-	142	165	104
Number of virtual meetings (audio-, video- and web-conferences)	13,227	5,700	4,600	6,500	1,609
Number of reimbursed delegates	30	1,980	3,476	6,800	3,759
Number of non-reimbursed delegates	0	178	1,008	1,500	1,347
Herbal monographs, new	3[13]	3	1	1	1
Herbal monographs, reviewed[14]	18	28	19	15	15
Herbal monographs, revised	2	2	3	8	10
EU herbal List entries	0	0	0	2	2

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings	100%	100%	100.00%	100%	100.00%

Pillar 2 – Public health activities

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Support the STAMP (European Commission Expert Group on Safe and Timely Access to	1.1 (ECP 1, ECP 4)	Several prioritised established medicines are enlisted in the pilot	**Delayed**	Completed scientific advice for all selected projects in April 2024. Then gathering and analysis of data on the candidates projects and scientific

[8] Including Management Board meetings.
[9] 47 face-to-face and 29 virtual meetings.
[10] New indicators introduced in 2024 Work Programme.
[11] New indicators introduced in 2024 Work Programme.
[12] New indicators introduced in 2024 Work Programme.
[13] Not included: two new public statements finalising the assessment of two substances that did not lead to the establishment of a monograph.
[14] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Medicines for Patients) scientific advice pilot for repurposing established medicines				advice outcome for the selected projects have been completed and currently the repurposing report is under drafting.
Provide parallel/joint EMA/HTA body scientific advice, also in anticipation of and with the new HTA Regulation	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	**Completed**	Procedures for parallel Health Technology Assessment (HTA) body/EMA scientific advice have been completed, as per requests and agreements with HTA colleagues.
Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers Conduct product-specific reviews with HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes	1.2 (ECP 1)	Stakeholder communication about regulatory assessment is enhanced	**On track**	Learnings from the EMA/EUnetHTA (European Network for Health Technology Assessment) review were integrated as part of the optimisation of the CHMP AR through the Revamp project. Regular contributions to meetings of MEDEV (Medicine Evaluation Committee)/ESIP (European Social Insurance Platform), providing feedback on completed product evaluations.
Set up and operate a Quality Innovation Group (QIG) 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) Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	3.1 & 5.5 (ECP 1)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	**On track**	Quality Innovation Group (QIG): Fully operational, 4 LLFG (Listen and Learn Focus Group) meetings delivered (2 in 2023 and 2 in 2024), product support mechanism established, guidance development, knowledge building/sharing ongoing, FDA collaboration initiated, action plan agreed and regular touchpoints set-up and operational. Pharmaceutical Quality Knowledge Management System (PQKMS): ICMRA pilots completed (3 inspection, 5 assessment), progress report on identifiers to enable a pharmaceutical quality knowledge management capability published July 2024. Risk-based approaches: Variation classification guideline revision completed and final guideline delivered to EC (Nov 2024). Staff awareness session developed and planned for January 2025. Risk-based/science driven principles implemented (implementing guidance preparation ongoing in Q1/2 2025), risk-based approach and toolkit developed, adoption by CHMP PROM (Preparatory and Organisational Matters) in January 2025 and implementation planned for Q1 2025 at BWP/QWP (EMA CHMP Biologics

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Working Party/Quality Working Party).
Deliver tailored engagement with academics and the community of ATMP (Advanced Therapy Medicinal Product) developers (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)	Increased support to the integration of scientific and technological progress in the development of ATMPs	**On track**	Comments on draft guidance for ATMP investigational medicinal products (IMP) collated and being addressed following second public consultation, targeting finalisation and publication by Q1 2025. Guidance on long-term efficacy/safety under revision. Three products onboarded into the ATMP support pilot — although little engagement has occurred with developers due to status of their programs. In addition, very few applications were received to fill the remaining slots — selection paused and reorientated towards other support mechanisms to enable a review/report of the experience with the first products by Q2 2025 as originally planned. The Agency also initiated an initiative with a support from a collaborative expert to develop tailored training for academics on scientific advice.
Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/ convergence of practices and training with the Pharmaceutical Inspection Co-operation Scheme, extend EU-US mutual recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA	5.3	Reinforced responsibility for product quality by harmonising and reinforcing guidance	**On track**	A draft of the Annex 11 on computerised systems and Annex on artificial intelligence haves been prepared by the GMDP IWG (Good Manufacturing and Distribution Practice Inspectors Working Group) until the end of 2024. A revision of chapter 4 on documentation, to complement requirements for computerised system, has progressed in parallel. The final draft version of Annex 11 (and Annex on AI) as well as Chapter 4 are expected to be adopted at the March 2025 IWG and will go for public consultation with interested parties in Q2 2025. A revision of Chapter 1 - Pharmaceutical Quality System and Annex 15 - on validation has been conducted by the GMDP IWG in collaboration with PIC/s (Pharmaceutical Inspection Co-operation Scheme), as a result of the revision of the ICH Q9 guideline on Quality Risk Management. The revision of the Annex 15 will also consider in parallel the ongoing revision for the extension of scope to APIs, as recommended in the Sartans with nitrosamines lessons learnt report, which is running in parallel. Following the US MRA extension to veterinary products in May 2023, further work has been undertaken for the finalisation of recognition of US

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				FDA of the remaining EU veterinary agencies and allow for the implementation of the batch testing waver clause. By the end of 2024, there were 24 EU veterinary authorities recognised by US FDA, with the finalisation of the process expected by 31 January 2025. There has been further operational progress on the MRA expansion on vaccines and plasma derived products the extension and on the recognition of third country inspections, however at the moment the expansions are currently pending.
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 significant number of markets or products	5.2	The exchange of information among MRA and PIC/s (Pharmaceutical Inspection Co-operation Scheme) partners is being actively promoted through international programmes, such as the API International Programme and PIC/s and ICMRA initiatives on hybrid inspections, in order to increase collaboration on reliance and hybrid inspections. As part of the implementation of the Sartans Lesson Learnt Exercise recommendations, Annex 15 of the GMP guideline on Qualification and Validation has been agreed to be revised with PIC/s in a global effort to extend scope to API manufacturers. Furthermore, the PIC/s aide memoire 'Evaluating management of quality risks at GMP facilities' has been revised for inclusion of reference to development of APIs and identification of impurities.	**On track**	The Active Pharmaceutical Ingredient (API) Programme on exchange of information on inspections of API manufacturers is continuing, and a revision to and enhancement on the logistics of the collaboration scheme for exchange of information on supervision of API manufacturing sites has been agreed and implemented. Discussions on the pilot on international collaboration on finished product inspections are currently pending. The ICMRA Collaborative Pilot on hybrid inspections has been finalised, and guidance on protocol for the hybrid inspection and lessons learned about conducting hybrid inspections has been published. 3 hybrid inspections were carried out under the pilot, the most recent in May 2024. The learning from the ICMRA Collaborative Pilot have been fed into the wider initiative at ICMRA on the PQKMS. PIC/s has finalised its revision of the aide memoire 'Evaluating management of quality risks at GMP facilities' for reference to development of APIs and identification of impurities, which is expected to be finalised in 2024.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	6.2	Improved benefit-risk communication	**Delayed**	Pilots have been delayed, awaiting a survey on the impact of patient preference studies on benefit-risk assessment. The outcome of the survey is necessary to inform any subsequent design of pilot studies. The outcome of the survey and re-discussion on any future pilots by CHMP is expected in Q2 2025.
Management of Medical Devices Expert Panels: Conduct a pilot for providing scientific advice to medical device manufacturers and have lessons learnt to establish an effective scientific advice service	Legislation	Experience gained to establish scientific advice for medical devices	**On track**	Although some of the procedures are still ongoing, the pilot has been concluded and an interim report is being drafted for publication. The launch of full advice is planned for February 2025.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1)	**On track**	Principles and Annex 1 (substantive part of the guideline) reached step 3 sign-off, and due for CHMP endorsement in Jan 2025.
Defining operational guidance for EMA responsibilities under the HTA Regulation, in cooperation with the HTA structures Contributing to stakeholder training 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**	EMA provided technical support to the establishment of implementing acts under the HTA Regulation by the EC and the Member States. The first one on joint clinical assessment (JCA) of medicinal products adopted; reflection of the interface with EMA in a dedicated article (Article 3). Development of operations were progressed on the basis of this tertiary legislation. Agreement between EC, EMA and HTACG (Member State Coordination Group on HTA) on the joint use of a modified letter of intent for applicants to notify upcoming MAA submission for products in the scope of JCA; joint review meetings since September 2024. Publication of guidance for applicants on these new operations as the first concrete operational delivery in preparation for the application of the legislation. In addition, the implementing acts for conflict of interest management, exchange of information with EMA, as well as JSC (joint scientific consultations) for medicinal products and for medical devices were developed by the EC with technical support from EMA. Joint training session was held with regulators and HTAs on the evolving interface under the HTA Regulation. A study visit was also organised for

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				SANTE C2 to get insights from EMA on the running of a secretariat for a European network. Development of a technical webinar series involving regulators and HTAs on the strength of evidence and management of uncertainties (lead HTA agency NCPE - National Centre for Pharmacoeconomics). Kick-off meeting for initial learning / mutual exchange followed by deep-dive discussions in November 2024.
Anticipate the changes stemming from the new pharmaceutical legislation by exploring possible ways to implement the legislative proposal and use this opportunity to future proof the operations of EMA	Legislation	Identify process improvements/increase in efficiency and gain experience with piloting some proposals	**On track**	The new pharmaceutical legislation team has been brainstorming various areas that may be impacted by the current draft of the new legislation. The goal of these discussions is to understand what the future state of these processes might look like. Additionally, change management activities have begun, including lunchtime talks to raise awareness among staff members about the current status of the legislative process. Preparations to engage with committees have also begun.
Implementation of the EU Regulation on medical devices (MDR) and on in vitro diagnostic medical devices (IVDR)	Legislation	Finalise the consultation procedure for medical devices composed of systemically absorbed substances	**Delayed**	Kick-off drafting group with CHMP sponsors for elaborating the consultation procedure by Notified bodies with EMA for medical devices composed of systematically absorbed substances. Drafting work is ongoing.
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	Legislation	Finalise the process for handling serious incident reports received by medical devices national competent authorities for ancillary medicinal substances and companion diagnostics	**On track**	Two partly overlapping implementation actions, one on handling of vigilance notifications received by medical device NCAs for medical devices with ancillary substances (pursuant relevant MDR articles) and the other on handling of vigilance notifications received by medical device NCAs for companion diagnostics (pursuant relevant IVDR articles). Ongoing discussions on both implementation actions at MDCG (EU Medical Device Coordination Group) working group level on content and system of transmission of relevant vigilance notifications between medical device and medicines authorities. Issue introduced and discussed at CMDh by MDCG topic lead in June following consultation with EMA. Interest from NL and SE expressed. Involvement of CMDh in further discussions at MDCG working group level will ensure that stakeholders impacted by the implementation of these articles are taking part in relevant MDCG discussions. Ongoing discussions at

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				MDCG-CMDh taskforce in which EMA is participating. Internally at EMA, procedural work with relevant teams ongoing. For the medical devices with ancillary substances related implementation action internal teams leading the implementation are confirmed and procedural documentation is being finalised. For the companion diagnostics related action internal teams leading the implementation are being confirmed. Mailbox for receipt of vigilance notifications was created.
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	Legislation	Application of Art 117: EMA/CMDh Q&A update	**Completed**	The update of the EMA/CMDh Q&A (rev.4) on MDR/IVDR has been completed and published in May 2024, to provide in particular more guidance of the application of the Art 117 to reflect on experience since MDR entry into force.

Veterinary Medicines Division

Pillar 1 – Product-related activities

Pre-authorisation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Innovation Task Force briefing requests (Vet)	6	0	10	5	11
Scientific advice requests received[15]	23	39	17	20	27
Requests for classification as limited market under Article 4(29) and eligibility under Article 23	3	21	17	10	14

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Scientific advice procedures completed within set timeframes	100%	100%	100.00%	100%	100.00%

Initial evaluation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Initial evaluation applications	9	22	25	33	27
New MRL applications	0	0	0	1	0
MRL extension and modification applications[16]	3	1	2	5	4
MRL extrapolations	0	0	1	1	0
Art. 10, Biocides	0	0	0	0	0
Review of draft Codex MRLs[17]	0	16	0	5	9

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Initial procedures completed within legal timeframes	100%	100%	100.00%	100%	100.00%

[15] Validated requests.
[16] Includes reviews requested in line with Article 11 of Regulation 470/2009.
[17] From 2022 includes also Codex extrapolations.

Post-authorisation activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Variations requiring assessment, of which[18]	n/a	252	337	304	268
Variation requiring assessment level 1	n/a	2	2	4	3
Variation requiring assessment level 2	n/a	75	104	80	63
Variation requiring assessment level 3	n/a	70	76	100	77
Variation requiring assessment level 4	n/a	105	155	120	125
Transfers of marketing authorisations	8	0	1	3	3

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Post-authorisation applications evaluated within the legal timeframes	100%	100%	100.00%	100%	99.00%

Arbitrations and referrals

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Arbitrations and Community referral procedures initiated	0	5	1	2	1

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Referral procedures managed within the legal timelines	100%	100%	75.00%	100%	100.00%

[18] Variations requiring assessment: New indicators introduced following Regulation (EU) 2019/6. For an explanation of the different variation levels, please refer to the Explanatory note on general fees payable to the European Medicines Agency

Pharmacovigilance activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Annual recording of signal management results and outcomes (Annual statements)[19]	-	-	-	250	271
Total signals submitted by MAHs of which:[19]	-	-	-	376	279
Emerging safety issues assessed by MAH and leading to regulatory action	-	-	-	1	0
Signals assessed by MAH leading to regulatory action (variations or other)	-	-	-	35	25
Signals classified for close monitoring by MAH	-	-	-	40	31
Signals classified as refuted by MAH	-	-	-	300	223
Signals submitted by Regulatory authorities following risk-based review[20]	-	-	-	40	16
Targeted signal management processes initiated by regulators[21]	-	-	-	4	1
Total adverse-event reports, of which:	80,709	167,546	149,059	120,000	164,360
Adverse-event reports (AERs) for CAPs	43,334	95,959	81,845	70,000	101,768
Adverse-event reports (AERs) for NAPs	37,365	71,587	67,214	50,000	62,592

Pillar 2 – Public health activities

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals	3.1 (ECP 1)	Guidance for novel therapies and biologicals developed	**Completed**	Activity completed in 2023.
Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL (Maximum Residue Limit) assessment and existing MRLs, and initiate the necessary preparatory and follow-up work	3.1 (ECP 1)	Analysis of impact and plan for future work on guidance and processes	**Completed**	Activity completed in 2023.

[19] New indicators introduced in 2024.
[20] New indicator introduced in 2024.
[21] New indicator introduced in 2024.

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)	Harmonised methodology in place: legislation, guidelines and templates revised; exposure assessment tool made available to CVMP experts	**On track**	The EC mandate was received on 1 July 2024. The EC deadline for the development of the common calculation tool is November 2026. The first two teleconferences of the EFSA working group took place on 7 November and 6 December 2024. SWP-V (EMA CVMP Safety Working Party) and CVMP were kept updated on progress.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	3.1 (ECP 1)	Guidance for surveillance and signal detection developed Enhanced communication with the network	**On track**	A final P-SMEG (Pilot Signal Management Expert Group) report was presented to the Committees in December 2024 on the basis of an agreed process for the follow-up of submitted signal to IRIS (regulatory & scientific information management platform between EMA and stakeholders). The technical implementation in IRIS and corresponding tutorials are planned for Q1 2025.
Using data on the sales of veterinary products, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use	3.1 (ECP 1)	Methodology established and guidance developed	**Completed**	The development work on the data warehouse to allow publishing the available reporting incidences was completed in January 2024.
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	**On track**	To harmonise monograph systems for H and V and avoid two different approaches, a pilot study is being performed for VMPs considering also relevant provision from the new pharmaceutical legislation.
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 2024, EMA participated to the following events: ERA ESEC (Environmental Risk Assessment European Specialised Expert Community) kick-off meeting, 31 October; Workshop on 'Emerging chemical risks for public health and the environment'

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				(organised by EFSA), 26–27 September 2024.
Provide scientific support to the European Commission and the EU network 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 2024.
Establish contributions to JIACRA (Joint Inter-agency Antimicrobial Consumption and Resistance Analysis) under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1 (ECP 1)	Establish governance for JIACRA report under EMA and CVMP	**On track**	EC agreed on the proposed focus of the 5th JIACRA report and the mandate for the report was received at end of 2024. The report is expected to be finalised by the end of 2026.
Implement use data collection by animal species	4.1	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578	**On track**	The ASU (Antimicrobial sales and use) Platform went live on 29 January 2024. The data call for 2023 data on volume of sales of antimicrobial VMPs, use of antimicrobial medicinal products in animals and animal population data was opened in Q2 with legal deadlines for sales data on 30 June and for use data on 30 September. All MSs submitted their 2023 data. For viable data analysis, a UPD/ASU product data quality campaign took place throughout the year. Thanks to coordinated efforts between EMA and MSs, the impact of data quality issues decreased from 20% of the products not being analysable to sales only being impacted 0.08%. All submitted data were validated and analysed using the ASU BI application and the first draft of the first ESUAvet (European Sales and Use of Antimicrobials for Veterinary Medicine) report was prepared and sent to the ESUAvet data analysis subgroup for revision. The report is on track for publication ahead of the legal deadline on 31 March 2025.
Communicate effectively on consumption data	4.1	The outline of the ESVAC report reviewed to improve communication	**On track**	Within the ESUAvet (European Sales and Use of Antimicrobials for Veterinary Medicine) WG (Working Group), a subgroup was created (analysis &

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		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)		reporting) to draft the outline of the future Agency's reports for both sales and use data. The group met several times to discuss and the first draft layout/outline was shared with ESUAvet WG and observers from the Commission. The proposal has been revised based on the comments received and was adopted by CVMP in November 2024. The first report is expected to be published in Q1 2025.
Foster development of POC (point of care) diagnostics for veterinary use	4.2	Review availability and characteristics of diagnostic tests	**On track**	The questionnaire was sent to the CVMP, CMDv members and CVMP interested parties list. 91 responses were received, the AWP (EMA CVMP Antimicrobials Working Party) is currently revising the reflection paper according to the feedback received.
Prioritise and trigger referral procedures and/ or support MSs in activities to review available data on emerging AMR risks, clinical effect, PK/PD, dose regimens	4.2	Support CVMP on VMP referrals and act on the recommendations from the Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation	**On track**	The report on the priority list is being drafted and will be shared with CVMP in January 2025.
Communicate on available tools like AMEG (Antimicrobial Advice Ad Hoc Expert Group) categorisation to stakeholders to ensure proper implementation to support responsible antimicrobial use	4.3	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	**On track**	No specific activities were concluded in 2024.
Participate in international initiatives to reduce the risk of AMR	4.1 (ECP 1)	Actively participating in international fora	**On track**	In the second half of 2024, EMA veterinary colleagues participated in: 3 Regulatory Agencies Global Network against AMR (RAGNA) meetings; 2 Trans-Atlantic Task force on Antimicrobial Resistance (TATFAR) video conference and monthly meetings; Hungarian presidency meeting with AMR keynote presentation;

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				AMR Training event for IPA (Instrument for Pre-accession Assistance).
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 3)	Develop and revise relevant guidance	**On track**	The 'Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances' and the 'Guideline on the conduct of efficacy studies for intramammary products for use in cattle' were adopted by CVMP at its June 2024 meeting, for release for consultation. Comments are being evaluated and the final guidelines are expected to be finalised in Q1 2025
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper	4.3 (ECP 3)	Reflection paper finalised and published Review of novel risk assessment methodologies for AMR in the environment	**On track**	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms	4.3 (ECP 3)	Reflection paper developed Communication with stakeholders	**On track**	The horizon scanning was launched on 9 April 2024 with deadline for 30 June 2024. The results from the survey were summarised and presented to the NTWP (EMA CVMP Novel Therapies and Technologies Working Party) and the CVMP in Q3 2024.
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	4.3 (ECP 3)	Guidance development Communication with stakeholders	**On track**	The questionnaire was sent to the CVMP, CMDv members and CVMP interested parties list. 91 responses were received, the AWP (EMA CVMP Antimicrobials Working Party) is currently revising the reflection paper according to the feedback received.
Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health	4.3 (ECP 3)	Guidance development on ATAm	**On track**	An analysis of the last 5 years advices on alternatives to antimicrobials has been initiated to get an overview and to identify data gaps, to understand areas in need of further guidance.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the	4.3 (ECP 3)	Cooperation at EU and international level for events	**On track**	EMA collaborated with EFSA, ECHA, ECDC and EEA on a scientific opinion on the impact of the use of azole fungicides on resistance in

Action	MAWP strategic goal	Expected result	Status	Achievements/results
responsible use of antimicrobials and their alternatives		Common approach agreed		Aspergillus which was finalised in 2024.
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 public consultation ended in November 2024. Comments received are now being evaluated, the final document is expected to be finalised in Q1 2025.
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)	4 (additional RSS recommendation)	Identify different benefit-risk approaches per type of vaccines Guidance on benefit-risk	**Completed**	The consultation period for: 'Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets' and 'Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6' ended on 31 January 2024. The guidelines have been adopted by the CVMP at its October meeting and published on the EMA website.
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 sustainable tick control and acaricide resistance and also community dialogues organised by FAO (5 webinars organised in 2024). There was also an interaction with Royal GD (Dutch CRO) on anthelmintic stewardship and prudent use.
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 revised draft guideline is foreseen to be published for public consultation in Q1 2025. The final revised VICH guidelines on efficacy of anthelmintics (VICH GLs 7, 12-16, 19-21) were adopted by CVMP at its meeting in November 2024 and published on the EMA website. The antiparasitic resistance section of the Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations was further revised; the final

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				reflection paper is foreseen to be adopted and published in Q1 2025. An infographic on lack of expected efficacy for antiparasitic veterinary medicinal products is under development by EWP-V (EMA CVMP Efficacy Working Party) and PhVWP-V (EMA CVMP Pharmacovigilance Working Party) and is expected to be finalised in 2025. 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 will start in Q1 2025.
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 2)	Analysis of current methodologies, development of harmonised approach and guidance	**Completed**	The final guideline has been adopted by CVMP at its meeting in November 2024 taking into account the comments submitted, and published on the EMA website.
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	**On track**	The EMA Veterinary Medicines Info Day was held in March 2024, and the CVMP Interested Parties Meeting was held in May 2024.
Coordinate and implement the Veterinary big data strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 2)	Compilation of a Veterinary data sources catalogue and metadata analysis	**On track**	A research study to develop a data sources catalogue was initiated in Q1 2023 and has been completed in Q2 2024. The final version of the report was submitted on 5 July and the internal EMA review completed by 31 August 2024. The plan for the next phase was delivered in September. The next phase is scheduled to start Q1 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. In parallel, agreement has been made with the RWE Catalogue

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				team to include appropriate data sources identified in this analysis in the RWE Catalogue. It is expected to upload selected veterinary data sources to the RWE catalogue in Q4 2025.
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) Consequently, implement the initiative as/if required	ECP 3	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**	EMA contributed as necessary to the on-going legislative process, as well as provided input in the framework of experts/working groups meetings. In 2024 EMA and EFSA had a series of deep-dive workshops on this topic.

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure		2021 result	2022 result	2023 result	2024 forecast	2024 result
	New scientific, regulatory and network portfolio curricula developed	1	1	0	2	2
	Number of training events advertised to the EU Network	77	76	79	60	158
	Number of reimbursed training events to the EU Network	0	4	3	8	4[22]
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	15	11	13	10	9
	Number of Epics completed or ongoing[23]	-	-	39	29	44

Achievements

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	**On track**	The Agency has continued to open up Digital Academy modules to the EU Medicines Regulatory Network. This included: Cloud computing Digital wellbeing Agile Design thinking Lean Prompt engineering and safe use of LLMs Collaborating digitally AI case studies in the Regulatory Network data literacy Protecting personal data In addition, the Agency developed and published a completely new Digital Academy module that was not part of the original Digital Skills framework on 'Process Mining'. This was a joint endeavour with the Audit team (AF-AUD). Work continued on the development of the following modules with a view to publishing in the near future: User experience (UX)/ user interface (UI) and Usability Data security Communicating digitally

[22] The number of training events that could be reimbursed in 2024 is more than 25% below 2024 forecast due to EMA budgetary constraints. The 2024 result only includes training events where participation of NCA staff was supported by the EU NTC. It does not include the number of training courses that have benefited from remuneration. In 2024, a total of 5 courses were remunerated.
[23] New indicator introduced in the context of EMA Agile transformation.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Establish an EU collaboration on AI with other Agencies in the EU Network	2.2. (ECP 2)	Develop and promote the AI community Increase synergies, re-use, and efficiency Share knowledge and increase maturity Collaborate for the implementation of common AI initiatives and projects	**On Track**	EMA is chairing the EUAN Working Group on AI since 2024. Participating organisations: 37 Agencies and 2 Joint Undertakings in total 15 new Agencies + 2 Joint undertakings represented since 2023 Working Group members: 88 SPOCs in total Average of 70 participants per meeting Number of events: 10 meetings and events 5+ invited external guest speakers Physical working session in Amsterdam Main activities: Survey to collect needs and expectations of the Working Group AI maturity Survey with 16 total replies AI use-cases map With participation from 39 EU organisations, the working group achieved several strategic objectives, including assessing AI maturity levels, mapping use cases and developing actionable plans to advance AI integration across the EUAN. Key deliverables, such as the EU AI innovation fund implementation plan, the AI maturity assessment, and guidance on copilot implementation, provided a robust framework for future growth and collaboration. The Working Group hosted numerous knowledge-sharing events through in-person and virtual workshops, fostering engagement, expanding the AI ecosystem, and establishing collective vision for 2025–2027. Through the development of shared services and solutions, coupled with the recognition of common challenges, the Working Group has emerged as a leading forum for advancing AI capabilities within the network.
Support future-proofing 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	**On track**	In 2024, EMA continued supporting the development and delivery of training courses for the EU Network. This included 125 courses, including 5 face-to-face courses: Pre-clinical Assessors Meeting (PAM), February 2024 Biologics Working Party (BWP)-Committee for Advanced Therapies (CAT) training on Adeno-associated virus (AAV) based gene therapy, May 2024 Environmental Risk Assessment (ERA), May 2024 Training for quality assessors, October 2024

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		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		Classification and data requirements for applications for veterinary medicinal products (VMPs) intended for limited markets. EMA also concluded its pilot on the new remuneration scheme, from which 8 new courses benefited in 2024: Annex 1 to the EU good manufacturing practice (GMP) guide (Manufacture of sterile medicinal products), delivered in April 2024 EMA-coordinated good clinical practice (GCP) and bioequivalence (BE) inspections online training course, available since June 2024 Risk management plans (RMPs): procedure management and assessment, delivered in September 2024 Risk minimisation measures (RMMs), delivered in December 2024 Training on the ICH M12 Guideline on drug interaction studies, delivered in December 2024 In addition, the agency modernised the EU NTC monthly newsletter by publishing it in Newsroom. 9 issues were published in 2024, from April to December. EMA also developed a new training curriculum in the area of oncology. Furthermore, the Agency opened up the EU NTC to: Patient/consumer and healthcare professional representatives; A subset of non-EU regulators (i.e. Instrument for Pre-accession (IPA) countries) drawing on the lessons learnt from the non-EU regulators pilot ran in 2023 in collaboration with International Affairs. EMA also launched the EU NTC portal, providing public access to our full training catalogue: https://euntc.ema.europa.eu/. Last but not least, the Agency hosted a global face-to-face event to mark the 10th anniversary of the EU NTC. The fruitful exchange of views and ideas has led to a number of concrete action points to take forward as part of the updated EU NTC strategy.

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Workload indicators[24]

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	-	-	-	1,100	1,319
Number of EudraVigilance Quality Assurance Test (QAT) requests received	-	-	-	130	153
Number of non-interventional studies performed	-	-	-	70	59
Number of methodological advice provided on product procedures	-	-	-	80	71
Number of active methodology guideline drafting groups led by MWP	-	-	-	15	12
Number of methodological contributions to guidelines led by other committees and working parties	-	-	-	10	11
Number of business validation for CTIS releases	-	-	-	18	20
Number of KPIs reports published	-	-	-	12	11
Number of EudraCT reports and number of CTIS data analyses and reporting	-	-	-	110	144
Number of ACT EU multi-stakeholder workshops	-	-	-	12	10
Number of regular CTIS/CTR events	-	-	-	86	76
Number of CTIS newsflashes and CT highlights newsletters	-	-	-	26	29

Performance indicators[25]

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	-	-	-	90%	94.00%
Percentage of monthly updates of the ADR report website performed according to the timelines	-	-	-	90%	100.00%
Studies performed within less than 24 weeks[26]	-	-	-	70%	66.00%
Non-Interventional Study (NIS) protocols and summary results registered in EMA NIS registry within a month after finalisation	-	-	-	90%	100.00%
Product procedure requests for methodological support completed as per timelines	-	-	-	90%	100.00%
Planned MWP contribution to guidelines led by other committees and working parties	-	-	-	75%	100.00%
ATD/RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	-	-	-	90%	73.00%
WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	-	-	-	90%	100.00%
ACT EU multi-stakeholder workshops organised according to workplan	-	-	-	80%	83.00%
News flash to CTIS users	-	-	-	90%	100.00%
Support to the secretariat for CTCG and physical hosting 4 times per year	-	-	-	100%	100.00%

[24] New indicators introduced in 2024 work programme.
[25] New indicators introduced in 2024 work programme.
[26] Excluding Framework contract studies. Duration changed to 26 weeks (instead of 24, as indicated before).

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Provide secretariat for CTCG weekly assessors round table	-	-	-	100%	100.00%

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Build capacity and capability to receive, store, manage and analyse raw data	2.1 (ECP 2)	CHMP proof-of-concept pilot for individual patient level data from clinical trials and non-clinical data launched and carried out Proof-of-concept pilot protocol developed Interim and final pilot reports developed Guidance for applicants developed	**On track**	10 pilot procedures successfully included in the clinical study data pilot. Interim lessons learned from the pilot presented to: - CHMP SRLM (Strategic Review & Learning Meeting) in Q2 2024; - EMRN and industry delivered in Q3 and Q4 2024; - MB presentation December 2024. Dedicated discussion with EC on pilot's interim learnings in support of the new pharmaceutical legislation took place in September 2024. Interim pilot report distributed to EMRN in Q2–Q3 2024. Interim pilot report and updated guidance for Applicants/MAHs made publicly available in October 2024. Pilot will now continue with increased focus on training and change management.
Implement the Clinical Trials Safety Monitoring Implementing regulation		Assure the 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 for safety assessing Member State (saMS) selection and ASR evaluation approved.
Support an initiative with the EC and HMA to transform CT in Europe. This includes: modernisation of CT design and good clinical practice; strengthening EU level governance of CT; improved coordination between NCAs and ethics committees through the 'CTR Collaborate' project,		Strengthen EMA support to ACT EU Project manage the 'CTR Collaborate' project which will deliver enhanced collaboration between NCAs and Ethics Committees to support sponsors/CROs (Contract Research Organisations), develop effective procedures and training/information sharing and support	**On track**	The Multi-Stakeholder Platform (MSP) and its Advisory Group established. Annual meeting of the MSP held in October 2024. Paid ads campaign on transitioning trials to CTR delivered with distinct phases targeting countries with most trials pending to be transitioned. Transparency of clinical trials data increased via the simplified CTIS transparency rules. Pilots for consolidated scientific & regulatory advice on clinical trials launched.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
including during public health emergencies; leveraging data on CT to support regulatory decision making; supporting non-commercial sponsors to conduct more multi-national clinical trials; enhanced dialogue between clinical trial stakeholders.		the development of an EU forum for ethics committees to come together Support communication and change management, including training on operation of CTR and CTIS Launch scheme to support large multinational CTs, including a one stop-shop for academic sponsors Engage external stakeholders and establish a multi-stakeholder platform and advisory group Adopt a plan for GCP modernisation Further develop and manage a stand-alone ACT EU website Develop a CT research agenda Develop a pilot for consolidated pre-clinical trial application (CSA) advice (CHMP SA linked with SNSA (Simultaneous National Scientific Advice)/CTCG (Clinical Trial Coordination Group) advice) Develop RACI matrix for network governance groups Strengthened process and regulatory approval of large, multinational clinical trials in the EU during public health emergencies		Mapping of EU groups and fora involved in clinical trials published with detailed information on each group to clarify the clinical trials landscape to sponsors. Signposting of existing national initiatives to support non-commercial sponsors created with CTCG and published. Launch of accelerated CTIS/CTR support for academia in October 2024. Annual ACT EU matrix meeting held in October 2024. Revised ACT EU 2025-2026 multi-annual workplan adopted with redesign of programme structure to increase synergies across priority actions and reduce siloed ways of working. Report of Data Analytics workshop published.
Business support to operations to Clinical Trials regulation,		Provide hands on support to the numerous sponsors and MS users of	**On track**	Continuous support to sponsors and Member States on the interpretation of the regulation and CTIS use delivered.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
including business support to CTIS		CTIS through the business service desk Assure the business testing of the candidate releases		Specific support for non-commercial sponsors launched. List of CTIS functionalities for improvements prioritised weekly. Users informed regularly, on monthly basis, on CTIS improvements.
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**	Delivered in 2024: 4 Bitesize talks; 5 Walk-in clinics; 24 issues of CTIS newsflash; 5 issues of CT newsletter; 3 CTIS Forum meetings; 9 CTCG plenary meetings and 41 CTCG Assessors Roundtable meetings; 3 info events (training on transition trials for academics, CTIS webinar: last year of transition – 'CTIS info day', CTIS demo – virtual event).
Deliver a data science curriculum for the EU Regulatory Network	2.2	Lead the work of the contractor to which the Data science curriculum has been outsourced	**On track**	5 modules delivered and made available to the EU Network via the EU NTC (EU Network Training Centre) platform: 1. Introduction to data science 2. Big data 3. AI 4. Data management 5. Data visualisation
Development of the EU Data Quality Framework for big data used in the regulatory context and of the data quality considerations for real-world data (RWD) and for adverse drug reactions (ADRs)	2.1	EU Data Quality Framework for big data used in the regulatory context and of the data quality considerations for real-world data (RWD) and for adverse drug reactions (ADRs)	**On track**	Following the adoption of EU Data Quality Framework by CHMP, and the publication in 2023, a draft of RWD considerations produced and published in 2024. Multi-stakeholder workshop on adverse drug reactions (ADR) considerations held. Creation of a first draft of ADR considerations (scheduled for publication in 2025) initiated.
Ensure compliance with the European Union Data Protection Regulation (Reg (EU 2018/1725) and guidance of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB) and		Yearly report on data protection activities to EMA Management Board	**On track**	Data Protection Officer (DPO) and Data Protection Coordinators continue to drive Data Protection activities and ensures compliance with the European Union Data Protection Regulation by providing advice on all data protection related matters at the Agency and additional support through training for the Network. More specifically, the DPO continues to provide assistance and guidance to Internal Controllers regarding data

Action	MAWP strategic goal	Expected result	Status	Achievements/results
provide advice on data protection related matters at EMA				protection obligations (update existing and develop new records, data protection notices, DPIA (data protection impact assessment) reports, joint controllership agreements; adopting instruments for international data transfers; advise on data protection provisions with data processors).
Enable clinical trial data standards in EMA and Network systems and processes	2.2.	Coordination of European contribution to ICH M11 activities Roadmap on clinical trial standardisation Identification of use cases for clinical trial analytics Network experts' contribution in clinical trial standards Updated version of the FHIR (fast healthcare interoperability resources)	**On track**	Progress on ICH M11 as planned. Network expert onboarded. Draft roadmap on clinical trial standardisation developed. Dedicated session to raise awareness on clinical trial standardisation held during ACT EU Clinical Trials Analytics Workshop in January 2024. To note: Update of clinical trial logical model updated and preparation of FHIR extension messages moved to 2025
Provide methodological expertise to support EMA scientific committees in alignment with external stakeholders' needs Strengthen the EU Network on methodology in committee advice and assessment Harmonisation of international methodological standards	2.2	Revised Methodology Work Plan Draft Methodology stakeholder interaction plan Draft methodology research needs Deliver guidance documents on emerging methodological topics Systematic lessons-learnt process for procedures with complex methodology, deliver first modules of the training curriculum in biostatistics, embed identification of committee requests with complex methodological aspects into EMA forecast and tracking processes	**On track**	Draft workplan 2025-2027 created and final version adopted. First EMA CHMP Methodology Working Party (MWP) Interested Parties meeting held; significant interest and engaging participation from regulators and industry noted. Stakeholder interaction plan outlined; first implementation planned for 2025. Drafting groups and operational expert groups established and managed. Milestones for 60% of the priority guidelines achieved (publication of guidance on AI and single arm trials). Clear roles and responsibilities in the Methodology domain defined; training ongoing. Draft operational instructions for the EMA European Specialised Expert Community(ies) (ESEC) and EMA CHMP Methodology Working Party (MWP) created and discussed. First biostatistics (and Clinical Pharmacology) training modules developed and delivered. Tracking and reporting tools established.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		Drafting groups and operational expert groups established and managed Clear roles and responsibilities in the Methodology domain to maximise resource efficiency Drafting of ICH E6(R3) Annex 2, E11A and E20 guidelines Organisation of cluster meetings		Progress of most ICH guidelines as per defined timelines: - ICH E11A adopted and published in Q2 2024; - ICH E6(R3) Annex 2, step 2, signed in November 2024; - work on E20 ongoing. Collaborative Special Interest Area (SIA) engagement, i.e. in the areas of Clinical Pharmacology & Biostatistics enabled. ESEC newsletter highlighting complex methodological procedures launched; repository for MWP outputs established; discussions on methodological topics within SIAs regularly scheduled.
Improving development and implementation of clinical trial methodology guidance in the EMRN Contributing to the delivery of CT curriculum		Methodology workshops with external stakeholders to scope and prioritise clinical trial methodology guidance topics Methodology guidance roadmap Process for aligning guideline development on multidisciplinary methodology topics involving a large variety of relevant Network expert groups Training plan for new guidance documents and associated process Completion of training needs assessments for regulators and defined stakeholder groups Training curriculum elaboration	**On track**	Methodology workshop report published in Q1 2024. Compilation of the gap analysis for assessors published on ACT EU's website in Q1 2024. Training needs analysis for academia and SMEs ongoing.
Further develop and maintain a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation	2.1	DARWIN EU® Coordination Centre maintained Access to various real-world data sources in terms of data type and geographical coverage	**On track**	47 studies performed (either completed or ongoing) by DARWIN EU® as per the following distribution (study type): 31 off-the-shelf (OTS) studies (including 7 studies initiated at the end of Phase II); 4 routine repeated (RR) studies;

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Network - DARWIN EU®). To support better decision-making on medicines by informing those decisions with robust evidence based on appropriate real-world data.		DARWIN EU® pilot with EHDS conducted Processes for EMA oversight of DARWIN EU® activities operated, including review of all deliverables and DARWIN EU® outputs		12 complex studies (including 4 studies initiated at the end of Phase II). 10 data partners onboarded in 2024. Note: onboarding of additional data partners in 2024 is in line with committees' request to obtain additional data not yet fully covered by the previous 20 data partners onboarded in 2022 and 2023 (2 specialised paediatric data sources, 2 specialised cancer registries, 1 additional nationwide registry, 1 multi-cohort dataset, and several hospital data sources).
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 for prioritising analytical requests established Development of a phenotypes library Users' training on utilisation of IHD and analytical templates	**On track**	89 study requests processed: - 76 addressed via DARWIN EU®; - 6 via framework contract (FWC); - 7 via in-house. Out of these 89 studies, 42 studies were feasible (15 are still under feasibility assessment at the end of 2024). During the year: - 33 studies initiated (after protocol approval – 29 via DARWIN EU®, 2 FWC and 2 in-house); - 29 studies completed (18 via DARWIN EU®, 6 FWC and 5 in-house — some of them were initiated in 2023). Training of Instant Health Data (IHD) users continuously provided.
Pilot the use of AI/machine learning to increase efficiency to extract information in EMA documents and real-world data		Successful experimentation on the extraction of information using AI/NLP (Natural Language Processing) techniques Report on lessons learnt from test use cases shared within EMRN Planning of additional experimentation with AI/NLP at EMA considering the lessons learnt	**On track**	EU product information Entity Extraction and Knowledge Acquisition (EurEKA) is a project to extract adverse drug reaction information from European public assessment reports: - EurEKA for centrally authorised medicinal products created and information from over 1000 EPAR SmPCs extracted. - EurEKA for nationally authorised products under signal work-sharing and EurEKA for veterinary medicinal products is under development and will be deployed early 2025.
Further development of a monitoring system for the post-authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform)		Core infrastructure for the prioritisation, launch and supervision of vaccine studies in place Working arrangements with	**On track**	9 EMA studies linked to the Vaccine Monitoring Platform completed or ongoing in 2024 (using either EMA's framework contract for scientific studies or DARWIN EU®) on COVID-19, HPV, mpox, seasonal influenza and RSV vaccines as well as for safety monitoring (background rates of adverse events of special interest).

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		ECDC established and operational EU networks with capacity to perform representative and reliable studies identified Processes in place to identify need for studies Results of studies made available to EU decision-makers and the public		Several manuscripts linked to these studies published. 4th meeting of the Immunisation and Vaccine Monitoring Advisory Board (IVMAB) held in October 2024. Work to identify further infrastructure in EU for evidence generation ongoing.
Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data		Establishment of the Health Data Lab as a stream following DigiLab's framework Pilot the experimentation framework with two pharmacovigilance-related projects	**On track**	Health Data Lab established. Two pharmacovigilance pilots initiated, and 3 legacy initiatives onboarded. Two pilots to be deployed early 2025 for additional user testing and validation: EurEKA and Enhanced Review of Abstracts with Transformer models (ERATO). ERATO aims to reduce by an estimated 80% to 90% the roughly 200.000 abstracts the Pharmacovigilance Office to be reviewed on a yearly basis. This could save more than 0.5 FTE per week. Three remaining initiatives are exploring the possibility to: 1. structure and reuse the signal review tracking table of over 25,000 reviews over 15+ years; 2. establish automated adjudication of certain adverse reactions to increase efficiency and reduce time-to-signal detection and finally; 3. improve the identification of individual case safety reports from literature abstracts.
Perform the EMA data governance and support EMRN data governance through development and implementation of an EMA and EMRN data strategy and data standardisation strategy as well as relevant policies, procedures as part of implementing a federated data governance at EMA, ensuring gradual evolution		Plans and activities to implement EMA data strategy, EMRN data standardisation strategy and EMA data governance, including roles, responsibilities, processes, policies, structures and a data catalogue & glossary EMRN data strategy Communications, training and	**On track**	EMA: - Monthly Data Board meetings organised. - Data asset identification ongoing: more than 100 data assets identified, the process is approximately 65% completed. - Data asset maturity assessment drafted. - Data owners and data stewards nominated for the first 77 data assets to perform the agreed essential Data roles. - Review of Data roles to identify improvements ongoing. - Data catalogue population by first Data roles cohort started.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		stakeholder engagement		- Data community kick off planned for January 2025 to receive input on mandate followed by adoption. - Business data glossary adopted, and user guide developed. - Communications disseminated, timely updates of internal Data governance webpage. - Onboarding and initial training completed i.e. Data roles cohort one roll out complete. - Data Strategy Area leads appointed and monthly meetings initiated. - Mapping of Data Strategy Area activities started for the implementation of the EMA Data Strategy. Network: - Monthly HMA-EMA Big Data Steering Group (BDSG) meetings organised. - BDSG work plan implementation coordination ongoing as planned and to be replaced by new Network Data Steering Group plan. - Draft Network Data Strategy published for consultation. - The new Network Data Steering Group mandate adopted and nominations for membership completed. - High level Data Quality concept drafted. Guidance in drafting.
Perform a capability and capacity assessment for big data use cases, as per HMA-EMA Big Data Steering Group (BDSG) work plan 2022-2025		A report including recommendations for actions	**Completed**	Survey completed in May 2024. Results discussed with BDSG in September 2024. BDSG acknowledged that the survey responses showed an appetite within the EMRN for fostering data access, sharing between national agencies and developing analytics capabilities at the EU level. Results will inform the development of the new Network Data Steering Group workplan in 2025 and the potential drafting of an EMRN data analytics strategy in 2025.
Support EMA operations and committees/working parties with advice and epidemiological expertise on: methods for RWE collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; portfolio of real-world data sources existing in Europe		Draft guideline on methodological aspects, formats and contents of RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of real-world data sources used in regulatory decision-making (e.g. registries, electronic healthcare records)	**On track**	Screening of pipeline of initial MAA initiated end of 2023 and led to 4 study requests in 2024. Pre-submission dossiers screened and discussed at CHMP PROM (Preparatory and Organisational Matters) monthly. In collaboration with PDCO (EMA Paediatric Committee), a proposal for a conceptual RWD framework to inform the possibility of adult-to-paediatric extrapolation developed. Active collaboration with PDCO, and its working groups, resulted in a detailed research agenda in the area of neonates. It drove the need for specific

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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.		Process for identification of procedures from relevant committees/WPs that need methodological input, participation and contribution to SAWP, pre-submission, PRIME and other relevant meetings where RWE is addressed		data partners within DARWIN EU® in 2024. Signal procedure generated 21 studies and Periodic Safety Update Report Single Assessment (PSUSA) procedure 8 studies. Due to this high output, signal and PSUSA processes to request and integrate generated RWE into the procedures were built and piloted in 2024 and are being currently formalised. In cooperation with HMPC (EMA Committee on Herbal Medicinal Products), 2 studies on herbal medicines delivered via DARWIN EU® to support the Agency's opinions on herbal substances and preparations. To support the geriatric medicines strategy 2 studies were initiated in the area of frailty and standard of care in older patients in line with the CHMP 2024 workplan. EMA use case study (on natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV-2 in the context of the Omicron variant) finalised as part of the HealthData@EU (EHDS2) Pilot. Espdite (early screening of product documentation for input on techniques and evidence) reports regularly provided. These reports are generated automatically and include all MAA and extension of indications (EoI) applications containing RWE-related keywords.

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Innovation Task Force briefing meetings	36	34	29	40	30
Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[27]	0	1	0	4	0
Business Pipeline briefing meetings	15	21	21	20	19[28]
Regulatory assistance, including SME briefing meetings	180	207	230	192	249
Requests for SME qualification	504	412	428	541	374
Requests for SME status renewal	1,293	1,432	1,432	1,323	1,412
Management of shortages of CAPs[29]	-	-	-	1,600	1,224
Number of notifications of critical shortages (centrally authorised products (CAPs) and nationally authorised products (NAPs)) , human + vet) circulated via Medicine Shortages Single Point of Contact (SPOC) Working Party[30]	-	-	-	60	69
Number of requests for information received from the SPOC Working Party and international partners[31]	-	-	-	70	26
Number of Medicine Shortages Single Point of Contact (SPOC) Working Party meetings (including subgroups)[32]	-	-	-	40	18
Number of Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) meetings[33]	-	-	-	12	11
Number of HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use meetings + Thematic working group 1[34]	-	-	-	12	16
Additional indicators					
Shortages discussed by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	-	-	-	-	9
Oral explanations to the Executive Steering Group on Shortages and Safety of Medicinal ducts (MSSG)	-	-	-	-	6
Voluntary solidarity mechanism (VSM)	-	-	-	-	7

[27] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[28] Portfolio and technology meetings (renamed in 2024).
[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.
[33] New indicator introduced in 2024 work programme.
[34] New indicator introduced in 2024 work programme.

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Satisfaction level of SMEs	98%	n/a	85.00%	80%	89.00%

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	Sharing insights from the Innovation Task Force and Portfolio Technology Meetings with the EMRN through monthly Committee and Working Parties briefings, as well as annual insights review presentations.
Identification of new technologies via horizon scanning and scientific advice activities and their integration into the EU Network Training Centre (EU-NTC)	3.1 (ECP 1)	New technologies identified and integrated within EU-NTC	**On track**	TRS-INO / EU-NTC co-organisation of a webinar on Faecal Microbiota Transplants (FMT) classification (following the FMT Horizon Scanning report recommendation) with EC SoHo (Substances of Human Origin) and DG SANTE on anticipated classification.
Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	3.4	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	**Delayed**	Topics, Relationships, Impact assessment, Proposal generation (TRIP) tool's minimal viable product testing and exploration of alternatives conducted
Integrate EMA's Regulatory Science Strategy (RSS) 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	**Completed**	Multiple discussions and active contributions on EMAN 2028 strategy
Innovation relevant preparation for the implementation of new legislation (Sandbox, Borderline Classification)		Proposals for re-designed processes for the implementation of new pharmaceutical legislation	**On track**	Multiple actions as laid out in Agile sandbox and academic New Pharmaceutical Legislation workstream.
Preparation for European Shortages Monitoring Platform (ESMP) database Extended mandate activities on shortages of Medicinal Products and Medical Devices		Extended mandate activities on shortages of Medicinal Products and Medical Devices	**On track**	The ESMP has gone live on 28 November 2024 with a core set of functionalities. Using this first version of the ESMP, MAHs can now submit data to routinely report shortages of CAPs. The launch was accompanied by a comprehensive engagement campaign which

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				included direct communication with all stakeholders, press releases, a media seminar of shortages with members of press across the EU/EEA, training and a wide range of documentation. The launch of the full range of ESMP functionalities for MAHs and NCAs is on track for Q1 2025.
Union list of critical medicines SPMPs organisations of SC meetings of the Task Force on Availability of authorised medicines for human and veterinary use (TF AAM) meetings (4 per year) TWG1 meetings (30 per year)		Human product availability, Veterinary product availability / MUMS	**Completed**	Union list of critical products version 2 was published on 16 December 2024. The list includes innovative medicines and generic medicines for human use covering a wide range of therapeutic areas — such as vaccines and medicines for rare diseases. The Union list results from the national competent authorities' review of 2,200 active substances groups and combinations, which account for 75% of the authorised medicinal products in the EU, including a consultation with stakeholders. After the publication of the Shortage Prevention Plans (SPPs) and Shortage Mitigation Plans (SMPs) templates on 18 June 2024, a pilot for the implementation of the SPPs and SMPs was launched on 9 December 2024. Guidance for industry on the implementation of SPPs and SMPs to facilitate this task were published on 9 December 2024. Five HMA/EMA TF AAM Steering Committee Meetings were facilitated in 2024. The HMA/EMA TF AAM was discontinued and the last Steering Committee meeting took place on 11 December. A report will be published consolidating the achievements of the TF from 2016 until 2024. The work of the TF (Steering Committee, Thematic Working Groups 1 and 2) will continue and be transferred to the MSSG, SPOC WP and Working Group of Communication Professionals WGCP), respectively. The respective calls for interest for the different groups will be launched in 2025.

Advisory functions

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

Pillar 2 – Public health activities and Business Services

Workload indicators[35]

Procedure		2021 result	2022 result	2023 result	2024 forecast	2024 result
	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	n/a	n/a	279	250	269
	Number of participations in external forums	n/a	n/a	34	40	30
	Number of external participants in training organised by International Affairs	n/a	n/a	630	700	679
	Number of visits to EMA / fellowships organised by International Affairs	n/a	n/a	15	15	12

Achievements

Chief Medical Officer

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1, ECP 4)	Increased awareness to facilitate the uptake of biosimilars	**On track**	EMA continued the work on updating information on biosimilars, conducting a survey among stakeholders, including NCAs, aiming at the final deliverable of a Toolkit for NCAs use. The work is expected to be finalised in 2025. Any continuous work is pending decision by HMA management board including the appointment of a new HMA Chair of the group.

Public Health Threats

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Define approaches for review of data with international regulators	4.2 (ECP 1)	Build on the experience acquired with COVID-19 to establish the approach for future emergencies	**On track**	A workshop conducted by ICMRA in February 2024 focused on the alignment of COVID-19 vaccine updates. Several discussions occurred with WHO and international regulatory bodies on vaccine development.

[35] New indicators introduced in the 2023 work programme.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA	**On track**	The first meeting of the Vaccine Outreach Group (VOG) took place in Q2 2024; the plan was presented to the HCPWP/PCWP. EMA, in collaboration with the ECDC, issued a joint recommendation for avian flu vaccines. Subsequent VOG meetings focused on defining strategies for addressing vaccine safety concerns and combating misinformation.
Engage with public health authorities and NITAGs (National immunization technical advisory groups) to better inform vaccine decisions	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute	**On track**	Active participation and contributions in meetings and webinars with NITAGs highlight ongoing collaboration.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval	4 (additional RSS recommendation)	Set up the platform and conduct first studies	**On track**	In May 2024, an alignment workshop on vaccine effectiveness (VE) studies in Europe was conducted, leading to the development of a VE report and the formulation of a roadmap for VE studies across the continent. Subsequent Immunization and Vaccine Monitoring Advisory Board (IVMAB) meetings and steering group discussions with the European Centre for Disease Prevention and Control (ECDC) followed.
Operate the ETF during COVID-19 public health emergency. As a working assumption for this MAWP, it is assumed that the COVID pandemic PHE will end December 2024		Proper regulatory decisions in the context of an emergency	**Completed**	The EMA Emergency Task Force (ETF) played a critical role during the COVID-19 pandemic, delivering over 220 Scientific Advices, 145 Informal Advices, 350 Product Interactions, and conducting 250 ETF meetings. Following the World Health Organization's declaration of the pandemic's end on 5 May 2023, the ETF has shifted its focus to preparedness for future public health emergencies, incorporating lessons learned from the pandemic.
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**	International discussions on aligning requirements for Antimicrobial Resistance, AMR, strategy took place in Q1-Q2 2024, alongside engagements regarding phage products within the framework of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR). Further international interactions with the International Coalition of Medicines Regulatory Authorities (ICMRA) and quadrilateral discussions focused on achieving global

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				alignment. Preparations for AMR-related work were also conducted.
Operate the ETF during COVID-19 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**	Engaged in multiple interactions with pharmaceutical developers and clinical trial networks to enhance drug development efforts for medical countermeasures. In November 2024, a joint workshop between the Emergency Task Force (ETF) and ACT EU, Priority Action 11, was held to discuss the practical and policy aspects of preparing for and responding to public health emergencies (PHE) within the EU clinical trials environment. Contributed to activities with Health Emergency Response Authority (HERA) on the clinical trials coordination mechanism and participated in several informal teleconferences with the network throughout 2024.

International Affairs

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	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, aligning COVID-19 global response and collaboration Regulatory communication	**On track**	EMA continued its mandate as chair of ICMRA and provide the ICMRA secretariat. 3 virtual and 2 face-to-face executive committee meetings, 1 face-to-face plenary meeting, 3 regulatory forums TCs (focusing on patients centred clinical trials and artificial intelligence); a virtual ICMRA workshop on regulatory cooperation on mpox vaccines; a virtual ICMRA workshop on decentralised and point-of-care manufacturing. Two new Associate Members joined ICMRA, the national

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				regulatory authorities of Paraguay and Philippines. EMA participated in all 7 active ICMRA workstreams, including as chair or co-chair in 4 of them. An ICMRA symposium and workshop on international regulatory cooperation in rare diseases was held in Lugano. Eight documents were published in the ICMRA website in 2024, including ICMRA achievements during COVID-19 pandemic, ICMRA paper on facilitating platform clinical trials during global public health emergencies, and the PQKMS (Pharmaceutical Quality Knowledge Management System) cooperative assessment pilot summary report. The work programme for 2025 was agreed with main focus areas of quality knowledge management, real world evidence, artificial intelligence, vaccines pharmacovigilance. Potential areas of interest identified included 3Rs (Replace, Reduce and Refine- for the ethical use of animals in medicine testing across the European Union) and rare diseases.
Support and foster use of the EU-Medicines for all (EU-M4all) pathway Support applications 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	Support to developers and promotion of parallel Art. 58 and centralised submissions	**On track**	Six 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. Improved interactions with WHO to optimise the information needed for experts' appointment and

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				update guidance for experts to increase their input. Support for WHO and national regulatory authority expert involvement for scientific advice on possible EUM4all opinions. Support to product team during evaluation of ongoing Article 58 EU-M4all submission expected for scientific opinion in 2025. Participation in various workshops and public forums to introduce EU-M4all as facilitated tool to promote access to quality-assured medicines. These include EMA-Medicines Patent Pool Workshop, Bill & Melinda Gates Foundation Grand Challenge Annual Meeting, WHO-EMA-Swissmedic-IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) workshop on facilitated pathways, and EMA-African Pharma Network on understanding EU-M4all and its role in health product security in Africa.
Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO-SRA (Stringent Regulatory Authority) collaborative registration procedure, facilitated approvals and other pathways	1.2	Capacity building in low and middle income countries	**On track**	Coordination of 13 collaborative registration procedures (SRA-CRP) with WHO, aimed at facilitating registration of 13 products in 15 countries. Participation in workshops organised by WHO to promote awareness, engagement and capacity building with CRP, including a WHO CRP Workshop in Kigali, Rwanda and the WHO Annual CRP meeting in Jakarta, Indonesia.
Support continued implementation of the EU-US FDA MRA Support extension of EU-US FDA MRA to include vaccines and veterinary medicines	5.2	Support for several operational meetings (internal, EC, FDA) related to discussions in preparation for the extension of the MRA to veterinary medicines, increase in the efficiency of the MRA for human medicines and preparations for the potential extension to vaccines and plasma derived medicines	**On track**	The International Affairs Department, including the EMA Liaison Official to the US FDA, provided support to EC and Inspections colleagues. This included discussions during the EC/EMA-FDA bilateral in April 2024.
Provide assistance to candidate countries and potential candidates (IPA), to	6.1	Participating authorities are better prepared for future potential EU accession, and integration	**On track**	Observers from candidate countries and potential candidates took part in the Medicine Shortages Single

Action	MAWP strategic goal	Expected result	Status	Achievements/results
align their standards and practices with those established in the European Union, and to further foster their integration process		to the European medicines regulatory network		Point of Contact (SPOC) Working Party (12 meetings), Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group - GMDP IWG (4 meetings), Good Clinical Practice Inspectors Working Group -GCP IWG (4 meetings) and Pharmacovigilance Inspectors Working Group - PhV IWG (4 meetings). Training in Amsterdam with over 60 participants joining in person and virtually on veterinary aspects of antimicrobial resistance (AMR) and the One Health approach. In December 2024, IPA beneficiaries were granted access to the EU Network Training Centre (EU NTC) and their international training offer. The training offer will be updated regularly with new suitable courses added monthly. EMA participated as member of the Advisory Board for the Establishment of the Ukrainian State Control Authority as well as national conferences of the regulatory agencies in Montenegro and Serbia. Three meetings with candidate countries and potential candidates contact points held in 2024.
Opening our procedures at EMA to Non-EU authorities (OPEN initiative): Implementation of new working model as agreed by Management Board March 2022	1.1	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 LMIC markets	**On track**	Number of new experts registered in 2024: 10 Number of new OPEN procedures initiated: 1 Ministry of Drug and Food Safety (Republic of Korea) joined OPEN as a participating authority, and meetings held to introduce them to the procedures. Responding to industry feedback, a major development in the procedure was introduced in 2024 to allow applicants to request inclusion of their products in the OPEN framework. The Q&A, OPEN process and playbook have been updated accordingly, and this was announced at various

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				stakeholder events (e.g. DIA Euromeeting).
Organisation of awareness sessions for international regulators	1.1	Increase awareness of the EU system Agency public image	**Suspended**	The activity is linked to 'Support and foster use of the EU-M4all pathway'. Webinar with Medicines Patent Pool members on EU-M4all organised.
Data protection impact assessment and simplification of personal data redaction for exchange with international partners		Protection of personal data	**Delayed**	Answers were provided to observations raised in the European Data Protection Supervisor (EDPS) audit on EudraVigilance database. Work continues towards finalising an Administrative Arrangement with Health Canada.
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**	Grant to AUDA-NEPAD for Pilot for continental listing of medicinal products (EMA/GRANT/2024/01/IA) was awarded. As part of this, two in-person training were organised in Amsterdam with the future AMA Evaluation of Medicinal Products Technical Committee (EMP-TC) and AMA Good Manufacturing Practices Technical Committee (GMP TC). Grants were awarded in 2024 to the first six EU NCAs in response to the call for proposals for regulatory systems strengthening (EMA/GRANT/2024/02/IA). Preparation to award a further six grants in early 2025. Work carried out to prepare a call for proposals for laboratory systems strengthening, for launch Q1 2025. Significant efforts made towards publication in Q1 2025 of an open procurement process to design, develop and deliver training curricula and e-learning courses for junior African assessors in three disciplines: pharmaceutical quality, clinical, and non-clinical. EMA provided input to AUDA-NEPAD on the continental reliance framework, and on the continental pilot on EMP assessment and GMP inspections.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				EMA provided regular support (including in-person participation) to the AUDA-NEPAD/AMRH Technical Committees responsible for Evaluation of Medicinal Product (EMP-TC), Good Manufacturing Practices and Inspection (GMP-TC), Regulatory Capacity Development (RCD-TC), Medicines Policy and Regulatory Reforms (MPRR-TC), Vigilance (V-TC), African Vaccine Regulatory Forum (AVAREF-TC), and African Medicines Quality Forum (AMQF-TC). EMA facilitated the participation of over 145 African regulators and inspectors from the South African Development Community (SADC), East African Community (EAC), GMP and EMP-TC in various webinars and workshops. EMA supported the face-to-face meeting of SADC in 2-6 December in Zimbabwe, with participation of 32 regulators. Three EC and partners alignment platform meetings held in 2024. EMA established a cadence of regular meetings with the Interim Secretariat of the African Medicines Agency to support operationalisation ahead of the appointment of the AMA Director-General.
Communication of information, answer to queries, internal coordination Monitoring of the matrix of the 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**	Update of 7 guidance, including the expert nomination and the sharing of documents with international partners Organisation of 60+ face to face meetings and teleconferences Management of 269 product-related interactions with international stakeholders including requests for information and requests for documents Management of 679 in person and remote participants in training organised by International Affairs

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Management of 12 visits organised by International Affairs Management of 15+ ICMRA meetings
Collaboration with WHO to support availability of child-friendly TB medicines in the EU	1.1	Approval and availability of paediatric anti-TB medicines for unmet medical needs in the EU	**Completed**	DG HERA (Health Emergency Preparedness and Response Authority)/HaDEA (European Health and Digital Executive Agency) call to accelerate the development, availability and access to anti-tuberculosis medicines for children (HADEA/2023/OP/0052) launched in April 2024.
Sustained development and operation of the International Cooperation Platform	1.1	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	**On track**	Two International Cooperation Platform meetings held in 2024.
Implementation and support to engagement with US FDA	1.1	Maintain and develop relationship between EMA and FDA Identify and develop existing and new areas of cooperation	**On track**	Organisation and support to visit of the FDA Commissioner and senior leadership to EMA in February 2024 Support to EC/EMA-FDA F2F bilateral meeting in April 2024: the meeting allowed the strategic partners to review their ongoing initiatives, exchange strategic priorities, strengthen existing collaborations, and explore new opportunities. Monitor and progress agreed actions: Quarterly meetings with FDA EO have taken place and a formal follow-up with EC/EMA-FDA took place in December 2024. Supported 5 visits from FDA colleagues to EMA and 2 visits from EMA/CHMP to FDA. Agreement on procedure for EMA participation in Project Orbis as observer; two procedures observed. Meetings and other interactions with FDA Oncology Center of Excellence to review / progress interactions. Regular interactions include scientific advice monthly meetings. Established contacts and first meetings/discussions for collaboration in the area of artificial intelligence.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Agreement on collaboration on gene therapies for ultra-rare diseases (CoGenT); first procedure in the pilot started in December 2024. Preparatory discussions for collaboration on combination products; formal collaboration started in November 2024. Preparatory discussions for collaboration on scientific advice for high risk medical devices. Contacts for discussion on misinformation/disinformation: regular interactions have been established to tackle strategies from both Agencies to fight misinformation/disinformation. Support to development of 3Rs IWG Support to collaboration in advanced manufacturing Discussions with FDA on third country engagement, including establishment of regular interactions with FDA India Office. Continued core engagement and support, including facilitating requests between EMA and FDA, and cluster activities Leading on the organisation of EMA/FDA Training Pilot. Outreaching activities of EMA/FDA Liaison Program and EMA/FDA collaborations, including presentations to various FDA Offices/Divisions, to EMA scientific committees, and a number of public conferences. Preparations for relaunch of EMA international fellowships programme.
Active participation in international forums and communication to stakeholders, including but not limited to DIA, ICH, IPRP	1.1	Greater visibility of the Agency and of its activities	**On track**	International team made placed active stakeholder engagement and communication as one its strategic objectives for 2024. In addition to internal communication efforts, external stakeholder engagement has included:

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				31 formal presentation opportunities at events with external partners 30 missions/duty travel opportunities attended either in-person or remotely
Maintenance, exchange of information and engagement with existing Confidentiality Arrangement partners; Establishment of new Confidentiality Arrangements; Establishment of new Ad Hoc Confidentiality Undertakings	1.1	Facilitate and foster international cooperation	**On track**	A confidentiality arrangement was signed between DG SANTE-EMA with Ministry of Drug and Food Safety, Republic of Korea, in April 2024.
Facilitate reliance on EMA scientific outputs	1.1	Facilitate and foster international cooperation	**On track**	Participation in the Joint EMA-Industry Focus Group on Regulatory Reliance aimed at promoting reliance practices and understanding challenges faced by industry in the reliance of scientific outputs of EMA committees. Participation in a number of workshops and conferences to promote international collaboration and reliance. Supported the launch of 8 pilot procedures promoting reliance by international regulators of post-approval changes to demonstrate feasibility and public health benefit of regulatory reliance. Supported the ICMRA regulatory collaboration pilots addressing facility inspections and CMC (chemical, manufacturing and control management) and post-approval change assessments and related regulatory actions.

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Number of EPAR summaries and EPAR summaries updates published[36]	239	204	173	170	214
Number of documents published on EMA website	6,712	6,403	6,611	7,500	7,490
Number of pages published and updated on EMA website	3,064	2,851	5,105	3,500	3,340
Number of press releases and news items published	220	164	124	120	115
Numbers of press and other external briefings conducted[37]	-	-	-	6	8
Numbers of social media posts published	975	704	1,016	650	501
Number of completed interviews[38]	-	-	-	20	26
Number of media queries responded[39]	-	-	-	1,000	781
Number of reports, brochures, leaflets laid out or printed, social media visuals	989	811	586	1,000	914
Number of professional membership organisation events attended by participating Agency staff	202	35	28	25	29
Number of sessions with agency representatives	27	157	168	150	204
Number of patients and consumers eligible organisations[40]	-	-	-	41	41
Number of healthcare professionals eligible organisations[41]	-	-	-	41	41
Active patients expert nominated by EMA[42]	-	-	-	180	186
Active healthcare professionals experts nominated by EMA[43]	-	-	-	81	84
Number of messages circulated via 'Early Notification System'	1,206	646	616	500	539
Number of EMA communications pro-actively sent to stakeholders	182	206	225	200	246
Access to documents, requests received	710	676	709	650	520
Access to documents, documents released	1,136	1,128	1,037	1,500	1,175
Requests for information received	12,500	7,342	6,965	7,500	7,285
Clinical data publication (CDP), procedures published	11	n/a	41	80	73
Clinical data publication (CDP), documents published	215	n/a	714	5,600	5,817

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Satisfaction level of patient and consumer organisations[44]	-	-	100.00%	-	-
Satisfaction level of healthcare professional organisations[45]	-	-	88.00%	-	-

[36] EPAR summaries have been renamed to medicines overview and medicines overview updates in 2018.
[37] New indicator introduced in 2024 work programme.
[38] New indicator introduced in 2024 work programme.
[39] New indicator introduced in 2024 work programme.
[40] New indicator introduced in 2024 work programme.
[41] New indicator introduced in 2024 work programme.
[42] New indicator introduced in 2024 work programme.
[43] New indicator introduced in 2024 work programme.
[44] Survey carried out every 2 years.
[45] Survey carried out every 2 years.

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Triage of incoming requests received via AskEMA within set timelines	100%	99.00%	99.30%	100%	100.00%
Responses to Access to Document (ATD) requests provided within set timelines	92%	88.50%	93.00%	90%	95.00%
Responses to Request for Information (RFI) within set timelines (for EMA)	85%	87.00%	83.00%	95%	84.00%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their Request for Information (RFI)	81%	68.00%	76.00%	75%	77.00%
Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'[46]	-	76.00%	-	80%	70.00%
Average rating of pages on corporate website during the year	3.2	3.2	3.8[47]	3.7	n/a[48]

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Contribute to the implementation of EMANS (European Medicines Agency Network Strategy) and RSS (Regulatory Science Strategy) ensuring that the views of stakeholders are brought into the process		Implementation of strategic plan for stakeholder engagement Support monitoring of implementation, reporting, and review and update of EMANS to 2028	**On track**	Monitoring and implementation of EMANS 2025 ongoing. Draft EMANS strategy to 2028 and reflection paper completed, published and released for public consultation.
Planning of communication activities and campaigns in key topic areas including: clinical trials and ACT EU, data driven legislation, cancer as a pathfinder to support development and approval of innovative medicines, work to address shortages, and preparing for implementation of the HTA regulation and for the review of the EU pharmaceutical legislation		Maximise public health impact of communication	**Completed**	Communication plans were prepared, agreed and actions implemented for the transition of clinical trials to CTIS, ACT-EU, data-driven legislation, cancer as a pathfinder, shortages, preparation for the implementation of the HTA Regulation and review of the EU pharmaceutical legislation. Some highlights of actions delivered: a media seminar for journalists on shortages; a paid social media campaign to encourage the transition to CTIS, a video on ACT-EU, a press briefing with a focus on cancer medicines, a press- and social media campaign to support behaviour changes on the use and prescription of Glucagon-Like Peptide-1 receptor agonists (GLP-1). A communication group to advise on issues related to the

[46] Survey carried out every 2 years.
[47] Based on data up to 5 December 2023 (website relaunch).
[48] New page rating feature to be released in 2025

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				ongoing pharmaceutical review was established and is operational.
Implementation of scientific publication strategy		Maximise public health impact of communication	**Completed**	Delivery of publications: 100 manuscripts reviewed internally and 85 manuscripts published in 2024, including 37 with EMA staff as leading author. 82% of papers published are Open Access. EMA covered the cost of 20 of these papers following internal evaluation. Policy on publications by EMA staff and EMA scientific committee members on EMA's work (Policy 0015) has been updated. Continued established collaboration with several high-impact journals, including BJCP (2 publications), Eur J Cancer (3 publications) and Clinical Pharmacology & Therapeutics (5 publications), and initiated a new collaboration with Lancet Regional Health Europe.
Manage and further develop EMA's social media activities		Expand outreach to broader targeted audience	**On track**	Paid social media campaigns on a number of topics were implemented, including CTIS transition, European Antibiotic Awareness Day, European Immunisation Week, shortages of Glucagon-Like Peptide-1 receptor agonists (GLP-1). Diversification of content has progressed: the social media team promoted videos, carousels, info cards, etc. on EMA's various social media channels. Engagement on Instagram has grown as part of EMA's participation in the joint ENVI account. A social media campaign in support of the EU elections, designed by a group of trainees, was successfully implemented, increasing the number of younger audiences who are aware of EMA's social media accounts.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Collaboration with EC (DG 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 held, continuous discussion of upcoming communication activities and alignment of messaging; continuous discussion of upcoming communication activities and alignment of messaging; active participation in EVIP Steering Committee and production of relevant materials and web content; development of new style guide for development of web content.
Work with Working Group of Communication Professionals (WGCP) to agree communication plans and appoint joint leads with EMA, as appropriate		Tailored communication at national level supported by strong co-ordination at EU level	**On track**	A joint communication plan with WGCP is in place; WGCP continues to explore possible campaigns, e.g. on rational use of medicines, AMR and shortages of medicines.
Coordination of International Coalition of Medicines Regulatory Authorities (ICMRA) communications		Increase the visibility of international collaboration of regulatory authorities	**On track**	Regular updates for ICMRA website provided and presentations for plenary meetings prepared; general slide deck and document summarising ICMRA achievements related to COVID-19 response under development
Continue work on automation of processes for requests for information and access to documents from third parties		Increased efficiency of ATD, RFI and CDP	**Completed**	Some of the planned automated systems are now in place where planned (e.g. DIVs, automated triage, etc.) and efficiency gains continue to be monitored. Replacement tool of AskEMA is to be identified in 2025.
Implementation of phase 2 of the strategy for CDP re-launch beyond COVID-19		Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs	**On track**	Finalisation of the strategy completed in 2024. Implementation of the agreed approach is currently underway and will continue throughout 2025.
Develop a more proactive approach to countering misinformation		Better and earlier awareness of mis- and/or disinformation, enabling tailored counter-information/transparency	**On track**	Vaccines Outreach Strategy meeting held and work reinitiated including updated LTT on COVID-19 vaccines, LTT shared with the network. Proposal for stakeholders listening prepared and endorsed.
Ensure day-to-day coordination of the overall Agency's response to ongoing crises, including public health emergencies		Ensure that actions required in the context of ongoing crisis events are taken in an efficient and coordinated manner	**On track**	There have been no crises for the Agency in 2024. Coordination of activities for crisis preparedness and monitoring of issues that may potentially evolve into crises has been ensured. Training activities and planning for an

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				EMA crisis exercise in 2025 conducted.
Review and improve crisis communication processes based on lessons learnt from COVID-19		EMA's ability to communicate effectively during a crisis is reinforced	**On track**	Final draft of the EMA crisis communication plan is ready for final endorsement by Crisis Preparedness and Response Steering Group and EXB for implementation in 2025

Information Management Division

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Number of information services/IT systems provided by EMA	25	28	28	28	32

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Satisfaction of EMA internal and external users	95.8%	96.00%	94.70%	80%	95.80%
Availability of IT systems and corporate website	99%	98.20%	99.96%	98%	99.97%

Administration Division

Workload indicators

Procedure	2021 result	2022 result	2023 result	2024 forecast	2024 result
Total TA staff recruited against vacant posts	70	45	35	50	47
Staff turnover rate (staff leaving against total no. of staff TA & CA)	5.10%	5.30%	4.10%	3%	3.50%
Total TA, CA, END at the Agency	875	-	928	950	969
Onboarding of staff (TAs, CAs, ENDs)	65	-	121	75	96
Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)[49]	-	-	-	72	45.6
Procurement procedures finalised[50]	-	-	43	46	42
Financial commitments initiated[51]	-	-	1,575	1,500	1,666
Payment transactions initiated[52]	-	-	35,403	27,000	40,638
Number of sales orders[53]	-	-	34,500	50,000	36,504
Number of registration activities[54]	-	-	13,200	14,000	14,083
PRE financial queries and disputes[55]	-	-	300	250	493
Receivable overdue for more than 30 days (including provision for bad debts)	2.89%	2.54%	4.15%	<10%	4.88%

Performance indicators

Performance indicators related to core business	2021 result	2022 result	2023 result	2024 target	2024 result
Posts on the Agency establishment plan filled	98.00%	99.40%	97.00%	100%	101.00%[56]
Average time to run selection procedures from vacancy notice to establishment of reserve list	65%	3.1 calendar months	average 3.5 months 36% <= 3 months,	100% average < 3 months	Average 2.95 months 52% <=3 months
Revenue appropriations implemented	99.87%	98.35%	97.82%	97%	100.05%
Expenditure appropriations implemented	96.38%	96.80%	99.00%	95%	99.72%
Payments against appropriations carried over from year N-1	92.87%	95.11%	95.16%	95%	97.08%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1 (reversal of traffic lights)	5.75%	4.34%	4.89%	10%	3.07%
Title 2 (reversal of traffic lights)	24.31%	26.38%	24.86%	20%	13.31%
Title 3 (reversal of traffic lights)	37.59%	40.06%	32.59%	30%	26.00%

[49] New indicators introduced in the 2024 Work Programme.
[50] New indicators introduced in the 2024 Work Programme.
[51] New indicators introduced in the 2024 Work Programme.
[52] New indicators introduced in the 2024 Work Programme.
[53] New indicators introduced in the 2024 Work Programme.
[54] New indicators introduced in the 2024 Work Programme.
[55] New indicators introduced in the 2024 Work Programme.
[56] EMA makes use of Article 38(2) Financial Rules applicable to the budget of the European Medicines Agency to offset workforce loss through part-time work undertaken by Temporary Agent staff.

Performance indicators related to core business		2021 result	2022 result	2023 result	2024 target	2024 result
	Payments made within 30 days' time	96.6%	97.98%	98.03%	98%	97.18%
	Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)	335	-	341	405	416

Achievements

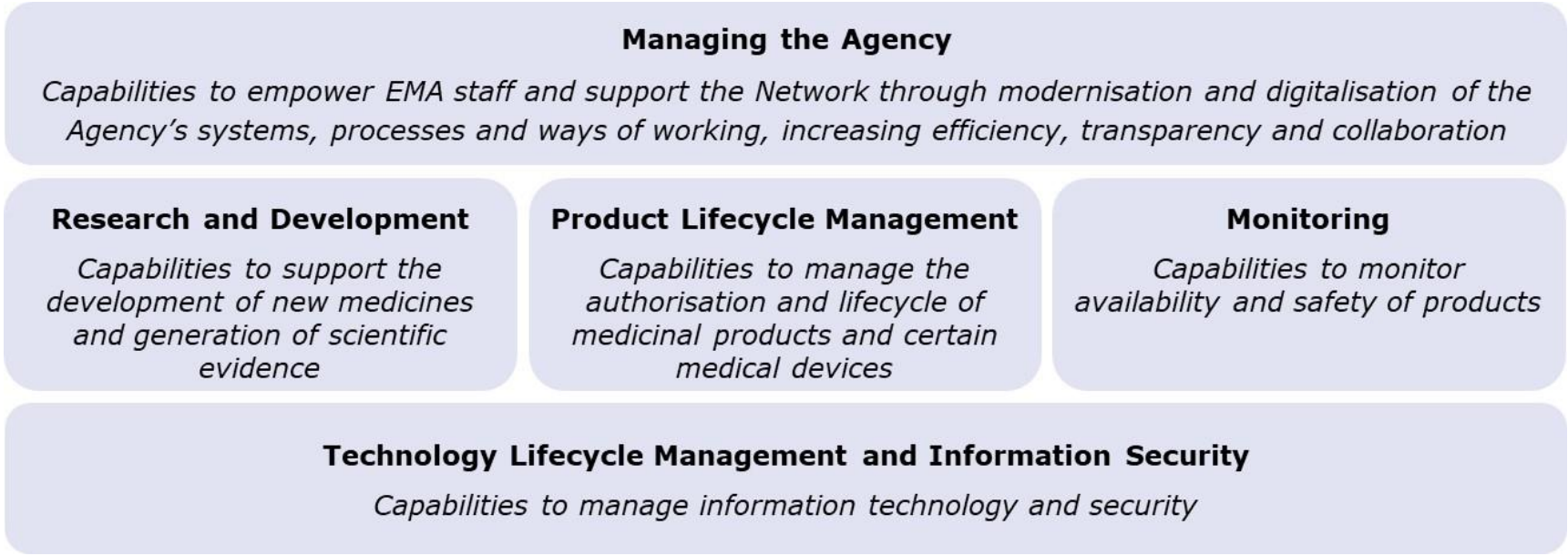
Action	MAWP strategic goal	Expected result	Status	Achievements/results
Implementation of the HR strategy & priorities 2023-2025	6.2	The following improvements are expected by strategic ambition: Sustainable organisation will see improvement in resources and competencies needed versus actually available 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 satisfaction with HR services	**On track**	As part of the HR Strategy Implementation, in 2024 the following products have been completed and rolled out: 1st EMA Development Day, job shadowing programme, fellowship programme, completion of the of the EUAN HR Strategy Collaboration Initiative with 15 EU Agencies producing a report and sharing it with the whole EUANetwork. Progress has also been made in other areas as well — data management framework, HR process review, Employee assistance programme, talent reviews, including succession planning. These deliverables will be completed in 2025, along with the First EUAN-HR Strategy conference which will be hosted EMA premises. Wellbeing as a broad topic and managers intranet page were completed and transitioned to business as usual.
Review of options for a replacement of the finance system Replacement of the human resource management system SAP and review of HR management processes	6.4	Gradual replacement of the financial and HR system in line with the future project plan	**On track**	SAP FIN replacement: More than 19 workshops conducted on all SAP FIN capabilities to capture the As-Is and identify improvement points; Change Management analysis (including stakeholder mapping, change impact assessment, stakeholder engagement plan, etc.) fully completed; Quoted Time & Means request completed, specific contract awarded for consultancy services;

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Interactions with vendors of financial systems; Engagement with the European Commission & Pilot Agencies onboarded to the EC's financial system (SUMMA). Replacement of the human resource management system: Deployed SAP Fieldglass Contingent workforce management for managing the Agency's interims. Configuration of core elements for managing organisational structure, positions, and staff (statutory and external), with seamless recruitment integration. Management of employment events such as hiring/rehiring; contract renewal decision and termination. Management of employee personal data. Management of allowances. Management of time off for short-term leave (e.g. annual leave; special leave; sick leave) and long-term leave (parental/family leave; unpaid leave) Management of permissions access for the features in the scope. Data migration activities: data mapping and configuration of Infoporter to support the data transfer from SAP HR to SuccessFactors.
Implementation of the new Fee Regulation: Review of processes Implementation of the tools enabling of the new fee regulation (3 Epics)	6.3	Support provided to the EU institutions in the review of the new fee regulation to ensure sustainability of the Agency and the European Medicines Regulatory Network	**Completed**	February 2024: Publication of the new fee regulation. June 2024: Release of the related working arrangements document. December 2024: Revision of the working arrangements document. November 2024: Launch of the new fee regulation webpage, complete with explanatory documents.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				January 2025: New fee revenue and expenditure amounts adjusted by the implementation date. Relevant tools largely rolled-out.

Pillar III 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 and long-lived, with fixed 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 2024; progress and delivery as of 31 December 2024 against what was planned in the work programme 2024 is reported using the following status:

On Track
Delayed
Suspended
Achieved

Note 1: The budget figures for 2024 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.

Note 3: End date column indicates the year when product development is expected to end, after which the product enters maintenance phase.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
Product Lifecycle Management Value Stream (PLM VS) **Budget 2024 (M€)13.6** *Capabilities to authorise and manage lifecycle of medicines and medical devices*						
Electronic Application Form (eAF) *(part of the Product Lifecycle Management Portal)*		2021	2026	– Human Variations Form go-live and support for centrally and non-centrally authorised products – Progression of work on the Initial Marketing Authorisation form for Human and Veterinary products	Delayed	New homepage launched in May. The eAF for variations strongly recommended for centrally authorised medicinal products for human use since May. Non-centrally authorised products (non-CAPs) data available in the human variation web-based eAF from October (no submissions to NCAs yet). Work on the eAF for initial marketing authorisation applications (MAA) for human and veterinary medicines is postponed.
Product Data Management User Interface *(part of the Product Lifecycle Management Portal)*		2023	2025	– Capabilities for viewing product data – Initial introduction of functionalities for submission and correction of product data	Achieved	NCAs, industry and general public can view Product data from Product Management Service (PMS) through the Product User Interface (PUI), in the Product Lifecycle Management (PLM) Portal. Centrally authorised products (CAP) data is available since May, and nationally authorised products (NAP) data since September 2024.
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2027	– RPM capabilities for Variations, Transfers, Art 61.3 – RPM capabilities for periodic safety update reports (PSUR), periodic safety update report single assessment (PSUSA), post authorisation measures (PAMs)	Achieved	Roll-out of more efficient regulatory procedure management capabilities for Variations, Transfers and Art. 61.3 started in January 2024 for a subset of medicinal products. In January 2025 a more efficient regulatory procedure management in IRIS rolled out for remaining post-authorisation

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
				– Support for implementation of the New Fee Regulation		procedures, for human and veterinary medicinal products. Support for implementation of New Fee Regulation provided.
Electronic Product Information (ePI) *(part of the Product Lifecycle Management Portal)*		2022	2026	– ePI Pilot with volunteer National Competent Authorities and industry – Preparations for further implementation of ePI	Achieved	Fast Healthcare Interoperability Resources (FHIR) implementation guide for ePI published in June. FHIR validation and import developed and successfully used by key testers with externally created ePI. ePI pilot completed in August. Pilot report published on EMA corporate website in December. Preparations for further implementation continue.
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	– Identification of medicinal products (IDMP) Implementation (Data migration/transformation into ISO IDMP format) – eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) integration with PMS – SIAMED data integration with PMS – FHIR (Fast Healthcare Interoperability Resources) Adaptor (Capabilities to import ISO IDMP compliant product data to PMS) – XEVMPD replacement strategy: Analysis and roadmap towards a simplification and replacement of the existing Article 57 legacy submission systems	On track	Migration of data for centrally authorised products (CAPs) and nationally authorised products (NAPs) from SIAMED and XEVMPD to PMS completed in April. Data for CAPs and NAPs made available in read-only mode in PMS application programming interface (PMS API) in May. PMS API gradually opened to stakeholders, with industry getting access in July, H&V NCAs in November, H only NCAs in December. Several PMS EU implementation guide (IG) chapters and specific PUI Guidance documents published in Q3/2024. XEVMPD replacement strategy analysis ongoing.
eCTD4 -electronic Common Technical Document (eSubmissions incl. European		2021	2026	– Completion of eCTD v4.0 specification and implementation guide update for the Europe (EU) region	On track	An updated draft version of the EU eCTD v4.0 implementation package, focused on CAPs, published in October.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
Review System (EURS)/Common Repository)				– Progression towards pilot and optional use support of eCTD v4.0 submissions for centrally authorised products		EURSNext Proof of Concept (PoC) with selected NCAs ongoing. Technical pilot for CAPs started at the end of 2024. Survey launched to map the current status of review tools among all human and veterinary NCAs, in preparation for the regional EU implementation of eCTD v4.0.
Union Product Database (UPD)	– Article 55 of Regulation (EU) 2019/6, and Commission Implementing Regulation (EU) 2021/16	2021	2026	– UPD maintenance and improvements to meet legislative requirements, improve usability and support improved data quality	Achieved	All users have the ability to receive any UPD updates via email. Capability to group NAPs and to convert them to MRPs following a CMDv harmonisation of the summaries of product characteristics (SmPC) procedure. Automated replacement of non-current substances with SMS-proposed current substances, eliminating the need for Competent Authorities updates. MAHs can see and get access to all products under their portfolio based on location.
European Medicines Web Portal (EMWP)	– Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2027	– Refresh of the strategy towards a European Medicines Web Portal for medicinal products for human use, in alignment with the existing portal for veterinary medicines	On track	Strategy refresh is ongoing and expected to conclude in Q1/2025.
Research and Development Management Value Stream (R&D VS) **Budget 2024 (M€) 12.6** *Capabilities to foster the development of medicines and generate scientific evidence*						
Regulatory Procedure Management (RPM) for R&D		2023	2026	– Paediatrics procedure – Support for implementation of the New Fee Regulation – Maintenance and improvements	Achieved	Paediatrics procedure go-live on 4 June. Support for New Fee Regulation (NFR) successfully completed to enable entry into force in January 2025. Maintenance and improvements ongoing.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82 – Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	tbc	– CTIS maintenance and improvements – CTIS Business Intelligence (CTIS BI) maintenance and improvements	Achieved	CTIS maintenance and improvements ongoing, incl. advanced search, system stabilisation and performance improvements. CTIS BI maintenance and improvements ongoing.
Clinical Trial Navigator (CTN)		2023	2024	– Development of Clinical trial study protocol conceptual and logical data model (ICH M11)	Achieved	Minimum Viable Product (MVP) delivered.
Real World Metadata Catalogues		2021	2024	– Go-live of the Catalogue of real-world evidence data sources and studies in Q1/2024 – Maintenance and improvements	Achieved	HMA-EMA catalogues of real-world data sources and studies launched on 15 February. Maintenance and improvements ongoing.
Scientific Explorer		2020	2025	– Completion of the Minimum Viable Product (MVP) for the interrogation of regulatory and scientific documents and Go-live in Q1/2024 – Maintenance and improvements	Achieved	Scientific Explorer go-live on 4 March for use by staff of the European Medicines Regulatory Network for human medicinal products scientific advice. Extension to veterinary medicinal products scientific advice go-live on 5 December. Maintenance and improvements ongoing.
TRIP (Horizon Scanning) Topics, Relationships, Impact assessment, Proposal generation - for collaborative horizon scanning and work on regulatory science		2023	2024	– Completion of the Minimum Viable Product (MVP) for the horizon scanning capability (identify future innovations and trends earlier to support development) and Go-live in Q1/2024 – Maintenance and improvements	Achieved	TRIP launched for EMA internal use in January. TRIP launched for use by European Medicines Regulatory Network in June. Maintenance and improvements ongoing.
Data Analytics Platform		2024	2024	– Support generation of scientific evidence	Achieved	Platform core set-up completed and initial capabilities for self-service analytics enabled. National Competent Authorities given access to Databricks in August.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
						Self-service portal enhanced with documentation, training links and example data products.
Monitoring Value Stream (MON VS) **Budget 2024 (M€) 9.3** *Capabilities to monitor availability and safety of products*						
European Shortages Monitoring Platform (ESMP)	– Regulation (EU) 2022/123	2022	2025	– Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) – Monitoring of Critical Medicines during PHE/major events – Interoperability of ESMP	Achieved	ESMP Interoperability approach agreed with Marketing Authorisation Holders (MAH) and NCAs and endorsed by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). Dedicated ESMP page on the EMA corporate website launched in April and updated in November. Routine shortage reporting by MAHs for Centrally Authorised Products went-live on 28 November.
Inspections		2023	2025	– Maintenance, improvements and support for implementation of the New Fee Regulation	Achieved	Fees have been modified to comply with the new fee regulation.
Parallel Distribution		2023	2025	– Maintenance, improvements and support for implementation of the New Fee Regulation	Achieved	Minimum Viable Product (MVP) for pre-payment process implemented in IRIS platform.
Union Pharmacovigilance Database (UPhV, formerly EVVet3 - Eudra Vigilance Veterinary version 3)	– Regulation (EC) 726/2004, art.57(d) – Regulation (EU) 2019/6; associated implementing acts	2017	2024	– Maintenance and improvements	Achieved	Several improvements implemented, including new pharmacovigilance inspections dashboard, pre-calculations for signal detection, and inclusion of incidence calculation in pharmacovigilance reports accessible to the public via www.adrreports.eu.
Antimicrobial Sales & Use (ASU)	– Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578 – Commission Implementing act 2022/209	2021	2024	– Minimum viable product completion – Maintenance and improvements	Achieved	ASU Platform (MVP) launched in January. All EU/EEA Member States reported their data from 2023, on the volume of sales and use of antimicrobial medicinal

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
						products in cattle, pigs, chicken, turkeys to EMA.
Signal and Safety Analytics (SSA)		2023	2025	– Signal and Safety Analytics – minimum viable product	Delayed	User Acceptance Testing of version 6.1 completed.
Managing the Agency Value Stream (MTA VS) **Budget 2024 (M€) 12.5** *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*						
SAP Finance replacement		2023	2026	– Finalise analysis and technology selection	On track	Analysis ongoing. Technology selection ongoing.
SAP HR replacement		2023	2025	– Kick off implementation of HR Data Organisation and processes	On track Achieved Delayed	SAP Core HR (Employee Central) replacement ongoing. Contingent workforce (interims) go-live on 2 September. Statement of Work (contractors) go-live delayed to 2025.
New Fee Regulation	– Regulation (EU) 2024/568 of 7 February 2024 on fees and charges payable to the European Medicines Agency	2023	2025	– Implementation of new fee process in existing EMA applications – Pre-payment process implementation for some procedures – Vet pharmacovigilance fees implementation	Achieved	Technical analysis and integration with IRIS platform for propagating fee details to financial and accounting application completed. Integration of case management for referrals completed.
EU Network Training Centre (EU NTC)		2022	2024	– EU NTC engagement portal for public	Achieved	Engagement portal for public go-live in January.
Documents and Records Management System replacement		2023	2025	– Kick off implementation of Documents and Records Management System (DREAM) replacement	Delayed	Vendor selection completed. Technology selection completed.
AskEMA		2023	2025	– AskEMA replacement implementation	Delayed	Selected solution not suitable; a new solution to be implemented in 2025.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results 2024
Customer Relationship Management (CRM) tool		2024	2026	– Kick off analysis for an Agency CRM tool	Suspended	Not started.
Audit workflow management tool *[new]*		2023	2024	– Audit workflow management tool	Achieved	Audit workflow management tool go-live in February.
Workplace Experience *[new]*		2024	2027	– Finalise analysis and technology selection	On track	Business analysis completed. Technology selection ongoing.
Technology Lifecycle Management and Information Security Value Stream (TLM VS) **Budget 2024 (M€) 4.2** *Capabilities to manage information technology and security*						
Information Security and Cyber Security enhancements		2022	2024	– Cyber & Information Security enhancements – Operational Security enhancements – Application Security enhancements	Achieved	Continuous improvements to information security and cyber security.
Remaining legacy application modernisation analysis		2023	2024	– Analysis on the future-proof solutions the current legacy apps could be migrated to – Prioritisation of the legacy apps – Proof of Concept for one app	Achieved	Analysis and prioritisation completed. Proof of Concept for two applications completed.
Data Centre 2.0 (DC 2.0)		2023	2024	– Migration of all workloads in the Amazon Web Services (AWS) cloud – Migration/activation of the infrastructure components – Decommissioning of the current physical equipment (physical data centre)	Achieved	Migration to cloud completed. Decommissioning of physical data centre completed.

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 2024 included:

- **Election of Rui Santos Ivo as Vice-Chair of the EMA Management Board:**
    - At its October 2024 meeting, the Board elected Rui Santos Ivo as vice-Chair of the Board for a three-year period. Professor Ivo is President of the Portuguese National Authority of Medicines and Healthcare Products (INFARMED), a post he has held since June 2019. He has been a member of the EMA Management Board since 2016.
- **EMA’s independence policies for competing interests of Scientific Committee members, Experts and Management Board members**
    - The Management Board adopted the revised Policy 0044 on handling of competing interests for Committee members and experts and the revised Policy 0058 on handling of competing interests for Management Board members. The objective of the revision of the policy is to implement the findings of the Court of Justice in Case C-291/22 P of 14 March 2024 (Hopveus appellate judgment) and in Joined Cases C-6/21 P and C-16/21 P (Aplidin appellate judgment) of 22 June 2023. These changes aim to strike the right balance between safeguarding impartiality and independence, and access to the best scientific expertise to support EMA’s assessments, whilst ensuring compliance with the recent judgements.
    - The Board also endorsed the EMA 2023 annual report on independence. The report covers implementation of all independence policies, including for staff and EXPAMED activities, and provides data on 2023 controls. The report outlines also improvement recommendations and planned policy updates in 2024 in line with aforementioned court rulings.
- **European medicines agencies network strategy to 2028**
    - The Board endorsed the updated European medicines agencies network strategy (EMANS) to 2028 prior to a public consultation. This is a review and extension of the original five-year strategy, which was developed to cover the period 2021 to 2025 (EMANS 2025). Extending the timeframe to 2028, the update has been initiated now to take into account progress made to date and the technological advances, environmental challenges and other developments that are reshaping the regulatory landscape. This includes preparing the network for the implementation of the revised European Union (EU) pharmaceutical legislation when finalised.

- **Preparation for the implementation of the new fee regulation (Regulation 2024/568)**
    - The Board adopted several documents in preparation for the coming into application of the new fee regulation (Regulation 2024/568) on fees payable to the Agency as of January 2025. These include the working arrangements that will clarify the requirements and terminology of the regulation, outline conditions for fee reductions for certain types of applications and provide further details on payment modalities. The new fee regulation aims to ensure the sustainability of the European medicines regulatory network, providing a sound financial basis to support its operations as well as the objectives outlined in the European medicines agencies network strategy.
    - The Board also adopted the revised templates for the Cooperation Agreement and Memorandum of Understanding with National Competent Authorities to align with the new fee regulation.
    - The Management Board adopted a MB decision on the financial arrangements on remuneration for (co-)rapporteur services provided by committee members appointed by the Commission to represent patients' organisations or healthcare professionals in COMP and PDCO.
- **Final activities of the joint HMA-EMA Task Force on Availability of Medicines**
    - The Board adopted the second phase of the Union List of Critical Medicines (ULCM) via written. Building on the initial 2023 version, the updated list includes 270 active substances identified through EMRN review and stakeholder input. It will guide EU-level actions to safeguard medicine supply and is subject to regular updates. The list's role will also support the Critical Medicines Alliance (CMA) to address supply chain vulnerabilities and prioritise resilience measures.
    - The Board noted the Good Practice Guidance for Communication on Medicines' Availability Issues. Reflecting 2023 stakeholder feedback, the revised guidance includes recommendations on engaging with media and the public.
    - The Board acknowledged the achievements of the HMA/EMA Task Force since 2016 and expressed appreciation for its foundational work on medicines shortages. With its mandate concluded in December 2024, the Task Force was dissolved, and its functions transferred to the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Medicines Shortages Single Point of Contact (SPOC) Working Party.
- **Mandate of the new Network Data Steering Group (NDSG)**
    - The Board endorsed the mandate of the newly established Network Data Steering Group (NDSG), formed to guide the strategic governance of data within the European medicines regulatory network. The NDSG consolidates the roles of the previous Big Data Steering Group and Network Data Board into a single advisory structure. It will prioritise data interoperability, digital innovation, and artificial intelligence, aligning with the European Medicines Agencies Network Strategy (EMANS) to 2028. The group, co-chaired by EMA and HMA, includes representatives from national authorities, the European Commission, and stakeholder organisations.

The most significant issues discussed at the Management Board in 2024 included:

- **Update on 30 Churchill Place**

- The Board was updated regularly throughout the year on the latest developments regarding the former EMA premises in London.
- At the March 2024 MB meeting, the Management Board endorsed the presented pre-final draft building dossier and delegated the final adoption of the finalised building dossier to the Topic Coordinators on 30CP before its submission to the EP and Council. The 30CP Topic Coordinators in mid-March 2024 adopted the final building dossier document for submission to the Budgetary Authority at the end March 2024.
- The Management Board also adopted at the March meeting the Amending budget 02-2024, to allow EMA to create the necessary budget appropriations supported by an additional EU budget contribution, to pay rent for its former premises.

- **Implementation of the new EU Health Technology Assessment Regulation**
  - The Board was regularly updated by the European Commission and EMA on the preparations for the EU Health Technology Assessment (HTA) Regulation, which became applicable on 12 January 2025. EMA presented the latest steps taken to align regulatory and HTA procedures, highlighting the first instances of parallel notifications by companies planning to submit marketing authorisation applications alongside joint clinical assessments under the new HTA framework.
- **Clinical Trials in the EU**
  - Throughout 2024, the Board was updated at all Management Board meetings on the implementation of the Clinical Trials Regulation (CTR) and the ongoing transition to the Clinical Trials Information System (CTIS). The Board welcomed EMA's continued efforts to support stakeholders via workshops, trainings and regular communications. At the December MB meeting, the Board noted the CTIS planning for 2024, which continues to focus on improving the performance of the system and enhancing user experience
  - The Board was informed of the revised CTIS transparency rules that entered into force on 18 June 2024 with the launch of a new version of the CTIS public portal. This revision aims to improve timely access to clinical trial data for stakeholders, while ensuring protection of commercially confidential information through document redaction. Additional CTIS enhancements included improved search functionality and a more user-friendly interface.
  - The Board were regularly updated on ACT EU initiatives in 2024, including the launch of the Multi-Stakeholder Platform and Advisory Group, new regulatory support for non-commercial sponsors, and pilot projects on integrated advice for clinical trials. Feedback from the first annual stakeholder meeting in October is being used to revise the ACT EU workplan for 2025–2026, which will also include a workshop on risk-based and low-interventional trials.
- **Medicines Shortages Management**
  - The Board received updates at most Board meetings in 2024 on the work of EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). The Board also welcomed the launch of the European Shortages Monitoring Platform (ESMP), which went live in November 2024 with a core set of functionalities. The Board recognised the ESMP as a critical tool to help ensure continuity of medicine supply for patients across the EU.
- **Activities of the joint EMA-HMA Steering Group on Big Data**

- The Board also received regular updates on the activities aligned with the priority recommendations outlined in the Big Data Steering Group (BDSG) workplan, including the launch of the HMA-EMA catalogues for Real-World Data (RWD) sources and studies. The Board commended the BDSG for its exceptional work over the past five years as it was succeeded by the Network Data Steering Group (NDSG).

- **Periodic reports from Chairs of Scientific Committees and Working Parties to the MB**
  - The Chair of EMA's Committee for Orphan Medicinal Products (COMP), Violeta Stoyanova was invited to the Board to present an overview of recent trends and challenges in the development of medicines for rare and very rare diseases. The Board acknowledged the pivotal role of patients in the rare disease ecosystem and the need for sustained regulatory innovation in this area.
- **Update on the implementation of Veterinary Medicinal Products Regulation**
  - At the December Board meeting, the Board welcomed a progress update on the implementation of the Veterinary Medicines Regulation, including scientific input for Implementing Acts on substances essential for equine treatment and for use in food-producing aquatic species.
- **International activities**
  - At its October meeting, the Board received an update on EMA's international engagements in 2024, including the EC/EMA/EFSA bilateral meeting with the U.S. Food and Drug Administration, the progress of the OPEN framework and EMA's continued leadership within the International Coalition of Medicines Regulatory Authorities (ICMRA).

Significant additional items adopted or decided by the Management Board in 2024 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 2024, these activities involved:
  - adopting the Board's assessment of the Executive Director's Annual activity report for 2023;
  - adopting the 2025-2027 Programming document, including the 2025 budget;
  - adopting the EMA's annual report for 2023; and
  - delivering an opinion on the Agency's final accounts for 2023.
- **Internal audit and advisory activities at the European Medicines Agency**
  - At its March meeting, the Board adopted a revised version of the 2024 audit plan;
  - In June, the Board adopted the annual report of internal audit and advisory activities at the European Medicines Agency 2023;
  - The Board adopted at its December meeting the 2025 Audit Annual Plan and Audit Strategy 2025-2027;
  - In addition, the Board also adopted the 6th biennial report on Pharmacovigilance audits.

2.2. Major Developments 2024

Revision of the EU Pharmaceutical legislation

With respect to preparations for the revision of the general pharmaceutical legislation, the Agency has been conducting a series of preparatory activities, exploring innovative ways to design more efficient and data-driven approaches and providing regular internal updates on the proposed legislation. Additionally, change management activities and preparations to engage with committees have also begun.

The EMA and HMA have also been working on a new European medicines agencies network strategy (EMANS 2028) which will lay the groundwork for the future implementation of this most significant reform of the EU medicines regulation in decades.

EU medicines agencies network strategy to 2028

The draft EU medicines agencies network strategy to 2028 was endorsed by the HMA in September 2024 and by EMA's Management Board at its October 2024 meeting. EMA and HMA expect to adopt the final strategy by March 2025. The updated strategy replaces the current network strategy to 2025 and incorporates the strategic aspects of EMA's Regulatory Science Strategy. It takes into account progress made so far with the EMANS 2025 (as outlined in the mid-term report) and has been developed in collaboration with HMA, with input from experts from across the EU medicines regulatory network.

New Fee Regulation

The adoption of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency is an important milestone in the strengthening of the financial sustainability of the European medicines regulatory network. Adopted in February 2024, the regulation came into effect on 1 January 2025, modernising the fee system that had been in place for nearly three decades by aligning fees with the actual costs of EMA and network's regulatory activities.

WHO Listed Authority process

On 20 May 2024, the whole European medicines regulatory network was designated as a WHO Listed Authority (WLA) by the World Health Organization (WHO). The announcement by WHO means that the network – including the European Commission, EMA and each of the 30 national authorities of the European Economic Area Member States – are recognised as meeting the highest international regulatory standards.

London Premises

During 2024 the Agency took an important step to mitigate the risk related to the former EMA's London premises. Following extensive negotiations to reach the best possible outcome, the new terms of agreement between the Agency and the sub-undertenant (amending the previous sub-underlease) were agreed on 20 March 2024. On 27 March 2024, the Agency submitted a building dossier to the Budgetary Authority seeking the authorisation of the Budgetary Authority to amend the sub-underlease of the Agency's pre-Brexit office premises in London. The respective Committees on budgets of the European Parliament and of the Council approved the building dossier in the meeting of the Committee on Budgets held on 8 April 2024, while the Council's approval was confirmed on 24 April 2024. The Agency continues to call on the institutions to resolve the matter of the London building at the political level.

2.3. Budgetary and financial management

Budget overview

The total 2024 budget (revenues and expenditure), as adopted by the EMA Management Board on 15 December 2023, amounted to EUR 478,482,000, representing a 6.8% increase compared to the 2023 budget (EUR 448,003,000).

Four amending budgets were adopted by the Management Board throughout the year to increase the budget appropriations by EUR 13,380,000 to cover the rent for the London premises, as documented in the 'building dossier' submitted and approved by the Budgetary Authorities in April 2024, and part of the salary adjustment applicable from July 2024.

The draft financial outturn 2024, a surplus of EUR 4,594,984.37, represents 0.9% (EUR 20,939, represents 0.005% in 2023) of the approved budget (including amending budgets) of EUR 491,862,000, 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 2024 amounted to EUR 492,127,783.68 (2023: EUR 438,811,276.00).

Of total C1 income, 89.8% (2023: 88.2%) derived from the evaluation of medicines and other business-related activities, 9.4% (2023: 11.4%) from the European Union budget to fund various public health and harmonisation activities, and 0.8% (2023: 0.4%) from various sources.

Expenditure (commitments and payments)

Total amount committed on fund source C1 was EUR 490,485,350.54, which represents 99.7% of the final appropriations of EUR 491,862,000 (2023: EUR 443,247,127.96 or 98.8%).

Payments totalled EUR 411,317,623.40, or 83.9% of the total commitments (2023: EUR 347,820,472.27, or 78.5%).

Appropriations carried forward from 2024 to 2025

Automatic carry-forward

Automatic carry-forward to financial year 2025, C1 to C8, totalled EUR 79,167,727.14, or 16.14% of the total commitments (2023: 95,426,655.69 or 21.53%).

Non-automatic carry-forward

Non-automatic carry-forward, i.e. fund source C2, from financial year 2023 to 2024 amounted to EUR 800.000, out of which EUR 650,000 or 81.3% were paid and the balance of EUR 150,000 carried forward to 2025 under C8.

Implementation of appropriations carried forward automatically from 2023 to 2024

Automatic carry-forward from financial year 2023 to 2024, i.e., fund source C8, totalled EUR 95,426,655.69 (2022: EUR 106,828,218.21), out of which EUR 92,644,527.02, or 97.1% were paid (2023: EUR 101,653,282.34, or 95.2%) and EUR 2,782,128.67 were cancelled (2023: EUR 5,174,935.87)

Appropriations from external and internal assigned revenue

The Agency’s available appropriations in 2024 included external and internal assigned revenue. In accordance with its Financial Regulation, 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.

External assigned revenue (R0) stems 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 2024, a total of EUR 2,643,930.16 in new R0-funds were received, and expenditure amounting to EUR 2,781,443.39 incurred (payments).

Internal assigned revenue (CL) stems from payments of 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 2024, **EUR 7,908,196.27** were received (including amount of unused amounts from the previous year carried forward), and expenditure amounting to **EUR 7,557,025.06** incurred (payments).

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.

During 2024 one transfer exceeded the 10% ceiling for transfer between titles and was approved by the Management Board in December together with Amending Budget 04-2024. Out of the ten transfers, eight involved expenditure appropriations and two revenue and expenditure appropriations.

The transferred expenditure appropriations were primarily needed to cover additional commitments for staff costs due to the higher-than-expected salary adjustments and pension contribution, commitments to Member States for the services related to the evaluation of medicinal products. Other transfers included higher IT operations expenditure related to licences and subscriptions and data centre infrastructure and translations expenditure linked to the higher number of scientific applications received.

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 1,376,649.46 remained unused, which corresponds to 0.3% of final appropriations of EUR 491.9 million (2023: EUR 5,355,872.04, 1.2%).

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

title I (staff expenditure) - cancelled appropriation of 0.4% (2023: 0.5%),

title II (infrastructure and operating expenditure) - cancelled appropriation of 0.3% (2023: 1.7%),

title III (operational expenditure) – cancellation of appropriation of 0.2% (2023: 1.5%).

Payment of interest on late payments

In compliance with the Agency's standard contract, the terms of payment, established in accordance with Art. 77 of the Financial Regulation, are 30 days upon receipt of a valid invoice. If these terms are not respected, from day 31 until the actual day of payment, default interest accrues 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%.[57] The default interest accrued is paid automatically to the supplier/contractor if it amounts to more than EUR 200 at the time of payment of the valid invoice.

In 2024, 1,424 payments (2023: 898), or 2.8% of the total payments made of 50,709, were processed beyond the time limits foreseen by Article 77 of the Financial Regulation (2023:45,552 or 2.0%). This resulted in default interest of EUR 13,949 being paid to suppliers and contractors (2023: EUR 1,593).

Procurement

In 2022/24, the procurement team, in line with the 4-year cycle of framework contracts, worked on the re-tendering of location-dependent contracts as the agency had moved into its current premises in January 2020, e.g. medical provider, interim staff, building security, restaurant, in addition to the procurement for operational activities, e.g. scientific studies, business- and ICT consultancy.

Whilst the number of procurement procedures carried out by EMA increased significantly, it also managed to benefit from an increased use of interinstitutional procurement procedures.

Procedure type	Closed 2024		Closed 2023	
Open procedure (GFR 164 (1)(a))	8	20%	8	28%
Competitive procedure with negotiations (Point 12.01, b (i) & (iii)	1	3%	0	0%
Negotiated procedure, middle value (Annex 1 - 14.2)	3	8%	5	17%
Negotiated procedure, low value (Annex 1 - 14.3)	0	0%	1	3%
Negotiated procedure, very low value (Annex 1 - 14.4)	3	8%	1	3%
Negotiated procedure, without prior publication (Annex 1 - 11.1)	2	5%	0	0%
Re-opening of competition	23	58%	14	48%
Total EMA-only procedures	**40**		**29**	
Interinstitutional EMA-led	2	14%	1	8%
Interinstitutional Non-EMA-led	12	86%	11	92%
Total interinstitutional procedures	**14**		**12**	

Cost and benefits of controls

In 2024, EMA allocated approximately 18.75 FTEs for control activities (amounting to EUR 2.2M euros or 0.45% of the Agency's 2024 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 Audit (ad interim), 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.

[57] Cf. Article 99 of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council

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

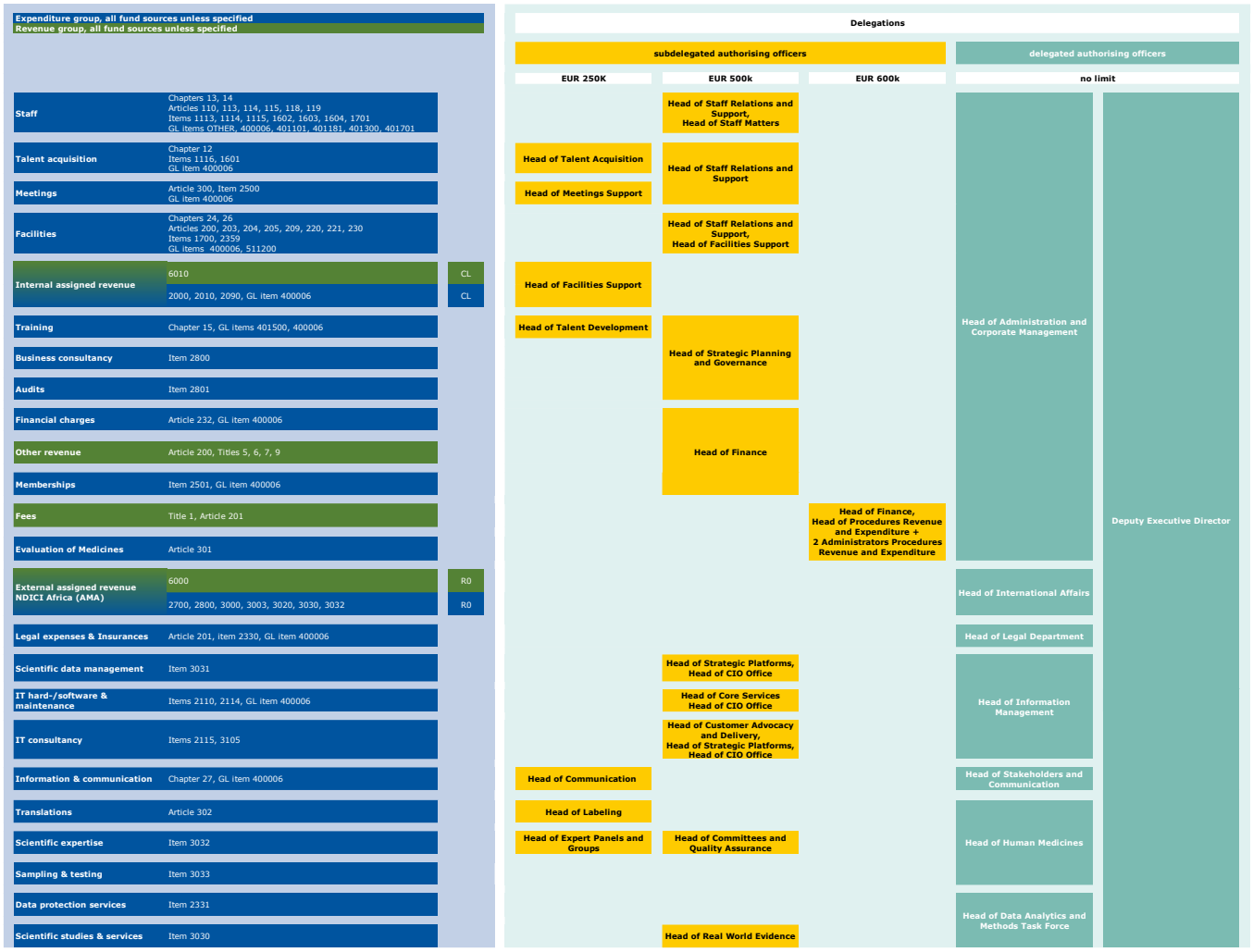
To enact the most effective management of the Agency, responsibilities are dispersed across various management levels to ensure proportionality and effective decision-making at the lowest possible level corresponding to the associated risks. To this effect, financial, operational and staff-related delegations 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
Applicable from 16 October 2024



2.5. Human resources management

Staffing

During 2024, the Agency recruited 84 statutory members of staff (48 TA and 36 CA).

12 national experts were seconded to the Agency, 44 trainees and 52 new interim assignments provided services to the Agency.

The total number of joiners therefore amounted to 192.

During the same year, 31 statutory staff members (21 TA, 10 CA) and 8 SNEs left the Agency.

51 interim assignments were terminated, and 38 trainees ended their contract in 2024. The total number of leavers was 128.

Turnover for TA and CA was at the rate of 3.5%.

The occupancy rate amongst temporary agent staff was 100%.

Human Resources Strategy

In 2023, the EMA HR community completed the development of the HR Strategy 2023-2025, and started the deployment of the HR Strategy which builds on the progress made over the past five years in improving ways of working in talent management. This includes the long-term strategic resources planning and initiatives supporting talent acquisition, onboarding, performance and development.

The HR Strategy 2023-2025 focusses on five ambitions with specific products and initiatives being developed and implemented for each ambition specifically:

- Sustainable Organisation (Resource Planning & Allocation)
- Optimised work environment (Managers' community, Peer recognition, Our workplace)
- Talent Management (Talent Reviews, Exchange & Rotation Programme, Development Day)
- Wellbeing (Wellbeing training, Social and employee assistance)
- One Agile Human Resources (Process review)

The HR Strategy was developed in close collaboration with the Agency's leadership team, managers and staff, to ensure its alignment with the real needs of the Agency (through consultations, focus groups and interviews). The HR Strategy was developed and defined in 2022 and an implementation plan for 2023-2025 was drawn up that undergoes periodic reviews every six (6) months. The backlog of products for 2024 was decided and converted into concrete annual objectives and deliverables aligning with the Agency's strategic priorities, adopting a holistic approach. Urgency, need and resources capacity available were taken into consideration. The Agency thrives using Lean Agile methodology to deliver on all HR strategy products.

Furthermore in 2024, EMA initiated and led a collaborative initiative within the EU Agencies Network (EUAN), focused on the development and implementation of HR strategies. The aim was to foster inter-agency collaboration, facilitate the exchange of best practices, and promote the sharing of knowledge and lessons learned in the field of HR strategy. This joint effort culminated in the production of a comprehensive report, capturing the valuable insights gathered throughout the initiative. The report was shared across the EUAN and now serves as a reference point for EU Agencies embarking on or refining their own HR Strategy journeys.

Continued modernisation of staff management processes and tools

As part of the administration digitalisation programme, which aims to modernise processes and tools that EMA uses in staff management, finance and planning areas, the work undertaken in relation to staff management in 2024 included:

- Work on the gradual replacement for SAP HR (which is set to run out of maintenance in 2027) continued as planned, with the analysis and development of the cloud-based Employee Central platform. The 'Employee Central' module of SAP SuccessFactors will enable the management of employee lifecycle and the integration of this module within the existing EMA Talent Hub will be a pivotal step to help streamline core HR processes, improve operational efficiency and, in turn, enhance the overall employee experience.
- The SAP Fieldglass Contingent Workers module for the management of interims was implemented in 2024. The effort to broaden Fieldglass's capabilities aims at process

improvements through task automation, ensuring consistency, fostering transparency, reducing administrative workload and promoting collaboration. The rollout for contractor management will be implemented in 2025.

Recruitment and selection

In 2024, in the area of recruitment and selection, the effort continued to fill vacant positions, and most importantly, to refresh reserve lists within core business, in particular, for FGIV Officer roles for which reserve lists were last established in 2018 before EMA relocation. As a result, e.g. 6 new FGIV reserve lists were established with 87 candidates placed on them, which will facilitate recruitment efforts in years to come.

Following the 2023 effort to revise, simplify and streamline the selection process, the Talent Pools have been established to organise candidates placed on the reserve lists by the job sub-family and grade. As result, 42 Talent Pools were established, providing managers with an easy way to search for qualified candidates to fill vacant positions.

Since 2020, following the Decision of the Executive Director on rules governing the traineeship programme at EMA, the Agency has been running a Traineeship Programme to provide recent university graduates with opportunities to perform tasks to increase their knowledge and to gain relevant experience, as well as get a unique and first-hand insight into the work of the Agency as an EU body and its role in the evaluation and supervision of medicinal products throughout the European Union. In 2024, EMA opened 54 traineeship opportunities which attracted an overwhelming number of 4,327 applications.

In early 2024, Talent Acquisition launched two inter-agency tenders, attracting more than 30 participating agencies. Both tenders are designed to meet the imminent selection and recruitment needs in the areas of sourcing candidates (both active candidates (marketing plans/publishing) and passive candidates (active candidate search)) and assessment of candidates (covering Assessment Centres/Development Centre, assessments of applications, assessments design).

A new HR implementing provision was adopted in 2024

The list of these can be found in Annex 4.

2.6. Strategy for efficiency gains

During 2024, 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.

As part of the process improvement dimensions, during 2024 the Agency worked on:

Organisational Change Management

The Executive Board endorsed an approach which ensures constant coordination and oversight of change management activities for the benefit of implementations in the Network Portfolio. This was operationalised over 2024. Agency’s staff and Network staff benefit from this increase in change management capabilities, as do external stakeholders through close collaboration with EMA's stakeholders and communication division.

The Change Management Centre of Expertise reviewed the change management tools available to teams implementing changes, identifying gaps and ensuring they are fit for use for a wider group of

staff. This is a key step in ensuring change management is embedded across the Agency in business operations and technology delivery.

Improved adoption and stakeholder experience when changes are being implemented from a business and/or technology perspective through integration of change management practices was achieved through heavy involvement of change enabler networks inside and outside the organisation. Furthermore, the Change Management Centre of Expertise continued its practice of organising “boot camps” to kick start implementation teams' change management activities.

User experience and User Interface in Digital Services

As part of the digitalisation dimension, in 2024 the Agency focused on:

The definition of a user experience hub (UX Hub) committed to accelerating the development of user-centric systems and improving user experience, by promoting and supporting the adoption of UX practices throughout IT solutions' life cycle and maintenance.

On the one hand, the UX Hub's fundamental objective is to promote the progressive adoption of UX design practices in EMA digital products as the golden rule, as it helps to achieve business objectives more quickly. On the other hand, it is to ensure that investments in UX design at an early stage prevent the need to fix problems after the implementation of new or existing digital services.

AI Implementation

In 2024, EMA has invested on further implementation of Artificial Intelligence (AI) for digital business transformation and improving EMA's way of working.

In order to gather needs and business requirements, EMA initiated an internal call to collect use cases. Based on the assessment of the collected information, EMA began developing various proof of concepts to explore the potential applications of AI in addressing business needs. The primary focus was on enhancing knowledge mining capabilities for searching, retrieving, and identifying data and information.

In addition, EMA has started collecting use cases from the Network and building a Knowledge Mining roadmap for the Network to bring those capabilities to the different Member States.

Other Digitalisation activities

During 2024 the Agency has continued to deliver on digital innovation, technology experimentation and automation through its Digital Innovation Lab (DigiLab) and the Analytics Centre of Excellence (ACE) including the following projects, several of which directly result in efficiency gains for EMA and its stakeholders:

Started, launched or piloted projects on automation:

Extended the implementation on the Certificates Process System to meet the requirements of the New Fee Regulation and enable prepayments by Industry stakeholders and modernised user interface for the submission of certificates requests.

Automatic translation of Annex I of the opinion for Referrals: Automate translation of Annex I for Referrals, by using the Standard Terms Database of the European Directorate for the Quality of Medicines & Healthcare.

Automation of electronic Reaction Monitoring Report (eRMR): Automate generation of electronic Reaction Monitoring Report (eRMR): Application to streamlines the pharmacovigilance team's data screening and validation by automating data import, filtering, distribution, and export, while enabling real-time collaboration and minimizing errors.

Automatic population of templates from FREUD Database: Automatic population of the referral templates via a direct connection to the FREUD referrals database.

Automate email distribution of invoices for Operational Initiating Agent's (OIAs) operational approvals: Automatic generation of reports in SAP and email distribution of invoices.

Phonetic and Orthographic Name similarity algorithm (PONSA): Application to populate and cross-check data from several databases.

Anonymization of Personal Data submitted via EMA webforms: Automatic cleansing of already submitted personal data in the database with possibility to regularly run the tool.

Discoverer: Application which allows quick access to positions expressed by the Committee for Medicinal Products for Human Use (CHMP) on a variety of topics (including endpoints, intercurrent events and other study design features) in any condition and across a multitude of outputs including guidelines, qualifications, scientific advice letters and European Public Assessment Reports (EPARs).

Automation of Procedural Timetables: Application to allow faster, more accurate and efficient way to create and extract Procedural Timetables and reports.

Speaker Request Monitoring Tool: Application to create an intelligent form (Microsoft Form) at the EMA external website, which can be filled in by external and internal stakeholders and automatically populates a database with the relevant information.

Quality review of document (QRD) Pilot with industry: Application opened to five participating companies to collect feedback for further improvements and assessing the value of the Quality review of document (QRD) tool to Industry.

Assisted Validation System (AVS): modernization of the original validation dashboard (feature of the tool), which eliminates the need to open several systems as all data required for validation is accessible through the Automated Validation System (AVS).

EUREKA for Vet: Application to adapt the Eureka algorithm so that it can be used to automate collection of information from Veterinary documents such as product literature including the Summary of product characteristics (SPCs) for signal management.

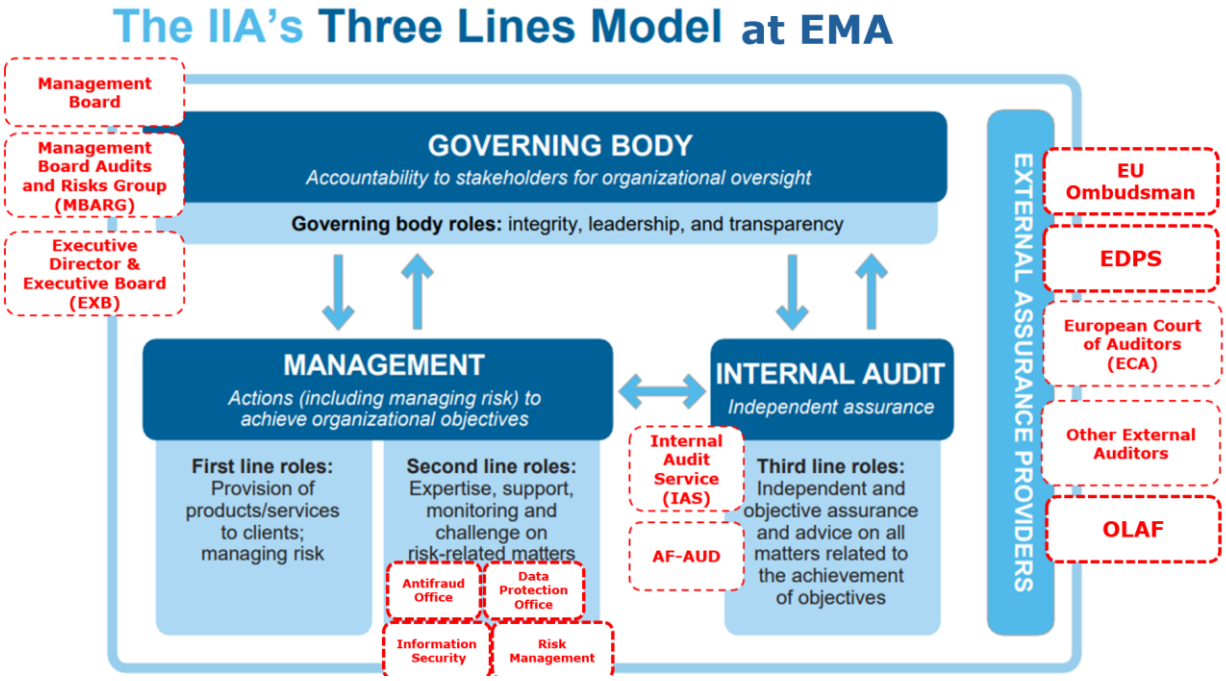
The Power Platform Community initiative started as a collaboration between TDT, I-Division, business representatives and consultants to design and propose a governance framework for a community of citizen developers. The goal is to enable EMA staff to capitalise on the capabilities of the Power Platform to deliver their own automations for their personal and team needs and accelerate EMA's digitalization journey.

Agile Governance

In 2024, the Agency continued to develop its Agile way of working. The Regulatory Optimisation Group (ROG) was reinstated to support the business processes. The Network Data Steering Group and EMA Data board were established and integrated into the Agile Governance to ensure wide stakeholder representation and coordination. This resulted in increased transparency with Network Industry as well as enhancing the collaboration between the various governance bodies via the Agile ceremonies.

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

EMA applies the following 'Three Lines Model', to ensure effective oversight, accountability, and continuous improvement in audit activities:



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

Internal Audit Service (IAS) audits at EMA in 2024

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 (IAC) for effective coordination, carried out in 2024 at EMA the following audit engagement:

'Management of the lease of the European Medicines Agency's former office premises in London'

Following the completion of their preliminary survey phase of the audit, IAS concluded that no weaknesses were identified in the risk management process put in place by EMA related to the lease, and considering the overall positive results of the review, no final report was issued. The audit was closed by a Closure Note concluding the preliminary survey.

Internal audit capability (IAC) audits at EMA in 2024

In accordance with its '2024 risk-based audit plan and 2024-2026 strategic audit plan' approved by the EMA Management Board in December 2023, the Internal Audit Capability (IAC) carried out in 2024 the following internal audit engagements:

'Management of PRAC secretariat and related working groups and working parties'

The main objective of this internal audit was to assess the effectiveness of the support provided to the Pharmacovigilance Risk Assessment Committee (PRAC) by the secretariat.

In addition to identification of number of strengths, the audit team issued three very important recommendations and no critical recommendation.

'Effective management of conflict of interest'

The objective of this internal audit was to assess the effective management of conflict of interest (CoI) of Management Board members and scientific experts, as supported by the Agency's new Experts Management Tool, and related operational processes as well as the internal controls (e.g. ex-post controls) around management of CoI.

In addition to identification of number of strengths, the audit team issued three very important recommendations and no critical recommendation.

'Veterinary Pharmacovigilance System'

The objective of this audit was to assess the effectiveness, efficiency, integrity and compliance of the implementation of the EU Veterinary Pharmacovigilance system at EMA and how it supports the EU regulatory network for veterinary medicines and veterinary healthcare professionals in safeguarding the health and welfare of animals.

In addition to identification of number of strengths, the audit team issued three very important recommendations and no critical recommendation.

'Management of metadata at EMA'

The main objective of this engagement, carried out by IAC together with co-sourced 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 report is to be finalised in 2025.

'Environmental management at EMA'

In preparation of the Agency's registration to the Eco-Management and Audit Scheme, this internal audit, carried out by IAC together with co-sourced experts, was performed to review EMA's compliance with the EMAS additional requirements laid down in Annex II part B of Regulation (EC) 1221/2009. The audit engagement team concluded that EMA fulfils the EMAS additional requirements laid down in Annex II part B of Regulation (EC) 1221/2009, in addition to all other requirements applicable to the Agency's Environment Management System.

Targeted Independent Review on 'Antifraud activities'

The objective targeted independent review was to conduct a thorough assessment of the structure and coordination of anti-fraud activities at EMA. The review concluded in a report with observations review results in report with observations (rather than recommendations, as for internal audits).

Overall, relying on the results of the internal audits carried out at EMA in 2024 by IAS, IAC and other assurance providers, including follow-up activities, quarterly monitoring with EMA senior management and independent analyses, the Head of Audit *ad interim* believes the internal control systems in place at the Agency provides 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 2024, for which EMA management has prepared adequate improvement action plans and continuously monitors the implementation.

European Court of Auditors

Non-financial audits

The European Court of Auditors, supported by IAC for effective coordination, carried out the following non-financial performance audit engagements at EMA in 2024:

'EU Agencies' response to the outbreak of COVID-19 pandemic'(reporting validation-publishing phase)

ECA's special report published in September 2024 acknowledged many EMA achievements, with the auditors concluding that the EU medical agencies generally managed well in unprecedented circumstances. In its response to the report, EMA clarified some of the ECA's observations and the report was accepted, including the recommendations addressed to EMA to fine-tune EMA's procedures and information dissemination.

- **'Have EU-level actions been effective in ensuring the availability of medicines?'**

The audit took place mostly in 2024, and ECA's special report is expected to be issued in 2025.

Financial audits

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2023[58] on 17 September 2024.

In ECA's opinion the Agency's accounts for the year ended 31 December 2023 are reliable and present fairly, in all material respects, EMA's financial position as at 31 December 2023 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 management and control systems related to delays in issuing invoices following the migration of data to a new corporate system (IRIS).

The observation is not considered critical as the Agency has put in place corrective actions to address the issue.

Observation on the management and control systems[59]	
Observation number	**Description**
3.19.9	During the first quarter of 2023, EMA carried out a data migration from the former veterinary inspection system to the new corporate system, IRIS. We found that following the migration, for 48 veterinary inspections carried out, amounting to €1.3 million, EMA had not respected the deadlines set out in Article 10 of Council Regulation 297/95 and had issued the corresponding invoices with significant delays. As a consequence, the related revenue was wrongly booked in 2023, instead of 2022. These delays were not reported in the register of exceptions. This shows a weakness in EMA's management and control systems and contravenes Article 30 of EMA's financial regulation. EMA's reply: EMA agrees with ECA's observation, however would like to highlight that these incidents were estimated to be below the materiality threshold and did not result in a loss of revenue. EMA will look for improving the process in the context of the implementation of the New Fee Regulation.

[58] Annual report on EU agencies for the financial year 2023
[59] Ibid, page 186

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

In 2024, several assurance providers including IAS, IAC and ECA (non-financial performance) carried out audit engagements at EMA, resulting in issuing **no** critical but **9** very important recommendations.

At the end of the year, IAC monitors with EMA management the implementation of a total of **38 major (i.e. critical and very important) recommendations**, in addition to 1 unclassified recommendation issued by ECA in the context of a performance/non-financial audit. The table below breaks down the number of major recommendations issued by various assurance providers.

	Number of major recommendations currently under implementation			**Issued in**					
Issued by	**Very important**	**Critical**	**Total**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**
IAC	26	11	**37**	1	1	2	3	10	9
IAS	1	0	**1**					1	
ECA (non-fin)		*N/A*	***1***[60]						*1*

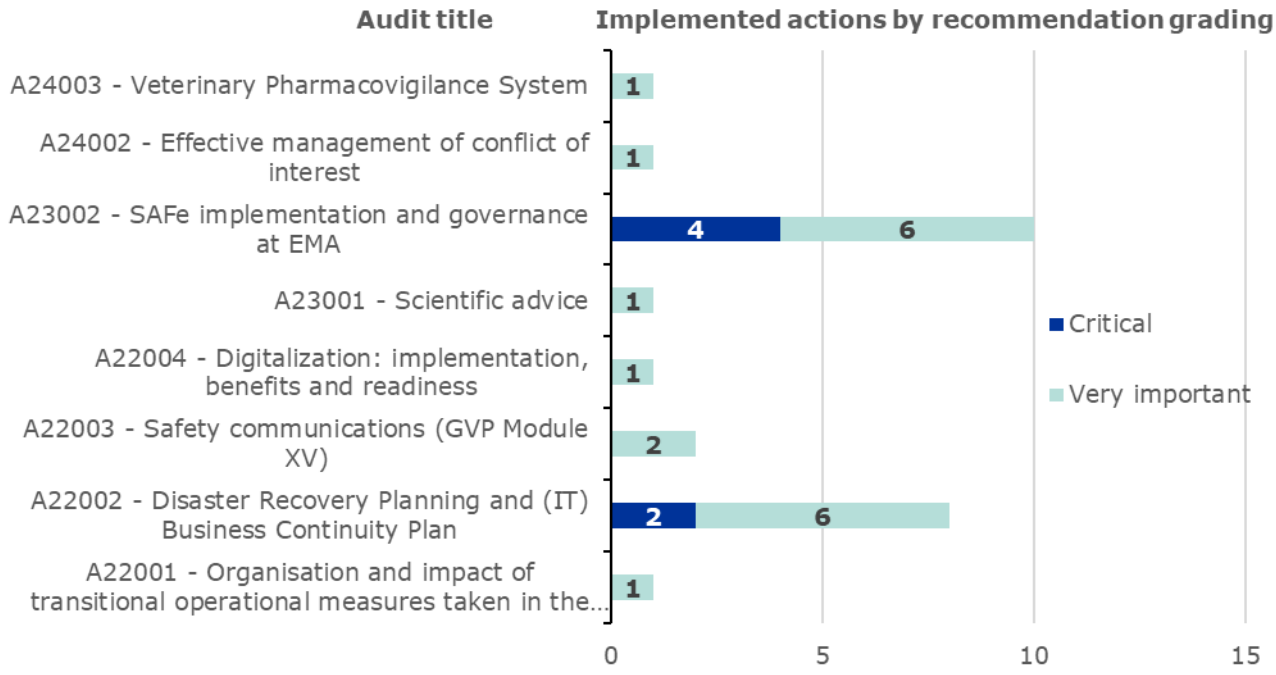
These major recommendations are due to be implemented in accordance with the actions and timelines set by EMA management in the Improvement Actions Plans finalised once the audit reports are completed. The table below outlines the implementation status vis-à-vis the established completion dates.

Recommendations implementation ongoing				
Grading	**On time**	**With some delays (deadline extended)**	**Overdue at the time of report**	**Subtotal**
Critical	0	8	3	*11*
Very important	11	11	5	*27*
Total				*38*

IAC recommendations implemented in 2024

In 2024, EMA management implemented 25 improvement actions linked to internal audits as per the chart below, leading to closure of 21 major recommendations (5 critical and 16 very important), and improvement of the governance, risk management and internal control system across the Agency.

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



European Court of Auditors

Financial audits

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2023[61] on 17 September 2024.

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

Follow-up of previous years' observations[53] [62]			
Year	**Summary of Court's observations**	**Summary of corrective action taken and other relevant developments**	**Status of the observation (Open/Closed)**
2022	EMA contributes towards certain types of staff childcare costs, such as pre- and after-school care in the Netherlands. For school meals, we found that EMA was not able to provide full evidence of the checks carried out to ensure that the costs of school meals were excluded, therefore calling into question whether such checks were systematically carried out.	EMA strengthened the checks regarding childcare contribution costs, ensuring that the required evidence is obtained.	Closed

[61] Annual report on EU agencies for the financial year 2023
[62] Ibid, page 187

Follow-up of previous years' observations[53] [62]			
2022	We found that EMA had not assigned clear identification to some of the 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 has started the process of labelling the previously unlabelled furniture items. A new inventory is planned for 2024	Open
2022	For one audited payment of €2 million, EMA authorised the related budgetary commitment only after the legal commitment was accepted. This goes against Article 73 (2) of EMA's financial regulation.	EMA revised its standard operating procedure and established and performed an annual ex post check of more than 1,500 budgetary commitments, which detected no cases of non-compliance in 2023.	Closed

European Data Protection Supervisor

- EDPS audit on EudraVigilance

The European Data Protection Supervisor (EDPS) issued the audit report on 2 May 2024 following the data protection audit conducted on EudraVigilance in 2023.[63] In this regard, four actions were 'deemed necessary' to comply with Regulation (EU) 2018/1725[64] (hereinafter 'EUDPR'). The EDPS retains the right to exercise the powers granted in Article 58 of the EUDPR should these recommendations not be fulfilled satisfactorily.

Summary of EDPS recommendation	Summary of EMA response	Status of the Recommendation (Open/Closed)
Conclude administrative arrangements with the regulatory authorities based in third countries to which EMA transfers personal data to comply with Article 48(3)(b) of the EUDPR. Alternatively, EMA should ensure that any transfers of personal data to administrative authorities in third countries are fully anonymised.	EMA highlighted the importance of collaboration at an international level to fulfil the protection of public health, central pillar to EMA's strategy. Given the resource and process implications of both options, EMA requested an extension of the deadline proposed by the EDPS in order to conduct an assessment.	Open
Inform the EDPS, in accordance with Articles 48(6) and 50(6) of the EUDPR, of all the categories of cases in which transfers subject to appropriate safeguards or based on derogations for specific situations have been carried out in 2022 and 2023.	EMA provided the requested information to the EDPS.	Closed
EMA to re-assess the necessity and proportionality of keeping personal data included in the reports in EudraVigilance for an unlimited period of time and ensure that personal data that are no longer necessary for the purpose for which they have been collected are erased or anonymised to ensure compliance with Article 4(1)(e).	EMA has been acting on this recommendation and will report to the EDPS accordingly.	Open

[63] https://www.edps.europa.eu/system/files/2024-12/ema_-_executive_summary_of_the_audit_report_on_eudravigilance_at_the_european_medecins_agency_case_2023-0042_en.pdf

[64] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

Summary of EDPS recommendation	Summary of EMA response	Status of the Recommendation (Open/Closed)
EMA to update its Data Protection Notice on EudraVigilance to include additional information.	EMA updated its DPN on EudraVigilance.	Closed

- EDPS Supervisory Opinion on the prior consultation regarding EMA's EudraVigilance Signal and Safety Analytics Platform

EMA launched a prior consultation on 5 June 2024 in accordance with Article 40(1) of the EUDPR with the EDPS regarding the Data Protection Impact Assessment (DPIA) for the EudraVigilance Signal and Safety Analytics Platform (EV SSAP). In its Supervisory Opinion received on 16 October 2024[65], the EDPS assessed whether the proposed mitigating measures in EMA's DPIA appropriately address the high risks identified. To ensure compliance with the EUDPR, the EDPS deemed necessary to implement four recommendations. EMA – with support from the joint controllers - should notify data subjects of changes in EudraVigilance or document reasons for not doing so, ensure least-privilege access for proposed security policies, regularly review log files for unauthorized operations, and assess risks associated with all processors and sub-processors involved in the processing operation. The Agency has been acting on the recommendations and will report to the EDPS accordingly.

2.8. (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. The Agency has been acting on that recommendation and will report to OLAF, accordingly.

2.9. Follow-up of observations from the discharge authority

As a follow-up to the discharge decision for 2022, in September 2024 EMA reported on the measures taken in light of the observations made by the Discharge Authority. These measures are described in the 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 and the Agency's responses and measures taken, is publicly available on the website of the European Parliament.

2.10. Environment management

In 2024, the Agency continued its work towards EMAS registration in accordance with the EMA Environmental Policy and the Environmental Management Roadmap 2020 to 2024.

The year started with the completion of the Internal Environmental Audit that was initiated in December 2023. The outcome concluded one minor non-conformity and five observations and confirmed the agency's readiness to EMAS registration.

The EMAS audit was performed in September and resulted in 6 minor non-conformities and nine observations. A Corrective Action Plan was prepared and accepted by the EMAS verifier and the

[65] https://www.edps.europa.eu/system/files/2025-01/2024-0531_edps_formal_supervisory_opinion_en.pdf

submitted evidence towards the corrections were approved on 16 December. Following receipt of the validated Environmental Statement a request for EMAS registration was submitted on 18 December with the EMAS certificate expected to be received mid-January 2025.

The EMA Environmental Policy was reviewed in accordance with the due date and the updated version was approved by EXB and signed by the Executive Director on 15 May, and published on the EMA intranet and on the external website.

During 2024, the carbon emissions from the Agency's activities were monitored and calculated in accordance with the Greenhouse Gas Protocol Scope 1, 2 and 3 by implementing improvement actions. One notable action is the continuous laptop replacement scheme, whereby laptops that are over four years old are recycled at zero cost. The devices are too old to be reused so they are broken down into components, which are then recycled for the constituent parts (for example each CPU contains 0.2g to 0.5g of gold, whilst a power supply can have 700gms of copper inside, along with a sizable aluminium heatsink). The recycling scheme includes recycling of laptops, docking-stations and the power supplies, which lead to recovery of a significant amount of raw materials, which are then put back into the manufacturing process. Both manufacturers of the Agency's laptops use at least 30% recycled materials in their new devices. Other small electrical devices, products and appliances are also replaced for further energy efficiency, when technically and financially justifiable. Further actions include continuous promoting of paper-less workflows and maintaining implementation of green criteria in its public procurement. From June to July 2024 a staff survey regarding commuting and teleworking habits was launched which provided 360 responses, close to 40% of all staff. The survey provided reliable results and was used to extrapolate a results for the agency which added 426,7 tonnes of carbon emissions to the Agency's total carbon footprint. The survey will be repeated on an annual basis to monitor these emissions and hopefully receive even higher response rate for increased accuracy, and is also followed by an information campaign with the main focus towards commuting habits and energy efficiency.

In 2024 the previous approach to allow up to one week of teleworking abroad per month was terminated and replaced with an allocation of a maximum of 10 days of teleworking abroad. Teleworking from the place of employment was maintained with up to 60% of the working time, on a weekly basis.

Based on the return to more regular working from the office, 2024 was confirmed as the first "normal" year for the building performance, with a slight increase compared with 2023 due to the increased occupancy. The outcome of 2024 will be used as a baseline for building consumption with a target to establish a reduction trend over the reporting period (2024-2028) for the total energy consumption per FTE.

EMA joined the Green Business Club (GBZ) Zuidas in 2024, where together with other organisations in Amsterdam Zuid there is a focus towards sustainability and greening office operations and activities. Activities in GBC Zuidas included participation in a survey regarding sustainable commuting to Amsterdam Zuid, in an open house to the nearby Community Garden and in several presentations regarding sustainable developments by other organisations in the area.

Following a joint initiative between the environmental management, Stakeholder and Communication Division and the Digital Transformation Task Force, EMA has replaced a majority of its paper business-cards with digital business-cards. The initiative removes the need to produce several thousands of business-cards on an annual basis, and was well received by both users and business contacts.

In October EMA submitted the in-house developed initiative of the digital business-cards to the GBC Zuidas Sustainability Awards. EMA did not win, but gained a lot of attention and interest from other

organisations as a good practice initiative, confirming a sustainability perspective embedded in normal operations and as a successful digitalisation initiative.

During 2024 the EMA Green Group mandate was updated to allow up to ten environmental ambassadors from the core business entities. The Green Group promoted more than 20 topics on the Viva Engage 'Go Green with EMA' community to raise staff awareness and engagement.

More detail of the outcome of the EMA Environment Management activities towards objectives, targets and actions can be found in Annex 7. Following the approved certification to EMAS, EMA will publish an Environmental Statement on an annual basis with detailed information about its Environmental Management performance.

2.11. 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

The latest external evaluation of the Agency's operation pursuant to Article 86 of the Regulation (EC) No 726/2004 [EMA's founding Regulation] 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 on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use (COM/2021/497 final)'. The study assessed the extent to which the current marketing-authorisation system for medicines met its objectives in the period 2010-2017.

A number of studies to evaluate legislative frameworks and other activities implemented by EMA have been performed for the European Commission in preparation of the revision general pharmaceutical legislation, which was published on 26 April 2023. These are the following:

European Commission's evaluation of experience with the operation of the Orphan and Paediatric Regulations, whose results were published by the European Commission on 11 August 2020.

Evaluation of experience with shortages of medicines, based on the study on medicines shortage (December 2021) which reviews activities carried out by EMA and National Competent Authorities in this area between 2004 and 2020.

Studies in support of the evaluation and impact assessment of the EU general pharmaceuticals legislation, which include an Evaluation report, an Analytical report and Impact Assessment Report, which were all published in April 2023.

Evaluation of the EMA fee system, which was finalised in 2019 in preparation of the legal proposal for the revised EMA's fees regulation published on 14 December 2022.

There are no conclusions or actions from these evaluations which are specific for EMA to follow up, as these evaluations were mainly aimed at informing and preparing future legislative initiatives of the European Commission.

3. Assessment of the effectiveness of internal control systems

3.1. Effectiveness of internal control systems

Internal control framework review

The framework is comprised of 17 internal control principles that cover five core components of the internal control framework: control environment, risk assessment, control activities, information and communication, and monitoring activities.

The framework is based on a principle-based system, whereby the managers are offered the necessary flexibility to adapt to their specific characteristics and circumstances while ensuring a robust internal control with a consistent assessment throughout the Agency.

To assess the implementation, functioning, and improvement of the 17 principles, a questionnaire was prepared. The questionnaire was then addressed to the managers and staff members in charge of specific principles or elements of the internal control framework. This year, like in previous years, several individuals with topics that needed elaboration were interviewed for further clarification of the questions/principles.

Regarding the functioning of the internal control system and its principles, the overall conclusion is that the internal control system, its components and principles are in general present and functioning reasonably well. Several principles were noted to benefit from minor clarifications or additional information, and/or some adjustments and improvements that would enhance the efficiency and effectiveness of the principle and its elements.

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	2022	2023	2024
Number of transactions verified	27,151	37,874	31,054

Comparison between verified and rejected transactions	2022	2023	2024
Number of transactions rejected	511	422	377
Rejections triggered by formal considerations or technical malfunctioning	301 (59%)	164 (39%)	129 (34%)
Rejections triggered by errors in the transaction (incorrect data, insufficient justification)	210 (41%)	258 (61%)	248 (66%)
Overall rejection rate	1.9%	1.1%	1.2%

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 2024 altogether 49 events were registered in total.

Exceptions: 20

Non-compliances: 26

Combined Exceptions & Non-Compliances: 3

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, experts, 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 2024 was performed on budget lines 3020, 3021, 3000, 3003 and 1420 and led to no major findings. More specifically, across the 536 samples drawn, 2 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 inspections, variations type IA and variations (veterinary) for the ex-post controls.

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 2024:

Handling of Digital Personal Files;

Handling of declarations of interests of staff;

Compliance with Probationary Periods requirements;

Managing of GCP, GVP and GMP inspection coordination;

Compliance with SAFe/Agile methodology;

Procedural compliance to SME status renewal applications ;

Check of ACL Compliance for HR-Restricted Documents;

Handing of declarations of interests of Management Board members and scientific experts.

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 2024. In total, 47 posts were identified as sensitive in 2024, compared to the number of sensitive functions in 2022 (45), as two new posts were created and deemed sensitive this year: The Head of Process Management Office and the Senior communication Specialist. Both positions resulted from organisational changes.

Advisory Committee on Procurement and Contracts (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 2024, the committee was requested to provide an opinion on 15 procurement procedures and expressed 8 favourable opinions, 1 negative opinion and 6 favourable opinions with recommendations.

Reconciliation of information in financial systems

Most of the Agency's operational systems are interfaced with the SAP system. During 2024, 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 the newly interfaced 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).

In 2024, the Data Protection Officer (DPO) continued supporting the internal controllers and data protection coordinators (DPCs) at EMA in pursuing the Agency's implementation of its EUDPR compliance framework. To address operational matters and discuss latest EDPS/European Data Protection Board (EDPB) data protection guidance and recommendations, the DPO organised a total of six meetings with the Agency's appointed DPCs.

The DPO also actively engaged in the EDPS' Support Group to prepare workshops for the bi-annual EDPS- DPO Network meetings focusing on the following topics: Artificial Intelligence (AI) and data protection, data subject rights and storage limitations and retention periods. The output of these meetings fed into EMA's data protection procedures where applicable. This is reflected in the detailed review of the Internal Guidance on Data Protection (Ref. 0055-2020) and its Annexes including two new topics i.e., international transfers and personal data retention. An internal consultation on a draft Guidance on data protection and the use of AI was also launched in Q4 2024.

To facilitate collaboration and to avoid duplication of efforts, the EMA DPO co-chaired with the DPO of the European Labor Authority two working groups on the drafting of the Microsoft Copilot Data Protection Impact Assessment (DPIA) and the update of the Microsoft 365 DPIA. The EMA DPO also participated in the Working Group on the drafting of DPIA templates led by the European Parliament and the Working Group on the drafting of a DPIA on administrative investigations and disciplinary procedures led by the Cout of Auditors. EMA also participated in the two Working Groups on Artificial Intelligence and International Transfers.

In May 2024, EMA received the audit report for the on-site audit on EudraVigilance (EV) conducted by the EDPS in March 2023. Following a detailed review, EMA provided the EDPS with an audit action plan in August 2024. In the same month, EMA received the final audit report on the remote audit of the Agency's corporate website, which the EDPS conducted in 2018 and 2020. EMA addressed all the EDPS's recommendations within the required timeframe.

Another important milestone in 2024 was the prior consultation of the EDPS on the EV Signal and Safety Analytics (SSA) DPIA in accordance with Article 40 of the EUDPR. The EDPS issued its opinion in October 2024, which was preceded by two rounds of clarifications on EMA's intended use of an of the shelf pharmacovigilance solution. The DPO, in consultation with the internal controller, prepared an

action plan to address the EDPS' recommendations which was communicated to the EDPS in December 2024.

Based on the data protection by design principle, four additional DPIAs were conducted in the following areas:

European Health Data Space (EHDS) HealthData@EU: focusing on the pilot participation of EMA in a study on the natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV- during the Omicron period.

French Health Data Hub (HDH)-EMC2: aiming at establishing a data warehouse on drug monitoring for analysis of health data by EMA with four French health institutions.

Data Analysis and Real World Interrogation Network (DARWIN) EU(R) studies: performing descriptive studies on incidence and prevalence of pathologies and the use of drugs (including vaccines) using the SDNS database.

Security Operation Center (SOC): providing a centralised system where the EMA information security team monitors, detects, analyses and responds to cybersecurity incidents, typically on a 24/7/365 basis.

Microsoft Copilot: assessing the conduct of a pilot to explore potential use of general-purpose AI at EMA.

On 8 March 2024, the EDPS adopted a decision[66] following its investigation into the European Commission's use of Microsoft 365. In the decision, the EDPS focused on compliance with provisions of Regulation (EU) 2018/1725 related to purpose limitation and international transfers and unauthorised disclosures of personal data. In response to this decision, EMA initiated a review of its Microsoft 365 DPIA.

In collaboration with the DPCs, the DPO continued to coordinate the performance of EMA's transparency obligations. This includes the preparation and publication of data protection notices and records of processing operations (the latter in accordance with Article 31 of the EUDPR).

As part of the technology selection and acquisition process and the procurement and tender procedures, efforts were specifically devoted to the data protection risk assessment of the potential data processors of the Agency and the negotiations of the relevant standard contractual clauses (SCCs) or Data Processing Addendums (DPAs) with the successful vendors (amounting to a total of 25 during 2024). This included a review of the Cloud security and data protection risk assessment questionnaires as applicable, providing support in performing six Transfer Impact Assessments (TIAs) to assess whether it is possible to transfer data to a third country by checking whether the destination country provides for an essentially EUDPR/GDPR equivalent level of data protection and to review the effectiveness of supplementary measures put in place by the processors to mitigate risks to data subjects.

The topic of international data transfers carried out by the Agency when performing its activities continued to be of importance in 2024. In July 2024, EMA submitted SCCs for international transfers with the vendor of the EudraVigilance SSA platform for authorisation to the EDPS. Furthermore, EMA drafted Administrative Arrangements (AA) with the European Directorate for the Quality of Medicines & HealthCare (EDQM) using the new EDPS model template arrangement for data transfers from a Union

[66] EDPS decision on the investigation into the European Commission's use of Microsoft 365 | European Data Protection Supervisor

institution, body, office or agency to an International Organisation and submitted the AAs for EDPS authorisation in November 2024.

Throughout 2024, the DPO supported the management of a total of 29 security incidents with personal data breaches, three of which required notification to the EDPS. In this regard, two quick guides for EMA staff were developed to facilitate the handling of personal data breaches and adherence to data protection principles.

The DPO also facilitated the handling of four data subject requests and participated in an EDPS survey on the same topic.

The development of new, specialised training modules on specific data protection topics with focus on DPCs remained a priority in 2024. These new modules will be delivered in Q1 2025. A data protection introduction training was developed in collaboration with the Digital Academy, which will be launched in the context of a dedicated data protection intranet page in 2025. A refresher data protection training for staff members in A-Division was also delivered.

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 and has a 'zero tolerance' approach to fraud.

To improve prevention, detection and the conditions for investigation of fraud, and to pursue adequate deterrence and reparation with proportionate and dissuasive sanctions, the Agency adopted its 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 and awareness-raising are the most important objectives of the AFS since its adoption back in 2014. This aspect has remained unchanged in 2024. 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.

The Agency opened one disciplinary proceeding at the end of 2024, following an OLAF investigation. The proceeding will be concluded in 2025.

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 35 (thirty-five) external whistleblowing reports in 2024 and followed-up on each of these cases in accordance with the Policy and SOP.

31 (thirty-one) cases have been closed, in 4 (four) cases the assessment is ongoing. For 22 (twenty-two) 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. In 2 (two) cases EMA coordinated the investigation with the involvement of the relevant NCAs/Rapporteurs. Three cases were not assessed further as no sufficient information was provided by the reporter.

For the reports in EMA remit, there were 6 (six) cases concerning manufacturing practice, two cases concerning pharmacovigilance practice and one case 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

Policy (0058) governing the Management Board's management of conflicting interests and the Breach-of-Trust procedure for Management Board members have been in place since 2023, harmonised with the updates to policy 0058, also became effective on January 1, 2023.

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.

Since 2016, an ex-ante control has been carried out systematically on all DoIs submitted by Management Board members to compare the details contained in each new declaration with the previous declaration, and with the CV provided. Members are required to undertake training before their declaration of interest can be submitted.

The involvement of members and alternates in Management Board activities takes into account several factors, namely, the nature of the declared interest, the timeframe of the interest, the type of Management Board activity/topic, and the likelihood of impact on the industry (the pharmaceutical/medical device industry or any other industry related to any declared personal interests), as well as the action requested from the Management Board (i.e. adoption or endorsement).

Moreover, members are informed in writing and ahead of each meeting, of the perceived competing interest which has been identified, and the applicable restriction to their involvement at the meeting. At the start of each meeting, members are further asked to declare any specific interests which could be prejudicial to their independence with respect to the items on the agenda. The names of members having declared competing interests which could affect their impartiality, with regard to specific items on the agenda, are noted in the MB 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 2024.

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. The Agency undertook a comprehensive revision of the policy in the light of emerging court judgments.

On 22 June 2023, with its judgment in Joined Cases C-6/21 P and C-16/21 P, the Court of Justice set aside the first-instance judgment of 28 October 2020 in Case T-594/18, Pharma Mar v Commission. The case concerned whether a university hospital may be classified as a "pharmaceutical company" for the purpose of EMA's Policy 0044.

In its appellate judgment, the Court of Justice took note of the fact that Policy 0044 seeks to ensure an appropriate balance between the requirement of impartiality of experts involved in EMA's activities and the requirement of scientific excellence. After reviewing Policy 0044, the Court of Justice found that a university hospital should not be qualified in its entirety as a pharmaceutical company, even when there is an entity within that organisation that would satisfy the definition of a pharmaceutical company under this Policy.

In that connection, the appellate judgment recognised the important contribution that the staff of a university hospital represent in the context of EMA's scientific evaluation procedures.

On 14 March 2024, with its judgment in Case C-219/22 P, the Court of Justice set aside the first-instance judgment of 2 March 2022 in Case T-556/20, D & A Pharma v Commission and EMA. The appellate judgment examined questions related to the organisation of EMA's Scientific Advisory Groups (SAGs) and ad-hoc expert groups (AHEGs), including questions related to the holding of current interests by members of these groups in products that are considered rival to the medicine under

evaluation. SAGs and AHEGs are groups of scientific experts that are called upon to respond to specific questions posed by EMA's committees during the evaluation of a medicine.

EMA immediately considered the impact of the appellate judgment on the evaluation of Hopveus and other ongoing or recently concluded regulatory procedures and took appropriate measures. Measures were also introduced to ensure the immediate implementation of the findings of this appellate judgment for prospective procedures, until the revision of Policy 0044 had been concluded.

The above-mentioned Court rulings have required the Agency to adjust certain aspects of its approach. A comprehensive revision of Policy 0044 was undertaken to ensure alignment with the Court's findings and to rule out any possible doubts as to the objective impartiality of EMA's assessments.

The revision of the policy was driven by the following elements:

Any current interest in a product should lead to restrictions not only for the product under evaluation but also for products in the same declared condition;
Related restrictions of an individual's participation should apply not only to final deliberation and voting but also to discussions;
The handling of competing interests should be aligned, to the extent necessary, across EMA activities (i.e. between committees and SAG / AHEGs) and across roles.

A draft revised version was open for public consultation from 10 October to 10 November 2024. EMA received comments from a wide range of stakeholders, including academia, research organisations or learned societies, patients' and healthcare professionals' organisations, and the pharmaceutical industry.

The revised policy was adopted by the Management Board in December 2024 and will apply as of 1 May 2025 to allow sufficient time to update the Experts Management Tool and related guidances.

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 the nature of the declared interest, before determining the length of time for which any restrictions may apply.

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 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 2022 (EMA/154320/2012 Rev 3) to align it to the latest changes to policy 0044 at that time.

One BoT procedure was initiated and concluded in 2024. The case concerned an expert who had not declared current and past consultancy interests in pharmaceutical companies which were incompatible with participation as expert in the activity concerned. It was found that the failure to declare the interest constituted negligence to comply with the EMA policy, but it had not occurred intentionally or through gross negligence. The expert was no longer allowed to be involved in the ongoing EMA activity concerned and was required to read and study the policy, take it into consideration for any future involvement in EMA activities and was reminded to update their declaration of interests when interests change or new interests arise.

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 2024, 12 delegates (7 scientific committee members: 1 CHMP, 3 CAT, 1 PRAC, 2 COMP; 5 working party members: 1 MWP, 1GCG, 3 inspectors working group) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector (EMA/267183/2015 Rev 1), 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 July 2023.

In 2024, 951 new experts registered in the Experts Management Tool and their DoI were checked. An error was noted in 36 DoIs (3.8%). The nature of the errors in 2024 (19 out of 36) was that these experts failed to declare in their DoI their recent employment, consultancy or (principal) investigator interests (in the past 3-year period) for a pharmaceutical company. 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 expert is important and is maintained to ensure a low number error on the DoIs of 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 advisors 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 D 4.3).

Interests from advisors 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 to the expert panels. 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 advisors can be assigned one of five roles: chair, rapporteur, co-rapporteur, reviewing member or temporarily assigned expert.

The restrictions applicable in the event that direct or indirect interests are declared, are set out in Annex 1 of the Policy. Some interests might result in an exclusion of the expert from any involvement in the expert panels' activities while others might result in a restricted involvelment (e.g. no involvement in procedures on the declared medical device or any medical device from the declared company) and others might result in no restrictions.

Of a total of 177 advisors that were screened as of 31 December 2024, 103 had no interest declared, 25 declared indirect interests and 49 declared direct interests according to the policy.

The DoIs and the CVs of all expert panels advisors 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 revision of the rules for staff commenced in 2024 to align, where relevant, to the changes to this policy. The revised rules for competing interests of staff and candidates before recruitment will be implemented as of 1 May 2025.

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 2024, the Agency received 22 requests for an outside activity during active service. All requests 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, on the basis of 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 2024, EMA staff and Seconded National Experts (SNEs) made a total of 6 applications, which were finalised within the year. These resulted in 1 authorisation without restrictions, 3 staff authorisations with restrictions, and 2 SNE 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.

Since November 2020, the Agency publishes on EMA's corporate website a specific register for senior staff leaving the Agency. For the purposes of this register, a 'senior staff member' includes the Executive Director, the Deputy Executive Director, the Head of the Legal Department, Heads of Division, Advisers, and Heads of Task Force.

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 2024, 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.

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.

Amsterdam, 23 May 2025

[signature on file]

Mario Benetti
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 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 2025. 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 2024, 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 € 370 million[67].

[67] Corresponding to £306 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 2024 (0.82918)

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 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, 26 May 2025

[signature on file]

Emer Cooke

Executive Director

Annexes

Annex 1. Core business statistics

Business statistics can be found in Part I.

2024 key figures

Human Medicines

Supporting research and development

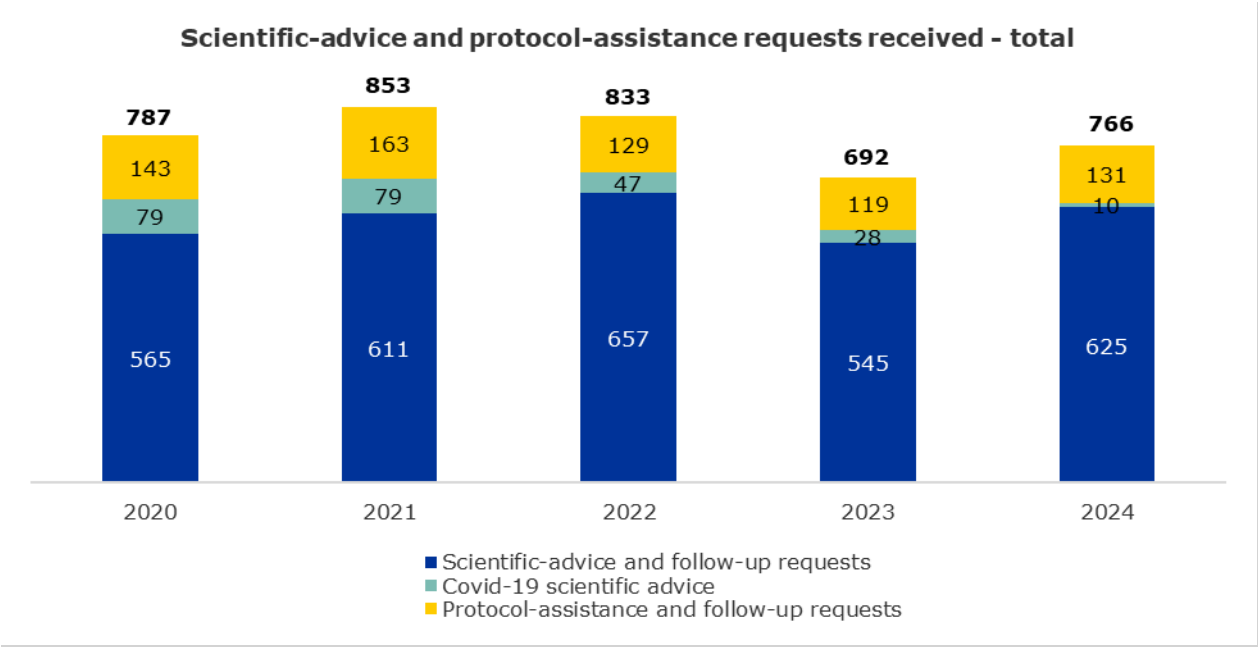
Scientific advice

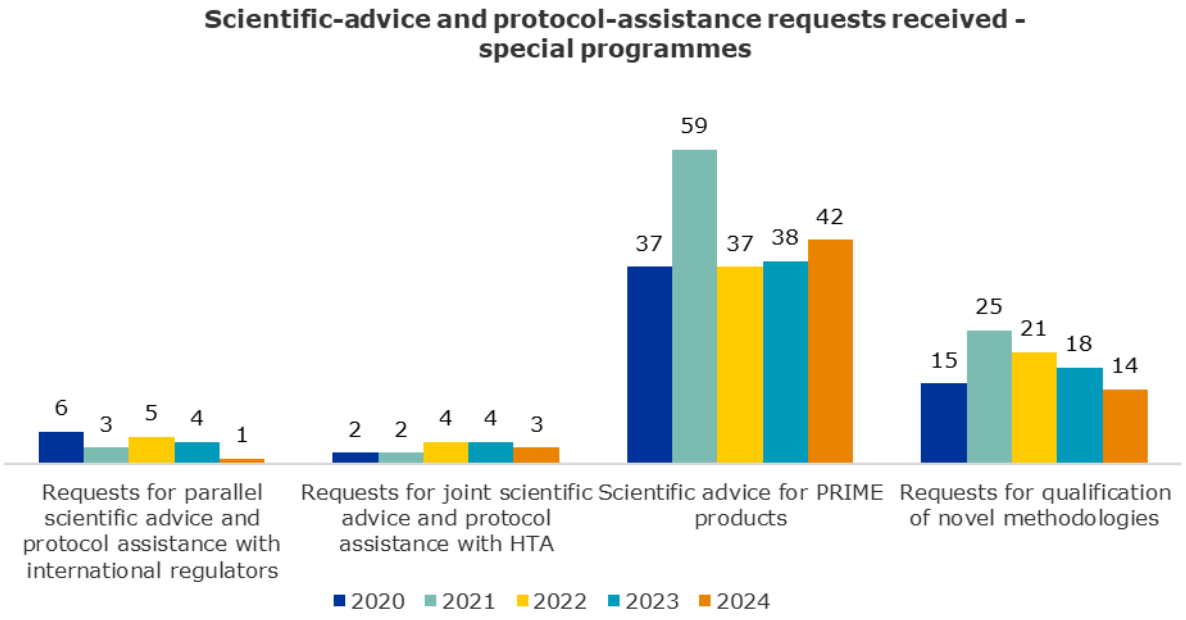
EMA provides guidance and support to medicine developers. This includes scientific and regulatory information on how to design and run clinical trials, compliance standards and obligations and incentives for developers of specialised medicines.

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.

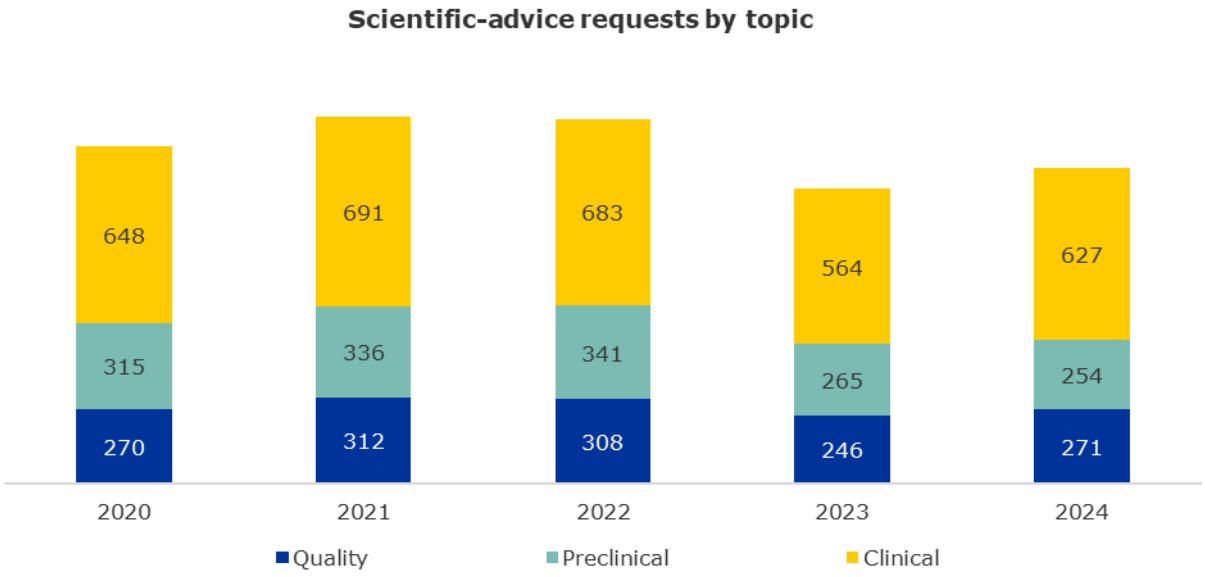
Scientific advice is one of the Agency's key instruments for supporting the development of high-quality, effective and safe medicines, for the benefit of patients. Early dialogue and scientific advice lead to better development plans, promote the collection of high-quality data and, most importantly, 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.

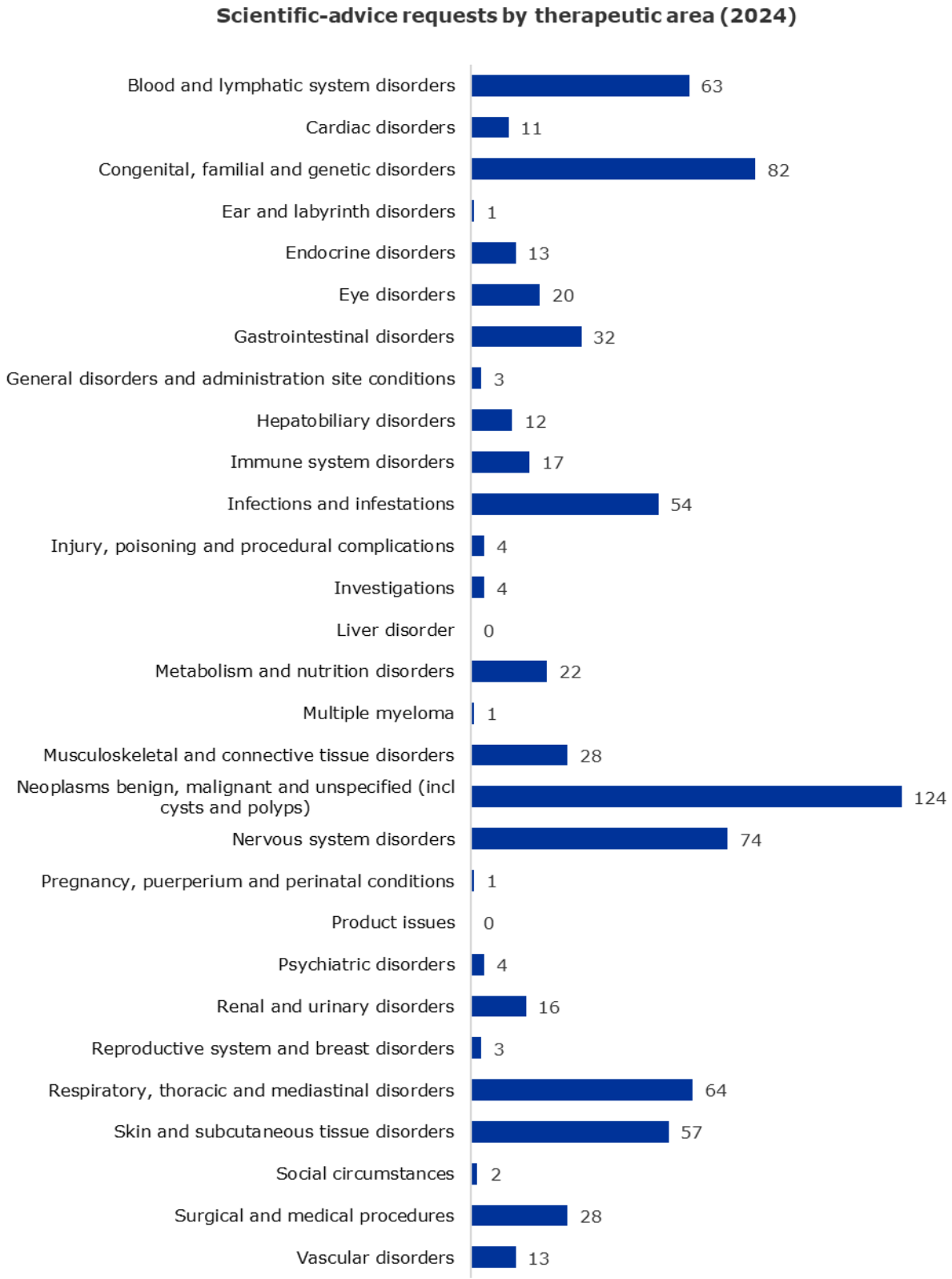
Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases.



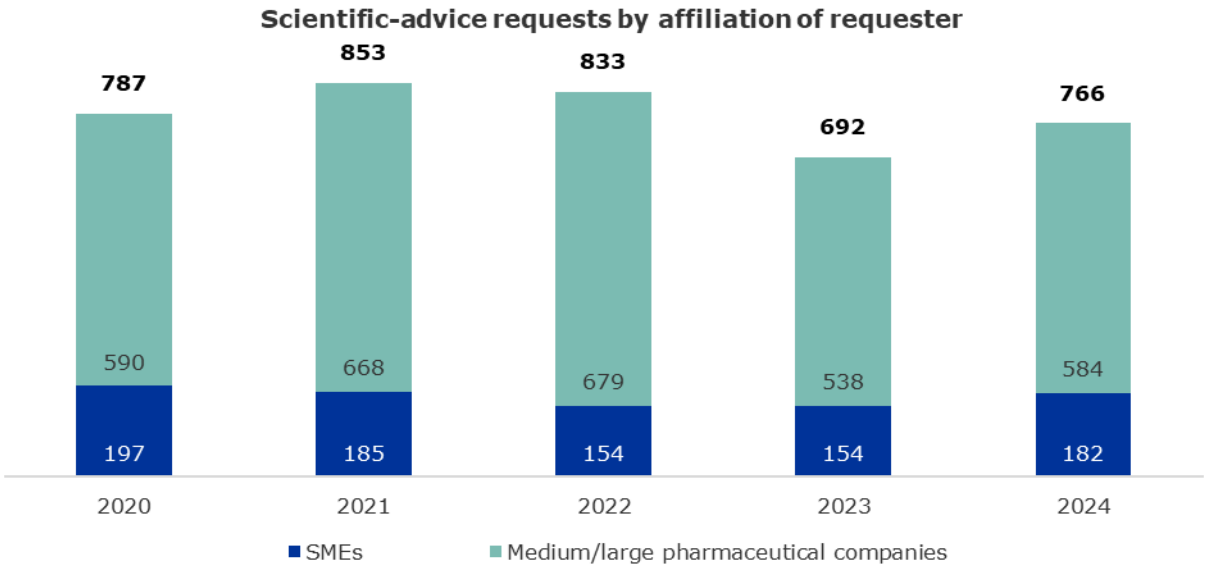


Note: requests for parallel scientific advice and protocol assistance with international regulators – value 2023 corrected.





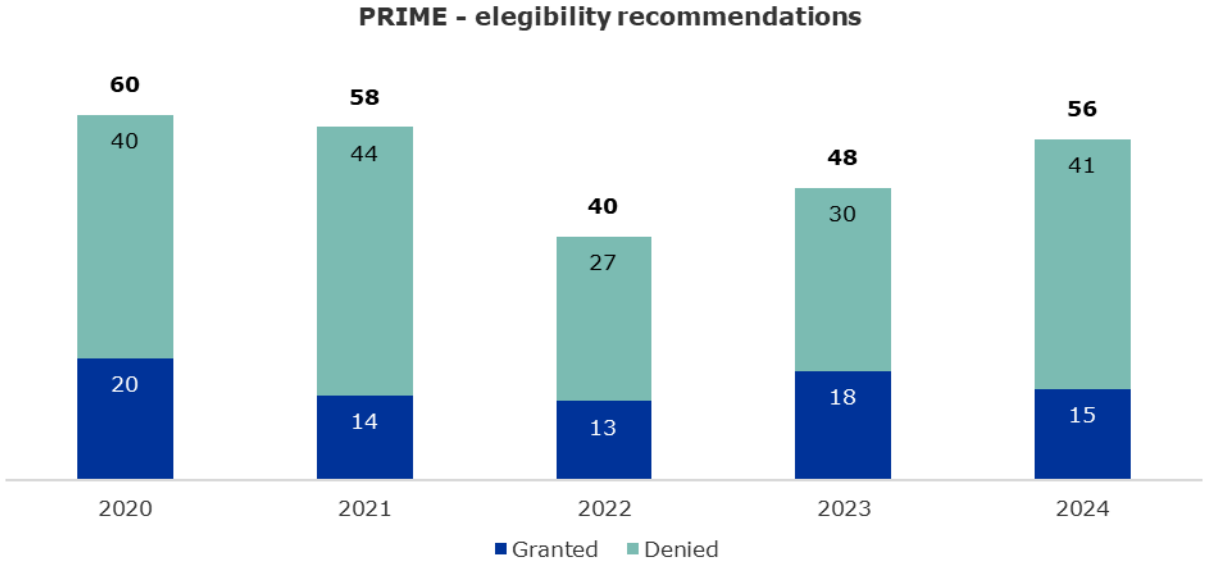
(excludes biomarkers)



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.

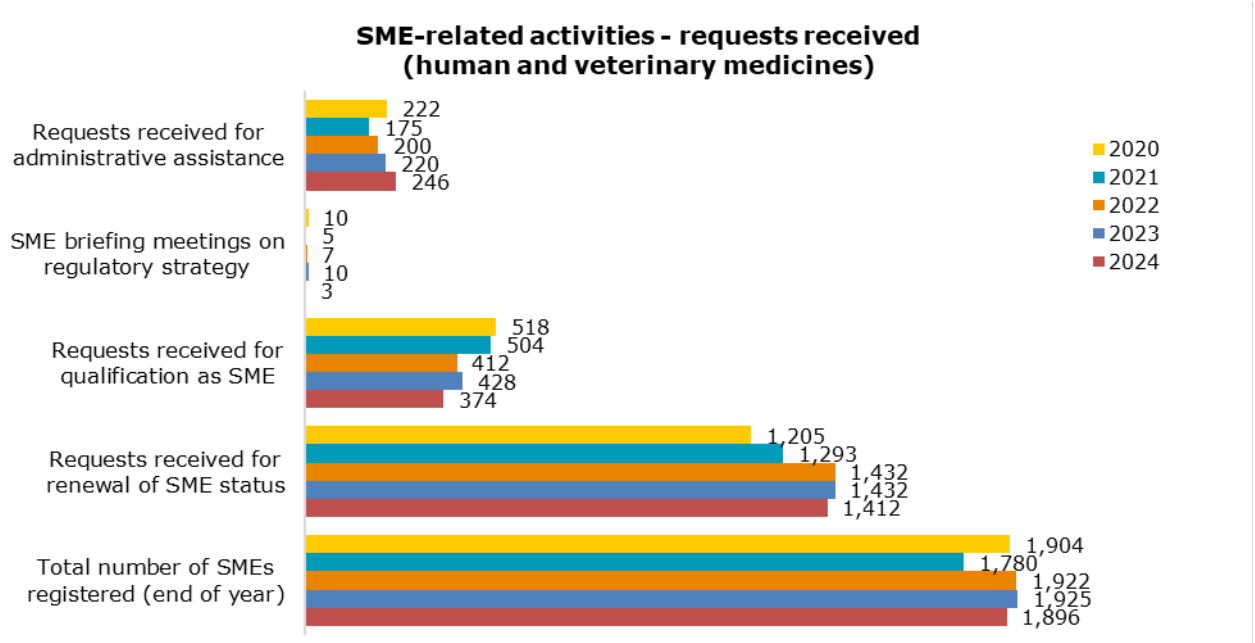
PRIME is meant for the most promising medicines and EMA focuses its attention on medicines that have the potential to bring a major therapeutic advantage. That is why only a limited number of applications are accepted into the scheme.



Support for 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.

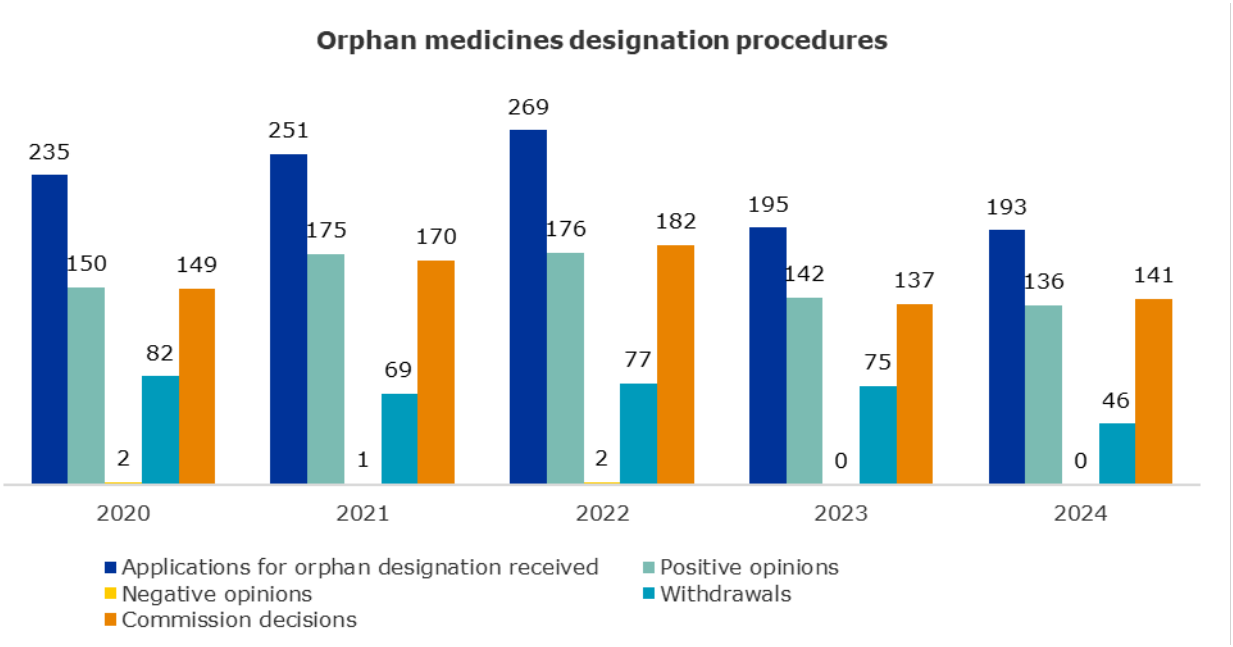


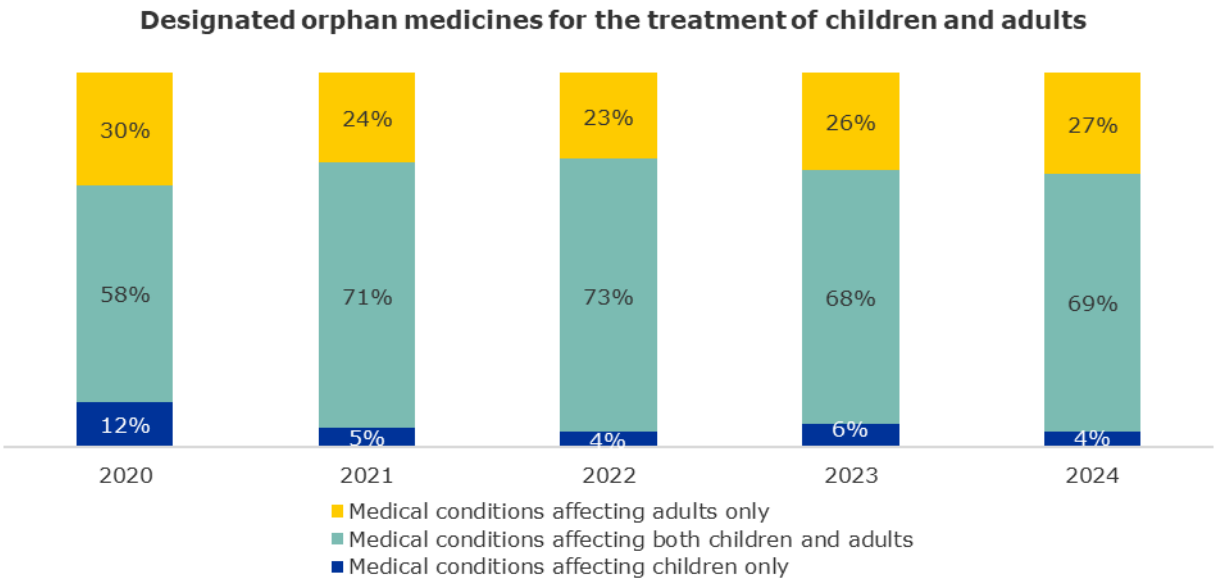
SMEs and initial MAAs (human medicines)					
	2020	**2021**	**2022**	**2023**	**2024**
Initial MAAs submitted by SMEs	23	10	13	10	10
of which orphan medicines MAAs	13	4	5	4	5
Positive opinions	16	11	5	9	7
of which new active substances	8	8	1	3	2
of which orphan medicines	8	4	2	3	1
Negative opinions	1	0	4	1	1
Withdrawals	1	4	3	2	0

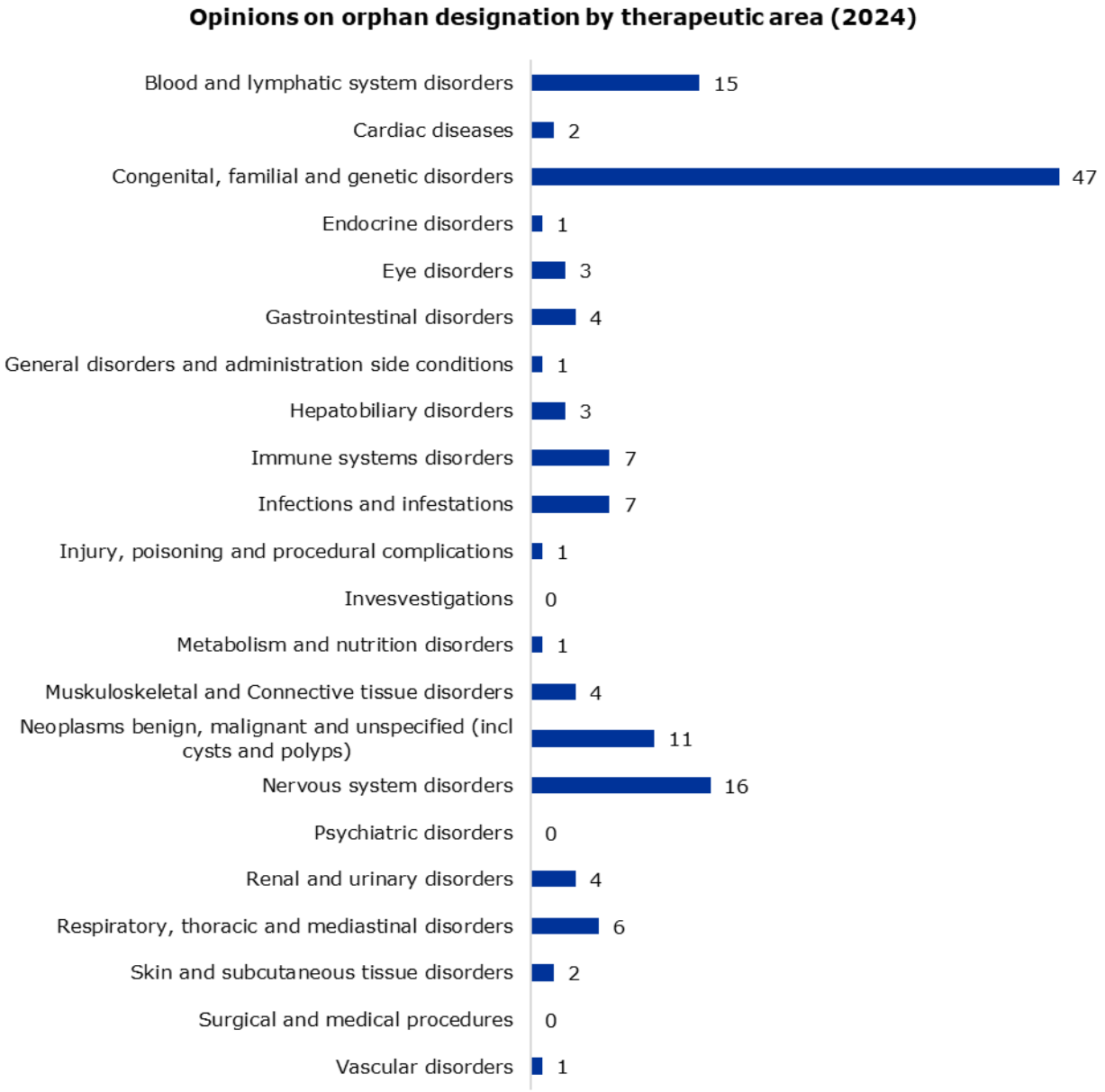
Orphan medicine designation

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) are also available for medicine developers. EMA's Committee for Orphan Medicines (COMP) is responsible for assessing orphan designation applications.


Orphan medicines designation procedures
235
150
2
82
149
251
175
1
69
170
269
176
2
77
182
195
142
0
75
137
193
136
0
46
141
2020
2021
2022
2023
2024
Applications for orphan designation received
Positive opinions
Negative opinions
Withdrawals
Commission decisions


Designated orphan medicines for the treatment of children and adults
30%
58%
12%
24%
71%
5%
23%
73%
4%
26%
68%
6%
27%
69%
4%
2020
2021
2022
2023
2024
Medical conditions affecting adults only
Medical conditions affecting both children and adults
Medical conditions affecting children only



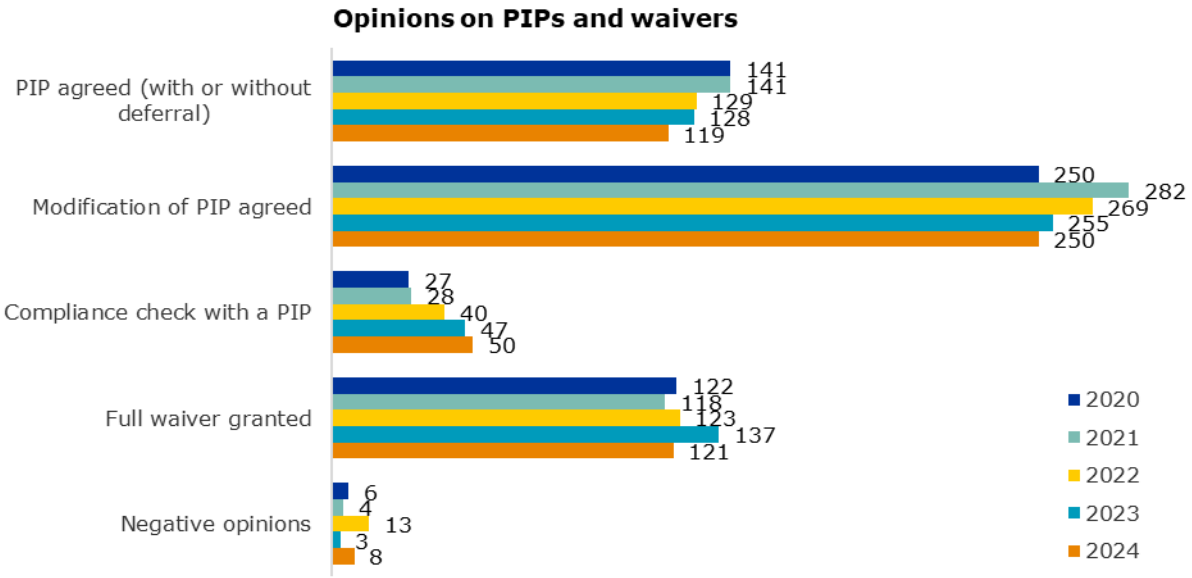
Total 2024: 136

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).

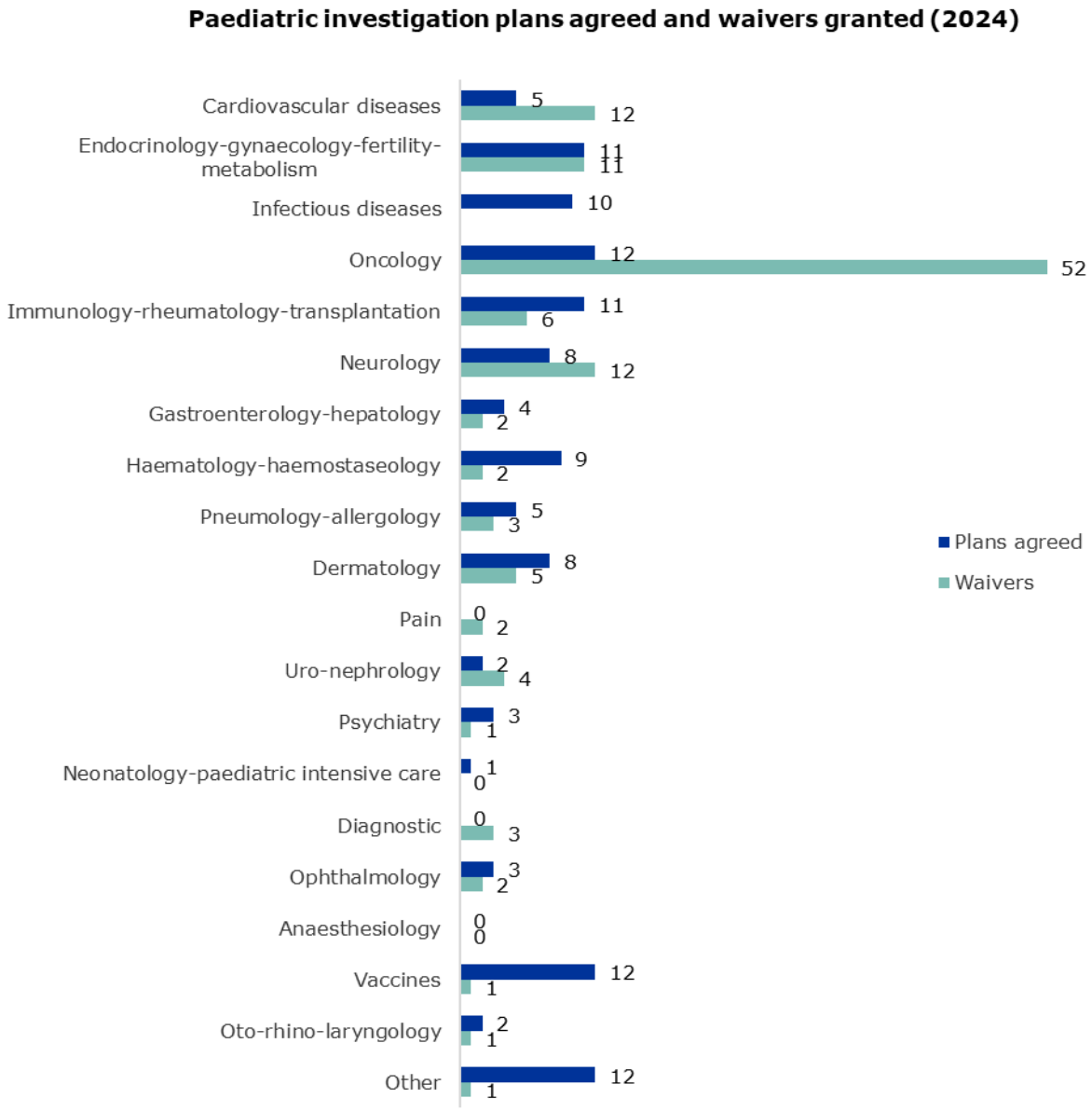
A PIP is a development plan aimed at ensuring that the necessary data are obtained through studies in children to support the authorisation of a medicine for children. Where studies in children are inappropriate or unnecessary, a waiver may be granted.

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 2024: **548**

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 2024: 118 plans agreed,120 waivers

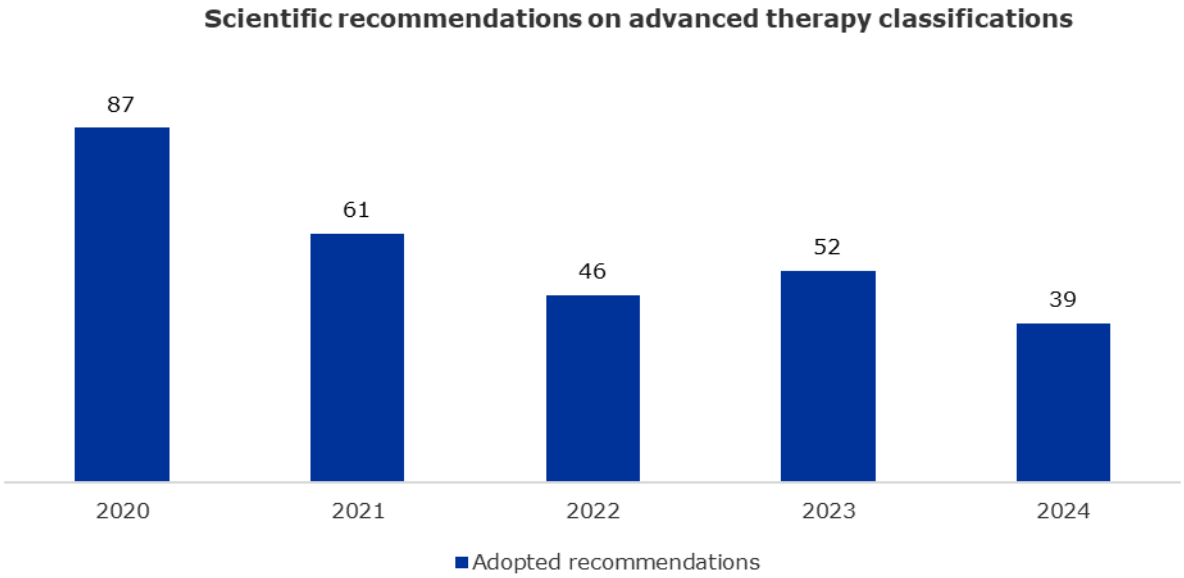
* Graph based on initial PIPs only. One opinion can cover several areas, therefore the total of areas is higher than the number of the opinions adopted.

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.

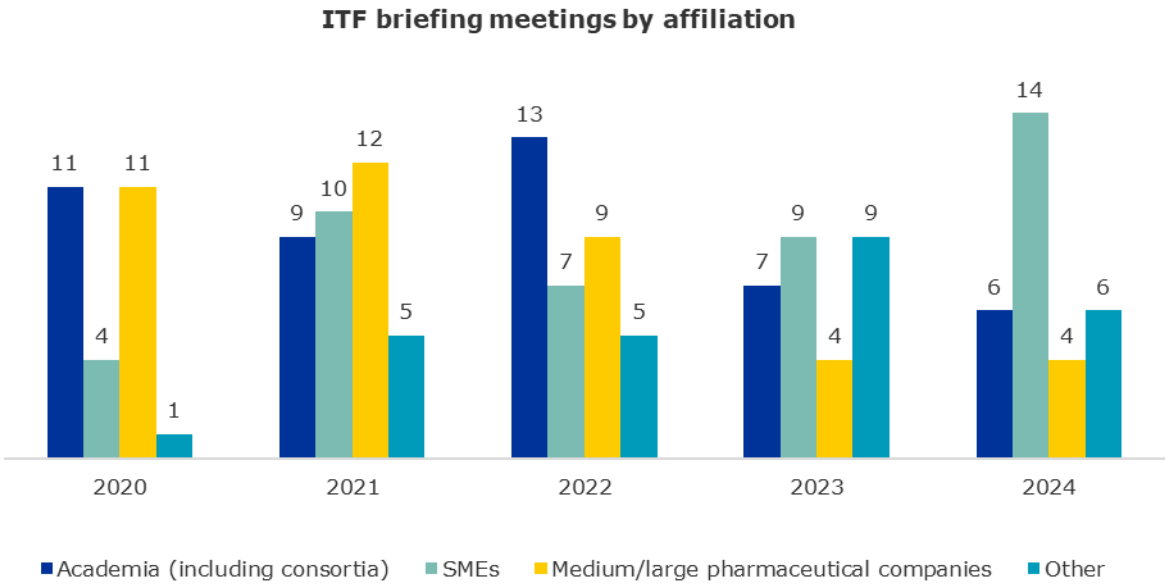
The Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety and efficacy of ATMPs. It prepares a draft opinion on each ATMP application before the CHMP adopts a final opinion for the medicine concerned. The CAT also reviews requests for the certification of quality and

non-clinical data for SMEs developing ATMPs and provides scientific recommendations on the classification of a medicine as an ATMP.



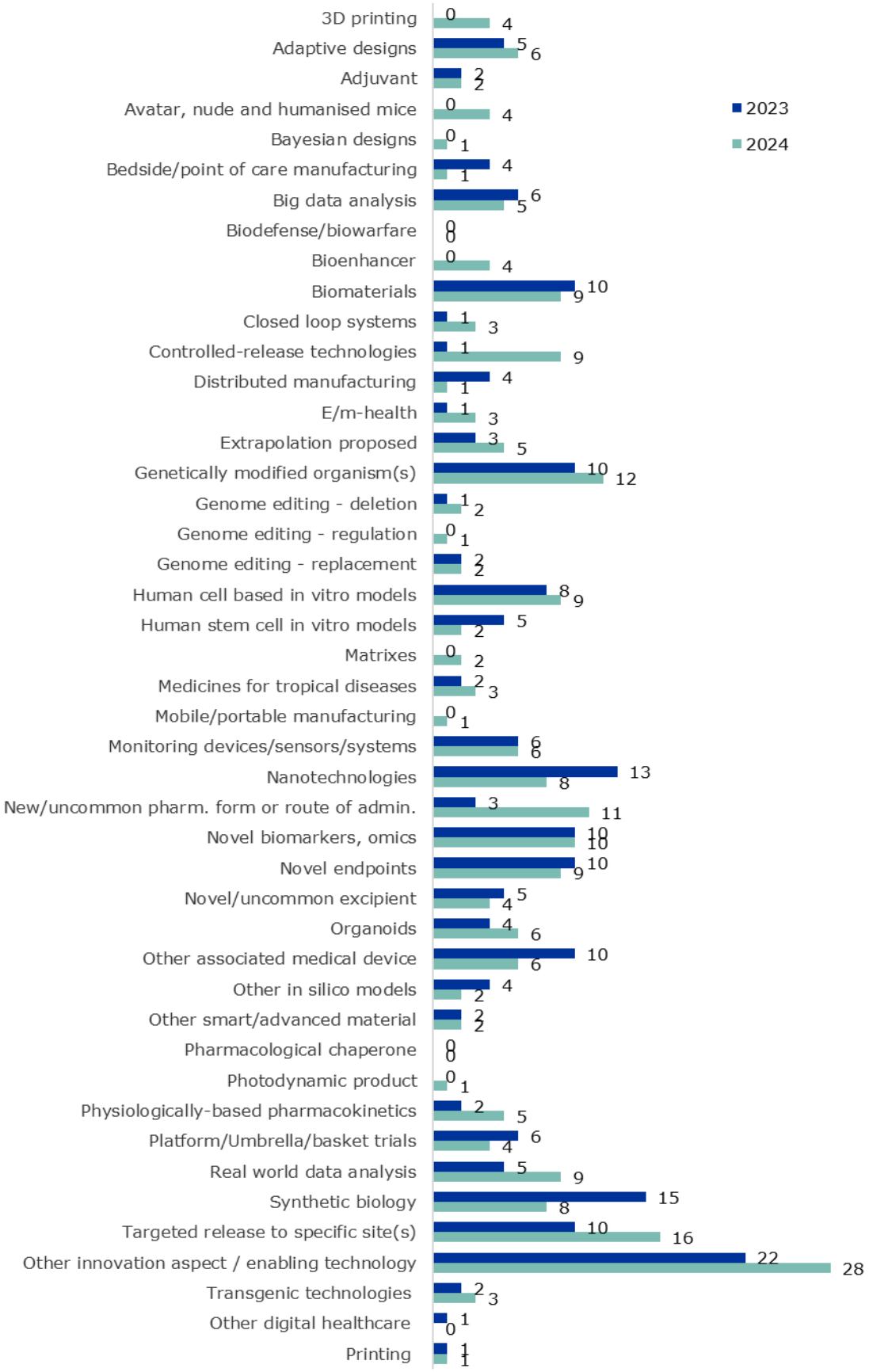
Innovation Task Force

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:

Enabling technology

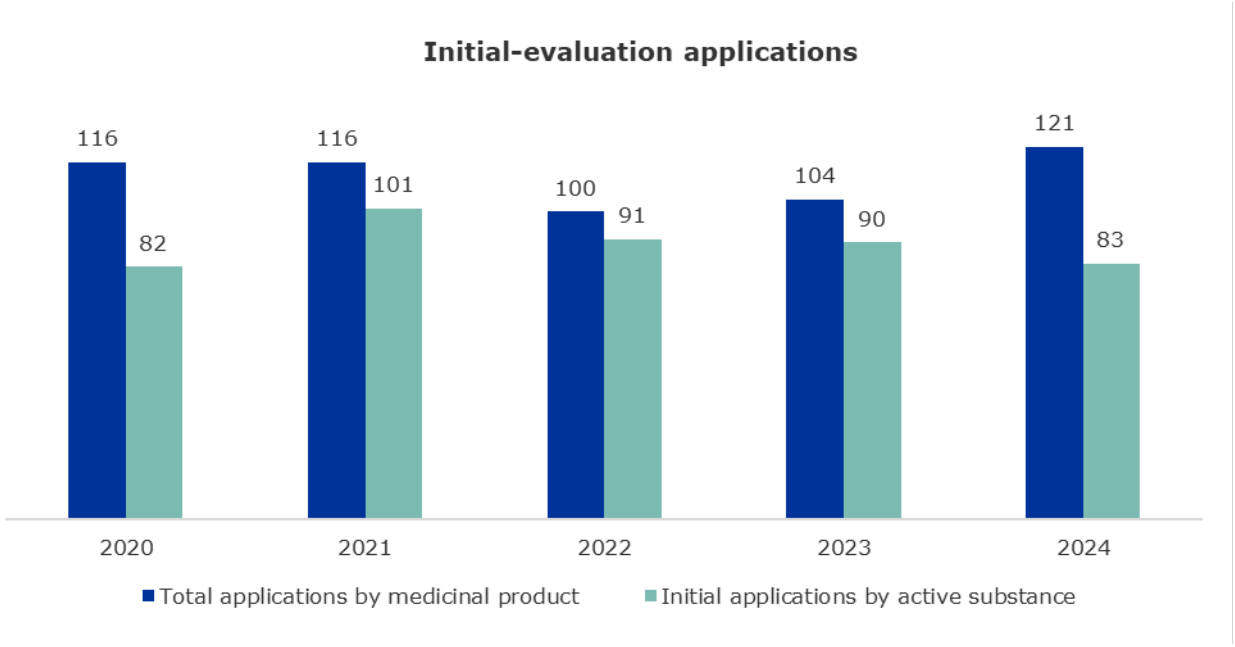


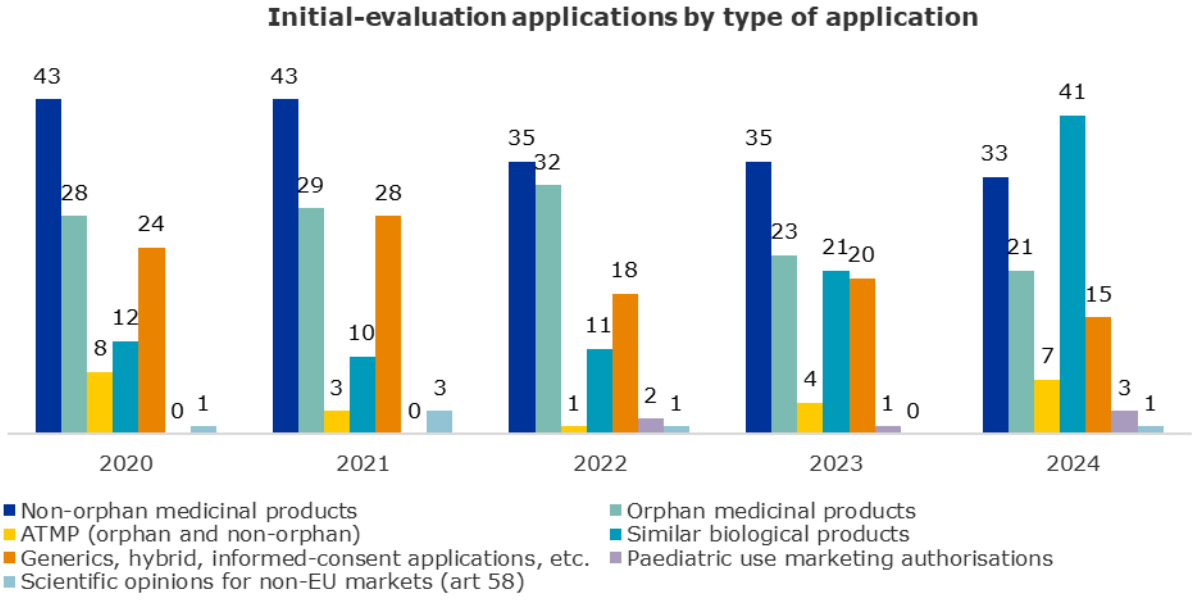
Recommendations for marketing authorisation

Applications for initial evaluation

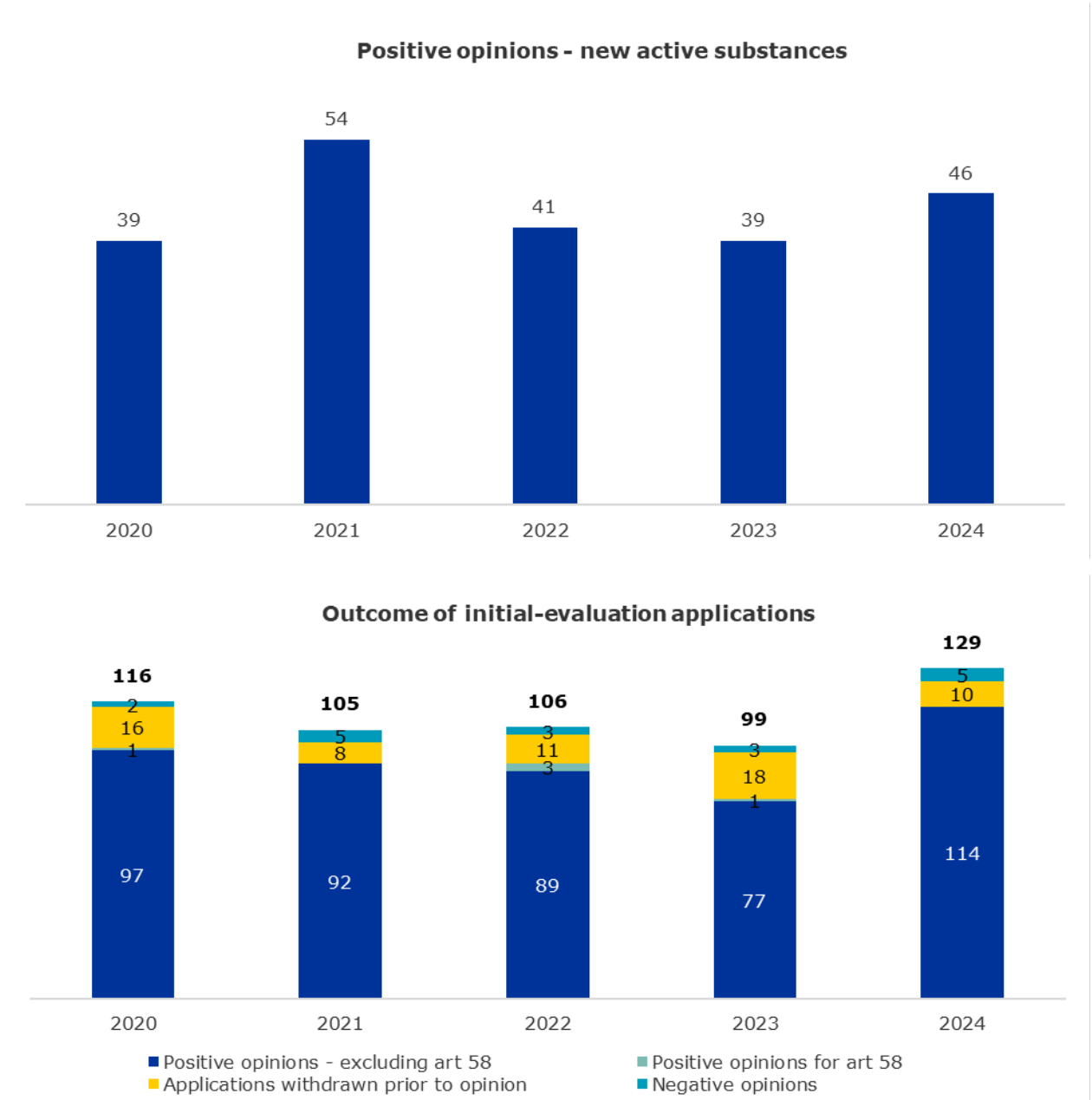
EMA's committee for human medicines, the CHMP, carries out robust scientific evaluations of medicines and issues recommendations for the European Commission, which ultimately decides whether or not to authorise a medicine for marketing throughout the EU.

Activities in the initial evaluation of marketing authorisation applications for new medicines which have never been authorised before range from the pre-submission discussion with future applicants, through to the evaluation by the CHMP and the granting of the marketing authorisation by the European Commission.





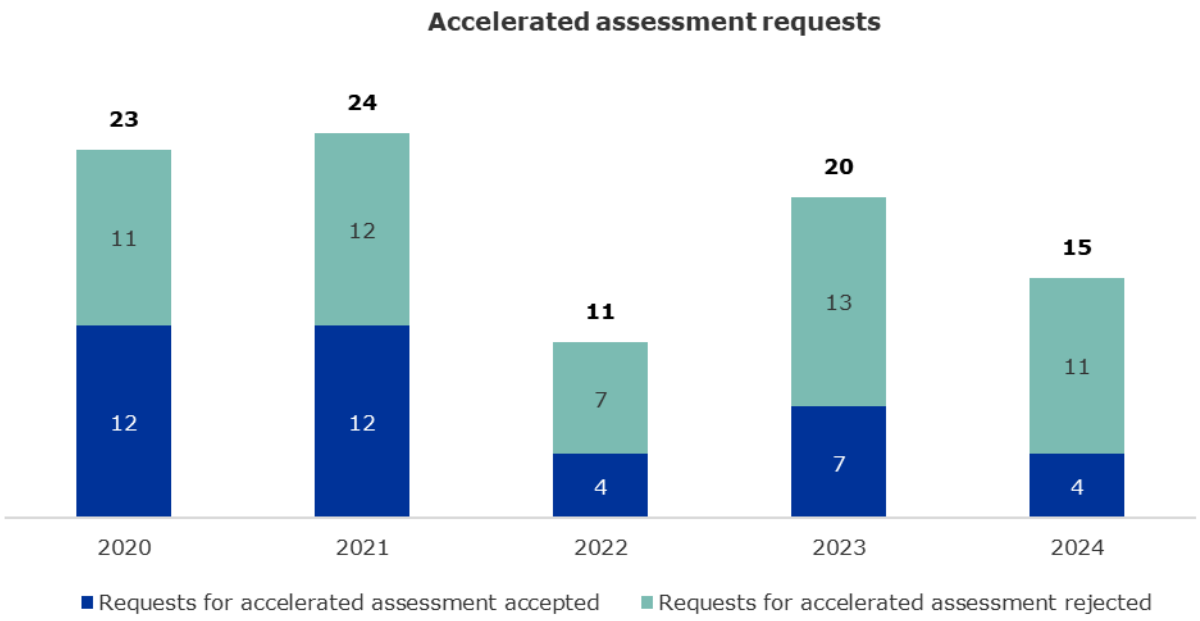
Outcome of initial evaluation



Conditional marketing authorisation and switch to standard marketing authorisation (excluding withdrawals)					
	2020	**2021**	**2022**	**2023**	**2024**
Positive opinions for CMAs	13	13	9	8	8
Opinions recommending switch of CMA to standard marketing authorisation	2	1	14	6	5
Opinions recommending revocation/non-renewal of MA	0	0	0	2	2

Accelerated assessment

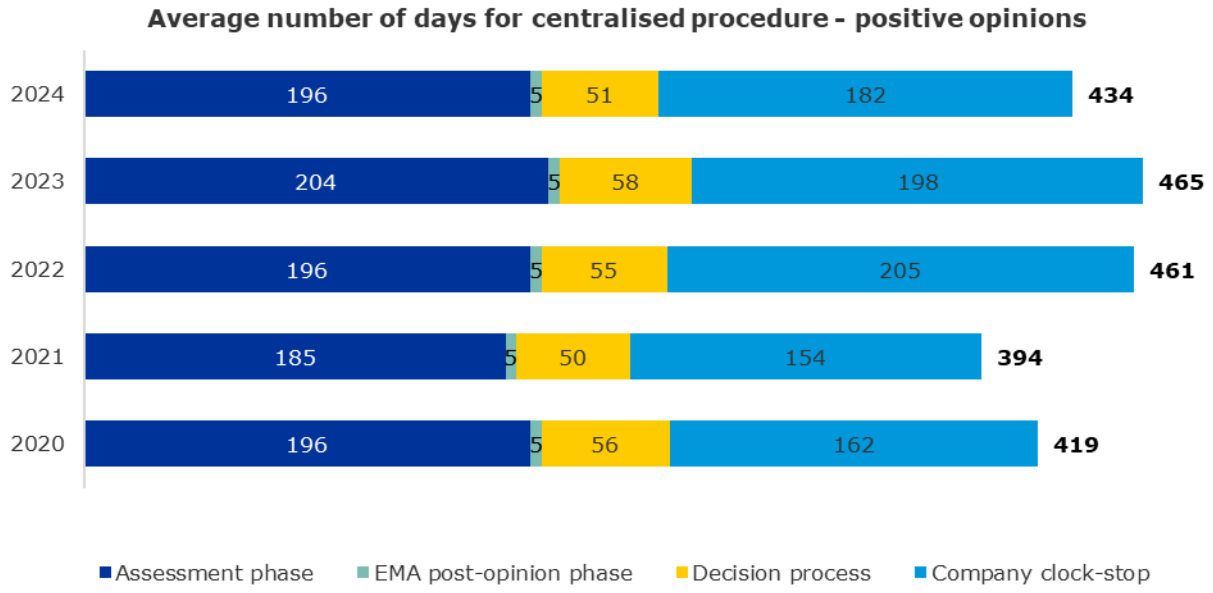
This mechanism is reserved for medicines that can address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees.

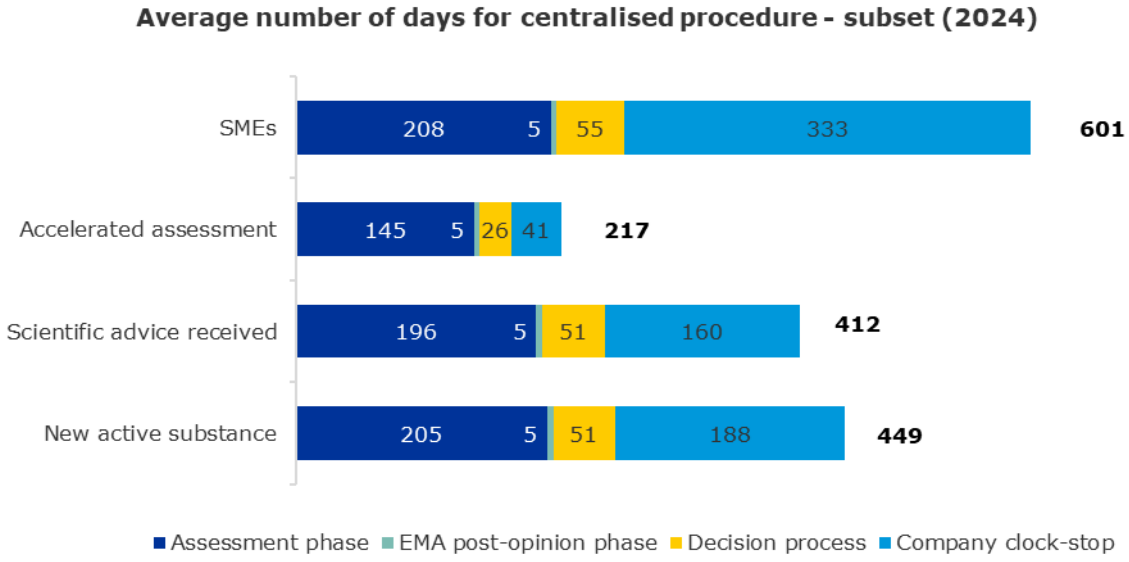


Average assessment time

EMA has a maximum of 210 active days 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, concerns with the application may be identified 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, the counting of the days continues.

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.





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.

Post-authorisation activities

In 2024, EMA started the evaluation of:

- 3,931 type-IA variations;
- 3,323 type IB variations;
- 1,333 type-II variations;

- 33 extensions of marketing authorisations.

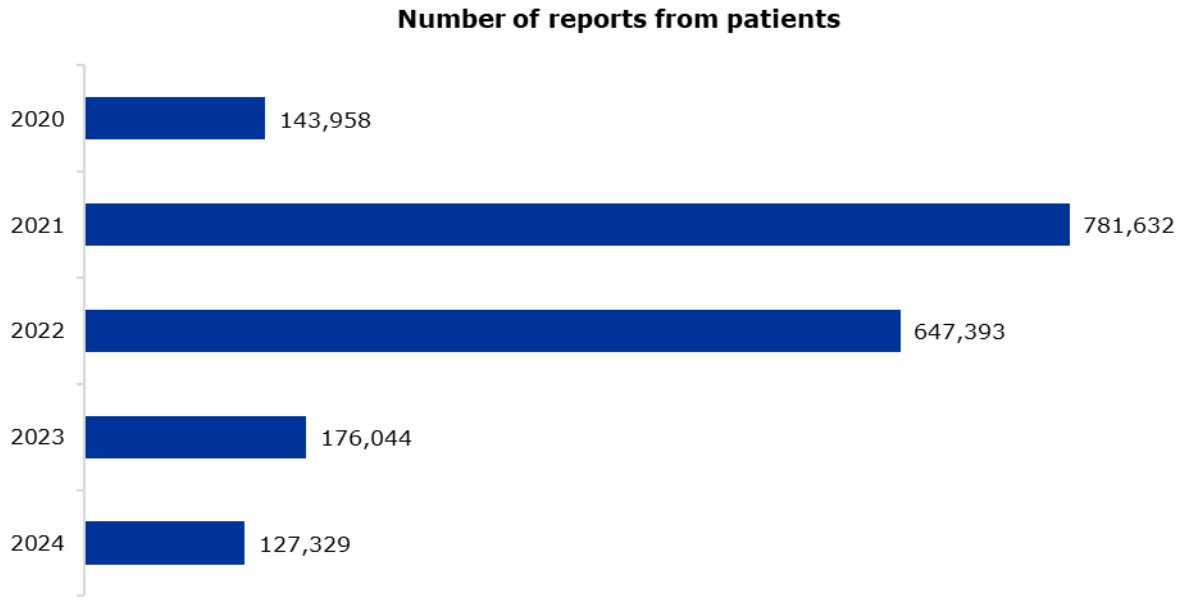
Safety monitoring of medicines

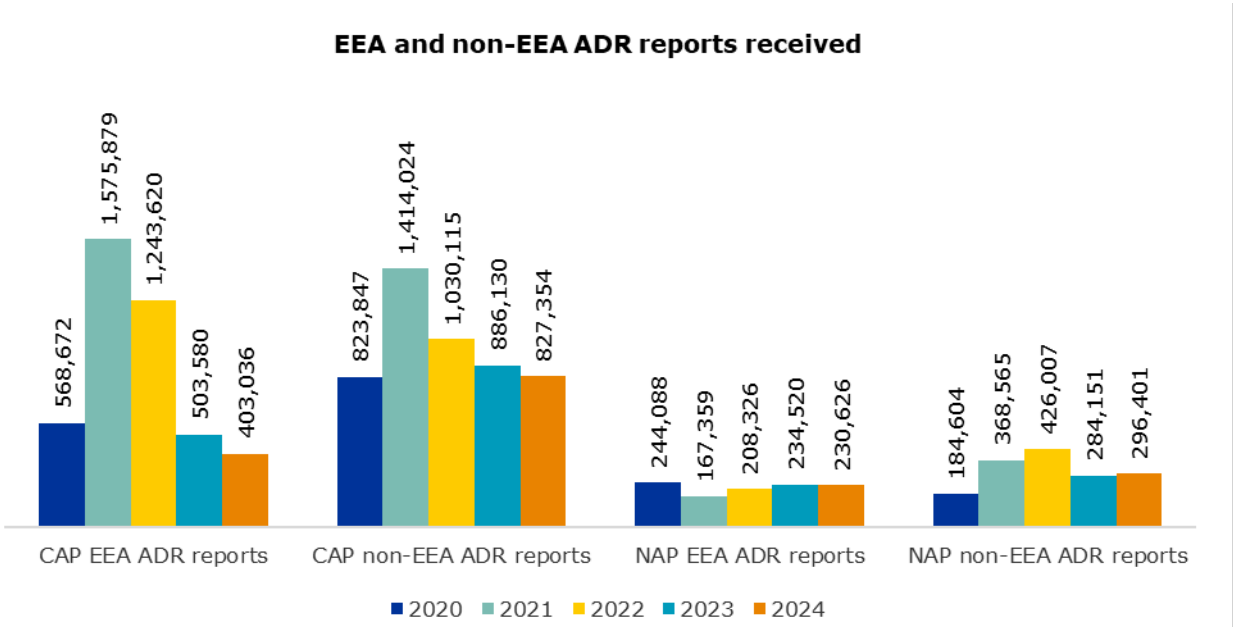
EMA and EU Member States are responsible for coordinating the EU's safety monitoring of medicines, also known as pharmacovigilance. Regulatory authorities constantly monitor the safety of medicines and can take action if there is plausible evidence that a medicine's safety profile or benefit-risk balance 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.



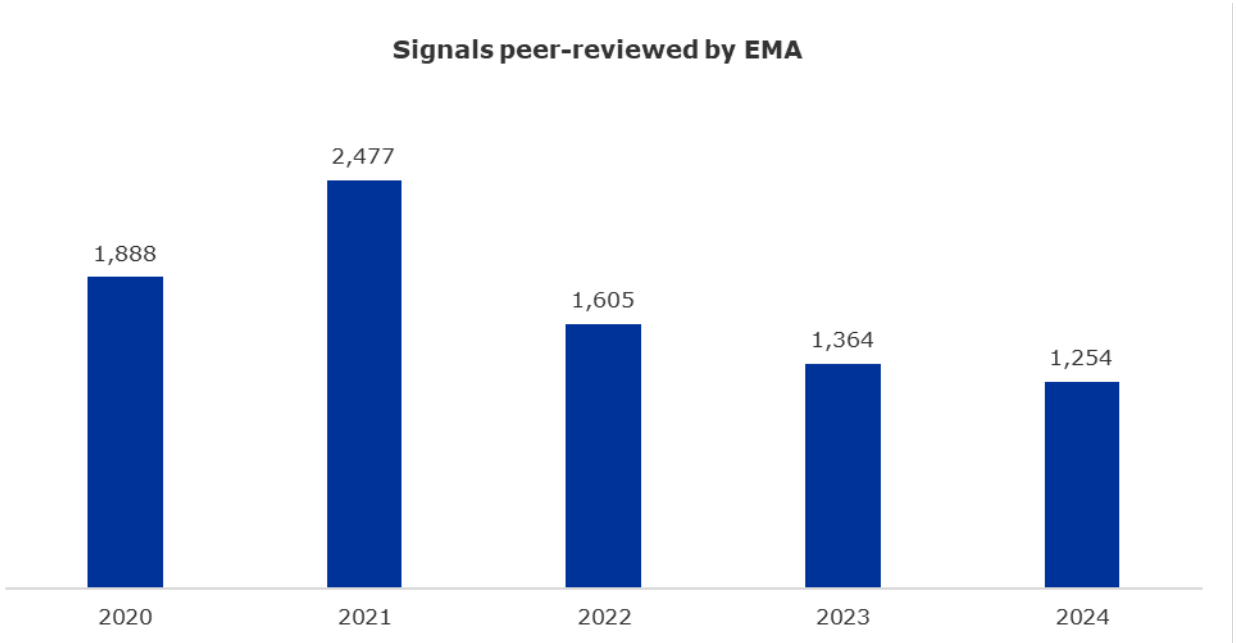


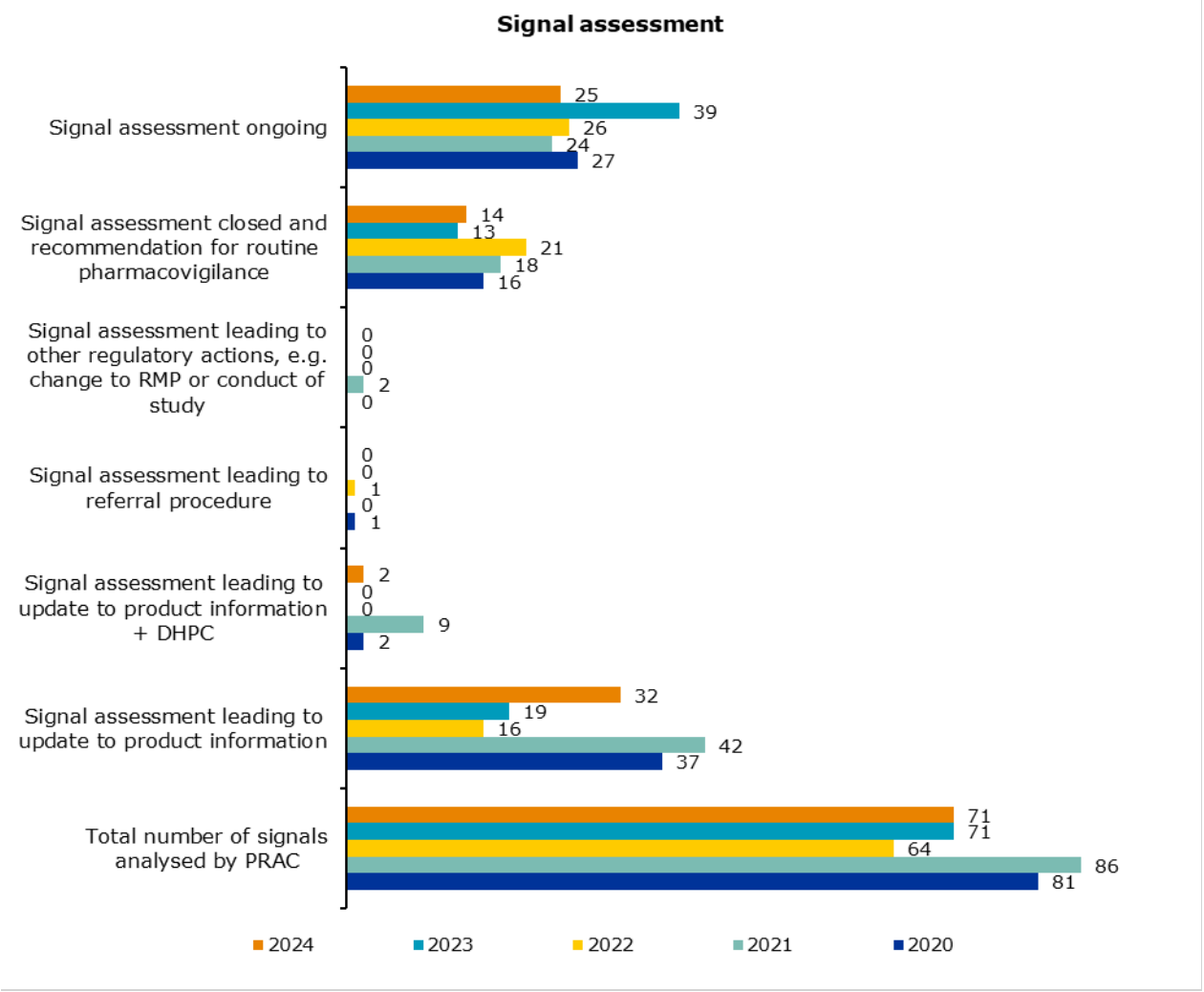
Total 2024: 1,757,417

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).





Signal assessment ongoing: Data from previous years (2020-2023) are all related to the situation at data cut by the end of each calendar year.

Outcome of signal assessment	2024
Signals peer-reviewed by EMA	1,254
Signals assessed by PRAC (validated by EMA)	39
Signals assessed by PRAC (validated by Member States)	32
Signal assessment leading to update to product information + DHPC	2
Signal assessment closed and recommendation for routine pharmacovigilance	14
Signal assessment ongoing	25

Periodic safety update reports (PSURs)

Marketing authorisation holders are required to submit a report on the evaluation of a medicine's benefit-risk balance 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 all studies carried out with it, 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					
	2020	**2021**	**2022**	**2023**	**2024**
PSURs standalone (CAPs only) finalised	516	575	542	570	627
PSURs single assessment finalised	258	336	318	276	283
PSURs single assessment (CAPs with NAPs) finalised	49	49	46	37	49
PSURs single assessment (NAPs only) finalised	209	287	272	239	234
Total outcomes	774	911	860	846	910

PRAC outcomes of PSURs and PSUSAs					
	2020	**2021**	**2022**	**2023**	**2024**
Maintenance	630	748	720	718	735
NAPs only	161	226	216	196	176
CAPs/NAPs and CAPs only	469	522	504	522	559
CHMP Variation	144	163	140	128	178
NAPs only	48	61	56	43	68
CAPs/NAPs and CAPs only	96	102	84	85	110
Total outcomes	774	911	860	846	913

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 safety studies					
	2020	**2021**	**2022**	**2023**	**2024**
Imposed PASS protocol procedures started	17 (4 PASS protocol + 13 PASS protocol follow up)	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)
Imposed PASS protocol procedures finalised	13 (2 PASS protocol + 11 PASS protocol follow up)	23 (8 PASS protocol + 15 PASS protocol follow up)	16 (5 PASS protocol + 11 PASS protocol follow up)	14 (2 PASS protocol + 12 PASS protocol follow up)	8 (4 PASS protocol + 4 PASS protocol follow up)
Non-imposed PASS protocol procedures started	158	143	217	189	129
Non-imposed PASS protocol procedures finalised	167	226	233	234	137
PASS amendment - started	19 (started), 14 (finalised) + 9 follow up amendments (started) and 7 (finalised)	17 (started), 18 (finalised) + 15 follow up amendments (started) and 11 (finalised)	20 (started), 18 (finalised) + 12 follow up amendments (started) and 14 (finalised)	21 (8 PASS amendment + 13 PASS amendment follow up)	17 (8 PASS amendment + 9 PASS amendment follow up)
PASS amendment - finalised				26 (13 PASS amendment + 13 PASS amendment follow up)	14 (6 PASS amendment + 8 PASS amendment follow up)
Imposed PASS result procedures started	4	11	2	7	5
Imposed PASS result procedures finalised	2	6	5	7	5
PASS scientific advice through SAWP	1	1	1	1	1

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 efficacy studies					
	2020	**2021**	**2022**	**2023**	**2024**
PAES (imposed)	8	8	10	13	10
PAES (non-imposed)	0	0	0	0	0

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.

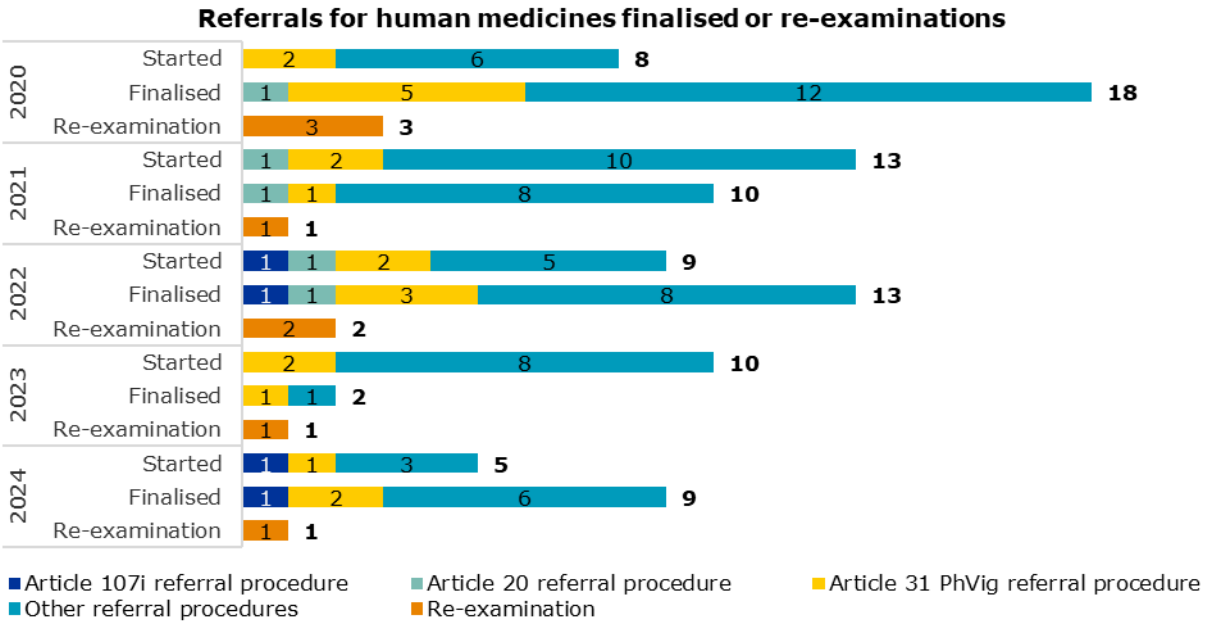
The European pharmacovigilance issues tracking tool (EPITT) is a database developed by EMA to promote the discussion of pharmacovigilance and risk-management issues between the Agency and Member States. It provides access to documents related to the safety of medicinal products/substances authorised 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	**2020**	**2021**	**2022**	**2023**	**2024**
Cumulative number of products on the list of products to be subject to additional monitoring	343	372	365	351	361
Number of Incident management plans triggered	6	4	2	0	1
Number of non-urgent information or rapid alert notifications submitted through EPITT	15	20	30	24	20
Number of external requests for EV analyses	15	30	16	14	20
Number of MLM ICSRs created	9,550	9,193	8,278	9,698	11,411

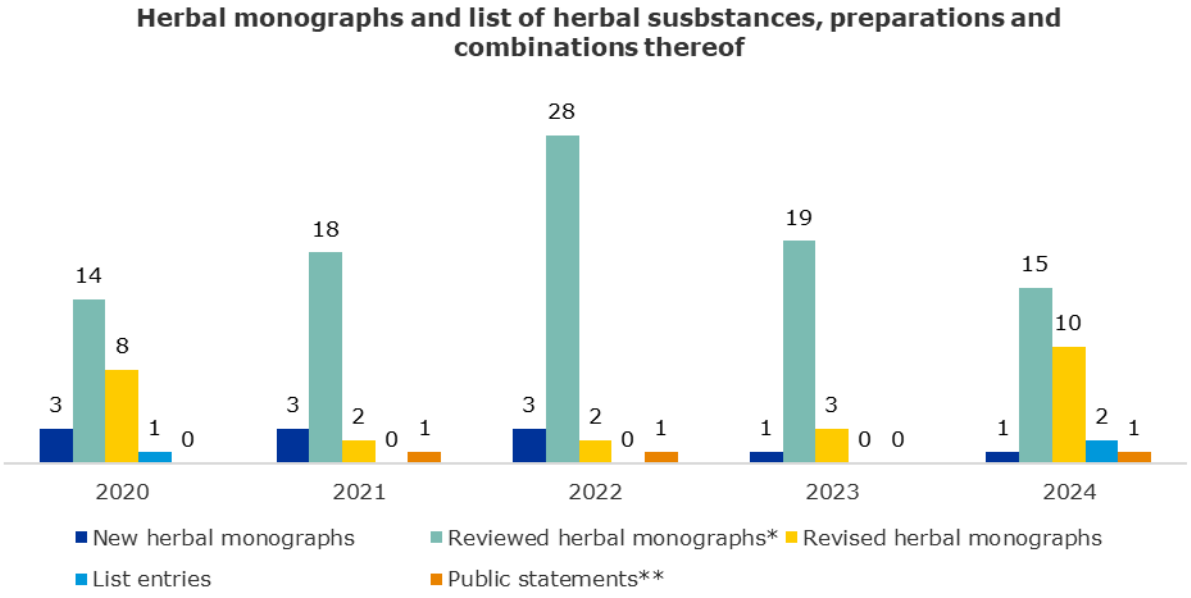
Referral procedures

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

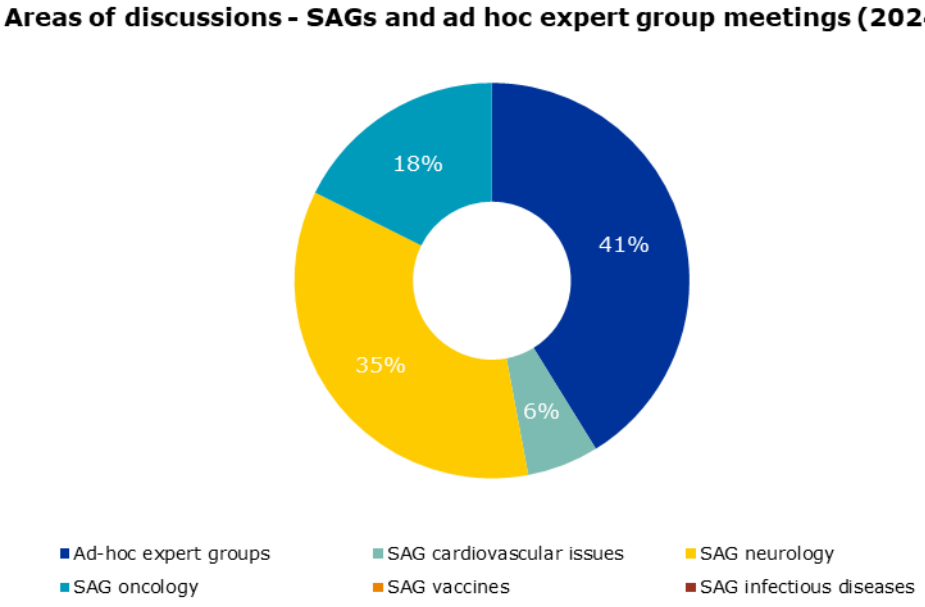
The Agency's Committee on Herbal Medicinal Products (HMPC) is responsible for preparing opinions on herbal medicines with the aim of promoting an increasingly harmonised process for licensing and information on herbal substances across the EU. The HMPC establishes EU monographs for traditional and well-established 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)					
	2020	**2021**	**2022**	**2023**	**2024**
Marketing authorisation (new MAA, new MAA re-examination, Art 58)	18	11	10	9	9
Extension of indication (including line extensions)	7	2	7	1	3
Referral (including re-examination)	0	1	2	3	3
Guideline	0	0	0	0	0
Other topics (renewal, orphan designation, PSUR, signal, class review)	3	1	0	5	2
Total	28	15	19	18	17

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 involvement in EMA activities					
	2020	**2021**	**2022**	**2023**	**2024**
Patient membership in MB, committees, working parties	57	56	57	60	62
EMA Management Board	2	2	2	2	2
Scientific committees	14	13	12	15	15
Patients' and Consumers' Working Party	41	41	43	43	45
Active patient experts nominated by EMA			80	163	186
Number of patients and consumers eligible organisations			42	43	41

Healthcare-professional involvement in EMA activities					
	2020	**2021**	**2022**	**2023**	**2024**
HCP membership in MB, committees, working parties	62	57	56	56	60
EMA Management Board	2	2	2	2	1
Scientific committees	12	12	12	12	12
Healthcare Professionals' Working Party	48	43	42	42	46
Active healthcare professionals experts nominated by EMA			140	87	84
Number of healthcare professionals eligible organisations			39	40	41

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.

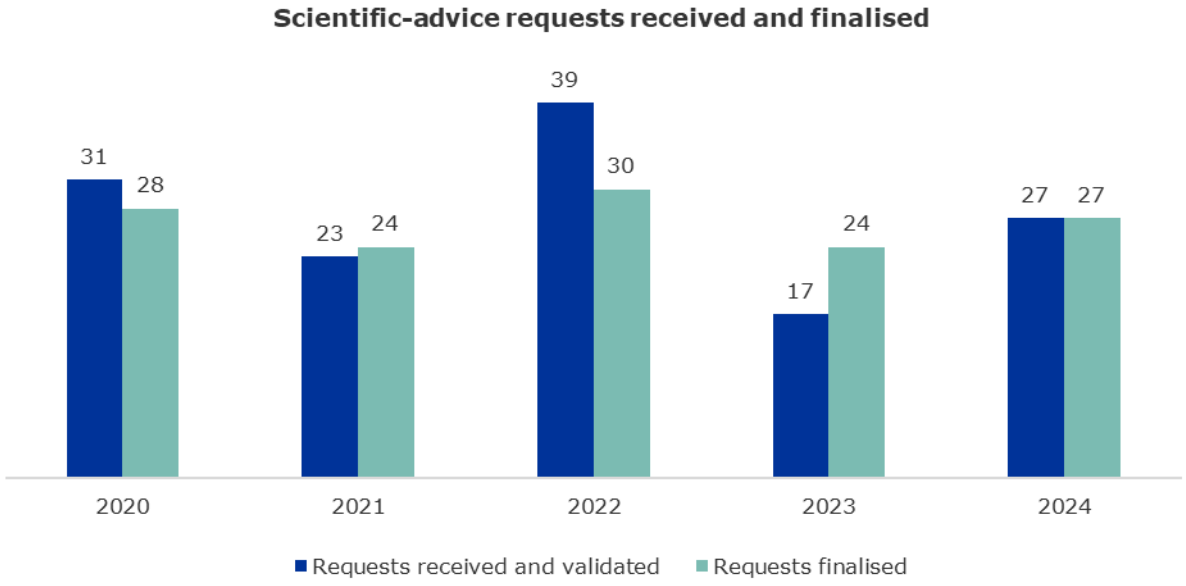
Detailed information about the work of the CMDh in 2024 in relation to pharmacovigilance and referrals can be found on the HMA website.

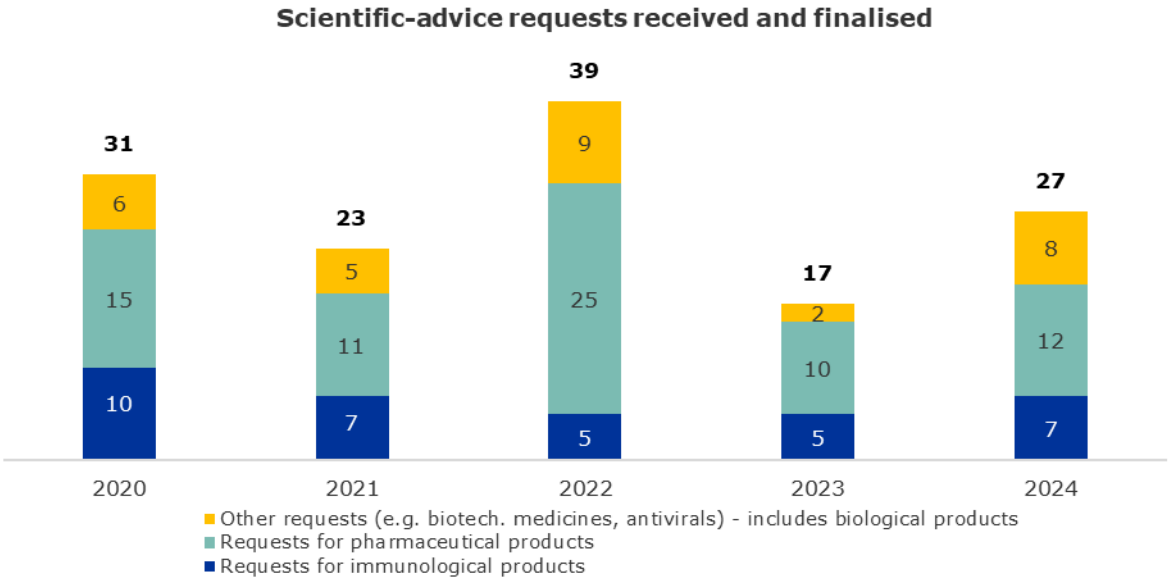
Veterinary medicines

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.

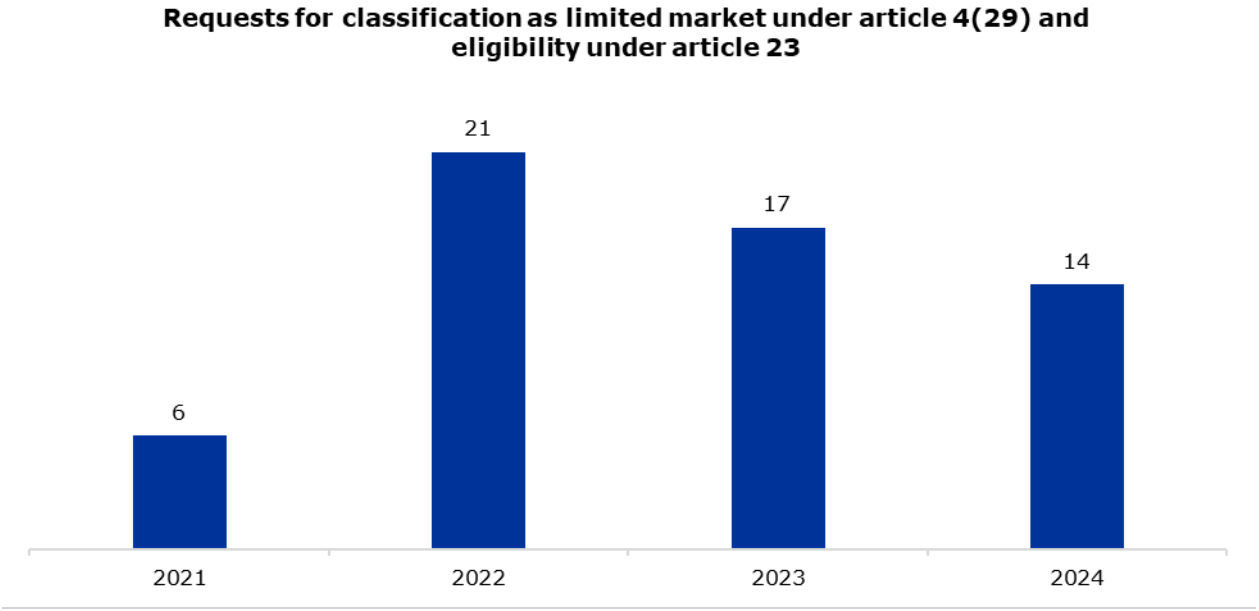




Veterinary limited markets

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.

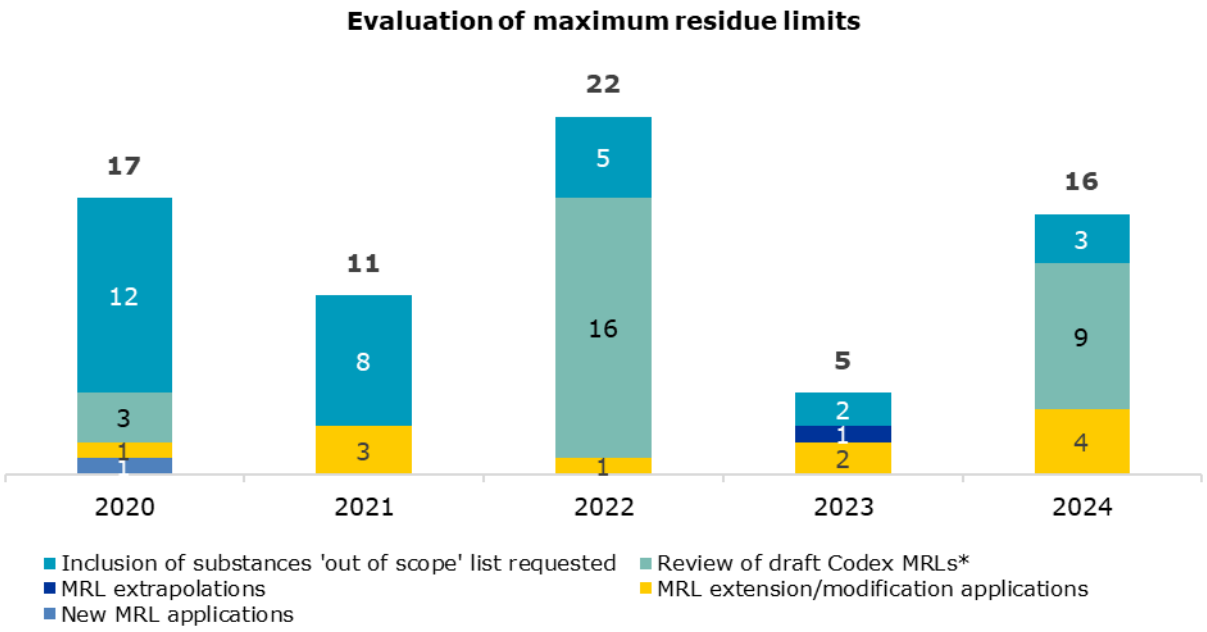


Innovation Task Force

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 2024, 11 meetings requests were received and 4 meetings were held with applicants.

Maximum residue limits

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.

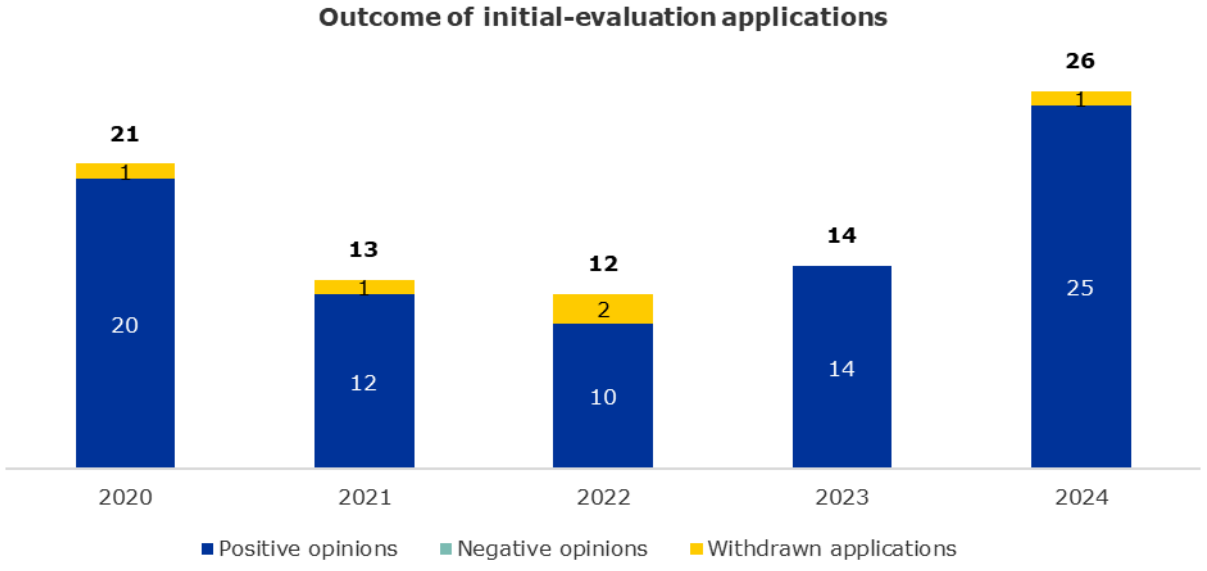


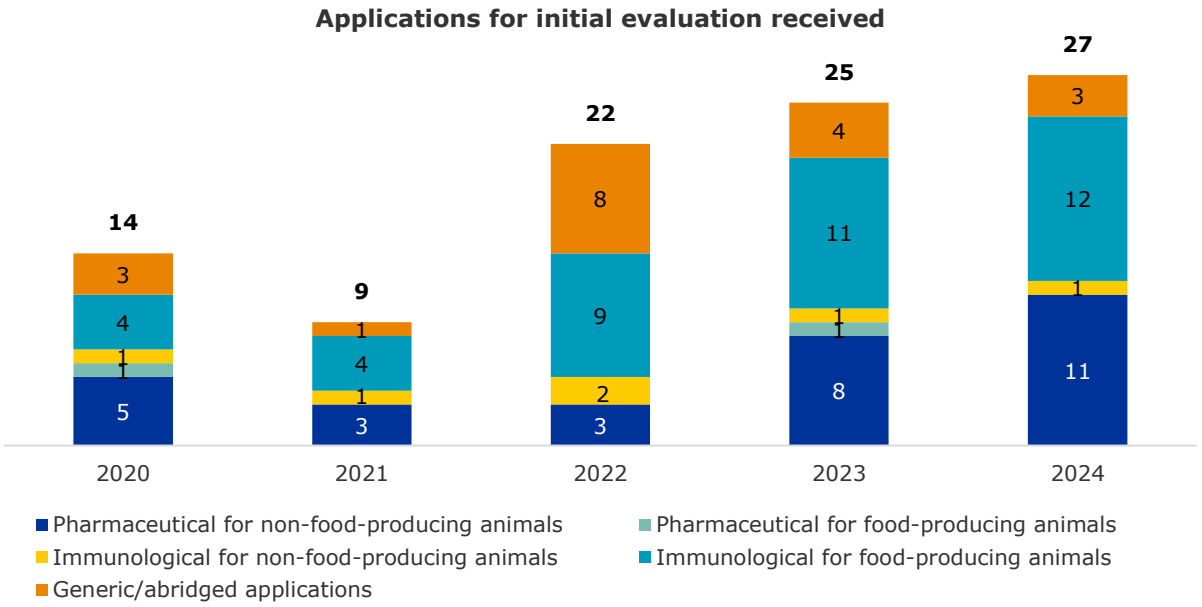
*From 2022, it also includes extrapolations.

Recommendations for marketing authorisation

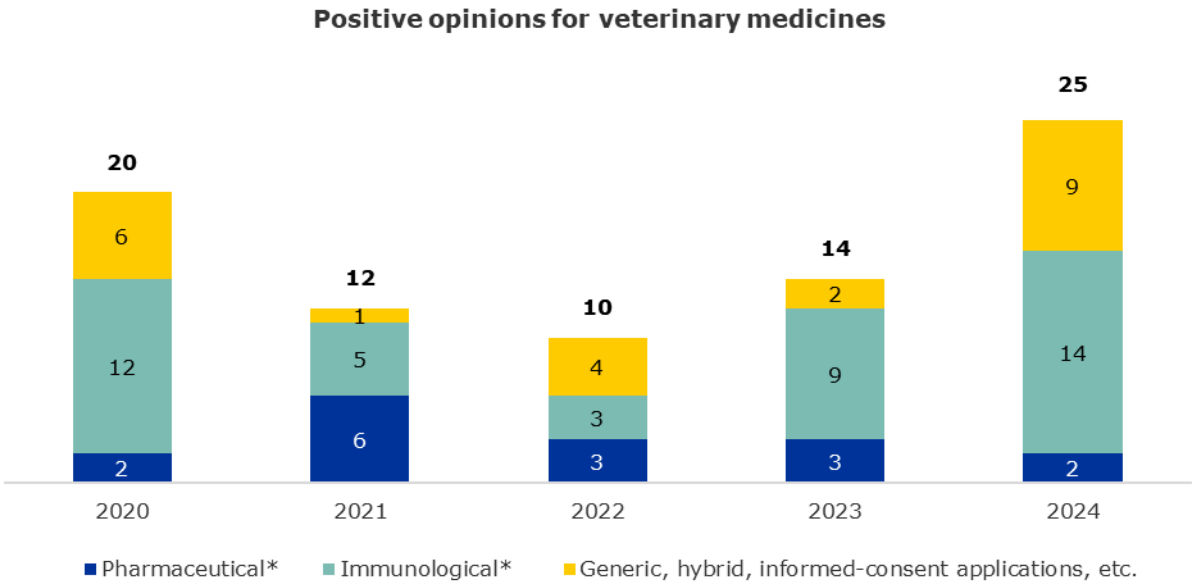
Applications for initial evaluation

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

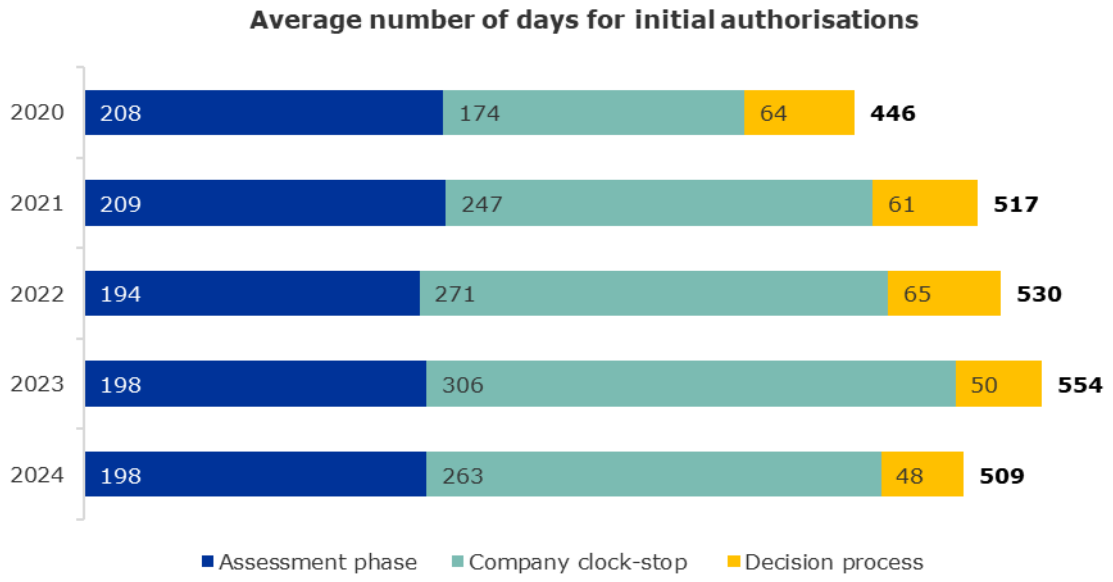




Recommendations for authorisation



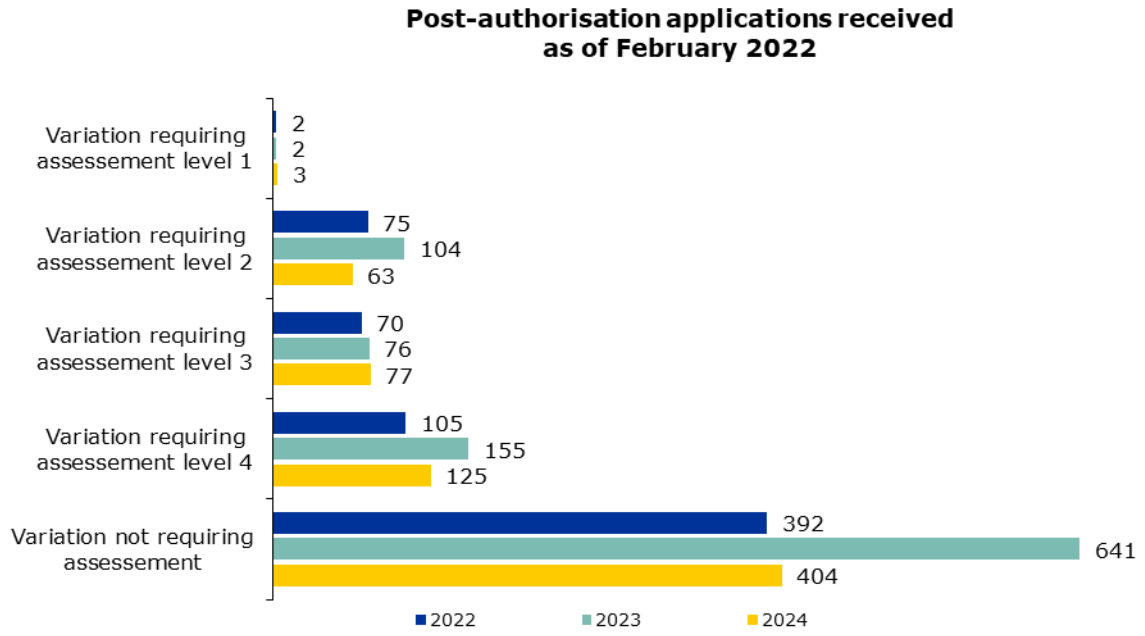
* if a product is generic/hybrid/informed consent this overruns any other feature (e.g., an immunological hybrid will be counted as 'hybrid' only)



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.



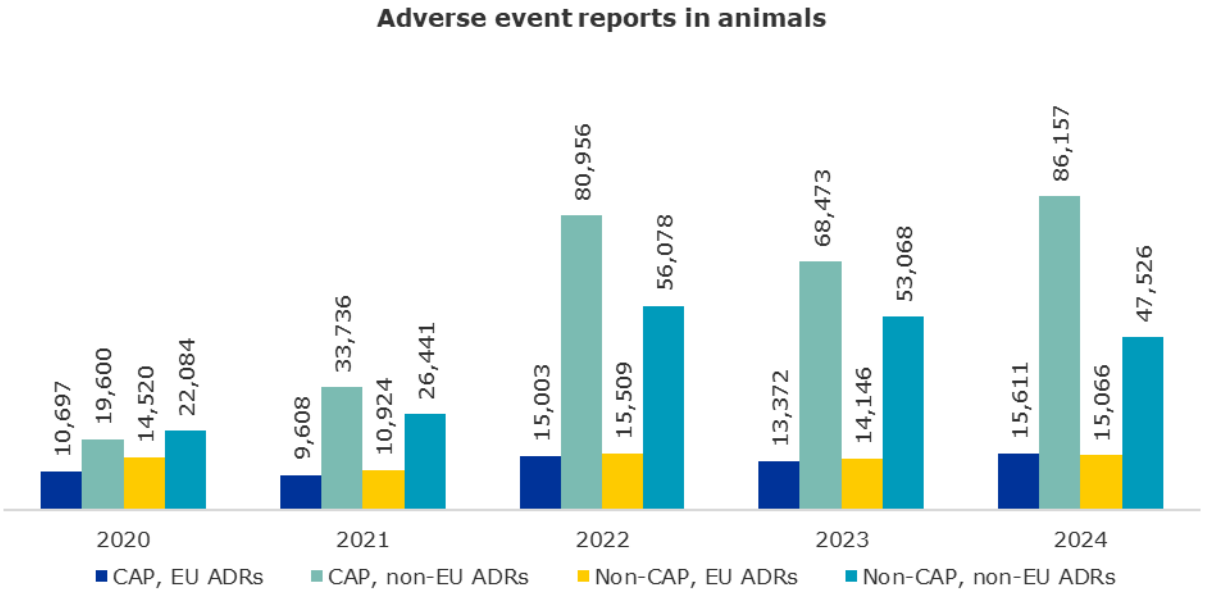
Total 2024: 672

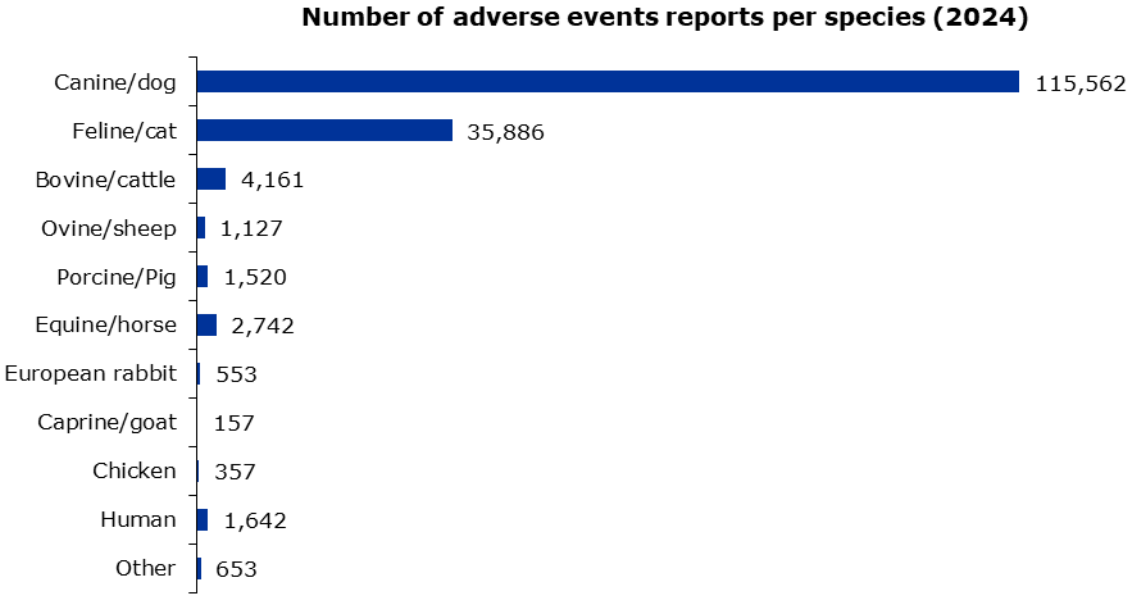
Safety monitoring of medicines

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).

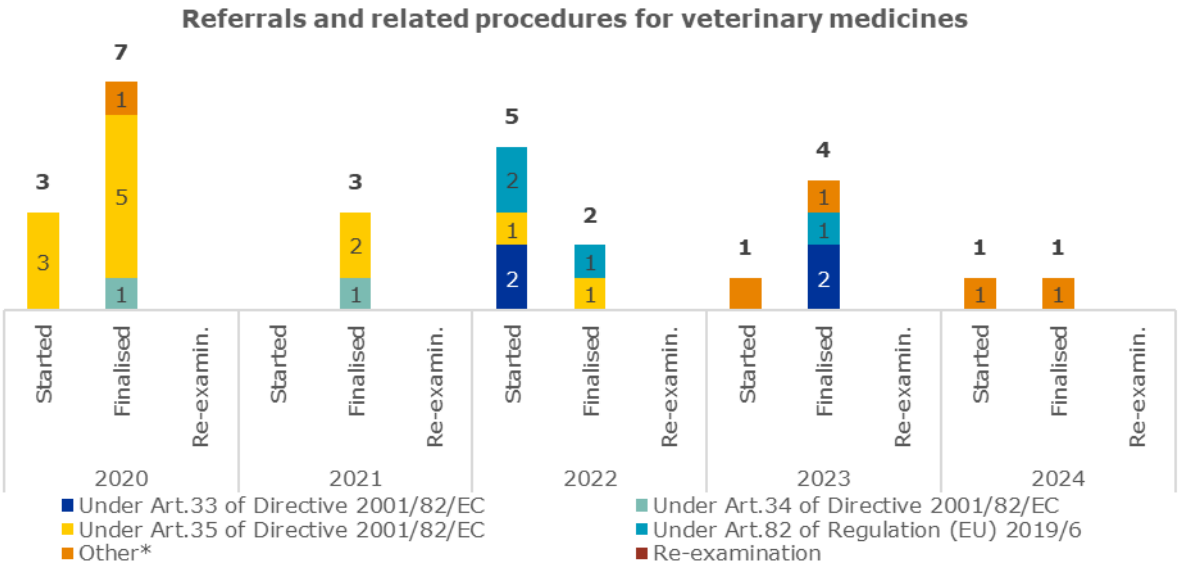




Total 2024: 164,360

Referral procedures

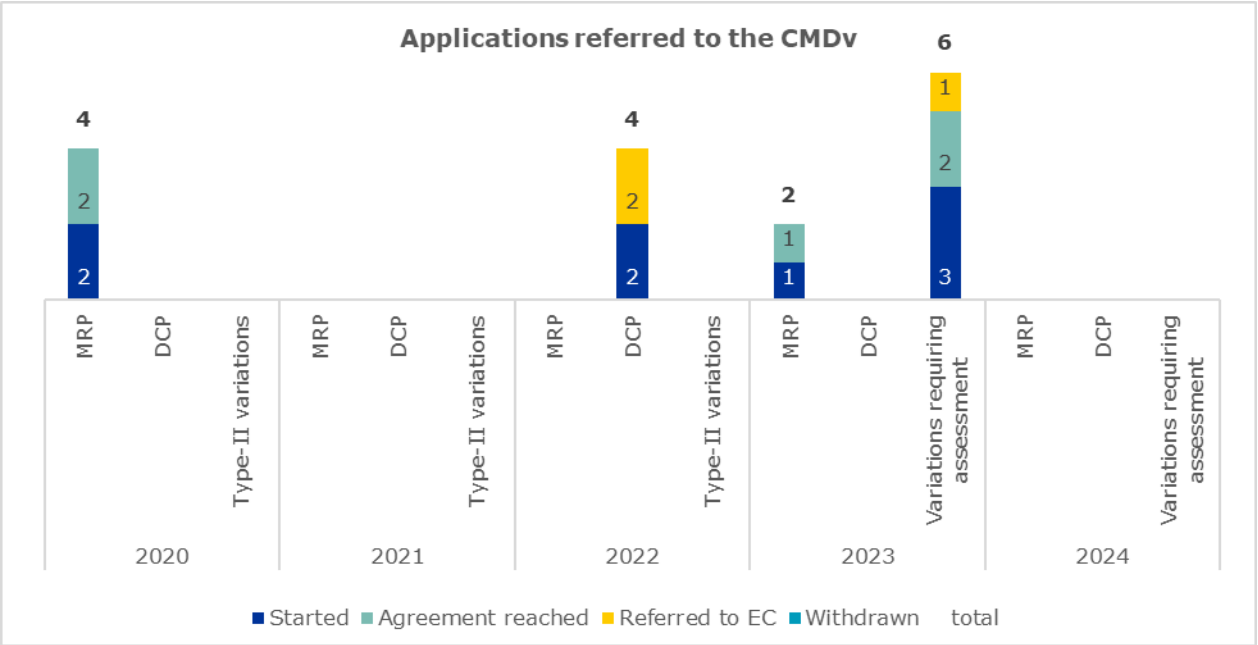
Referral procedures are used to address concerns over the quality, safety, efficacy or benefit-risk balance of a veterinary medicine, or disagreement among Member States on the use of a veterinary medicine. In a referral, the Agency is requested, on behalf of the EU, to conduct a scientific assessment 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.



No applications referred to the CMDv in 2024.

Inspections and compliance

In the European medicines regulatory network, the responsibility for carrying out inspections rests with EU NCAs, but EMA plays an important role. The Agency coordinates 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 by request of the CHMP or CVMP in the context of the assessment of marketing authorisation applications and/or matters referred to these committees in accordance with EU legislation.

EMA coordinates an inspection programme at the EU level to verify compliance with the principles of GMP, GCP and pharmacovigilance. It 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 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.

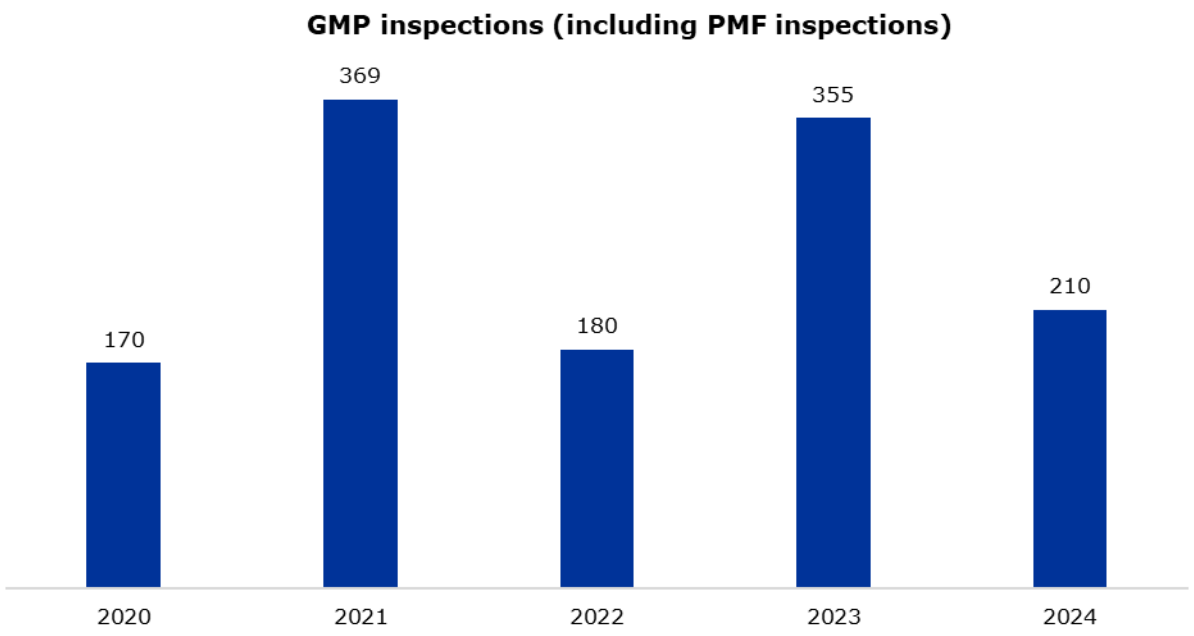
EMA promotes mutual reliance and work-sharing with other international authorities to ensure the best use of resources. For GMP inspections, there are several mutual recognition agreements in place.

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 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

CHMP and 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

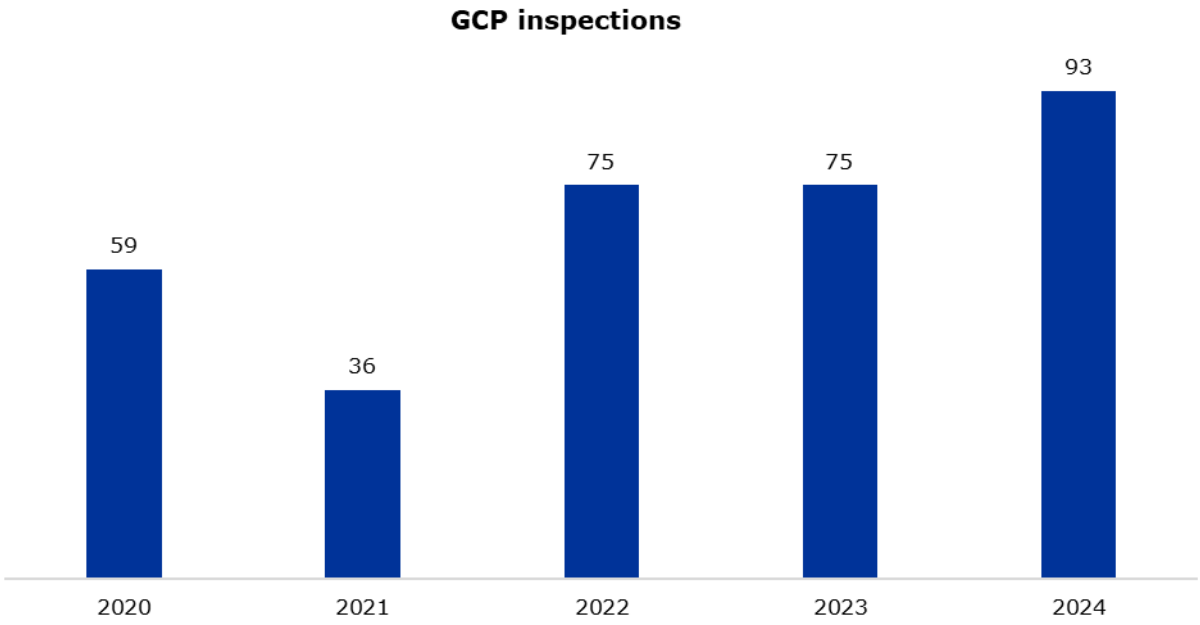


GMP certificates and non-compliance statements issued by EEA authorities

	2020		2021		2022		2023		2024	
	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	1,695	1	1,825	5	1,730	2	1,857	2	1,634	4
China	11	0	24	0	15	0	44		53	1
India	64	0	29	0	81	2	101	4	105	5
USA	35	0	52	0	118	0	155		165	0
Rest of the world	38	0	52	0	187	2	231	1	153	0
Total	1,843	1	1,982	5	2,131	6	2,388	7	2,110	10

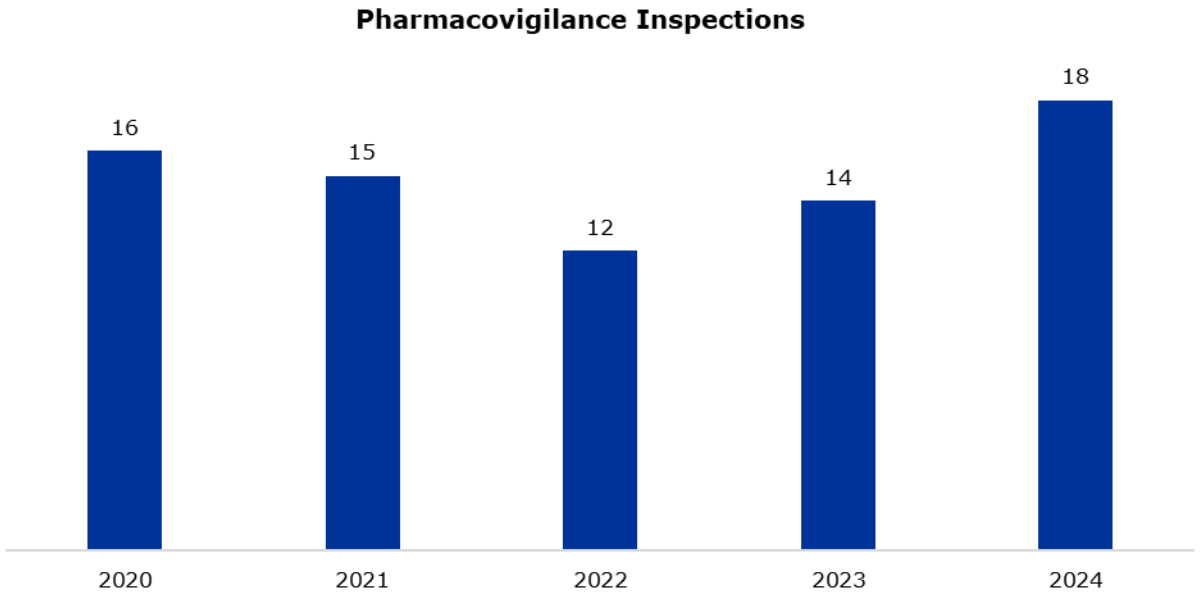
Note: This table shows the number of GMP certificates and non-compliance statements issued by EEA authorities as an outcome of GMP inspections conducted between 2020 and 2024. It includes GMP inspections requested by the CHMP or the CVMP.

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 CVMP and in inspection follow-up.



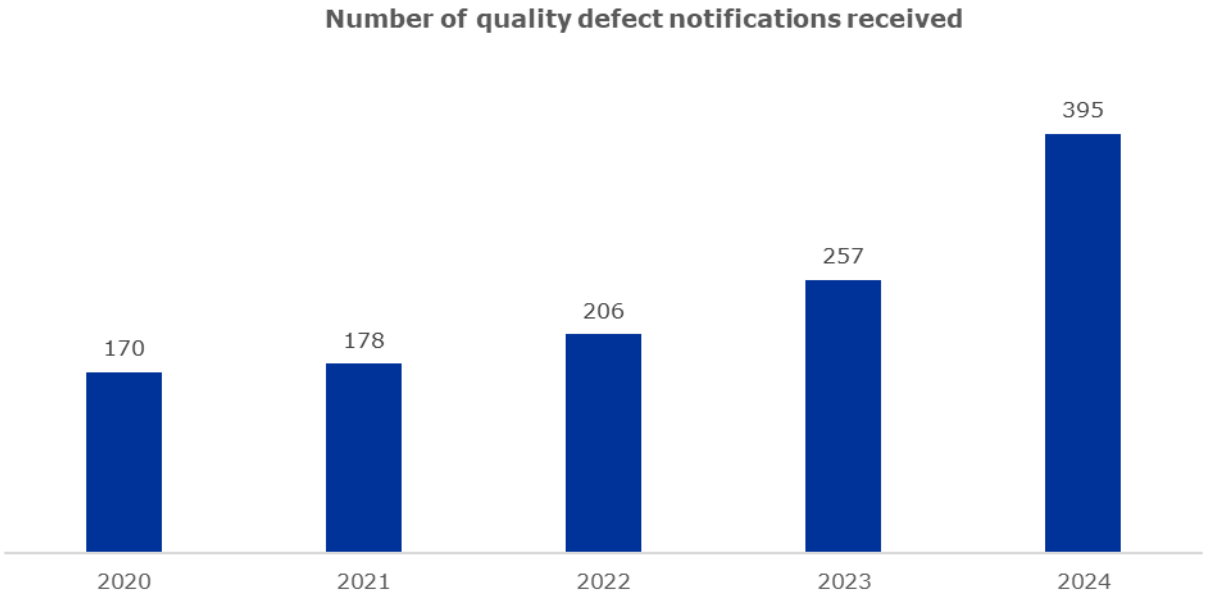
Market surveillance and quality defects

Manufacturers are required to inform authorities of quality defects in manufactured product. This can lead to a recall of batches from the market or 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.



Quality defects reported					
	2020	**2021**	**2022**	**2023**	**2024**
Quality defects confirmed cases		164	185	188	221
Recalls	15	10	11	9*	9
Class 1	3	1	2	0	0
Class 2	3	7	5	6	5
Class 3	9	2	4	2	4

* 1 recall not classified

Parallel distribution

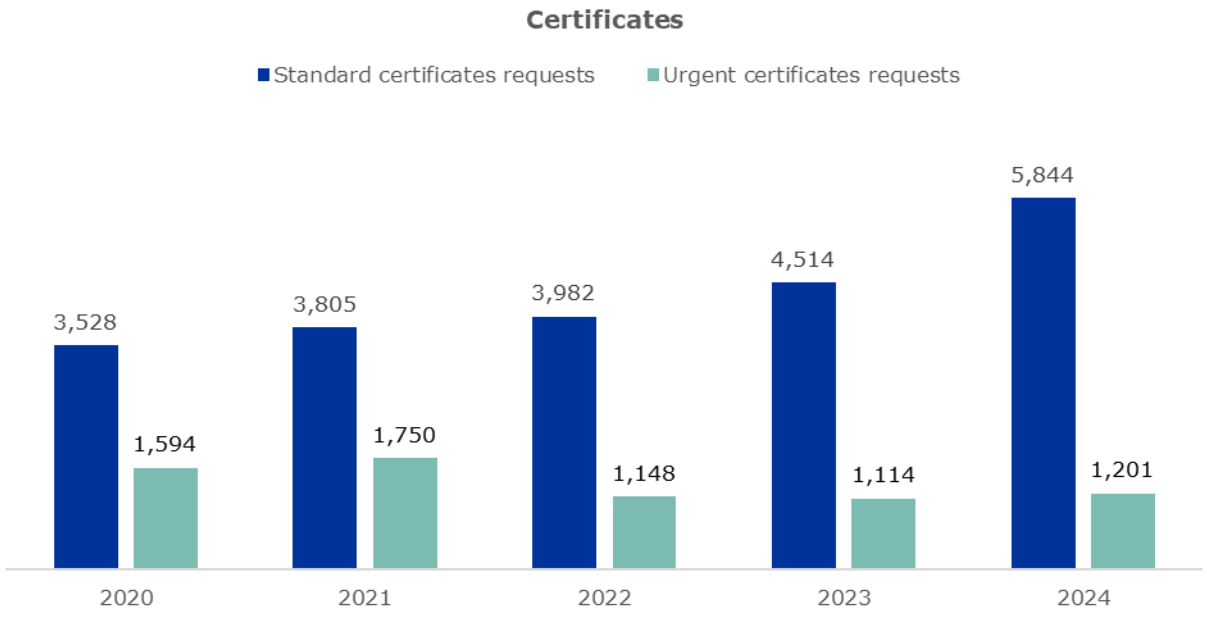
EMA checks that the parallel distribution of CAPs from one Member State to another by a company independent of the marketing authorisation holder is compliant with the rules.

Parallel distribution notifications received

	2020	2021	2022	2023	2024
Initial notifications	3,172	2,555	1,816	2,092	2,656
Notifications of change		0	0	0	0
Notifications of bulk change	10	19	32	21	18
Annual updates	11,624	4,816	5,509	5,477	5,691
Total	14,806	7,390	7,357	7,590	8,365

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 by expert panels on high risk Medical Devices

	2021	2022	2023	2024
Number of finalised screened applications for CECP	9	29	48	73
Number of finalised scientific opinions for Clinical Evaluation Consultation Procedures CECP	3	7	1	6
Number of finalised Performance Evaluation Consultations PECP	15	1	2	4
Number of finalised advice procedures to Medical Device Coordination Group MDCG			3	2
Number of finalised Scientific Advice Pilot procedures			3	17

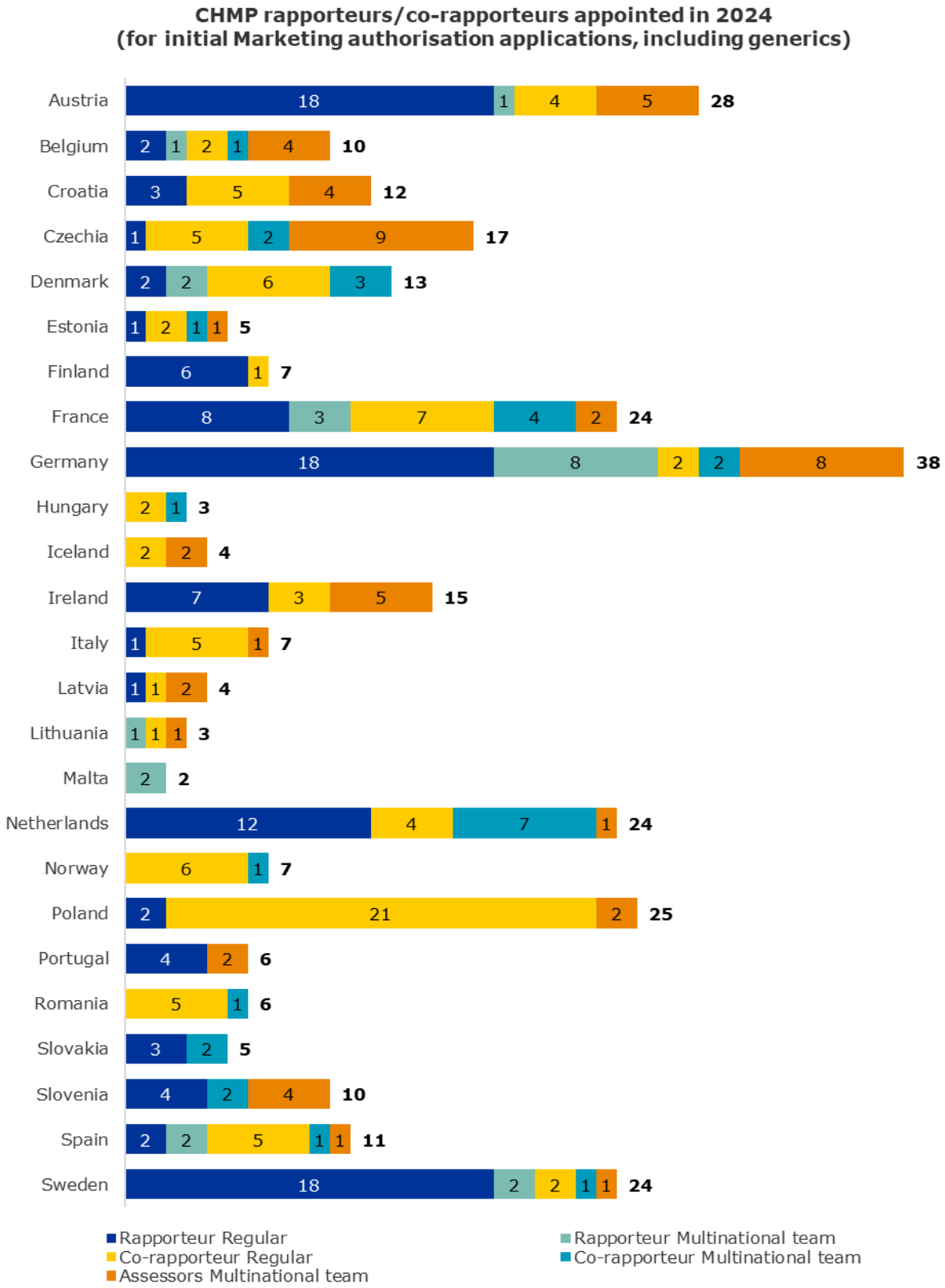
European medicines regulatory network

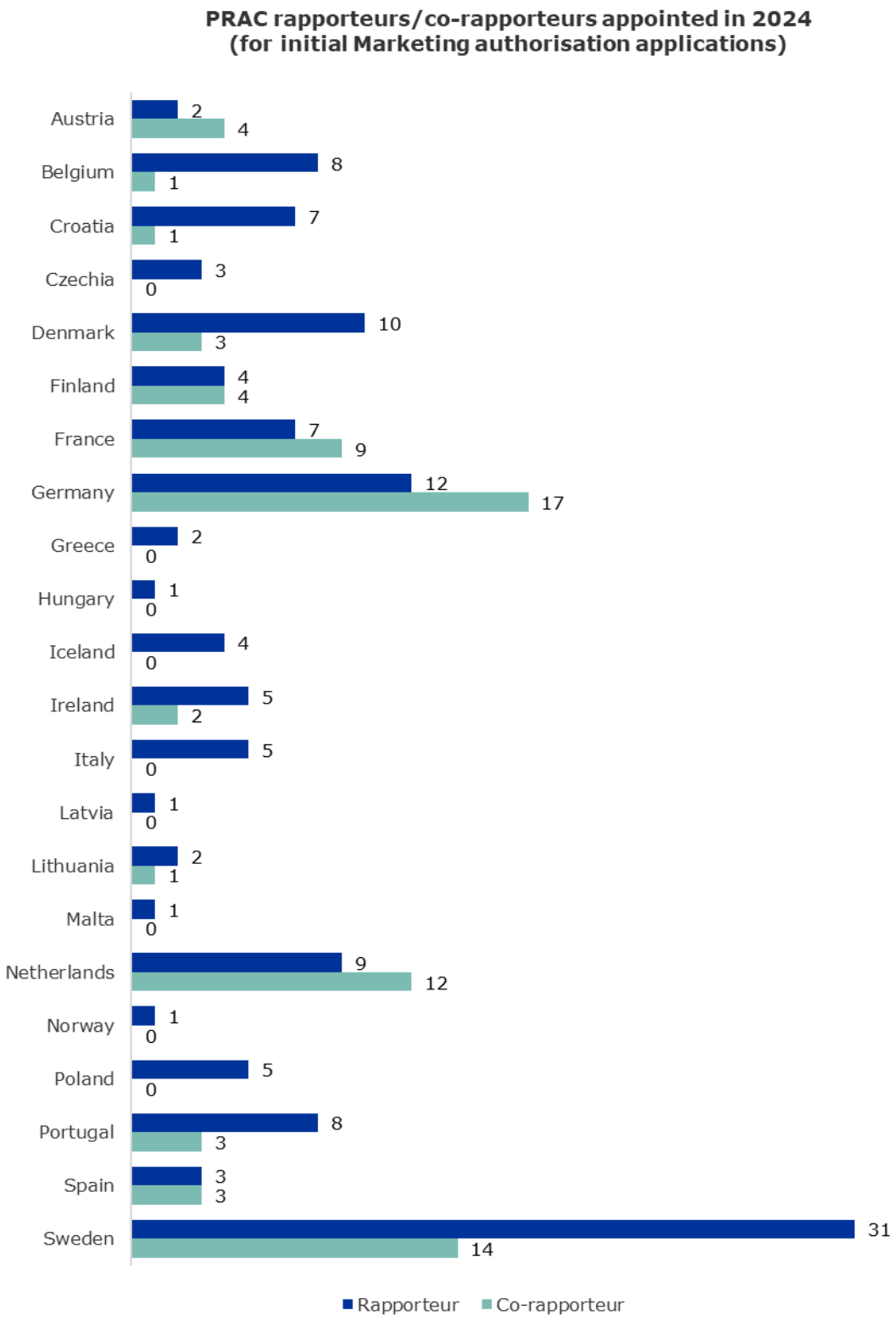
The European medicines regulatory network is the cornerstone of EMA's work and success. EMA plays a central role in this network, coordinating and facilitating collaboration between more than 50 national competent authorities across the EU and EEA for both human and veterinary medicines.

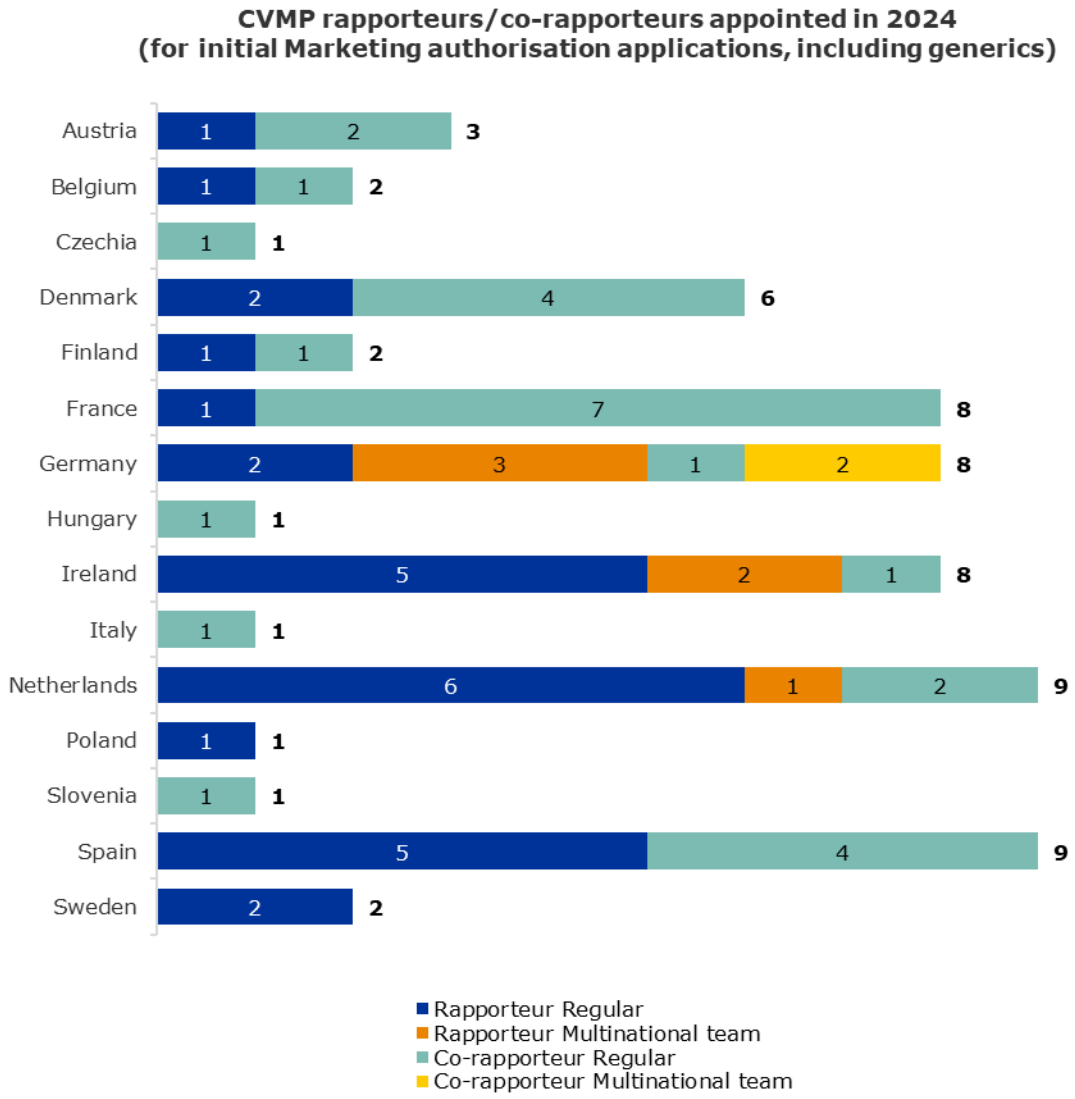
Through the network, EMA can draw from a pool of over 4,000 specialists, who provide the highest level of scientific expertise to the regulation of medicines in the EU. These experts contribute to EMA's scientific committees, working groups, and other bodies, and are also involved in the evaluation teams that carry out the evaluation of medicines.

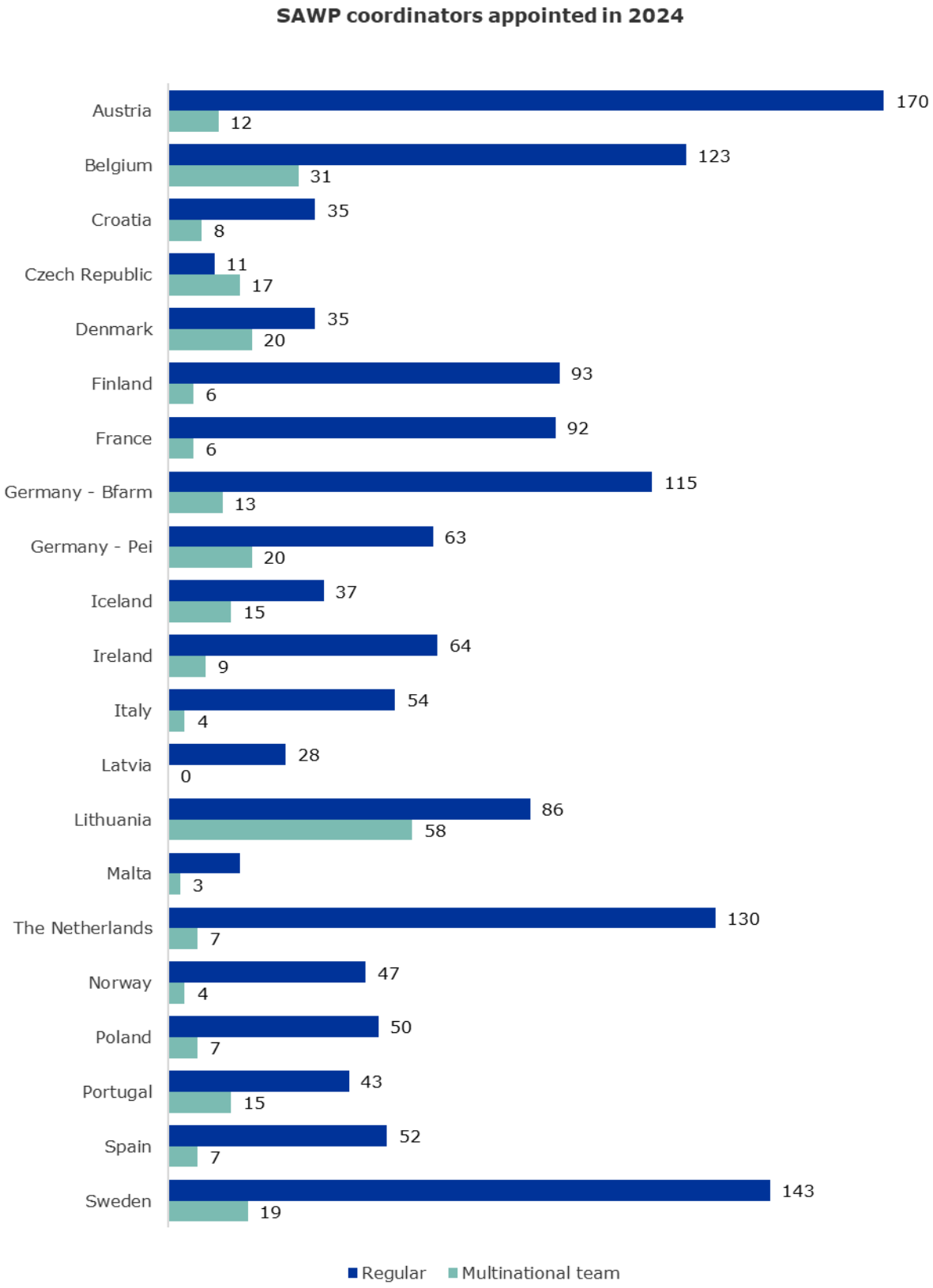
Rapporteurships and co-rapporteurships

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 the 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.


CHMP rapporteurs/co-rapporteurs appointed in 2024
(for initial Marketing authorisation applications, including generics)
Austria 18 1 4 5 28
Belgium 2 1 2 1 4 10
Croatia 3 5 4 12
Czechia 1 5 2 9 17
Denmark 2 2 6 3 13
Estonia 1 2 1 1 5
Finland 6 1 7
France 8 3 7 4 2 24
Germany 18 8 2 2 8 38
Hungary 2 1 3
Iceland 2 2 4
Ireland 7 3 5 15
Italy 1 5 1 7
Latvia 1 1 2 4
Lithuania 1 1 1 3
Malta 2 2
Netherlands 12 4 7 1 24
Norway 6 1 7
Poland 2 21 2 25
Portugal 4 2 6
Romania 5 1 6
Slovakia 3 2 5
Slovenia 4 2 4 10
Spain 2 2 5 1 1 11
Sweden 18 2 2 1 1 24
Rapporteur Regular
Co-rapporteur Regular
Assessors Multinational team
Rapporteur Multinational team
Co-rapporteur Multinational team


PRAC rapporteurs/co-rapporteurs appointed in 2024
(for initial Marketing authorisation applications)
Austria 2 4
Belgium 8 1
Croatia 7 1
Czechia 3 0
Denmark 10 3
Finland 4 4
France 7 9
Germany 12 17
Greece 2 0
Hungary 1 0
Iceland 4 0
Ireland 5 2
Italy 5 0
Latvia 1 0
Lithuania 2 1
Malta 1 0
Netherlands 9 12
Norway 1 0
Poland 5 0
Portugal 8 3
Spain 3 3
Sweden 31 14
Rapporteur
Co-rapporteur


CVMP rapporteurs/co-rapporteurs appointed in 2024
(for initial Marketing authorisation applications, including generics)
Austria 1 2 3
Belgium 1 1 2
Czechia 1 1
Denmark 2 4 6
Finland 1 1 2
France 1 7 8
Germany 2 3 1 2 8
Hungary 1 1
Ireland 5 2 1 8
Italy 1 1
Netherlands 6 1 2 9
Poland 1 1
Slovenia 1 1
Spain 5 4 9
Sweden 2 2
Rapporteur Regular
Rapporteur Multinational team
Co-rapporteur Regular
Co-rapporteur Multinational team


SAWP coordinators appointed in 2024
Austria 170 12
Belgium 123 31
Croatia 35 8
Czech Republic 11 17
Denmark 35 20
Finland 93 6
France 92 6
Germany - Bfarm 115 13
Germany - Pei 63 20
Iceland 37 15
Ireland 64 9
Italy 54 4
Latvia 28 0
Lithuania 86 58
Malta 3
The Netherlands 130 7
Norway 47 4
Poland 50 7
Portugal 43 15
Spain 52 7
Sweden 143 19
Regular
Multinational team

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 2024.

EU Network training centre										
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**
New scientific, regulatory and network portfolio curricula developed	1	8	0	2	2	2	1	1	0	1
Number of training events advertised to the EU Network	105	140	100	60	40	46	77	76	79	158
Number of reimbursed training events to the EU Network	7	25	20 * (14 by EU NTC)	8 (5 by EU NTC)	12	1	0	4	3	4
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	6	14	8	7	10	7	15	11	13	9
Number of users registered to the EU NTC Learning Management System		2,117	3,583	4,424	5,121	5,290	5,916	6,610	7,036	7,776
Number of NCA experts registered to the EU NTC Learning Management System		1,225	2,668	3,480	4,143	4,297	4,872	5,485	5,832	6,452

Communication and stakeholders

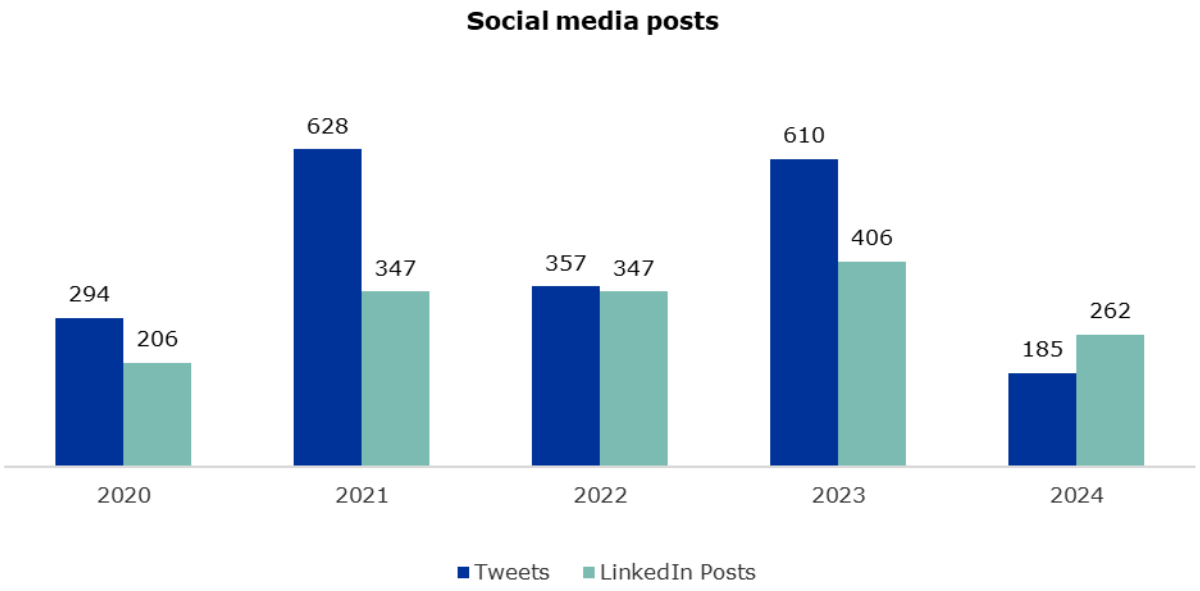
External communication

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'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 2024, 3,340 webpages were added and updated and 7,490 documents were published on the site.

Additionally, EMA's social media presence kept expanding through experimenting different tools to engage new audiences. By the end of the year, 501 posts and 31 videos were shared across social media platforms. Five live events were organised on EMA's social channels, on psychedelics, clinical trials, antimicrobial resistance, approval timelines and regulatory science priorities.

EMA staff and experts contributed to 85 articles on scientific and regulatory subjects to international journals.

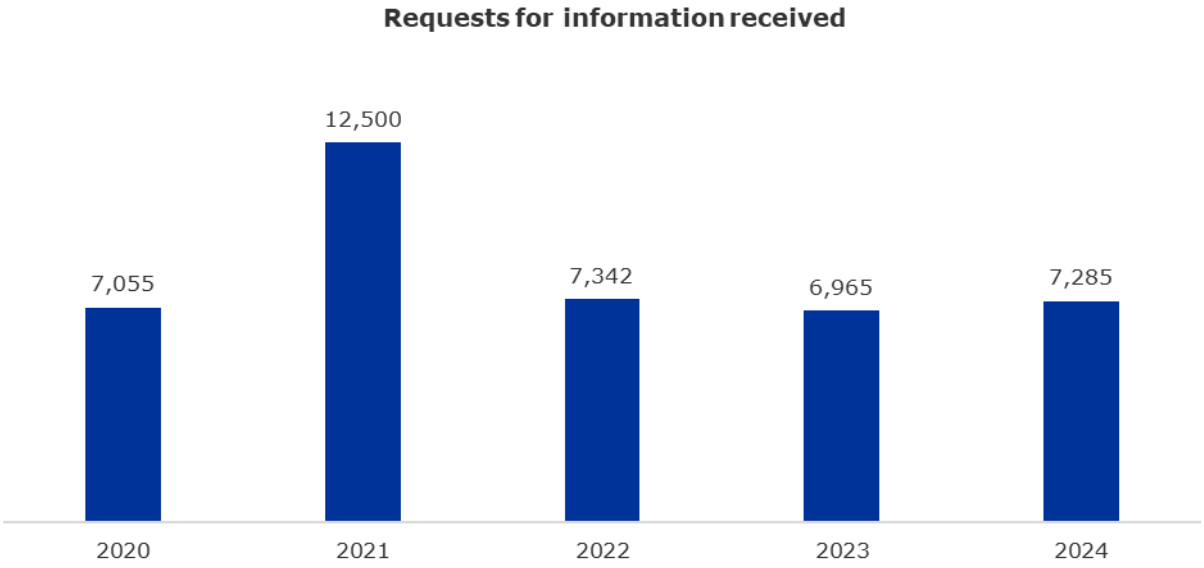


Total 2024: 447

Requests for information and access to documents

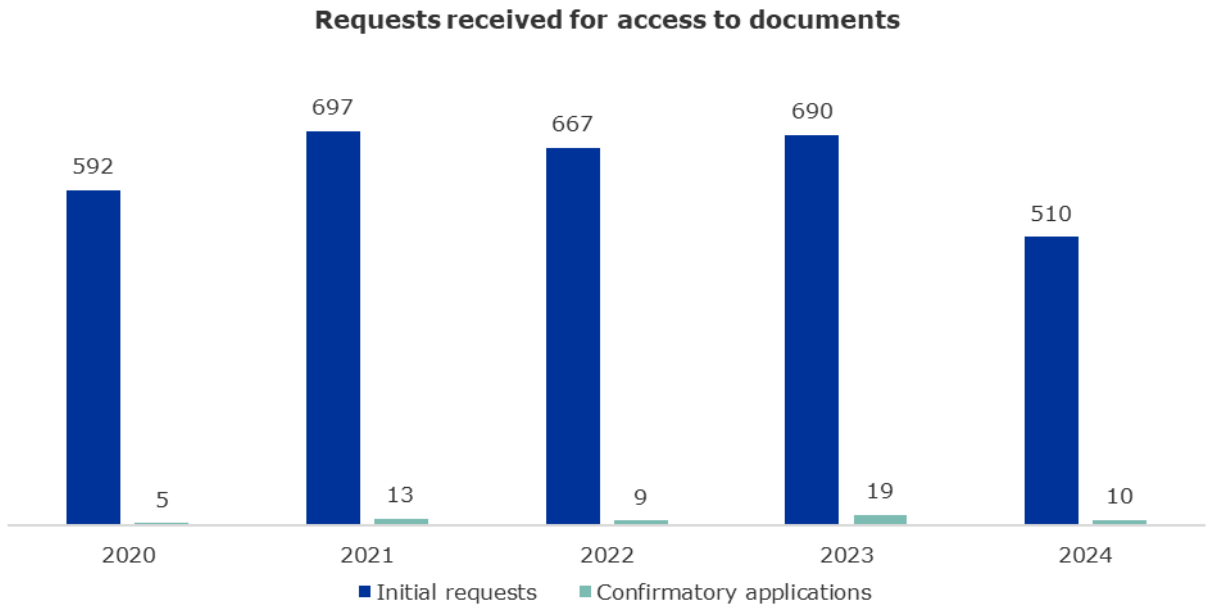
Providing citizens with clear, transparent information about its activities is a fundamental aspect of EMA's work.

- Requests for information



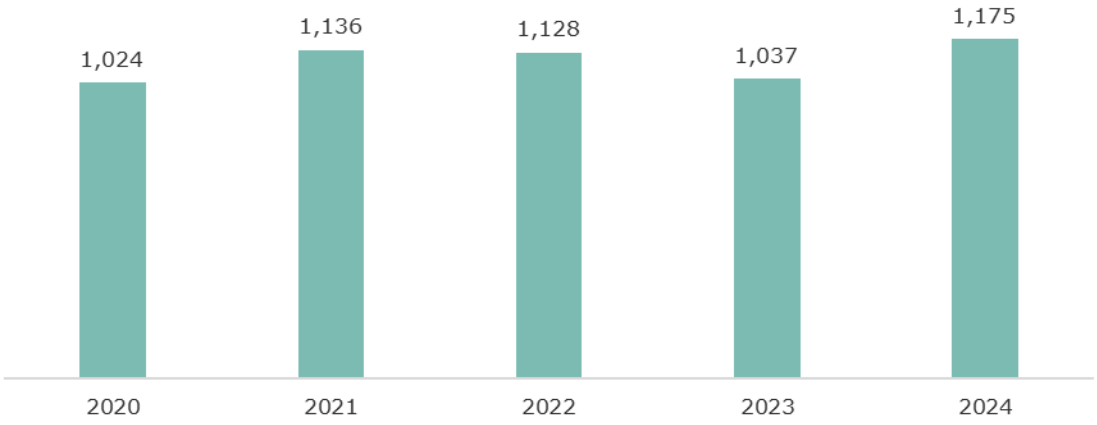
- Access to Documents requests

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.

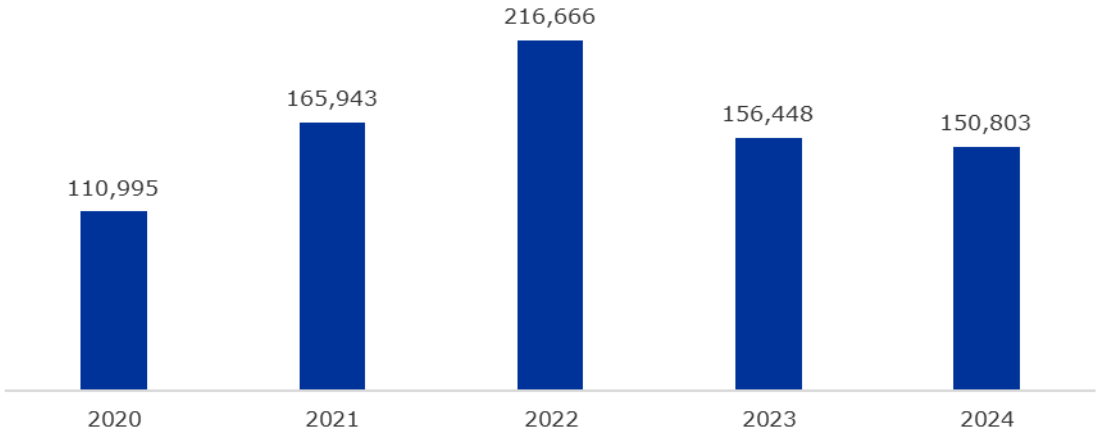


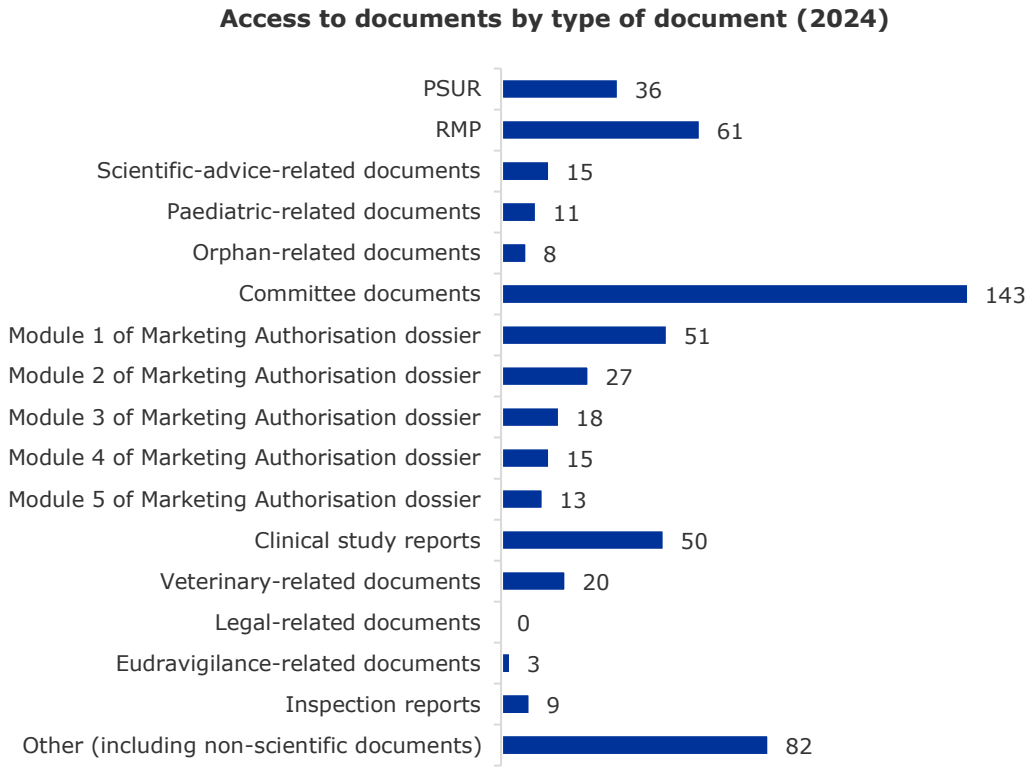
Total 2024: 520

Documents released following access to documents requests

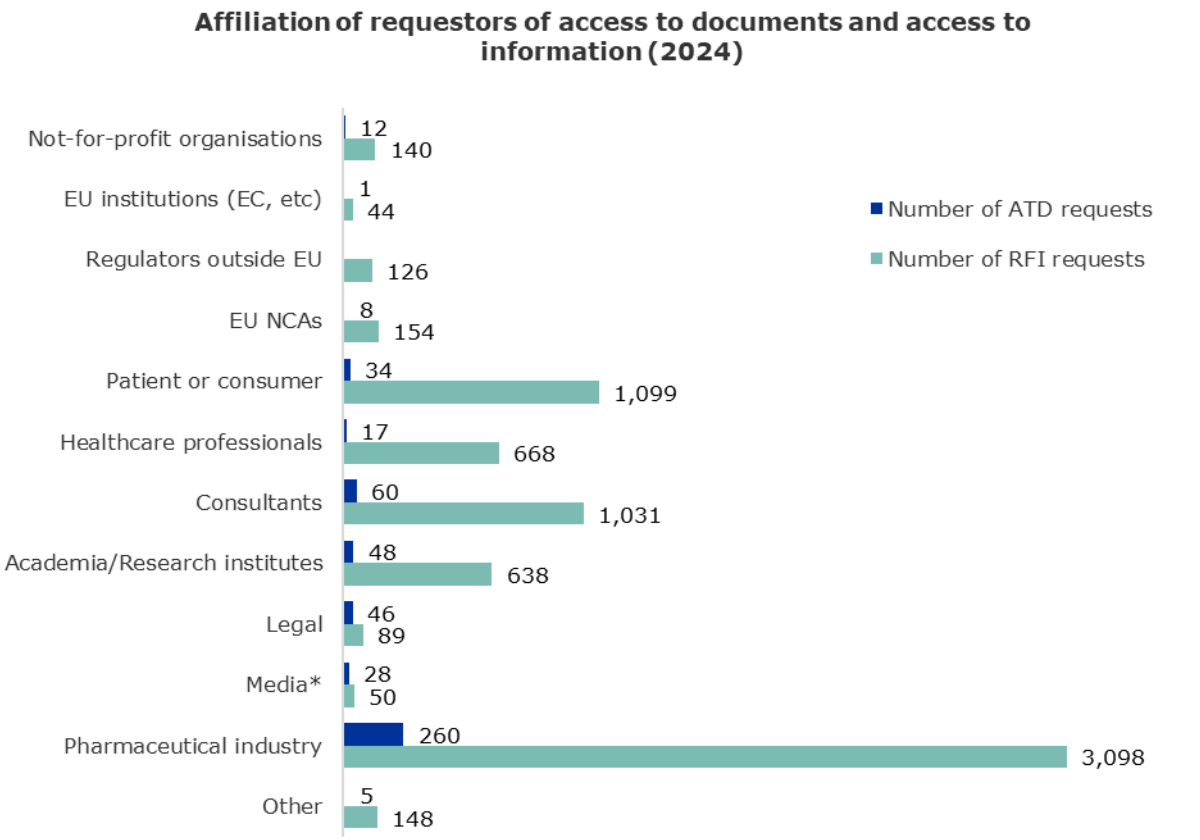


Pages released following access to documents requests





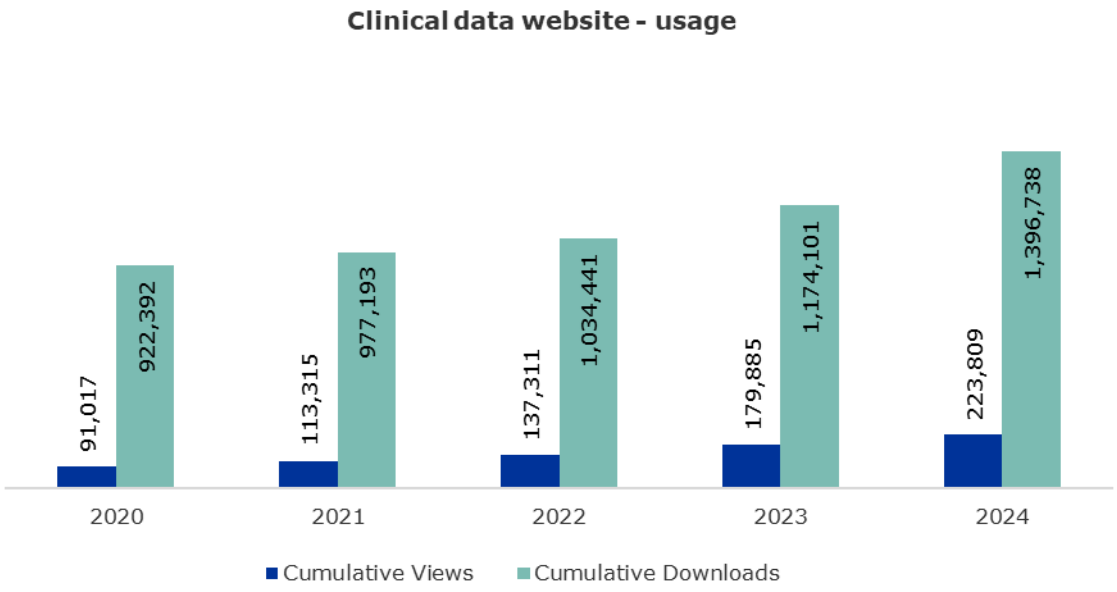
Note: More than one type of document can be requested per ATD.

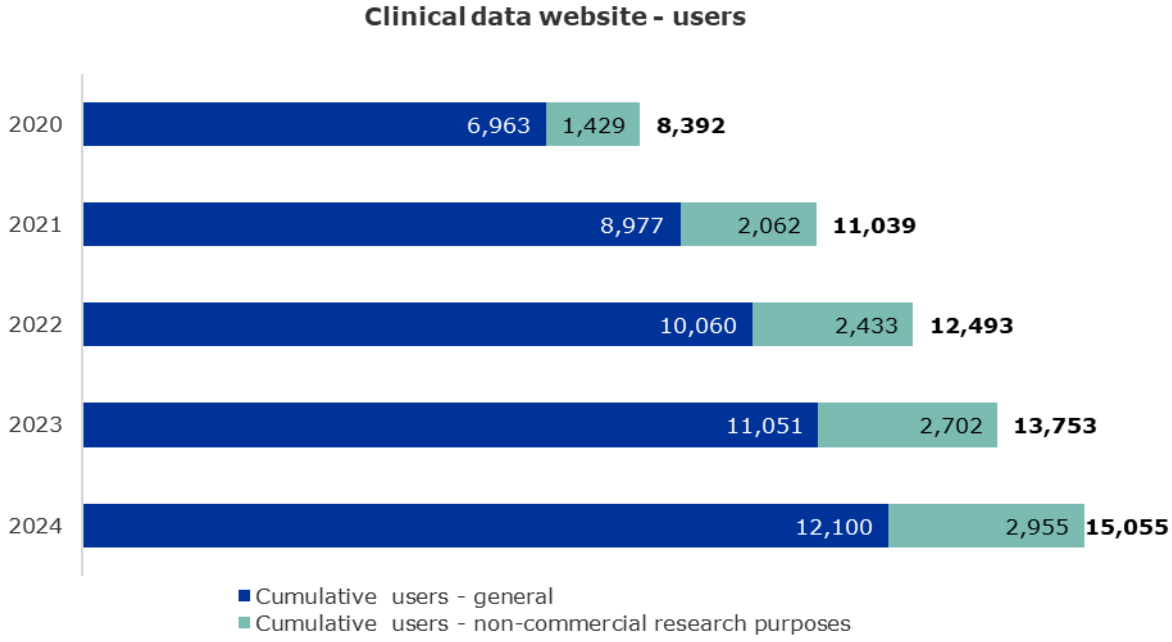


* Requests from the media submitted via the online form do not include requests sent directly to the press email inbox.

Publication of clinical data

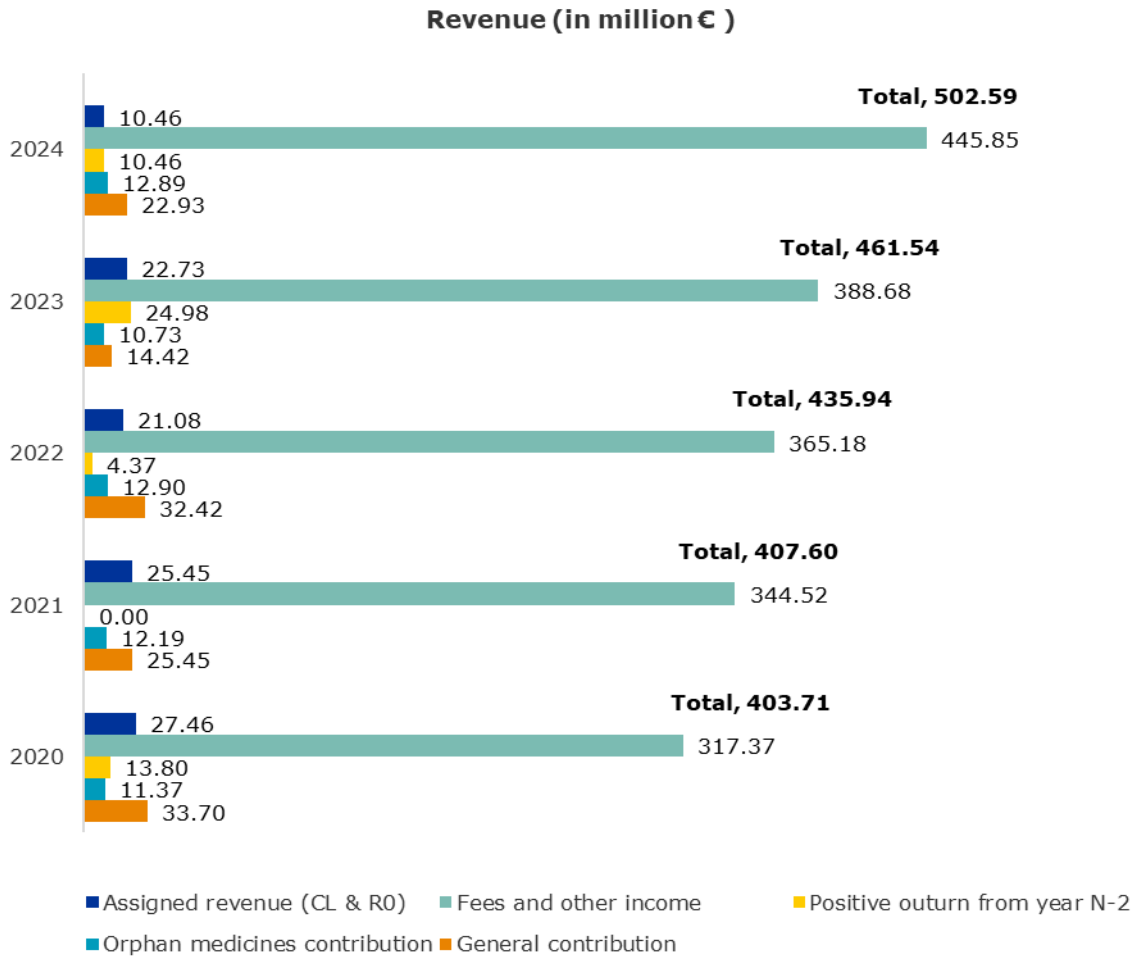
EMA releases clinical data provided by pharmaceutical companies to support their regulatory submissions for human medicines under the centralised procedure. This follows the agency's flagship policy on the publication of clinical data.


Clinical data website - usage
91,017
922,392
113,315
977,193
137,311
1,034,441
179,885
1,174,101
223,809
1,396,738
2020
2021
2022
2023
2024
Cumulative Views
Cumulative Downloads


Clinical data website - users
2020
6,963
1,429
8,392
2021
8,977
2,062
11,039
2022
10,060
2,433
12,493
2023
11,051
2,702
13,753
2024
12,100
2,955
15,055
Cumulative users - general
Cumulative users - non-commercial research purposes

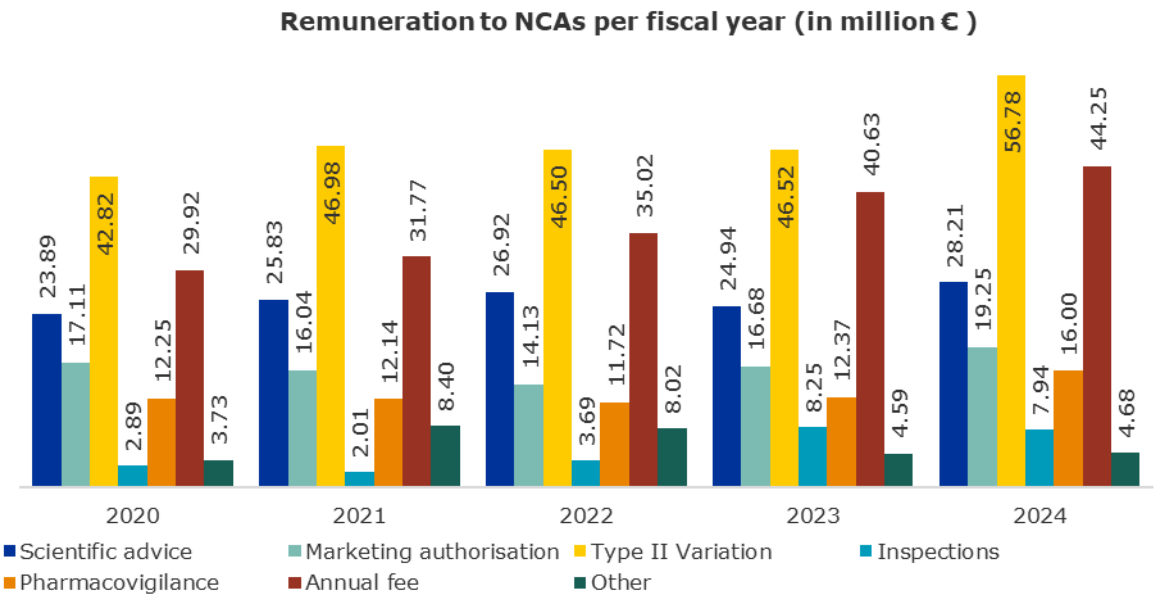
Administrative aspects

Financial information



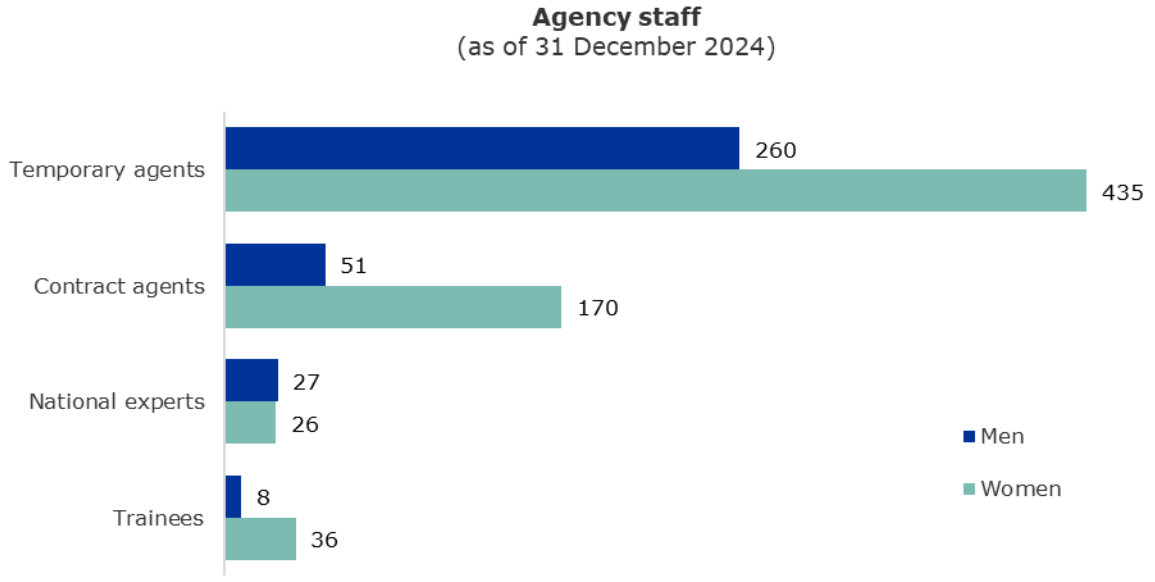
Remuneration to national competent authorities

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.

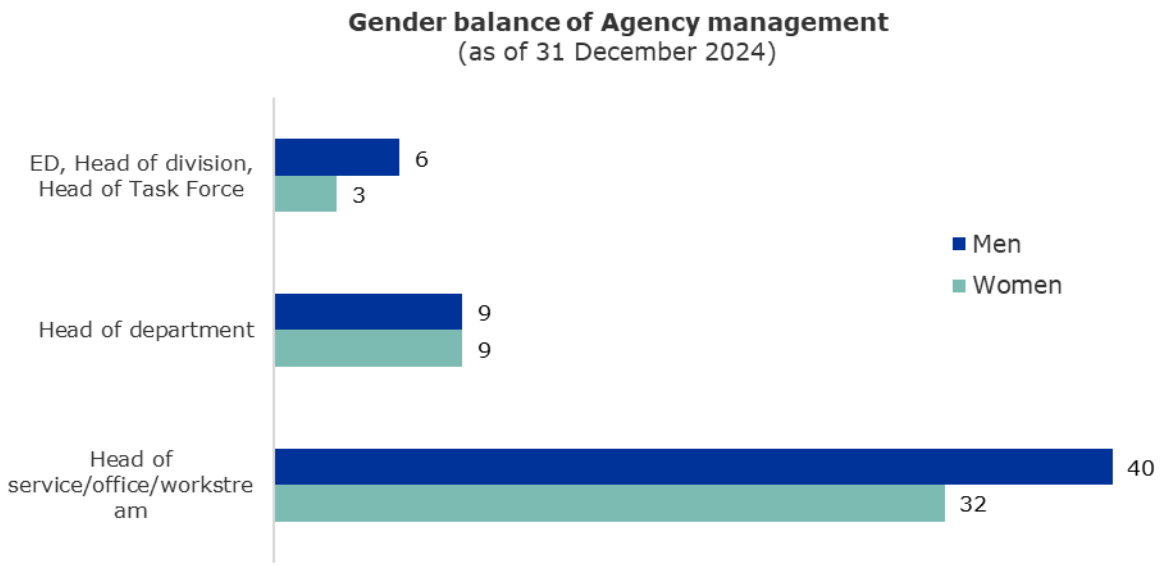


Total 2024: 177.10

Agency staff

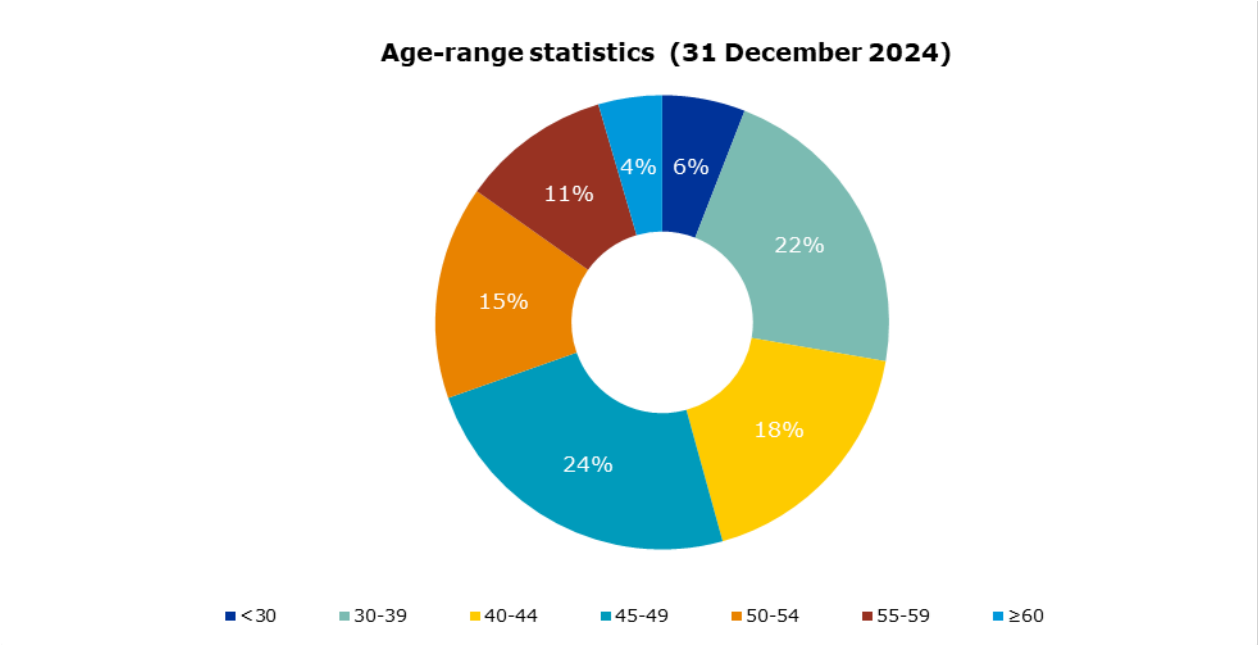


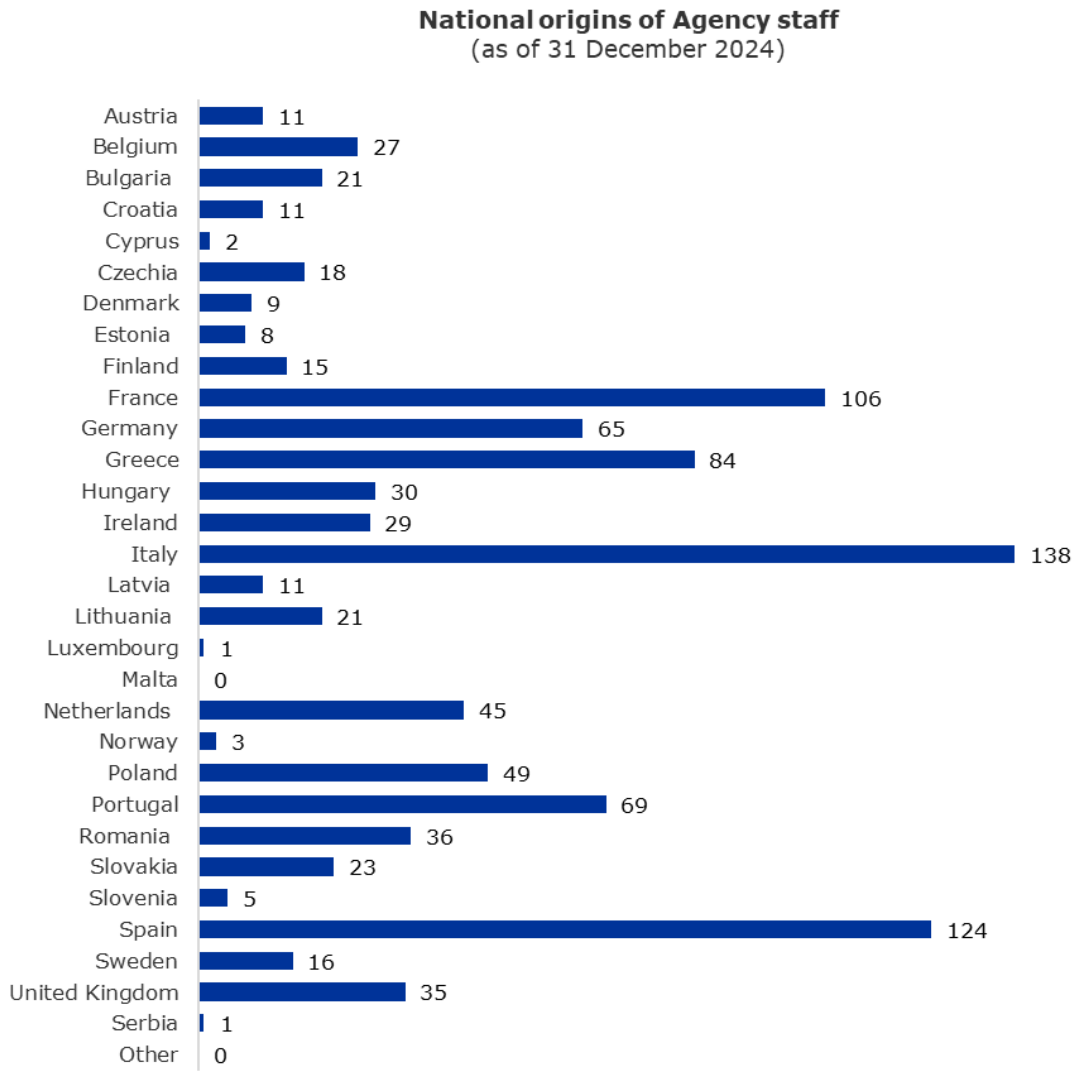
Total 2024: 1,013



Total 2024: 99

Gender balance 2024												
Status	**Category AD (administrators) and FGIV**				**Category AST (assistants) and FGIII**				**TA/CA - all grades**			
	Men		**Women**		**Men**		**Women**		**Men**		**Women**	
Temporary agents	225		239		35		196		260		435	
Contract agents	35		87		16		83		51		170	
Total	**260**	**44%**	**326**	**56%**	**51**	**15%**	**279**	**85%**	**311**	**34%**	**605**	**66%**





Includes TA, CA, SNE and trainees

Annex 2. Statistics on financial management

Budget outturn	2020	2021	2022	2023	2024
Revenue actually received (+)	€ 376,246,022.54	€ 382,156,343.70	€ 414,862,609.76	€ 438,811,276.00	€ 492,127,783.68
Payments made (-)	-€ 290,132,295.87	-€ 274,400,002.19	-€ 301,496,618.72	-€ 347,820,472.27	-€ 411,317,623.40
Carryover of appropriations (-)	-€ 75,300,936.06	-€ 91,090,698.54	-€ 106,828,218.21	-€ 96,226,655.69	-€ 79,167,727.14
Cancellation of appropriations carried over (+)	€ 2,423,908.71	€ 5,372,131.21	€ 4,455,177.77	€ 5,174,935.87	€ 2,782,128.67
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 3.26	-€ 0.01	€ 0.00
Exchange rate differences (+/-)	-€ 585,264.08	€ 2,944,406.68	-€ 533,910.72	€ 81,854.69	€ 170,422.56
Adjustment for negative balance from previous year (-)	-€ 8,283,114.28	€ 0.00	€ 0.00	€ 0.00	€ 0.00
TOTAL	**€ 4,368,320.96**	**€ 24,982,180.86**	**€ 10,459,043.14**	**€ 20,938.59**	**€ 4,594,984.37**

The financial outturn was a surplus of 0.93% of the approved budget, including amending budgets, of EUR 491,862,000, equivalent to EUR 4,594,984.37 (2023: EUR 20,939 and 0.005%).

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 improved in 2024 compared to 2023 as indicated below:

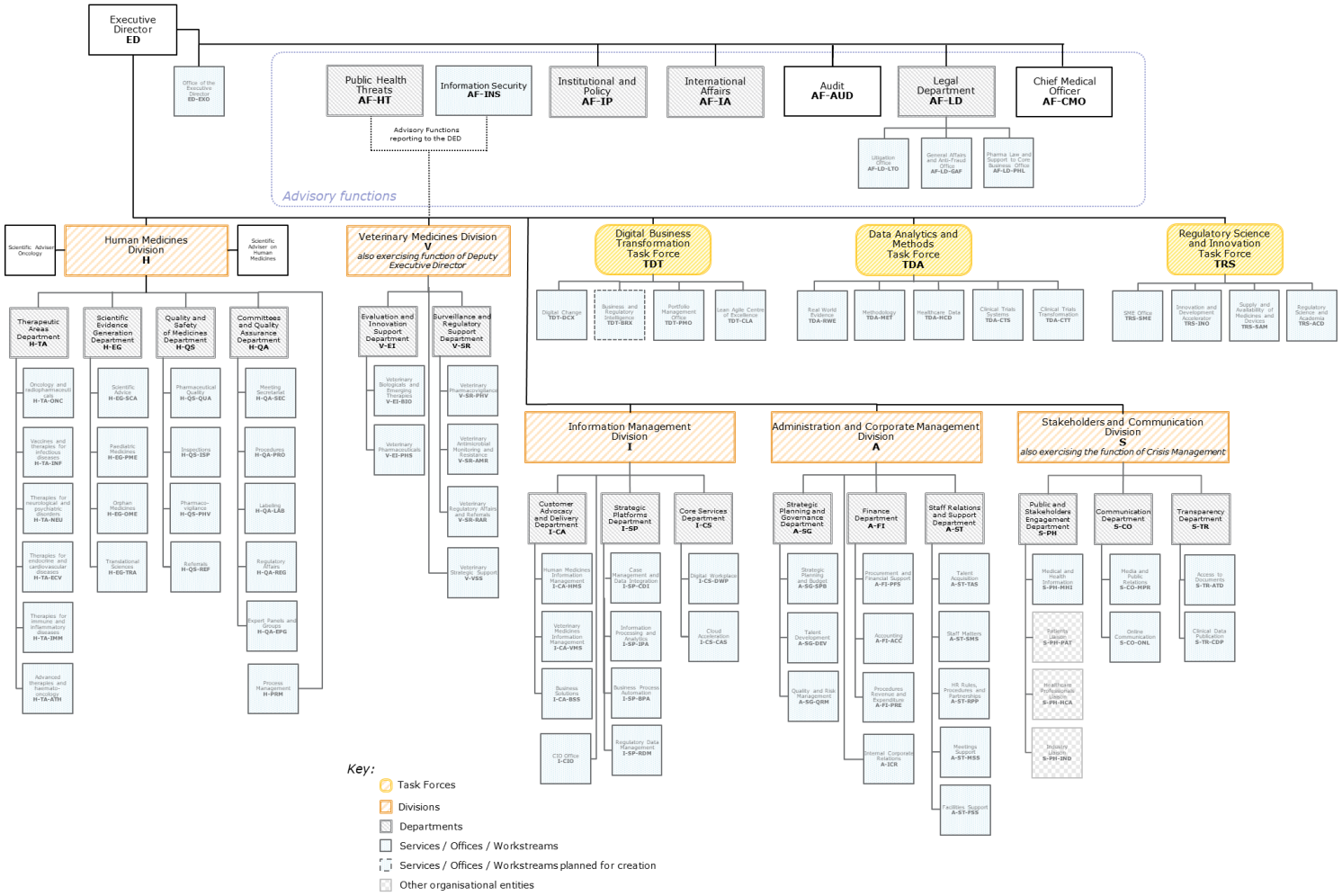
- Title I -Staff expenditure - final implementation was 99.6% (99.5% in 2023), which is considered a good result
- Title II - infrastructure and operating expenditure - final implementation was 99.7% (98.8% in 2023), which is considered a good result
- Title III - operational expenditure - final was 99.8% (98.7% in 2023), which is considered a good result.

In 2024, the Agency complied with the ceilings/KPIs of amounts carried forward from 2024 to 2025 (C1 to C8) of 10% for title I, 20% for title II and 30% for title III as indicated below:

- title I - Staff expenditure: 3.07% (4.89% in 2023)
- title II - infrastructure and operating expenditure: 13.31% (24.86% in 2023)
- title III - operational expenditure: 26.00% (32.59% in 2023).

In the Agency managed to reduce the overall carry forward to 16.1% from 2024 to 2025 down from 21.5% from 2023 to 2024.

Annex 3. Organisation chart as of 31 December 2024


Executive Director
ED
Office of the Executive Director
ED-EXO
Public Health Threats
AF-HT
Information Security
AF-INS
Institutional and Policy
AF-IP
International Affairs
AF-IA
Audit
AF-AUD
Legal Department
AF-LD
Chief Medical Officer
AF-CMO
Advisory Functions reporting to the DED
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
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
Information Management Division
I
Administration and Corporate Management Division
A
Stakeholders and Communication Division
S
also exercising the function of Crisis Management
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	2023				2024				2025	
	Authorised budget		Actually filled as of 31/12/2023		Authorised budget		Actually filled as of 31/12/2024*		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		0		3		3		3
AD 14		12		3		12		12		12
AD 13		12		11		12		12		15
AD 12		57		52		61		61		64
AD 11		49		49		50		50		49
AD 10		53		53		57		57		59
AD 9		66		66		82		82		94
AD 8		87		87		78		78		81
AD 7		89		89		90		90		85
AD 6		67		67		55		55		43
AD 5		0		0		0		0		0
AD TOTAL	**0**	**495**		**477**	**0**	**500**		**500**	**0**	**505**
AST 11		2		2		3		3		3
AST 10		7		7		7		7		7
AST 9		10		10		10		10		13
AST 8		14		14		15		15		19
AST 7		25		25		29		29		38
AST 6		31		31		35		35		26
AST 5		43		43		49		49		56
AST 4		43		43		32		32		22
AST 3		12		12		11		11		15
AST 2		0		0		0		0		0
AST 1		0		0		0		0		0
AST TOTAL	**0**	**187**		**187**	**0**	**191**		**191**	**0**	**199**
AST/SC1										
AST/SC2										
AST/SC3										
AST/SC4										
AST/SC5										
AST/SC6										
AST/SC TOTAL	**0**	**0**			**0**	**0**			**0**	**0**
GRAND TOTAL	**0**	**682**		**664**	**0**	**691**		**691**	**0**	**704**

Grade filled refers to the number of staff occupying posts of a given grade, regardless of the staff member's actual grade.

*) EMA makes use of article 38(2) FR to offset workforce loss through part-time work undertaken by TA staff. In 2024 the average part-time loss was -13.1 FTE, allowing for the appointment of 4 additional staff not included above.

Contract agents	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	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
Function Group IV	122	107	114	125	111	119	128
Function Group III	81	97	102	78	100	99	75
Function Group II	0	0	0	0	0	0	0
Function Group I	0	0	0	0	0	0	0
Additional CA[1]	0	0	0	0	0	0	0
TOTAL	**203**	**204**	**216**	**203**	**211**	**218**	**203**

1) Additional staff to cover Brexit-related additional work (FTE)

Seconded National Experts	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024
Total	30	42	47	45	48	53

Interims

	Total FTEs in year 2024
Number	123

Other Human Resources | Structural service providers

	Actually in place as of 31/12/2023
Security	23
IT service desk	29
IT maintenance and support 'time&means' contracts only	4
Reception	10
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
Special functions			

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 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 2024

	2023 (%)	2024 (%)
Job Type (sub) category		
Administrative support and Coordination	**14%**	**18%**
Administrative Support	13%	16%
Coordination	2%	2%
Operational	**79%**	**76%**
Top level Operational Coordination	1%	1%
Programme management and Implementation	26%	28%
Evaluation & Impact assessment	34%	33%
General operational	18%	14%
Neutral	**7%**	**6%**
Finance/ Control	7%	6%
Linguistics	**0%**	**0%**
Total	**100.00%**	**100.00%**

4.4. HR implementing rules adopted in 2024

Implementing rule	Adopted	Effective date
Decision of the Management Board on application by analogy of Commission Decision C(2024) 1038 final of 21 February 2024 amending Commission Decision C(2011)1278 final on the general implementing provisions for Articles 11 and 12 of Annex VIII to the Staff Regulations on the transfer of pension rights	14 June 2024	14 June 2024

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
1 Evaluation activities for human medicines	**278**	**111**	**64,693**	**21,947**	**5,868**	**165,791**	**13,049**	**271,347**
1.1 Pre-authorisation activities	58	22	13,877	3,411	3,092	27,873	8	48,261
1.2 Initial evaluation activities	47	13	10,824	2,247	0	16,997	1,345	31,413
1.3 Post-authorisation activities	70	25	14,858	8,224	78	104,675	2,452	130,287
1.4 Referrals	8	2	1,476	392	0	251	396	2,515
1.5 Pharmacovigilance activities	44	23	10,539	3,192	1,537	15,995	5,803	37,065
1.6 Other specialized areas and activities	46	25	12,086	4,148	1,162	0	2,718	20,113
1.7 Medical Devices	5	2	1,034	333	0	0	326	1,693
2 Evaluation activities for veterinary medicines	**30**	**13**	**6,534**	**3,603**	**342**	**4,447**	**432**	**15,358**
2.1 Pre-authorisation activities	1	0	326	72	83	333	0	814
2.2 Initial evaluation activities	8	4	2,025	472	25	2,211	174	4,907
2.3 Post-authorisation activities	9	3	1,710	593	0	1,791	209	4,303
2.4 Arbitrations and referrals	0	1	112	32	0	0	49	193
2.5 Pharmacovigilance activities	5	2	962	1,882	196	112	0	3,153
2.6 Other specialized areas and activities	6	3	1,398	552	38	0	0	1,987
3 Horizontal activities and other areas	**217**	**92**	**52,553**	**56,407**	**7,890**	**7,936**	**10,263**	**135,049**
3.1 Committee coordination	45	24	11,298	2,611	4,691	0	0	18,601
3.2 Inspection and Compliance	26	17	5,768	1,870	857	7,936	2	16,434
3.3 Partners and Stakeholders	35	11	8,879	1,836	1,559	0	974	13,248
3.3a Transparency and access to documents	20	8	3,766	1,243	0	0	0	5,009
3.3b Information	42	21	10,397	11,099	116	0	2,270	23,882
3.4 International activities	16	2	4,379	615	537	0	0	5,532
3.5 Information Management (incl. EU Telematics)	33	8	8,066	37,132	129	0	7,016	52,343
4 Corporate Governance and Support activities	**166**	**42**	**40,290**	**15,410**	**558**	**0**	**497**	**56,756**
4.1 Governance, Quality Management and Internal Audit	23	5	5,910	1,191	416	0	362	7,879
4.2 Finance	28	12	7,843	6,052	0	0	113	14,008
4.3 Information technology	54	16	13,104	3,343	142	0	0	16,588
4.4 Human resources	48	9	10,933	4,241	0	0	22	15,196
4.5 Infrastructure services	13	0	2,500	583	0	0	0	3,083
Total	**691**	**259**	**164,070**	**97,367**	**14,658**	**178,173**	**24,241**	**478,509**

Less - Earmarked fund from Ministry of Foreign affairs as contribution for rent and building maintenance cost (R0)	491
Less - Non-automatic carry forward (C2)	800
Plus - exceptional expenditure related to London premises	13,268
Current year (C1) net of exceptional expenditure for London premises	**490,485**

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

	General information					Financial and HR impacts				
	Date of signature	Total amount	Duration	Counterpart	Short description		2023		2024	
Grant agreements										
STARS 825881	01/01/2019 (EMA's accession)	EUR 6,000.00	30/06/2022	European Commission, DG RTD	Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice	Amount	CA	PA	CA	PA
							€ 1,659	€ 1,659	€ 0	€ 0
						Number of CA	0		0	
						Number of SNEs	0		0	
ConcePTION 821520	06/05/2019	EUR 85,000.00	31/12/2024	Innovative Health Initiative Joint Undertaking (IHI JU)	Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding	Amount	CA	PA	CA	PA
							€ 5,012	€ 5,012	€ 0	€ 0
						Number of CA	0		0	
						Number of SNEs	0		0	
SISAQOL 945052	09/11/2020	EUR 78,756.25	31/12/2025	Innovative Health Initiative Joint Undertaking (IHI JU)	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life endpoints	Amount	CA	PA	CA	PA
							€ 8,658	€ 8,658	€ 17,953	€ 17,953
						Number of CA	0		0	
						Number of SNEs	0		0	
PREMIER 875508	24/06/2020	EUR 47,000.00	31/08/2026	Innovative Health Initiative Joint Undertaking (IHI JU)	Prioritisation and Risk Evaluation of Medicines in the Environment	Amount	CA	PA	CA	PA
							€ 20,162	€ 20,162	€ 1,045	€ 1,045
						Number of CA	0		0	
						Number of SNEs	0		0	

RealiseD 101165912	12/12/2024	EUR 554,458.75	31/12/2029	Innovative Health Initiative Joint Undertaking (IHI JU)	Comprehensive methodological and operational approach to clinical trials in rare and ultra-rare diseases	Amount	CA	PA	CA	PA
							€ 0	€ 0	€ 0	€ 0
						Number of CA	0		0	
						Number of SNEs	0		0	
Total grant agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 35,491	**€ 35,491**	**€ 18,997**	**€ 18,997**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Contribution agreements										
IPA II IPA/2019/413-383	19/12/2019	EUR 254,919.00	31/12/2023	European Commission, DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	CA	PA	CA	PA
							€ 0	€ 0	€ 0	-€ 16,528
						Number of CA	0		0	
						Number of SNEs	0		0	
ePI SANTE/2021/SI2.869573&SI2.869590	13/04/2022	EUR 1,500,000.00	31/12/2023	European Commission, DG SANTE	Development of electronic product information (ePI) for EU medicines	Amount	CA	PA	CA	PA
								€ 745,988	€ 0	€ 0
						Number of CA	0		0	
						Number of SNEs	0		0	
IPA III 700001692	11/12/2023	EUR 600,000.00	31/12/2026	European Commission, DG NEAR	EU4 Alignment on medicines regulation in the Western Balkans and Turkiye	Amount	CA	PA	CA	PA
							€ 0	€ 0	€ 600,000	€ 570,000
						Number of CA	0		0	
						Number of SNEs	0		0	
NDICI AFRICA/2023/448-916	20/12/2023	EUR 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
							€ 10,000,000	€ 2,141,720	€ 0	€ 0
						Number of CA	0		0.5	
						Number of SNEs	0		0	

ePI II	31/05/2024	EUR 1,700,000.00	31/12/2028	European Commission, DG SANTE	Implementation of the action 'electronic Product Information (ePI) for medicinal products'	Amount	CA	PA	CA	PA
							€ 0	€ 0	€ 1,700,000	€ 1,500,000
						Number of CA	0		0	
						Number of SNEs	0		0	
Total contribution agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 10,000,000	**€ 2,887,708**	**€ 2,300,000**	**€ 2,053,472**
						Number of CA	**0**		**0.5**	
						Number of SNEs	**0**		**0**	
Service-level agreements										
none						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
						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**	
TOTAL						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 10,035,491	**€ 2,923,200**	**€ 2,318,997**	**€ 2,072,469**

	Number of CA	**0**	**0.5**
	Number of SNEs	**0**	**0**

Annex 7. Environment management

Aspect	Environmental objectives	Environmental targets	Actions to achieve environmental objectives	Reporting
Direct	Energy efficiency: "EMA drives energy efficiency in line with good practices"	100% renewable energy for electricity achieved Actions targeted to directly support the objective	Replacement scheme of electronic equipment such as laptops and small electricity for further energy efficiency, when technically and financially justifiable	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.
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor consumption of materials used (paper, plastic) to reduce or maintain levels during the pandemic	Promote reduced use of single-use materials along a circularity approach Promote paper-less workflows and digitisation	The total number of printed copies continues to be at low levels despite the stabilised occupancy of the offices in 2024.
	Water – not relevant due to the water efficiency at the EMA building	N/A	N/A	N/A
	Waste: "EMA drives waste reduction in line with good practices"	Monitor the generation of waste with a target to reduce, and to reduce hazardous waste	Monitor total waste per FTE and year and manage waste along a circularity approach	Despite increased on-site working the volume of total waste as well as the individual waste streams are well maintained.
	Biodiversity – not relevant due to no further land being taken into use	N/A	N/A	EMA did not perform any actions regarding biodiversity at its premises.
	Emissions: "EMA drives emission reduction,	Emissions of greenhouse gases [t] Air emissions [t]	Monitor travel by staff and delegates to align with internal interim mission rules, for a	EMA has received the new draft mission rules expected to come into effect in 2025. Meanwhile the Agency

Aspect	Environmental objectives	Environmental targets	Actions to achieve environmental objectives	Reporting
	including carbon zero by 2050"		balanced approach between face to face and virtual meetings Enable agile working for employees, thus reducing transport needs by providing support to remote and home working	continues to use the temporary rules from June 2022 for staff missions as well as maintain a hybrid approach to committee meetings with every other meeting virtual. The teleworking from abroad was reduced to 10 days per year in line with the updated teleworking rules, and the removal of temporary rules allowing additional up to 5 teleworking days per month. Teleworking from the Netherlands is maintained with up to 60% per week. To further manage the continuous improvements EMA implements green criteria in its public procurement procedures (GPP criteria) when available. When GPP criteria are available, the procurement includes a wide range of green criteria that are a result of consultations with the EP Green Public Procurement Helpdesk.
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2022-2025	Actions as included in the SPD 2022-2025	Actions and outcome of reviewing Environmental Risk Assessments as part of marketing authorisations are presented in the operational sections of this AAR.

Further environment performance reporting will be presented in the EMA Environmental Statement 2024, as part of EMA's registration to the EU Eco-management and Audit Scheme (EMAS), Regulation (EC) No 1221/2009 as amended, and in line with the voluntary use of the Sectoral Reference Document on best environmental management practices, sector environmental performance indicators and benchmarks of excellence for the public administration sector, Commission Decision (EU) 2019/61.

Annex 8. Draft annual accounts

Following a positive opinion by the European Court of Auditors, the Agency's annual accounts for the financial year 2023 were successfully adopted by the Management Board in June 2024 and sent to the Budget authority (European Parliament and Council) by 1 July 2024.

During the assessment of the Annual Activity Report, EMA management board has been involved in the review of 2024 provisional annual accounts.

At the time of writing, the Court of Auditors had not yet provided the Agency with their observations on the provisional accounts 2024 and therefore, the Agency’s final accounts 2024 has not been issued yet.

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. 2024 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 2024:

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	Scientific Officer	17 years	17/06/2024	25/06/2024	During a period of six months, to be counted as of the date of leaving 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 4 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	28/06/2024

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
2	Biostatistician (Seconded National Expert)	4 years	7/06/2024	26/06/2024	During a period of six months, to be counted as of the date of leaving 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.	28/06/2024
3	Scientific Officer (seconded National Expert)	4 years	11/04/2024	15/05/2024	During a period of 6 months to be counted as of the date of leaving the service, they should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity they may have dealt	22/05/2024

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
					with in the performance of their responsibilities at the Agency during The last three years of Secondment. The distance clause is without prejudice to the possibility of liaising 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	
4	Scientific Business Champion	10 years, 6 months 15 days	18/03/2024	11/04/2024	During a period of six months, to be counted as of the date of leaving 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	15/04/2024

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
					members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders	
5	Scientific Officer	2 years 9 months	19/01/2024	29/01/2024	During a period of six months, to be counted as of the date of leaving 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.	1/02/2024

Annex 10. Administrative appropriations – Building policy

#	Building name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	Non-office space	Total	Rent (€/year)	Duration of the contract	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	11,159,597 (for 2024; yearly indexation)	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (Central Governement 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.

#	Building name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	Non-office space	Total	Rent (€/year)	Duration of the contract	Type	Break - out clause Y/N	Conditions attached to breakout clause	
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 1 July 2014 to 30 June 2039	Lease agreement with Canary Wharf Limited	N	No break-clause	None
TOTAL			40,520	23,231	63,751	11,159,597 (rent for EMA 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

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 had managed to sub-underlet the premises in 2019 (respective building dossiers EMA/104158/2019 of 21/02/2019 and EMA/119300/2019 of 28/02/2019) with the Agency's sub-undertenant covering fully the rent and costs that the Agency is contractually obliged to pay to its landlord (Canary Wharf Limited).

The COVID-19 pandemic and changes in the global economy following the pandemic, affected the office sector and the parent company of the Agency's sub-undertenant who experienced difficulties as of Q3 2023. Specifically:

- On 7 November, the parent company of the Agency's sub-undertenant filed for Chapter 11 proceedings in the United States.
- While the Agency's sub-undertenant was not part of the Chapter 11 proceedings, the parent company's situation in the United States and the financial outcome of the activities at 30 Churchill Place resulted in the Agency's sub-undertenant reassessing its operations at EMA's former premises and its obligations vis-à-vis EMA under the sub-underlease. During the Chapter 11 bankruptcy process, the company vacated numerous global and London locations.

The Agency submitted to the Budgetary Authority a pre-information note on 5 December 2023 (pre-information note EMA/546071/2023) for the purpose of providing early information to the European Parliament and the Council on the developments in the Agency's sub-underlease, as listed above.

Following extensive negotiations to reach the best possible outcome, the new terms of agreement between the Agency and the sub-undertenant (amending the previous sub-underlease) were agreed on 20 March 2024.

On 27 March 2024, the Agency submitted a building dossier to the Budgetary Authority (building dossier EMA/122997/2024) seeking the authorisation of the Budgetary Authority to amend the sub-underlease of the Agency's pre-Brexit office premises in London. The European Parliament approved the building dossier in the meeting of the Committee on Budgets held on 8 April 2024, and the Council's approval was confirmed on 24 April 2024.

The Agency continues to call on the institutions to resolve the matter of the London building at the political level.

Annex 11. Annual report 2024

Please see the Agency's Annual report 2024, publicly available on the EMA corporate website.

Annex 12. Pharmacovigilance Fee Regulation- Key Performance Indicators and performance information for the calendar year 2024

Context

The Pharmacovigilance Fee regulation (Regulation (EU) No 658/2014) was adopted on 15 May 2014. The first procedural fees were charged as of 26 August 2014 and the first annual fees in July 2015.

The aim of the regulation is to enable the Agency to charge fees for the pharmacovigilance tasks introduced by the pharmacovigilance legislation i.e. Union pharmacovigilance procedures (PSURs, PASS, pharmacovigilance referrals), literature monitoring and improved use of information technology tools. Financing the activities contributes to *"achieving an internal market as regards medicinal products, taking as a basis a high level of protection of health"* and inseparable from this is the aim *"to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products".*

Article 15 of the regulation, dealing with transparency and monitoring, states that the Executive Director of the Agency shall provide the Commission and the Management Board once per year with the performance information set out in part V of the annex to the regulation based on a set of performance indicators adopted by the Agency.

Section 2 of this report presents these key performance indicators for the calendar year 2024, and section 3 presents the more detailed performance information required by the regulation.

Part 1: Key Performance Indicators

KPI 1: procedures started within the year for which a fee has been charged

Pharmacovigilance activities financed by PhV fees	2024 actual
Number of PSURs and PSUSAs procedures started	887
Number of imposed PASS protocol procedures started	5
Number of imposed PASS report procedures started	5
Number of pharmacovigilance referral procedures started	2

Number of pharmacovigilance annual fee chargeable units invoiced	145,982

KPI 2: percentage of marketing authorisation holders eligible for fee exemption or fee reductions within a given year for procedures carried out at Union level

Pharmacovigilance activities financed by PhV fees	* 2024 estimated	2024 actual	2024 percentage
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **CAPs only**:		287	
· Micro sized enterprises	2.25%	1	0.35%
· Small and medium sized enterprises	7.50%	4	1.39%
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **NAPs or CAPs/NAPs**:		3,671	
· Micro sized enterprises	2.50%	18	0.49%
· Small and medium sized enterprises	7.50%	165	4.49%
MAHs invoiced for **Imposed PASS protocol** procedures started for **CAPs only**:		2	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%
MAHs invoiced for **Imposed PASS protocol** procedures started for **NAPs or CAPs/NAPs**:		353	
· Micro sized enterprises	2.50%	0	0.00%
· Small and medium sized enterprises	7.50%	1	0.28%
MAHs invoiced for **Imposed PASS report** procedures started for **CAPs only**:		5	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%

MAHs invoiced for **Imposed PASS report** procedures started for **NAPs or CAPs/NAPs**:		0	
· Micro sized enterprises	2.5	0	0.00%
· Small and medium sized enterprises	7.50%	0	0.00%
MAHs invoiced for Pharmacovigilance **referral** procedures started for **CAPs only:**		0	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%
MAHs invoiced for Pharmacovigilance **referral** procedures started for **NAPs or CAPs/NAPs:**		371	
· Micro sized enterprises	2.50%	4	1.08%
· Small and medium sized enterprises	7.50%	33	8.89%

* Estimates based on the impact assessment

KPI 3: percentage of chargeable units eligible for fee exemption or fee reductions within a given year for annual fees for information technology systems and literature monitoring

Pharmacovigilance activities financed by PhV fees	* 2024 estimated	2024 actual	2024 percentage
Eligible for pharmacovigilance **annual fee** chargeable units invoiced		145,982	
· Micro sized enterprises	2.5%	1,000	0.69%
· Small and medium sized enterprises	7.5%	8,596	5.89%
· Generics (non-SME)	36.0%	64,441	44.14%

· Authorised homeopathic, authorised herbal, and well-established use product	0%	25,020	17.14%

Target: the estimated percentages

* Estimates based on the impact assessment

KPI 4: percentage of fees which has been recovered for the procedures invoiced within a given year and committed/paid to NCAs

Pharmacovigilance activities financed by PhV fees	[68] Invoiced in 2024	Cash collected in 2024	[69] Percentage	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	23,121	21,697	94% (98% in 2023)	15,586
Income recovered for imposed PASS protocol procedures started	106	98	92% (100% in 2023)	45
Income recovered for imposed PASS report procedures started	160	160	100% (100% in 2023)	79
Income recovered for pharmacovigilance referral procedures started	427	377	88% (100% in 2023)	284
Income recovered for pharmacovigilance annual fee chargeable units invoiced	9,228	9,164	99% (99% in 2023)	n/a

[68] The figures in this table differ from the ones in tables 4,5,6 and 9 because they also include adjustments and corrections related to 2024 and processed in 2025, whereas the amounts shown in the tables below show only the value of the invoices related to the applications started between January and December 2024. In addition, some of the applications received at the end of the year were processed in the financial system in January 2024.

[69] Invoices are issued with 30 days credit which means that the payment of the invoices issued in November and December 2024 were paid for in 2025. The final 2024 cash recovery rate as of May 2024 is 99.9% for PSURs and PSUSAs, 100% for PASS, 99.1% for Referrals and 99.5% for Annual fee.

Part 2: Performance information criteria defined in Part V of the Annex to the Regulation

Fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use - Regulation (EU) No 658/2014: Performance Information

Reporting period: 1st January - 31st December 2024

Table	Performance Information (Part V of the Annex)
1	Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Article 4 to 7.
2	Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.
3	Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Article 4 to 7.
4	Performance information relating to periodic update safety reports (PSURs)
5	Performance information relating to post-authorisation safety studies (PASS)
6	Performance information relating to referrals initiated as result of the evaluation of pharmacovigilance data
7	Information on marketing authorisation holders that have claimed a small and medium-sized enterprise or micro enterprise status
8	Information on marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees
9	Performance information relating to the annual fees

10	Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
11	Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

Note: the Agency has made every effort to complete the detailed reporting requirements of the following tables but in a small number of cases some data has not been available for the full calendar year 2024 pending the development of additional IT reporting functionality, in which cases the relevant fields are left blank.

1) Number of FTEs involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees.	**Full Time Equivalence (FTEs)**
Periodic safety update reports	9
Post-authorisation safety studies	1
Referrals initiated as a result of the evaluation of pharmacovigilance data	2
TOTAL	**12**

	2024		
2) Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.	**Units**	**Units**	**Cost €'000**
Identifying and managing duplicates	Number of duplicate couples assessed	205,187 (109,689 in 2023)	2,635
	Number of 'master' reports generated based on duplicated data	112,995 (105,033 in 2023)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded	46,438 (77,598 in 2023)	
	Number of adverse reaction reports recoded:	56,563 (66,461 in 2023)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review	186 (160 in 2023)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected	187,381 (163,013 in 2023)	
[70]Monitoring of substance groups and selected medical literature	Number of literature references screened and reviewed	780,343 (581,041 in 2023)	2,288

[70] The European Medicines Agency (EMA) is responsible for monitoring 409 substance groups (309 chemical & 100 herbal) and selected medical literature to identify suspected adverse reactions with medicines authorised in the European Union, and for entering the relevant information into the EudraVigilance database.

	Number of individual case safety reports (ICSRs) entered into Eudravigilance database and made available to National Competent Authorities and Marketing Authorisation Holders.	11,411 (9,698 in 2023)	

[1]The European Medicines Agency (EMA) is responsible for monitoring 409 substance groups (309 chemical & 100 herbal) and selected medical literature to identify suspected adverse reactions with medicines authorised in the European Union, and for entering the relevant information into the EudraVigilance database.

3) Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees.	**Staff costs `000**	**Non-staff costs `000**
Cost for assessment of periodic safety update reports	1,465	16,125
Cost for assessment of post-authorisation safety studies	243	214
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	316	401
Annual cost for information technology systems and literature monitoring		9,300
Overall pharmacovigilance costs	**28,063**	

4) Performance information relating to the assessment of periodic safety update reports (PSURs)

Number of procedures started	Number of reports received	Number of MAHs expected to submit	Number of MAHs who submitted	Number of CUs[2]	Number of joint submissions[3]	Number of MAHs who submitted joint report[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
887	n/a	1,344		40,355	262	3,333	117	0	17	0	21,020,409

5) Performance information relating to the assessment of draft protocols and of final reports of post-authorisation safety studies (PASS)											
Number of procedures started	Number of protocols and reports submitted[1]	Number of (parent) MAHs[2]	Total number of MAHs [2]	Number of joint submissions[3]	Number of (parent) MAHs in case of joint submission[4]	Total number of MAHs in case of joint submission[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
5	n/a	30	355	31	28	357	1	0	0	0	106,650
5	n/a	5	5	0	0		0	0	0	0	160,200

6) Performance information relating to referrals initiated as a result of the evaluation of pharmacovigilance data							
Number of procedures started	Number of MAHs	Number of CUs	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
2	371	1,061	33	0	4	0	426,953

7 (a) Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	117	0
Fee for assessment of post-authorisation safety studies	1	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	33	0
Annual fee for information technology systems and literature monitoring	395	0

7 (b) Number of marketing authorisation holders that have claimed micro enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	17	0
Fee for assessment of post-authorisation safety studies	0	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	4	0
Annual fee for information technology systems and literature monitoring	136	0

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2024
Generic application (Article 10(1) of Directive No 2001/83/EC)	1,785
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,767
Authorised homeopathic medicinal product	79
Authorised herbal medicinal product	225

9) Performance information on annual fees

Number of marketing authorisation holders invoiced for annual fees	Number of CUs	SME status claimed?	SME status denied?	Micro status claimed?	Micro status denied?	Number of CUs: Generic Application	Number of CUs: Well-established Use Application	Number of CUs: Authorised Homeopathic	Number of CUs: Authorised herbal	Total Amount Invoiced (€)	Average Amount Invoiced (€)
3,403	145,982	395	0	136	0	69,579	24,361	2,731	1,677	10,316,883	70.67

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	**PASS**	**Referral**
Austria	52	0	0
Belgium	25	0	0
Bulgaria	3	0	0
Czech Republic	28	0	1
Germany	78	1	1
Germany	48	0	0
Denmark	53	2	0
Estonia	5	0	0
Spain	39	0	0
Finland	34	1	0
France	55	1	0
Greece	2	0	0
Croatia	28	0	1
Hungary	12	0	1
Ireland	34	0	0
Iceland	4	0	0
Italy	40	1	0
Lithuania	12	0	0

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	**PASS**	**Referral**
Latvia	17	0	0
Malta	9	0	0
Netherlands	125	1	0
Norway	7	0	0
Poland	45	1	0
Portugal	28	0	0
Romania	3	0	0
Sweden	88	2	0
Slovenia	3	0	0
Slovakia	10	0	0
Total	**887**	**10**	**4**

11) Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

	PSUR and PSUSA			PASS		Referrals	
NCAs	No. of procs.	Total hours	Average per proc.	No. of procs.	Total hours	No. of procs.	Total hours
Austria	44	3,073	70				
Belgium	26	2,652	102				
Bulgaria	2	110	55				
Croatia	31	1,873	60			1	703
Czech Republic	10	600	60				
Denmark	45	6,282	140	1	114		
Estonia	3	194	65				
Finland	37	2,802	76				
France	40	5,279	132				
Germany-BfArM	77	9,955	129	1	167		
Germany-PEI	28	1,400	50				
Hungary	8	742	93			1	970
Iceland	2	124	62				
Ireland	35	2,552	73				
Italy	35	2,870	82	1	82		

11) Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.							
	PSUR and PSUSA			PASS		Referrals	
NCAs	No. of procs.	Total hours	Average per proc.	No. of procs.	Total hours	No. of procs.	Total hours
Latvia	4	300	75				
Lithuania	6	1,279	213				
Malta	2	544	272				
Netherlands	108	4,670	43				
Norway	4	376	94				
Portugal	27	1,220	45				
Romania	3	251	84				
Slovakia	3	374	125				
Slovenia	5	441	88				
Spain	35	3,490	100				
Sweden	83	4,974	60	2	0		
Grand Total	**703**	**58,427**	**83**	**5**	**363**	**2**	**1,673**

The data in the above table was provided by each NCA in line with the reporting requirements of the relevant cooperation agreement and include only finalised procedures. On-going procedure will be reported in the next reporting period.

The data in the table above is based on the information provided by the end of April. It was noted that not all NCAs were in a position to provide data for 2024.

Annex 1

Performance information required as per Part V of the regulation

The following information shall relate to each calendar year:

Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of hours outsourced to third parties with specification of the activities concerned and cost incurred.
Overall pharmacovigilance cost and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of procedures relating to the assessment of periodic safety update reports, as well as number of marketing authorisation holders and number of chargeable units per procedure; number of reports submitted per procedure and number of marketing authorisation holders that have submitted a joint periodic safety update report.
Number of procedures relating to the assessment of draft protocols and of final reports of poste-authorisation safety studies; number of marketing authorisation holders having submitted a draft protocol; number of marketing authorisation holders having submitted a final study report; number of marketing authorisation holders that have submitted a joint study.
Number of procedures relating to the referrals initiated as a result of the evaluation of pharmacovigilance data as well as number of marketing authorisation holders and number of chargeable units involved per marketing authorisation holder and per procedure.
Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure; number of marketing authorisation holders whose claim has been denied.

Number of marketing authorisation holders that have claimed a micro enterprise status; number of marketing authorisation holders whose claim for fee exemption has been denied.
Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees; number of chargeable units per marketing authorisation holder concerned.
Number of invoices sent out and annual fees charged in respect of the annual fee and average and overall amount invoiced to marketing authorisation holders. Number of marketing authorisation holders that have claimed a small and medium-sized enterprise or a micro enterprise status for each application of the annual fee; number of marketing authorisation holders whose claim has been denied.
Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

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 2024 the authorising officer has waived recovery orders for a total of EUR 13,791 as the amount receivables could not be recovered due to the insolvency of the debtors

Terms and abbreviations

Term/abbreviation	Definition
AA	Administrative Agreement
AAR	Annual Activity Report
AAV	Adeno-associated viral vector
ACE	Analytics Centre of Excellence
ACL	Access-Control Lists
ACPC	Advisory Committee on Procurement and Contracts
ACT EU	Accelerating Clinical Trials in the EU
AD	administrator category post
ADR	Adverse drug reaction
AER	Adverse event report
AFS	Anti-Fraud Strategy
AHEG	Ad Hoc Expert Group
AI	Artificial intelligence
AMA	African Medicines Agency
AMEG	Antimicrobial Advice Ad Hoc Expert Group
AMQF	African Medicines Quality Forum
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization programme
API	Active pharmaceutical ingredient
AR	Assessment report
ASR	Annual Safety Information
AST	Assistant category post
ASU	Antimicrobial sales and use
ATAm	Alternative to Antimicrobials
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUD	Audit
AUDA-NEPAD	African Union Development Agency

Term/abbreviation	Definition
AVAREF	African Vaccine Regulatory Forum
AVS	Assisted Validation System
AWP	Annual Work Programme
AWS	Amazon Web Services
BDSG	Big data steering group
BE	bioequivalence
BI	Business Intelligence
BJCP	British Journal of Clinical Pharmacology
BWP	Biologics Working Party
CA	Contract agent
CAP	Centrally authorised product
CAT	Committee for Advanced Therapies
CATT	FDA Center for Biologics Evaluation and Research Advanced Technologies Team
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CE	Conformité Européenne
CECP	clinical evaluation consultation procedure
CGREA	Central Governement Real Estate Agency of The Netherlands
CHMP	Committee for Medicinal Products for Human Use
CHMP SRLM	Strategic Review & Learning Meeting
CMA	conditional marketing authorisation
CMC	Chemistry, Manufacturing and Controls
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
COMP	Committee for Orphan Medicinal Products
CP	Centralised procedure
CRM	Customer Relationship Management
CRO	Clinical research organisations
CRP	Collaborative Registration Procedure
CSA	consolidated pre-clinical trial application

Term/abbreviation	Definition
CT	Clinical trial
CTA	Clinical Trial Application
CTCG	Clinical Trials Coordination Group
CTD	common technical document
CTIS	Clinical trial information system
CTN	Clinical Trial Navigator
CTR	Clinical Trials Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
DARWIN EU	Data Analytics and Real World Interrogation Network
DC	Data Centre
DCP	Decentralised procedure
DG	Directorate-General of the European Commission
DG INTPA	European Commission Directorate-General for International Partnerships
DG NEAR	European Commission Directorate-General for Neighbourhood and Enlargement Negotiations
DG RTD	Euoropean Commission Directorate-General Research and Innovation
DG SANTE	European Commission Directorate-General for Health and Food Safety
DHPC	Direct healthcare professional communications
DIA	Drug Information Association
DIVS	Document Identification Validation System
DPA	data processing agreement
DPC	Data Protection Coordinators
DPIA	Data Protection Impact Assessments
DPN	Data Protection Notice
DPO	Data Protection Officer
DREAM	Document Records Electronic Archive Management system
EAC	East African Community Region
EC	European Commission
ECA	European Court of Auditors

Term/abbreviation	Definition
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission priority
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMC2	French Health Data Hub
EMP-TC	Evaluation of Medicinal Products Technical Committee
EMRN	European medicines regulatory network
EMWP	European Medicines Web Portal
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
END	Seconded national expert (Experts nationaux détachés)
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
EO	Economic Operators
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
eRMR	Electronic Reaction Monitoring Report
ESEC	European Specialised Expert Community
ESIP	European Social Insurance Platform
ESMP	European Shortages Monitoring Platform

Term/abbreviation	Definition
ESUAVeT	European Sales and Use of Veterinary Antimicrobials Working Group
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	Emergency Task Force
ETT	FDA Emerging Technology Team
EU	European Union
EUAN	EU Agencies Network
EUDPR	European Union Data Protection Regulation
EU-PAS	EU Post-Authorisation Study register
EUR	Euro
EurEKA	EU product information Entity Extraction and Knowledge Acquisition
EURS	European Review System for eCTDs
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVIP	European Vaccination Information Portal
EV-SSAP	EudraVigilance Signal and Safety Analytics Platform
EVV	Union Pharmacovigilance Database
EWP	Efficacy Working Party
EXB	EMA Executive Board
EXPAMED	Expert Panels on Medical Devices
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FMT	Faecal Microbiota Transplantation
FR	Financial regulation
FTE	Full-time equivalent
FWC	Framework contract
GBC	Green Business Club
GBZ	Green Business Club (GBZ) Zuidas
GCG	CHMP Guideline Consistency Group

Term/abbreviation	Definition
GCP	Good clinical practice
GDPR	General Data Protection Regulation
GFR	General Financial Regulation
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
GPP	green criteria in public procurement procedures
GVP	Good pharmacovigilance practice
HaDEA	European Health and Digital Executive Agency
HCIN	Heads of Communication and Information Network (EU agencies network)
HCP	Healthcare professional
HCPWP / PCWP	Healthcare Professionals Working Party/ Patients and Consumers Working Party
HDH	French Health Data Hub
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
HTACG	Member State Coordination Group on HTA
HTAR	regulation on health technology assessment
IAC	Internal audit capability
IAS	Commission's Internal audit service
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report

Term/abbreviation	Definition
ICT	Information and communication technologies
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IHD	Instant Health Data
IHI	Innovation Health Initiative
IMP	Investigational medicinal product
INFARMED	Portuguese National Authority of Medicines and Healthcare Products
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme
IRIS	Platform facilitating the exchange of regulatory and scientific information between EMA and organisations developing medicinal research products for potential use in the European Union
ISO	International Organisation for Standardisation
IT	Information technology
ITF	Innovation Task Force
IVDR	In vitro Diagnostics Regulation
IVMAB	Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JCA	Joint Controllership Agreement
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
JSC	Joint Scientific Consultations
JU	Joint Undertaking
KPI	Key performance indicator
LLFG	Listen and Learn Focus Groups
LLM	large language processing models
LMIC	Low-and middle-income countries
LMS	EU Network Training Centre Learning Management System
LTT	Line to take

Term/abbreviation	Definition
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MAWP	EMA multiannual work programme
MB	Management Board
MDCG	Medical Device Coordination Group
MDR	Medical Devices Regulation
MDSSG	Medical Devices Shortages Steering Group
MEDEV	Medicine Evaluation Committee
MLM	Medical literature monitoring
MON VS	Monitoring Value Stream
MPRR-TC	Medicines Policy and Regulatory Reforms Technical Committee
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MRP	Mutual recognition procedure
MS	Member State of the European Union
MSP	Multi-Stakeholder Platform
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA VS	Managing the Agency Value Stream
MUMS	Minor use, minor species
MVP	Minimum viable product
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority
NCPE	National Centre for Pharmacoeconomics, Ireland
NDSG	Network Data Steering Group
NFR	New Fee Regulation
NIS	Non-Interventional Study
NITAG	National immunization technical advisory groups of WHO
NLP	Natural language processing

Term/abbreviation	Definition
NRA	National Regulatory Agencies
NTC	EU Network training centre
NTWP	Novel Therapies and Technologies Working Party
OIA	Operational Initiating Agent's
OLAF	European Anti-Fraud Office
OPEN	Opening our Procedures at EMA to Non-EU authorities
OTS	off-the-shelf (studies)
PAES	Post-authorisation efficacy study
PAM	Pre-clinical Assessors Meeting
PASS	Post-authorisation safety study
PDCO	Paediatric Committee
PECP	performance evaluation consultation procedure
PEI	Paul-Ehrlich-Institut, agency of the German Federal Ministry of Health
PHE	Public Health Emergency
PhVWP-V	EMA CVMP Pharmacovigilance Working Party
PI	Programme increment
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/Pharmacodynamic
PLM	Product Lifecycle Management Value Stream
PMF	Plasma master file
PMS	Medicinal Product Management System
POC	Point of Contact
PONSA	Phonetic and Orthographic Name similarity algorithm
PQ	Pre-qualification
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure

Term/abbreviation	Definition
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROM	CHMP's preparatory and organisational matters meeting
P-SMEG	Pilot Signal Management Expert Group
PSUR	Periodic safety-update report
PSUSA	PSUR single assessment
PUI	Product User Interface
QAT	Quality control, assurance and acceptance testing
QIG	Quality Innovation Group
QRD	EMA Working Party on Quality Review of Documents
QWP	Quality Working Party
RACI	Responsible, Accountable, Consulted, Informed
RAGNA	Regulatory Agencies Global Network against AMR
RCD	Regulatory Capacity Development
RFI	Request for information
RMM	Risk minimisation measures
RMP	Risk Mitigation Plan
ROG	Regulatory Optimisation Group
RPI	Research Product Identifier
RPM	Regulatory Procedure Management
RR	routine repeated
RSS	Regulatory Science Strategy
RSV	Respiratory syncytial virus
RWD	Real world data
RWE	Real-world evidence
SA	Scientific advice
SADC	Southern African Development Community
SAFe	Scaled Agile Framework
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SC	Scientific committee

Term/abbreviation	Definition
SCC	Standard Contractual Clauses
SDNS	Système National des Données de Santé (SNDS) - French National Healthcare (insurance) Data
SIA	Special Interest Area
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SMP	Shortage Mitigation Plans
SmPC	Summary of product characteristics
SMS	Substances Management Services
SNE	Seconded national expert
SNSA	Simultaneous National Scientific Advice
SOC	Security Operations Center
SOP	Standard Operating Procedure
SPC	Summary of product characteristics
SPD	Single Programming Document
SPMP	Shortage prevention and mitigation plan
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
SPP	Shortage Prevention Plans
SSA	Signal and Safety Analytics
STAMP	Expert Group on Safe and Timely Access to Medicines for Patients
STARS	Coordination and Support Action on Strengthening Training of Academia in Regulatory Science
SUMMA	EC's financial system
SWP-V	EMA CVMP Safety Working Party
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TC	Technical Committee
TDA	EMA Data Analytics and Methods task force

Term/abbreviation	Definition
TDT	EMA Digital Business Transformation task force
TF	Task force
TF AAM	Task Force on Availability of authorised medicines for human and veterinary use
TIA	Transfer Impact Assessments
TLM	Technology Lifecycle Management and Information Security Value Stream
TRIP	Topics of innovation, Relationships between external and internal topics, Identification of challenges and opportunities, Proposals for action.
TRS	EMA Regulatory Science and Innovation Task Force
TRS-INO	Regulatory Science and Innovation Task Force - Innovation and Development Accelerator
UI	User interface
UK	United Kingdom
ULCM	Union List of Critical Medicines
UP	Union Pharmacovigilance Database
UPD	Union product database
US	United States of America
UX	user experience
VE	Vaccine Effectiveness
VF	VICH Forum
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform
VNRA	Variations not requiring assessment
VOG	Vaccine Outreach Group
VRA	variations requiring assessment
VS	Value Stream
VSM	Voluntary solidarity mechanism
WG	Working group
WGCP	Working Group of Communication Professionals
WHO	World Health Organization

Term/abbreviation	Definition
WHO-SRA	Stringent Regulatory Authority
WLA	WHO listed authorities
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary