EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# ANNUAL REPORT 2024

**The European Medicines Agency's contribution to science, medicines and health in 2024**

An agency of the European Union

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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# Foreword by Lorraine Nolan

## Chair of EMA Management Board

Welcome to the 2024 EMA annual report, which highlights milestones and achievements of the past year, and our regulatory network's commitment to bringing value to public and animal health in the European Union (EU).

As I reflect on another big year of change and progress for the European medicines regulatory network, several highlights that will help shape the future direction of our work over the next few years really stand out.

Last year marked a significant milestone in our strategic planning as EMA and the Heads of Medicines Agencies (HMA) started to update the European medicines agencies network strategy (EMANS), extending our vision to 2028. Titled 'Seizing opportunities in a changing medicines landscape', this comprehensive update to the original EMANS strategy to 2025 responds to the rapid changes we are seeing on the regulatory and technological landscape.

Our vision is to have a well-resourced, competitive network that leverages technological advances to increase productivity. By setting measurable goals and objectives, the EMANS to 2028 will keep the network aligned with the evolving healthcare needs within the EU and accountable for the part that it plays.

In 2024, the network continued to take a proactive approach on its broader sustainability. The EU Network Training Centre plays an important role in supporting capacity development. Its comprehensive training courses have continued to offer high-quality scientific regulatory training opportunities. This has led to continuous sharing of expertise across Member States and contributes to improving capacity to handle complex assessments.





### Progress on clinical trials and use of artificial intelligence in medicines regulation

In 2024, we saw continued progress in the implementation of the Clinical Trials Information System (CTIS) with increasing adoption across the EU and more sponsors transitioning their trials to this harmonised platform. Though work continues, the system is delivering on enhancing transparency and efficiency in clinical trials across Europe.

As a network it is important for us to examine how technologies such as AI can be deployed in a practical, safe and secure way and the AI work plan to 2028 does just that: setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks. The ongoing AI pilots running at EMA are very encouraging – and I can see how AI will further boost our network without sacrificing our core public health principles of safety, quality and efficacy.

Medicines availability remained a pressing concern of the Board. Throughout 2024, our network continued to work closely with all stakeholders to address shortages and ensure continuity of supply across the EU.

### Transparency and collaboration

The strength of this network lies in its willingness to collaborate. Throughout the year, I have witnessed first hand the exceptional commitment of national competent authorities (NCAs), working together with unwavering dedication to advance public health across Europe. I am confident that our initiatives will continue to enhance our ability to fulfil our mission in the coming years.

I am always aware of the important twin pillars of transparency and trust in medicines regulation. They are fundamental and remain at the heart of this network. In 2024, the Management Board endorsed EMA's updated policies on managing competing interests among our scientific committee members, experts and Management Board members. These revised policies respond to recent Court of Justice judgments while maintaining our commitment to robust and balanced governance – demonstrating our ongoing commitment to ensuring the highest standards of independence in our scientific decision-making processes.

I extend my heartfelt thanks to my fellow Board members, particularly our new vice-chair, Rui Santos Ivo, and our dedicated topic coordinators who provide invaluable expertise and leadership. The Board's newly established audits and risks group (MBARG) deserves special recognition for its contributions in 2024. The group's strategic insights significantly strengthened our governance framework during last year.

I am also grateful to the European Commission for their partnership, support and trust throughout 2024. I would also like to thank my colleagues in our network, whose hard work and dedication to public health is reflected in this report. I look forward to our continued collaboration to support the EU's public health goals in 2025. Let the achievements documented here remind us of the immense value that science brings to our world.

Thank you all for your continued support.

# Introduction by Emer Cooke

## EMA Executive Director

Welcome to the 2024 EMA annual report. This year was full of innovation, advancement and breakthroughs for patients and animals in the EU. From addressing medicine shortages to advancing digitalisation initiatives and tackling antimicrobial resistance, we made significant strides forward.

In 2024, the Agency issued its highest number of recommendations for new medicines and treatments in 15 years. For the first time since 2009, we delivered over 100 positive opinions, including recommendations for 114 new medicines for human use. Among these, 46 contain a completely new active substance, and 16 are for the treatment of rare diseases.

### Benefits for EU patients

Notable approvals include the first medicine to treat early Alzheimer's disease, a nasal spray adrenaline for allergic reactions, a treatment for tumours associated with von Hippel-Lindau disease, and two new antibiotics for severe infections. Cancer was the leading therapeutic area, with 28 recommendations for oncology products. We also approved Durveqtix, a new gene therapy for haemophilia B, Qalsody for a rare motor neurone disease (ALS), and the first vaccine to protect adults from Chikungunya, a virus transmitted to people by mosquitoes.

There were also 28 recommendations for new biosimilar products, covering a wide range of diseases, including several types of cancer, osteoporosis, macular degeneration and diseases that involve an abnormal immune response like plaque psoriasis, ulcerative colitis and Crohn's disease. This is certainly good for European patients, as biosimilars make treatments more accessible and can provide broader access to potentially life-changing medicines.

### Progress for animal health

In 2024, EMA also recommended 25 veterinary medicines for marketing authorisation – the highest number ever. Among them, 14 were vaccines, including seven that had been developed through a biotechnological process.

With bird flu continuing to be a public health concern in 2024, EMA's veterinary medicines committee, the CVMP, recommended a new vaccine against the strains of highly pathogenic avian influenza that were circulating last year. EMA works with public health authorities in the EU and worldwide to monitor the risk and prepare to respond in the event of a public health emergency.

EMA also certified the first veterinary vaccine platform technology master file (vPTMF) in November 2024. Such platforms play an important role in animal and public health preparedness because they can be adapted rapidly, thus speeding up the development and approval of new veterinary vaccines in the EU in response to emerging diseases.





### A coordinated approach to shortages

In 2024, medicine shortages remained a high priority on the public health agenda. The reasons for shortages are always multifaceted but a specific case of difficult supply-and-demand dynamics emerged in 2024 with shortages of GLP-1 receptor agonist medicines. Increased demand for these medicines for both diabetes and obesity, coupled with significant supply challenges, jeopardised treatment programmes for many patients.

To address this issue, we launched coordinated actions across the EU. We stepped up communications to influence prescribing and consumption behaviours, ensuring that those who needed the medicines received them. When it was most needed, we also oversaw the redistribution of stocks among EU Member States to prevent patients from missing their medications. By closely monitoring the market situation, including the status of current and anticipated shortages, we could see where our mitigation actions were effective.

At the end of 2024, we organised the soft launch of the European Shortages Monitoring Platform (ESMP), introducing a limited set of functionalities for marketing authorisation holders. A full launch followed in January 2025. This platform enables the fast exchange of information between regulators and pharmaceutical companies to support the management of shortages in the EU.

On the communications side, we hosted a media seminar towards the end of the year, bringing together EU journalists and EMA experts. By providing greater access to our experts, we aim to bridge the knowledge gap and prevent behaviours that contribute to medicine shortages.

### Digitalisation: AI enabling our work

AI is influencing all parts of our lives today and continues to bring dramatic changes to all industries with important applications for medicines regulation. We continue to explore how AI systems can be used to bring benefits to patients, our broader regulatory system and to the work our scientists do in a safe, transparent, ethical and unbiased way.

We are proud of our proactivity in the AI field. With the HMA, we published our 2023-2028 multi-annual AI work plan early in 2024, to help the European medicines regulatory network (EMRN) harness AI opportunities in the regulatory and medical field. We have several ongoing AI initiatives under this work plan that are already changing the way scientists work.

In March, for example, we launched Scientific Explorer, an AI tool to help EU regulators access information from thousands of scientific advice procedures to simplify their work, support their decision-making and save them time. In the field of rare diseases, CollaboRARE was launched in April. This is a co-creation between EMA and EURORDIS to develop and pilot an AI-based patient-validated methodology to capture and use patient experience data (PED) for orphan medicines. The validation by patient organisations of the PED gathered by AI will help further integrate the patient perspective into medicines development and evaluation.

As regulators learn more about how best to realise the potential of AI, we need to also understand and educate ourselves about how to manage possible risks, and keep training and preparing our staff for the future. As more use cases are implemented, we need to continue to ask the right questions and to challenge and course correct where necessary.

### Clinical evidence and real-world evidence

High-quality clinical evidence is at the heart of every well-informed decision on medicines. We know that our biggest opportunity for medicines development in Europe lies in cultivating a robust, modern clinical trials ecosystem. Through our Accelerating Clinical Trials in the EU initiative, or ACT EU, we continued to bring all the ecosystem's stakeholders together – patients, healthcare professionals, industry, regulators, academia and Member States.

The year 2024 was the last of the three-year transition period for the Clinical Trials Regulation. I appreciated all the efforts by NCAs and EMA that went into ensuring that clinical trials taking place in the EU were transitioned into the Clinical Trials Information System (CTIS), which support the flow of information between clinical trial sponsors, EU Member States, European Economic Area (EEA) countries and the European Commission platform. Work on the simplification and modernisation of CTIS can now continue as a priority.

CTIS will also become a World Health Organisation (WHO) Primary Registry of the WHO International Clinical Trials Registry Platform (ICTRP), a major step forward from its previous status as data provider. This new status increases the recognition of CTIS for data sharing, reliability and promoting transparency.

While clinical trials remain our first source for evidence generation, we continue to develop real-world evidence (RWE) capabilities to fill knowledge gaps and complement the picture. In 2024, we continued to generate evidence based on knowledge and expertise, embracing diverse data and methods, and exploring, enabling and validating new approaches. We also made further progress to integrate RWE into our decision-making so that it brings value to public health in the EU. The Data Analysis and Real World Interrogation Network (DARWIN EU) became fully operational as the main pathway to generate RWE; the network now has access to 160 million patients' health data in 16 European countries and is generating studies that can tell us how medicines perform in the real world.

In 2024, these included research on the prevalence of rare blood cancers in Europe, the prescription of antibiotics and a study examining the characteristics of patients who have been prescribed GLP-1 receptor agonists, used for diabetes and weight management, and how these have changed over the past ten years.

## Antimicrobial resistance: addressing an invisible threat

WHO launched a public health campaign in 2024 on the theme that antimicrobial resistance is invisible, but its victims are not. This campaign highlights the silent crisis that antimicrobial resistance has become, causing 35,000 deaths annually in Europe and imposing significant costs on all systems. Coordinated action is essential to combat this health crisis.

The International Coalition of Medicines Regulatory Authorities (ICMRA) provides a unique platform for international regulators and other key stakeholders to develop strategic responses to antimicrobial resistance. At the 11th ICMRA Summit in November 2024, EMA co-chaired a crucial panel discussion on this topic where international regulators shared feedback and insights. This led to the publication of a statement reiterating the critical importance of preserving the effectiveness of antimicrobials and the crucial role regulators play in addressing the challenge collaboratively.

On the veterinary side we have a remarkable success story to tell. One of our past projects, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, has significantly reduced sales of veterinary antibiotics in the EU. ESVAC was a voluntary project – a concerted effort by farmers, veterinarians and national authorities – that led to sales of veterinary antibiotics in Europe dropping by more than 50 % over 12 years. This demonstrates that we can reduce antimicrobial resistance through a combination of monitoring, collecting data and communication. These principles are now embedded in EU legislation. The collection of data on sales and use of veterinary antimicrobials is now mandatory for all Member States.

## Collaboration across the network

In 2024 we made a huge difference across the board to patients and animals in the EU, and we look ahead to 2025, our 30th anniversary, with renewed determination, enthusiasm and passion.

Through 30 years of operations our Agency has impacted millions of lives of Europeans for the better. This year, the Agency will maintain its focus on accelerating and optimising the assessment of key medicines, working collaboratively on the joint EU medicines agencies network strategy to improve both accessibility and availability of medicines, as well as working on future-proofing our activities in preparation for the new pharmaceutical legislation.

It will be another exciting year for medicines regulation. I am enormously grateful for all the wonderful stakeholders and partners whose support and collaboration inspires us and drives our network forwards in these challenging times.



# CHAPTER 1

# Key achievements in 2024

# Evaluation and monitoring of medicines: highlights

## Human medicines

### Medicines recommended for approval

The authorisation of new medicines is essential to advancing public health as they bring new opportunities to treat or prevent certain diseases. In 2024, EMA recommended 114 medicines for marketing authorisation, including 46 with new active substances. The medicines recommended for approval in 2024 selected in this overview represent significant progress in their therapeutic areas:

Beqvez, a gene therapy treatment for haemophilia B, a rare inherited bleeding disorder.

Emblaveo, an antibiotic for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia and infections caused by aerobic Gram-negative bacteria resistant to many current treatments for patients.

Emcitate, the first treatment for peripheral thyrotoxicosis in patients with Allan-Herndon-Dudley syndrome, a rare, chronic and severely debilitating disease caused by mutations in the gene coding for the thyroid hormone transporter MCT8 protein.

Eurneffy, the first nasal spray emergency treatment against allergic reactions, providing an alternative to traditional injections.

Fabhalta, an oral treatment for adults with paroxysmal nocturnal haemoglobinuria, a rare genetic disorder and potentially life-threatening blood disease leading to the premature destruction of red blood cells by the immune system.

Ixchiq, the EU's first Chikungunya vaccine for adults. Chikungunya is endemic in many (sub) tropical countries and causes recurrent epidemics. Due to climate change, it may also spread to regions so far spared. Ixchiq was assessed under EMA's OPEN initiative that fosters international collaboration and the sharing of scientific expertise to promote global public health.





Qalsody, a new therapy for the treatment of adult patients with amyotrophic lateral sclerosis (ALS), a rare and often fatal disease that causes muscles to become weak and leads to paralysis. This medicine is indicated for the treatment of adults with ALS, who have a mutation in the superoxide dismutase 1 (SOD1) gene.

Leqembi, a treatment of mild cognitive impairment (memory and thinking problems) or mild dementia due to Alzheimer's disease (early Alzheimer's disease) in patients who have only one or no copy of ApoE4, a certain form of the gene for the protein apolipoprotein E.

Voydeya, the first oral treatment against residual haemolytic anaemia in patients with paroxysmal nocturnal haemoglobinuria.

Welireg, for the treatment of tumours associated with von Hippel-Lindau disease and advanced clear cell renal cell carcinoma. This is the first medicine to treat von Hippel-Lindau disease, a rare genetic disorder causing cysts and tumours.

Winrevair, a treatment for adults with pulmonary arterial hypertension, a rare, long-term, debilitating and life-threatening condition in which patients have abnormally high blood pressure in the arteries in the lungs.

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## Early access to medicines that address public health needs

In 2024, **three medicines** received a recommendation for marketing authorisation following an **accelerated assessment: Emblaveo, Ixchiq** and **Kavigale.** This mechanism is reserved for medicines that address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees (within a maximum of 150 days rather than 210 days).

**Eight medicines** received a recommendation for a **conditional marketing authorisation,** one of the possibilities in the EU to give patients early access to new medicines: **Augtyro, Beqvez, Filspari, Incellipan, Iqirvo, Ordspono, Seladelpar Gilead and Welireg.**

The conditional authorisation allows for early approval on the basis of less complete clinical data than normally required, because the benefit of earlier patient access weighs out the potential risks of limited data. These authorisations come with specific post-authorisation obligations to generate complete data on the medicines and are subject to annual re-evaluation of benefit-risk.

**Four medicines** (**Adzynma, Gohibic, Kayfanda** and **Qalsody**) were authorised under exceptional circumstances, a route that allows patients access to medicines that cannot be approved under a standard authorisation as comprehensive data cannot be obtained, either because there are only very few patients with the disease, or the collection of complete information on the efficacy and safety of the medicine would be unethical. These medicines are subject to specific post-authorisation obligations and monitoring.

**The enhanced development support provided by EMA's PRIority Medicines (PRIME) aims at helping patients to benefit as early as possible from promising medicines that target an unmet medical need, by optimising the generation of robust data and enabling accelerated assessment. This year, six medicines with PRIME designation were recommended for approval (Beqvez, Fabhalta, Ixchiq, Seladelpar Gilead, Voydeya and Winrevair).**

**Fourteen medicines under development were accepted in the scheme in 2024: oncology (5) endocrinology-gynaecology-fertility-metabolism (4), infectious diseases (2), other, congenital, familial and genetic disorders (2) and gastroenterology – hepatology (1).**






## Consolidation of the Cancer Medicines Pathfinder

In 2024, EMA made substantial progress with its Cancer Medicines Pathfinder initiative. Launched in 2023, this project aims to further support the development and approval of cancer medicines that could have a meaningful impact on transforming patient care. It takes a holistic approach to leverage all areas where EMA's actions can make a difference. Some of the activities included:

- **Building capacity and enhancing excellence throughout the EU network.** EMA consolidated its Oncology European Specialised Expert Community (ESEC), a platform to promote information sharing among European experts on scientific and regulatory topics. The Agency also launched a multinational pilot programme designed to inform experts outside of EMA and the NCAs about regulatory work and encourage the development of relevant regulatory knowledge to support regulatory activities. It reinforced its engagement with the US Food and Drug Administration (US FDA) in the area of oncology, notably by participating as an observer in Project Orbis, US FDA's framework for concurrent submission and review of oncology products, and by increasing information exchanges. In addition, EMA implemented a comprehensive communication strategy, which included the launch of a dedicated cancer newsletter, in partnership with a national regulator, the German BfArM, to raise awareness and disseminate information among stakeholders.
- **Improving the efficiency of the centralised procedure.** EMA established a focus group with industry representatives to pinpoint areas for improvement. Areas for actions included enhancing communication flows during the assessment process and accelerating responses from companies when questions arose during the assessment.
- **Addressing the complexity of approval and access decisions.** Through the Cancer Medicines Forum, established in 2022 in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), EMA continued to facilitate discussions between academics, healthcare professionals, patients and regulators on how to optimise treatments with oncology medicines.

EMA is also looking to apply the knowledge gained from their experience with cancer to advance the assessment of medicines in other therapeutic areas.

## Medicines for rare diseases

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

Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting the medicine ten years of market exclusivity. Among the 114 medicines recommended for marketing authorisation in 2024, **15 had their orphan designation confirmed** by the end of the year.

Six medicines lost their orphan status before receiving a marketing authorisation, which means they were still authorised as medicinal products but not as orphan medicinal products. These are: Agilus, Andembry, Beyonttra, Hympavzi, Ordspono and Wainzua.

## New uses for existing medicines

In 2024, **90** extensions of indication were recommended, including 40 for paediatric use. The extension of use of a medicine already authorised for marketing in the EU can also offer new treatment opportunities for patients. Notable extensions of indication included:

**Ofev,** for the treatment of progressive fibrosing interstitial lung diseases (ILDs) in children and adolescents from the age of six.

**Pegasys,** for the treatment of polycythaemia vera and essential thrombocytopenia in adults.

**Xromi,** for the prevention of vaso-occlusive complications of sickle-cell disease in children from the age of nine months.

EMA provided **scientific advice or protocol assistance** to applicants during the development of **60 % of the medicines that were granted a positive opinion**. The figure increases to 79 % for medicines with new active substances. Early engagement with developers allows EMA to clarify the kind of evidence required to later evaluate a medicine for authorisation. This encourages the generation of more robust data for regulatory assessment, and protects patients from taking part in unnecessary or poorly designed clinical trials.

## Negative opinions

The Committee for Medicinal Products for Human Use (CHMP) adopted a **negative opinion for five medicines** in 2024 after concluding that the benefits did not outweigh the risks: **Cinainu, Kizfizo, Masitinib AB Science, Nezglyal** and **Syfovre**. Detailed information is available for individual products on EMA's website.

**92 % of all opinions** (positive and negative) were reached by consensus among CHMP members, without divergent opinions.





## Expert views: Interview with Bruno Sepodes, Chair of the CHMP

**This has been your first year as CHMP chair. What are some of the major achievements of the committee in 2024?**

Overall, 2024 has been a very successful year for the CHMP and the EMRN. We recommended 114 medicines for marketing authorisation, 46 of which had new active substances previously not authorised in the EU. In addition, we introduced several measures to enhance the efficiency of the marketing authorisation review process. These include the implementation of a standard template for clock-stop extension requests and the update of assessment report templates to improve clarity and reduce duplication. We also provided better guidance and training for assessors to ensure consistency and efficiency. Automatic email notifications to marketing authorisation holders were also introduced to improve the predictability of post-marketing activities. Furthermore, we fostered closer dialogue with applicants to address challenges such as the low predictability of submission dates and the high percentage of companies requesting more time to respond to the committee's questions due to immature data in their applications. All these initiatives aim to accelerate the availability of safe and effective treatments for patients in Europe.

**What are some of the main challenges that the committee is facing in 2025?**

Staying ahead of scientific progress to ensure robust assessments is a top priority. We need the right expertise to deal with innovation from new directions, such as the use of new methodologies, AI, dealing with increasingly large data sets and integrating them in a meaningful way in the CHMP's assessment. We will continue to invest in training our assessors in cutting-edge areas of drug development. We must also be prepared for the new pharmaceutical legislation, effectively the largest reform of EU medicines regulation in decades. This is a once-in-a-generation opportunity to streamline and improve the medicines regulatory system. We are discussing legislative proposals and are committed to finding efficient solutions that will further improve our work.

Another upcoming challenge for the CHMP will be the implementation of the HTA Regulation and our new responsibilities to provide information to the Coordination Group responsible for the joint clinical assessment by EU HTAs. This will initially apply to new active substances to treat cancer and to all advanced therapy medicinal products (ATMPs). It will later be expanded to all centrally authorised medicines that are submitted for assessment to EMA with a full dossier.

In 2025 we also hope to consolidate the efficiency gains in the evaluation process of marketing authorisation applications that stem from our review and streamlining of processes. We started this initiative in 2024 and will continue throughout 2025.

**How do you see the future of regulatory science?**

The development of regulatory science is key to the public health achievements we may expect in the future. Regulatory science developed in partnership with academia and with the pharmaceutical industry will allow a faster knowledge transfer of new technologies and methodologies, and we remain committed to be part of this open and constructive dialogue with stakeholders, with the ultimate goal of bringing better medicines faster to the market. As Chair of the CHMP, I want to reinforce the committee's role as a global reference for regulatory science and innovation by adopting new processes and new technologies, improving the efficiency and effectiveness of regulatory processes, while fostering a culture of innovation to better support the development of innovative and promising therapies. I firmly believe the CHMP has a crucial role to play in ensuring that regulatory science in Europe remains at the forefront of global drug development and patient care. Together with our colleagues at EMA, the CHMP will be instrumental in delivering on the promise of innovative medicines for the benefit of all EU citizens.

# Keeping patients safe

## Monitoring medicines after their authorisation – Optimising safe and effective use

EMA and the EU Member States continuously monitor the quality, safety and the benefit-risk balance of authorised medicines when they are used in real life on the market. This is to optimise how the medicine is used by patients to achieve its full benefit and to protect them from avoidable side effects. Regulatory measures range from a change to the product information to the suspension or withdrawal of a medicine or recall of a limited number of batches.

**The product information for 401 centrally authorised medicines was updated on the basis of new safety data in 2024. Every year, the Pharmacovigilance Risk Assessment Committee's (PRAC) recommendations on safety warnings are also included in the product information of many thousands of nationally authorised products (NAPs). The revised information helps patients and healthcare professionals to make informed decisions when using or prescribing a specific medicine.**

Important new safety advice issued in 2024 included:

- **CAR T-cell medicines,** recommendation on the need for life-long monitoring of secondary malignancies in patients treated with these medicines.
- **Fluroquinolones,** recommendation to include anxiety, suicidal ideation, panic attack, neuralgia and concentration impairment as potential aspects of fluoroquinolone-induced, long-lasting and disabling adverse drug reactions.
- **GLP-1 receptor agonists,** new measures to minimise the risk of aspiration and pneumonia aspiration in patients who undergo surgery with general anaesthesia or deep sedation.
- **Hydroxyprogesterone-containing medicines,** recommendation to suspend the marketing authorisations for medicines containing 17-hydroxyprogesterone caproate (17-OHPC) in the EU, because of a possible but unconfirmed risk of cancer in people exposed to 17-OHPC in the womb. In addition, the review considered new studies, which showed that 17-OHPC is not effective in preventing premature birth. There are also limited data on its effectiveness in other authorised uses.
- **Medroxyprogesterone acetate,** new measures to minimise the risk of meningioma, a type of brain tumour. The measures include recommendations to not use this medicine in patients who have a meningioma or have had one in the past unless medroxyprogesterone acetate is needed for the treatment of an oncological indication, and monitoring symptoms of meningioma in patients taking high doses of medroxyprogesterone.
- **Metamizole,** updated warnings to increase awareness of agranulocytosis among patients and healthcare professionals, and facilitate its early detection and diagnosis to minimise the serious outcomes of this serious side effect that can lead to serious or even fatal infections.
- **Mysimba** (naltrexone/bupropion), recommendation to strengthen existing advice to minimise the risks from interactions with opioid-containing medicines, such as the opioid painkillers morphine and codeine, other opioids used during surgery, and certain medicines for cough, cold or diarrhoea.
- **Ocaliva** (obeticholic acid), recommendation to revoke the conditional marketing authorisation of Ocaliva, a medicine used to treat adults with a rare liver disease known as primary biliary cholangitis, because its benefits are no longer considered to outweigh its risks.
- **Oxycodone,** new warning in a black box added to the existing warning in the patient leaflet stating that oxycodone is an opioid that can cause dependence and/or addiction.





- Dependence and addiction are important risks of oxycodone and remain of concern in the EU/EEA.
- **Paxlovid** (nirmatrelvir, ritonavir), new warning on the co-administration of Paxlovid with certain immunosuppressants with a narrow therapeutic index, such as calcineurin inhibitors (ciclosporin, tacrolimus) and mTOR inhibitors (everolimus, sirolimus), which can result in life-threatening and fatal reactions due to pharmacokinetic interactions as Paxlovid is a strong CYP3A inhibitor.
- **Reyataz** (atazanavir), new contraindications on the co-administration of Reyataz with encorafenib and ivosidenib, and with carbamazepine, phenobarbital and phenytoin.
- **Valproate,** new precautionary measures for the treatment of male patients with valproate medicines to address a potential increased risk of neurodevelopmental disorders in children born to men treated with valproate during the three months before conception.
- **Veoza** (fezolinetant), new recommendation to conduct liver function tests before and during treatment to minimise the risk of liver injury. Treatment with Veoza should be discontinued in certain cases of transaminase and bilirubin elevations, or if liver enzyme elevations are accompanied by symptoms suggestive of liver injury.

## Ensuring integrity of clinical trial conduct and the manufacture and supply of medicines

Regulators ensure that development and manufacturing processes of any medicine marketed in the EU adheres to the standards set by EU legislation.

## Medicines tested by Synapse Labs Pvt. Ltd

Based on serious concerns about the data from bioequivalence studies conducted at Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Pune, India, the CHMP recommended suspending or not granting the marketing authorisations of a number of generic medicines tested by this CRO. The list of the medicines concerned is available on the EMA website.

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## Expert views: Interview with Ulla Wändel Liminga, Chair of the PRAC

**You took on the role of PRAC Chair in the second half of 2024, and you have also been a member for a long time. What are the highlights of the committee's work during this year for you?**

In 2024, the PRAC carried out a broad range of activities to monitor the safety of medicines in the EU and issued important safety advice for healthcare professionals and patients.

A notable procedure was the review of secondary T-cell malignancies for CAR T-cell immunotherapies used to treat certain cancers. The committee also reminded healthcare professionals of the important risks, including serious side effects involving the nervous system, tendons, muscles and joints related to the use of fluoroquinolones, a class of antibiotics. GLP-1 receptor agonists, a group of diabetes and weight-loss medicines, were high on the PRAC agenda. We recommended new measures to minimise the risk of aspiration and pneumonia aspiration for people taking these medicines who undergo surgery with general anaesthesia or deep sedation. Another review of these medicines concerned a signal of suicidal ideation and self-injurious ideation, for which the PRAC did not find sufficient evidence for a causal relationship.

We also concluded a number of EU-wide safety reviews (referrals). To note one example: the committee recommended suspending the marketing authorisations of medicines containing 17-hydroxyprogesterone caproate (17-OHPC) because of a possible but unconfirmed risk of cancer in people exposed to this substance in the womb.

There were many more noteworthy recommendations that are described in detail in a separate section of this document. They show the relevance and the breadth of the responsibilities of the PRAC.

**What are your priorities and your vision for the future work of the PRAC?**

Our key task is the safety monitoring of medicines, and my priority is the protection of public health and patient safety in the EU through the work of the committee.

We build on the collective experience of our experts to ensure that the safety of medicines is constantly monitored and evaluated through appropriate methods, and that the recommendations issued by the PRAC are proportionate, robust and timely.

Our focus remains on delivering high-quality scientific assessments and on reinforcing close collaboration within the PRAC, with EMA's other scientific committees, and with the whole of the EU regulatory network.

**How can PRAC adapt to meet emerging challenges in medicine safety?**

The principles and elements of pharmacovigilance will remain our North Star during the safety assessment of medicines. Nevertheless, the pace of innovation in the pharmaceutical field keeps increasing, which we have to be aware of and adapt to as needed.

In terms of expertise, we rely on the EU medicines regulatory network, but I can certainly see the need to ensure that the right skills continue to be in place and that the network's requirements are addressed in the long term. Training is therefore an important activity within our network.

We are also embracing new methods and ways of working. The availability and use of real-world evidence generated within our network for decision-making is growing. Furthermore, the use of machine learning and AI is becoming a reality in the development and regulation of medicines. EMA and the HMA have a multiannual workplan on AI, with a vision to enable safe and responsible use of AI for the benefit of public and animal health. Since pharmacovigilance is one obvious area for such methods, the PRAC follows these developments and will be involved in drafting guidance that will shape the field in the years to come.





# Veterinary medicines

## New medicines to benefit animal health in Europe

In 2024, EMA recommended 25 veterinary medicines for marketing authorisation – the highest number ever. Of these, two had a new active substance that had not previously been authorised in the EU. Among the 25 medicines recommended for marketing authorisation, 14 were vaccines, including seven that had been developed through a biotechnological process. The new biotechnological vaccines include:

- Cirbloc M Hyo, for the active immunisation of pigs to reduce viraemia (presence of viruses in the blood), virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, the severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection, and to reduce the loss in body weight gain.
- Divence IBR Marker Live, for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia (high body temperature) and clinical signs caused by bovine herpesvirus type 1 (BoHV-1).
- Divence PENTA, for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia (high body temperature), clinical signs and lung lesions caused by bovine respiratory syncytial virus and parainfluenza virus 3; to reduce virus shedding, hyperthermia and clinical signs caused by infectious bovine rhinotracheitis virus; to reduce viremia (presence of viruses in the blood), hyperthermia and leukopenia (decrease in the number of white blood cells) caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2, and virus shedding caused by bovine viral diarrhoea virus 2; and for the active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of bovine viral diarrhoea virus (type 1 and 2).
- Divence Tetra, for the active immunisation of cattle against bovine respiratory syncytial virus and parainfluenza-3 virus to reduce virus shedding, hyperthermia (high body temperature), clinical signs and lung lesions, and against bovine viral diarrhoea virus (type 1 and 2) to reduce viremia (presence of viruses in the blood), hyperthermia and leukopenia (decrease in the number of white blood cells) caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2, and virus shedding caused by bovine viral diarrhoea virus 2; and for active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of bovine viral diarrhoea virus (type 1 and 2).
- Innovax-ND-H5, for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 type.
- Porcilis PCV M Hyo ID, for the active immunisation of pigs to reduce viremia (presence of viruses in the blood), virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection, and to reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *Mycoplasma hyopneumoniae.*
- Poulvac Procerta HVT-IBD-ND, for the active immunisation of one-day-old chickens and 18-19 day old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus; reduce mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus; and reduce mortality and clinical signs caused by Newcastle disease (ND) virus.

**Vaccine platform technologies**

**EMA certified the first veterinary vaccine platform technology master file (vPTMF) in November 2024. The certified Innovax vPTMF is based on a turkey herpesvirus platform, which is already used in several approved vaccines for chickens. Vaccine platform technologies have a set of core components common to all vaccines based on the same platform. They play an important role in animal and public health preparedness because they can be adapted rapidly, thus speeding up the development and approval of new veterinary vaccines in the EU in response to emerging diseases.**

**Responding to the threat of avian influenza**

**In April 2024, EMA's veterinary medicines committee, the CVMP, recommended a new vaccine against the strains of avian influenza (bird flu) that were circulating in 2024. Innovax-ND-H5 is authorised for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 type that was predominant in 2024.**

**Other bird flu vaccine candidates are at different stages of development. As part of its preparedness activities, EMA works with public health authorities in the EU and worldwide to monitor the risk and prepare to respond in the event of a public health emergency.**

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## Optimising the safe and effective use of veterinary medicines

EMA and EU Member States continuously monitor the quality, safety and efficacy of the veterinary medicines on the market in the EU. The aim is to optimise the safe and effective use of a veterinary medicine, to achieve its full benefit, and to protect animals and users from avoidable adverse effects. If the benefit-risk balance of a veterinary medicine changes, EMA can take regulatory measures that range from an amendment to the product information to the suspension or withdrawal of a medicine. The Agency can also recommend recalling batches of the medicine concerned.

At the end of 2024, the CVMP completed a major revision to the Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products. This guideline provides the high-level framework for assessing the positive effects of a veterinary medicine in relation to any risks posed by the use of that medicine to animal or human health, or to the environment, including any risk of development of antimicrobial resistance.

In the area of pharmacovigilance, a three-year pilot set up jointly between EMA and the HMA on processes supporting veterinary signal management was completed in 2024. A new operational expert group of the CVMP pharmacovigilance working party (PhVWP-V) is consequently being established to support the PhVWP-V in the evaluation of the results and outcomes of signal management, and overall surveillance of veterinary medicinal products in the EU.

## Important new safety advice issued in 2024

The product information for six medicines was updated based on new safety data. The revised information is expected to help animal owners and healthcare professionals to make informed decisions when using or prescribing a medicine. These included:

- **AdTab** and **Credelio,** changes to the product information to include hyperactivity, ataxia (incoordination), muscle tremor, tachypnoea (rapid shallow breathing), pruritus (itching), anorexia (appetite loss) and lethargy as potential side effects in cats. Furthermore, changes to the product information to include bloody diarrhoea, polydipsia (increased thirst), pruritus, inappropriate urination, polyuria (increased urination), and urinary incontinence as potential side effects in dogs.

- **Eluracat,** changes to the product information to include bradycardia (slow heart rate) and hypotension (low blood pressure) as potential side effects. In addition, a new contraindication to no longer use the product in cats with hypersomatotropism (excessive growth caused by too much growth hormone).

- **Kexxtone,** suspension of the marketing authorisation of Kexxtone 32.4g continuous-release intraruminal device for cattle (monensin) due to a quality defect which has resulted in cases where cattle regurgitated the device while it still contained monensin tablets. This resulted in increased accidental exposure, including deaths, in non-target species (dogs) and a potential lack of efficacy in cattle. To minimise the risk of exposure to non-target species, all batches of Kexxtone have been recalled from the market.

- **Librela,** changes to the product information to include ataxia (incoordination) together with proprioceptive ataxia, urinary incontinence, anorexia (often related to a transient reduced appetite) and lethargy as potential side effects.

- **Profender,** changes to the product information to include diarrhoea, anorexia (loss of appetite), lethargy and behavioural disorders, such as hyperactivity, anxiety and vocalisation as potential side effects.

- **Strangvac,** changes to the product information to include muscle stiffness around the injection site as a potential side effect and to add information that the majority of injection site swellings exceeding 8cm have been observed in the pectoral muscle.

## New safety information for animal healthcare professionals

In 2024, EMA published two direct animal healthcare professional communications (DaHPCs) to inform veterinarians and other animal healthcare professionals about safety issues and the actions they should take. These include:

- **Kexxtone** 32.4g continuous-release intraruminal device for cattle (monensin): marketing authorisation suspension and market recall of all batches; and
- **Senvelgo** (velagliflozin) oral solution: known risk of diabetic ketoacidosis (DKA) in cats with diabetes mellitus.

## Protecting consumers against medicine residues in food of animal origin

If a medicine is intended to be used in a food-producing animal, it needs to be safe for people to eat the food that comes from this animal. EMA recommends maximum residue limits (MRLs) that reflect the level of residues of a veterinary medicine in food derived from a treated animal that can be considered safe for human consumption. The MRL is established before a medicine can be authorised for food-producing animals in the EU and entered in the annex to Commission Regulation (EU) No 37/2010.

In 2024, a positive opinion was adopted recommending MRLs for the following active substance:

- **Ketoprofen,** establishment of numerical MRLs in all ruminants, porcine and equidae (animals of the horse family).

More information and figures on veterinary medicines are available in Chapter 2.





## Expert views: Interview with Gerrit Johan Schefferlie, Chair of the CVMP

**Can you share any particular successes from the past year that you believe will have a lasting impact on animal health in the EU?**

In 2024, the CVMP issued the first certificate for a vaccine platform technology master file, a novel concept that facilitates the faster development and availability of veterinary vaccines. Additionally, the CVMP issued a positive opinion for a vaccine for highly pathogenic avian influenza under the provisions for exceptional circumstances – the first such opinion under the new Regulation. These examples demonstrate our ability to respond effectively to the evolving needs of the veterinary field, including during disease outbreaks.

**In 2024, how did the CVMP contribute to efforts to combat antimicrobial resistance?**

The CVMP, in collaboration with EMA and the Member States, stepped up the collection of data on the use of antimicrobials in animals in the EU, in line with our mandate from the veterinary regulation. This builds on the success of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, which was a voluntary initiative. These data will help to determine the trends in use, and identify possible risk factors that could lead to the development of further measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced.

**Looking ahead, what are some of the most significant challenges the CVMP anticipates in ensuring the safety and efficacy of veterinary medicines, and how do you plan to address these issues in the coming years? What key developments should stakeholders expect in the near future?**

Novel technologies are evolving fast in the veterinary field. The CVMP continues to build its capacity and capability in new areas, including through increasing collaboration with our international partners. Our aim is to continue to enable high quality scientific assessments of dossiers that ensure the authorisation of veterinary medicines with sufficient quality, safety and efficacy.

# Better evidence to translate innovation into medicines

Evidence on safety, quality and efficacy is the basis on which regulators assess medicines. In 2024, EMA strengthened processes and procedures to ensure that the European regulatory network can harness health data and benefit from rapid technological advancements, especially the use of AI for the benefit of patients. When used safely and responsibly, data and new digital tools can help regulators assess scientific innovations and translate them into safe and effective treatments.

Clinical trials remain the bedrock of clinical evidence on medicines. The Accelerating Clinical Trials in the EU initiative (ACT EU) is ongoing and the Clinical Trials Regulation is fully implemented as of 30 January 2025. The year 2024 was important in preparing the EU's regulatory system to fully embrace the potential of data to complement the results of clinical trials. EMA increased efforts to generate real-world evidence (RWE) from everyday healthcare data. Expanding data sources allowed access to more diverse data across Europe, resulting in a higher number of studies to support EMA committees and EU regulators. In response to the fast development of new technologies, the network continued delivering a multiannual AI work plan to coordinate efforts in maximising the benefits of AI while mitigating the risks.

## Strengthening the ecosystem for clinical trials in the EU

EMA, the HMA, and the European Commission have an ambitious vision: transforming the clinical trials environment in the EU. The umbrella for this transformation is the ACT EU initiative, which aims to bring all stakeholders together to enhance the clinical trials landscape.

ACT EU is a collaborative effort, crucial for promoting the development of high-quality, safe and effective medicines, and better integrating clinical research into the European health system. The initiative has established a multi-stakeholder platform (MSP) to ensure engagement across stakeholders on clinical trials. In March 2024, the MSP advisory group held its first meeting, marking a significant milestone. The launch of the MSP promotes open dialogue around the challenges and opportunities represented by advances in clinical trials regulation, methodologies and technology for the benefit of EU citizens.

A central focus of the efforts in 2024 was supporting stakeholders in the final year of transition to the Clinical Trials Regulation (CTR). All ongoing clinical trials in the EU approved under the previous legal framework, the Clinical Trials Directive, needed to be transitioned to the CTR by 30 January 2025 through submission to the Clinical Trials Information System (CTIS). CTIS serves as the single-entry point for sponsors and regulators for the submission and assessment of applications for clinical trials in the EU. The system includes a public searchable database for healthcare professionals, patients and the public, delivering the high level of transparency mandated by the regulation.

Throughout 2024, sponsors were reminded of the approaching end of the CTR transition period. To ensure a smooth migration and enhance the quality of clinical trial applications, guidance and support were offered to stakeholders through various resources, including guidance documents, best practice guides and dedicated training activities.

In June, a new version of CTIS was launched, allowing earlier and more efficient access to clinical trial information. Revised transparency rules eliminated the previously available deferral mechanism, which allowed clinical trial sponsors to delay publishing certain data and documents for up to seven years after a trial's completion to protect commercially confidential information. Under the new rules, more than 8,600 clinical trials with issued decisions are now publicly accessible through the CTIS search.

Beyond the support to the CTR transition, ACT EU launched two new advice pilots in 2024 to improve the quality of clinical trial applications. The first pilot offers joint scientific advice on clinical trials and marketing authorisation applications. The second provides technical and regulatory support on the dossier of a clinical trial application before submission through CTIS. By strengthening the coordination of the European medicines regulatory network, these advice pilots offer applicants additional support to enhance the quality of their applications for marketing and/or clinical trial authorisation.

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

## Enhanced use of real-world evidence

High-quality clinical evidence is at the heart of well-informed decisions on medicines. While clinical trials remain central, experts can use real-world data (RWD) from routine healthcare settings to generate real-world evidence (RWE). The use of RWE helps regulators address knowledge gaps and complement the evidence picture by enhancing their understanding of the use, safety and benefits of medicines.

In 2024, EMA continued to generate evidence based on knowledge and expertise, embracing diverse data and methods, and exploring, enabling and validating new approaches. Together with the HMA, the Agency worked towards a joint vision of establishing the use and enabling the value of RWE in regulatory decision-making.

EMA took steps to help regulators, researchers and companies navigate, identify and utilise health data. Two public RWD catalogues for data sources and for studies were launched, promoting transparency, good practices and trust in RWD research. EMA also developed guidance on RWD, engaged with stakeholders through public consultations and events, and collaborated internationally to initiate common guidelines for RWD studies. A big data newsletter was launched to share the latest updates.

The Agency ramped up efforts to generate robust evidence for its committees and national regulators. The second report on regulator-led RWD studies summarises the progress made, covering 40 studies completed between February 2023 and February 2024. These included 13 studies on vaccine safety and effectiveness, and two on medicines at risk of shortages, such as antibiotics. One study examined the risk of suicide and self-harm in people using GLP-1 receptor agonists, helping EMA's safety committee to conclude there is no causal link.

Studies were conducted via three pathways: Data Analysis and Real World Interrogation Network (DARWIN EU), EMA's framework contract and by in-house experts. The number of studies continued to grow throughout the year, with 47 studies completed or ongoing by year-end via DARWIN EU.

In 2024, DARWIN EU became fully operational, emerging as the main pathway to generate RWE. The network provides the structure, data and tools to access relevant and reliable RWE on diseases, populations and medicine performance across Europe.

The inclusion of different real-world data sets increases the value of DARWIN EU for medicines evaluation. DARWIN EU onboarded ten new data partners, bringing the total to 30, including healthcare data from primary care, hospitals, registries and biobanks. This expanded the network's access to the health data of 160 million patients in 16 European countries.

Since its establishment in 2022, 58 studies are completed or ongoing via DARWIN EU. In 2024, these included research on the prevalence of rare blood cancers in Europe, the prescription of antibiotics and a study examining the characteristics of patients who have been prescribed GLP-1 receptor agonists, used for diabetes and weight management, and how these have changed over the past ten years.

The results from the studies are published in the HMA-EMA RWD catalogue and shared with the relevant EMA committees and stakeholders to support the evaluation of medicines.

All this work was coordinated by the Big Data Steering Group (BDSG), set up by EMA and the HMA to enhance the analysis and use of big data in medicines regulation. By the end of 2024, the BDSG wrapped up its five-year mandate, and the new Network Data Steering Group (NDSG), which merges the BDSG and Network Data Board, will lead the transformation towards more data-driven medicines regulation going forward.

**From creating a European real-world data network of 160 million patients to building an expert workforce, the BDSG has demonstrated the value of large datasets in medicines regulation. It has ensured benefits to Europeans in multiple data-related areas, including data quality, discoverability and training. Within the past year, the BDSG has delivered an AI-driven knowledge mining tool, Scientific Explorer, and the HMA-EMA catalogues of real-world data sources and studies, which we as a competent authority consider to be of great importance, since they allow us to integrate big data in our regulatory procedures. Once again it proves that collaboration between the medicines agencies is highly valuable.**

Nils Bjerregaard, Director General of the Danish Medicines Agency (DKMA). The DKMA has been the co-chair of the BDSG.





**Support to innovative manufacturing**

**Innovation extends beyond developing new medicines: it encompasses how they are made. From ultramodern factories and AI-driven quality batch testing to 'mini-pods' producing medicines at the point-of-care, ensuring trust in these technologies is essential.**

**EMA's Quality Innovation Group (QIG), established in 2022, supports the integration of innovative approaches in the design, manufacture and quality control of medicines. Its role is to help the EU network keep pace with innovation in this area, and to address gaps to ensure that the EU regulatory framework is reliable and predictable for developers of innovative technologies and fosters innovation.**

**In 2024, the QIG focused on process models and platform technologies. It organised two listen-and-learn focus groups, during which stakeholders from industry, academia and international regulators presented case studies that might represent the future of manufacturing, and their implications in terms of medicines regulation challenges.**

**This year also marked the first year of the QIG's new three-year work plan, establishing both short- and longer-term strategic goals.**

# From vision to action: Enabling safe and responsible use of AI

In 2024, the use of AI and machine learning (ML) expanded remarkably, impacting even more facets of people's lives, including the regulation of medicines. As AI applications evolve, so do the ethical and policy considerations around their use. When used responsibly, digital tools help us to be more productive and efficient, as well as to understand diseases, treatments and medicine risks, with the potential to speed up medicines authorisation and ensure safe use. This leads to a more proactive and responsive regulatory system.

Companies increasingly apply AI tools in medicines development. Regulators must keep up with these developments to provide appropriate oversight, ensuring that AI is used safely and responsibly and benefits human and animal health.

To maximise the benefits while mitigating risks, the EU regulatory network began implementing its first work plan on AI that guides the use of AI in medicines regulation in Europe until 2028. This includes applying AI for personal productivity, process automation, and better insights into data and decision-making support. The approach embeds key ethical and patient-centric values and fosters stakeholder cooperation.

Within the AI work plan, EMA prepared for the implementation of the EU AI Act, which entered into force in August. The world's first comprehensive AI law provides a legal framework for Europe, aiming to be a global leader in safe AI.

Support is key in ensuring stakeholders can fully benefit from AI. EMA published the final reflection paper considering the use of AI throughout a medicine's lifecycle. Over 1,300 comments received from stakeholders via public consultation were valuable in consolidating the paper and informing the development of guidance. In response to the rapid developments of Large Language Models (LLMs), the Agency and the network developed guiding principles for EU regulators to support the safe and responsible use of these tools.

Keeping up with the pace of change, EMA leveraged the potential of AI to improve organisational and personal efficiency. The Agency accelerated experimentation with AI and explored opportunities to build pragmatic solutions for different business needs and automating routine processes. Scientific Explorer, an AI tool to help EU regulators find scientific information, was launched to simplify daily work and support the delivery of high-quality scientific advice to companies.

In a complex environment, collaboration and knowledge-sharing promote certainty and predictability. EMA launched a data science-training curriculum for the EU network and engaged with stakeholders through events and a well-attended public workshop on AI.

# Regulatory cooperation to improve global health

EMA's operating environment in 2024 was characterised by technological advances and evolving healthcare needs. Multiple challenges shaped the regulatory landscape, from public health threats, such as antimicrobial resistance and new variants of viral diseases such as COVID-19 and mpox, to the transformative potential of AI in medicines development and advance in medical innovations. These developments reinforced the critical importance of a collaborative approach to medicines regulation and global health, both at EU level and internationally.

Throughout the year, EMA intensified its efforts to address these challenges by building on its strong partnerships across the EMRN and with its global partners and stakeholders.

## EMA at the heart of the EU network

The EMRN remains the cornerstone of EMA's work and success. Operating at the heart of this network, EMA coordinates and supports interactions between NCAs for human and veterinary medicines across Europe, ensuring a harmonised approach to medicines regulation.

### Advancing the European medicines agencies network strategy to 2028

A significant milestone in 2024 was the publication of the draft joint EU medicines agencies network strategy to 2028 (EMANS 2028) by EMA and the HMA for a two-month public consultation. The strategy, 'Seizing opportunities in a changing medicines landscape', represents a comprehensive update to the original EMANS to 2025 framework, responding to changes in the regulatory and technological landscape, some more rapidly than anticipated.

**The overarching theme of our updated strategy to 2028 is that of change – rapid, somewhat unpredictable but nonetheless full of promise. It will guide the network as it seizes opportunities and meets the challenges of the near future, including preparing for and responding to public health emergencies and threats such as antimicrobial resistance.**

Emer Cooke, EMA's Executive Director

The EMANS 2028 also aligns with the EU's ongoing extensive revision of its pharmaceutical legislation, and lays the groundwork for the most significant reform of the EU medicines regulation in decades.

EMA and the HMA aim to finalise the strategy in the first quarter of 2025 with the final adoption expected by March 2025. Once finalised, the strategy will guide the work of EMA and the network until 2028.

**The six focus areas have been carefully chosen to support the network's core work of evaluating medicines as we take strides to promote the development of medicines and ensure that they reach those who need them.**

Maria Lamas, Chair of the HMA Management Group

**Focus areas for EMANS 2028**

- Accessibility
- Leveraging data, digitalisation and artificial intelligence
- Regulatory science, innovation and competitiveness
- Antimicrobial resistance and other health threats
- Availability and supply
- Sustainability of the network

## Collaboration on digitalisation

Throughout 2024, EMA worked with its partners in the EU to accelerate and strengthen the digitalisation of services and operations.

The HMA/EMA Regulatory Optimisation Group (ROG) represents a key initiative in advancing the EMRN's digital transformation. Its focus is on aligning the NCA's IT strategies with IT systems and services managed by EMA, the so-called Network Portfolio. It does so by providing a platform for dialogue between EMA, the HMA, the NCAs and external stakeholders of the network.

A notable success in 2024 was the development of a stepwise model for the integration of the NCAs in the data qualification process, a vital step toward establishing Product Management Services (PMS) as a single source of medicinal product information.

EMA and several EU partner agencies have joined forces to contribute insights on the use of trustworthy, human-centric AI in the workplace to foster greater collaboration among EU agencies and Member States.

In 2024, the network of EU agencies (EUAN) elevated the AI virtual community to the EUAN Working Group on AI, building on its established governance frameworks and collaborative culture. The group is chaired by EMA.

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 co-pilot 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 to 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.

> **As the network continues to evolve, it will need to take into account the diverse level of digitalisation across the EU Member States, as well as ensuring a more comprehensive digital interface to optimise interaction with our stakeholders and EU citizens more widely.**
>
> EMANS 2028





## The EU Network Training Centre – a decade of excellence

The post-pandemic era has accelerated technological advancement, introducing new ways of working and innovative digital solutions for adult learning. To keep pace with rapid developments in medicines regulation, the continuous enhancement of skills and sharing of expertise between EMA and national regulators remains essential.

The EU Network Training Centre (EU NTC), a strategic collaborative endeavour between EMA and EU Member States, promotes and ensures the sharing of best scientific and regulatory practices across the EMRN through the EU NTC Learning Management System (LMS).

The year 2024 marked a decade since the launch of the EU NTC. Key achievements over the last ten years include:

- implementation of the Learning Management System;
- development of a learning and development toolkit;
- launch of the EU NTC portal, an online platform offering scientific, regulatory and digital training for experts involved in EU regulatory procedures;
- monthly online newsletter with training offers;
- launch of the remuneration scheme for the development and delivery of training aimed at fulfilling a critical unmet learning need;
- extending access to the training catalogue to members of the Healthcare Professionals' Working Party (HCPWP) and the Patients' and Consumers' Working Party (PCWP);
- providing access to the EU NTC LMS to EU candidate countries in the context of the Instrument for Pre-accession Assistance (IPA); and
- expansion of the training catalogue to include digital skills through the Digital Academy.

Looking ahead, the EU NTC plans to professionalise its training curricula, expand to new target audiences and pioneer digital approaches incorporating AI and immersive learning technologies.

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# EMA in the world

## EMA and European medicines agencies network designated as a WHO Listed Authority

In 2024, WHO designated the EMRN as a WHO Listed Authority (WLA). This is the first regional regulatory system to receive this designation. It is recognition and a significant achievement for those involved in medicines regulation in the EU: the European Commission, EMA and the 31 national authorities of all EU Member States.

This prestigious designation is recognition that the network meets international regulatory standards, guidelines and practices, which reinforces the EMRN's position as a global leader in medicines regulation.

> **I am delighted that the EU medicines network has now been officially recognised by WHO as a global reference authority, operating at the highest regulatory standards. This acknowledgement provides a formal basis for the important work that EMA and the EU are already doing to promote reliance practices globally. We will continue our commitment to ensuring that available medicines are safe, effective and of high quality, and look forward to our work with WHO and other regulatory authorities around the world to improve global public health.**
>
> Emer Cooke, EMA's Executive Director

## Supporting the establishment of the African Medicines Agency: building global regulatory capacity

International collaboration is crucial for protecting public health beyond European borders. In 2024, EMA launched a five-year partnership to support the establishment of the African Medicines Agency (AMA), a specialised agency of the African Union (AU). The goal is to strengthen regulatory systems across Africa to improve patient access to safe and effective medicines while preventing substandard or falsified medicines from reaching the market and harming people.

Throughout 2024, EMA and the EMRN shared its unique experience and regulatory model for continental medicines regulation to support the development of the AMA. Actions focused on:

- providing expertise to make the AMA operational and strengthening cooperation between European, African and international partners;
- capacity building for the African regulatory network;
- coordination of initiatives across the European network and partner organisations.

A key milestone in 2024 was EMA's grant to the African Medicines Regulatory Harmonisation (AMRH) initiative, led by the African Union Development Agency (AUDA-NEPAD). The grant funds a one-year pilot to test continent-wide procedures for medicines evaluation and inspections. It will help to develop processes, facilitate national authorisations of medicines and enhance information sharing.

Sharing knowledge and building capacity are at the heart of our collaboration. In June, EMA hosted two AMRH technical committees to share knowledge and provide insights into EMA's regulatory procedures that could inform the development of Africa's regulatory system.

Together with African partners and WHO, EMA identified key training areas and mapped expertise within the European network. Based on the insights, we invited national competent authorities in the EU to apply for grants to strengthen the scientific and regulatory expertise of national authorities in Sub-Saharan Africa.

EMA's efforts are part of a broader 'Team Europe' initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (MAV+), launched by the European Commission in 2021.

> **As African Medicines Regulatory Harmonisation (AMRH) lays the foundation for the AMA, our collaboration with EMA marks a crucial stride towards the realisation of the AMA's mission. Together, the AMRH and EMA will expedite the establishment of the AMA, fostering greater collaboration among African nations. This partnership not only signifies a shared commitment but also accelerates AMA's journey to becoming a beacon for regulatory efficiency and healthcare advancement in Africa.**
>
> Chimwemwe Chamdimba, Head of the AMRH initiative at AUDA-NEPAD


Video

EMA's support to the African Medicines Agency: improving access to quality medicines

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## Leading the International Coalition of Medicines Regulatory Authorities

As chair of the International Coalition of Medicines Regulatory Authorities (ICMRA), EMA spearheaded global efforts to strengthen regulatory cooperation on critical global health issues in 2024. Under EMA's leadership, ICMRA advanced strategic initiatives and projects to address common global challenges and harmonise regulatory standards. Key initiatives led by EMA focused on addressing:

- antimicrobial resistance;
- emerging public health threats, particularly mpox;
- mis- and disinformation on public health topics; and
- collaboration in pharmaceutical quality knowledge management.

## Supporting the international fight against antimicrobial resistance

Since its inception, ICMRA has provided a platform for international regulators and other key stakeholders to develop strategic responses to antimicrobial resistance. At the 11th ICMRA Summit in November 2024, EMA co-chaired a crucial panel discussion on this topic where international regulators shared feedback and insights. This led to the publication of a statement reiterating the critical importance of preserving the effectiveness of antimicrobials and the crucial role regulators play in addressing the challenge collaboratively.

> **I cannot stress enough that we need a multidimensional approach. From the regulatory perspective, we can focus on the prudent use of existing treatments, enabling the development of novel antimicrobials, better use of vaccines, research on alternatives, and better diagnostic tools at the point of care.**
>
> Emer Cooke, EMA's Executive Director and Chair of ICMRA

## Coordinating a global response to public health threats

Following WHO's August 2024 declaration of mpox as a public health emergency of international concern (PHEIC), ICMRA worked to align the global regulatory response. On 2 October 2024, EMA convened international regulators and WHO experts to discuss available knowledge supporting mpox medicine development and support measures to improve access to mpox medicines in the most affected countries during the ongoing outbreak.

**COVID-19: Key ICMRA achievements during the pandemic**

**The COVID-19 pandemic posed unprecedented challenges to global health systems, but it also highlighted the importance of regulatory cooperation in times of crisis.**

**In 2024, EMA collected information and facilitated the development of an ICMRA report documenting the coalition's approach to the COVID-19 response and its key achievements during the pandemic. The report demonstrates how collaboration between global medicines regulators led to improved regulatory convergence and alignment, better use of real-world evidence in regulatory decision-making and enhanced safety monitoring of vaccines.**





EMA co-chaired the ICMRA working group on public health emergency clinical trials, and in this role the Agency led the development of a reflection paper in 2024 that outlines key opportunities, challenges and regulatory considerations for planning and conducting platform trials.

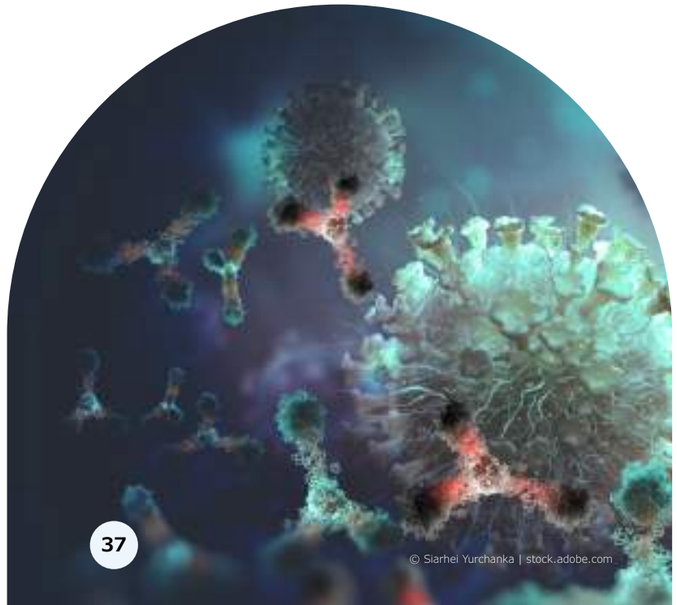
Addressing mis- and disinformation is high on the agenda of many regulators. In 2024 EMA led a project aiming to map the landscape of mis- and disinformation management and to identify effective response strategies among ICMRA members. Twenty-three regulatory authorities from different countries and regions (Europe, Asia, North and South America, Middle East and Australia) contributed to the project and provided information on their approaches, tools, challenges and successful initiatives to combat mis- and disinformation. The ICMRA Communications Group, which is chaired by EMA, is planning to facilitate the regular information sharing and exchange between ICMRA members to further foster collaboration to counter false narratives.

## Pharmaceutical quality knowledge management system

ICMRA has been active in exploring a common Pharmaceutical Quality Knowledge Management System (PQKMS) facilitating collaboration and reliance with the aim to achieve faster changes in supply chains and thus improve the availability of medicines. In 2024, EMA, the US FDA and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) collaborated with several other regulatory authorities, including Health Canada (HC), Swissmedic, the UK Medicines & Healthcare products Regulatory Agency (MHRA), in two pilot programmes on:

- collaborative assessments of changes related to the supply of key medicines, which aim to enable greater cross-regional access to high-quality, critical medicines through parallel assessments and approvals in different regions; and
- hybrid inspections of manufacturing sites that allow multiple regulators to participate in a single inspection, either on-site or remotely, and take one joint regulatory decision, to maximise the use of limited resources.

The ICMRA PQKM project reached a major milestone in May 2024, when the initial phase of both pilots was completed. All collaborative assessments and hybrid inspections were finished within the agreed timelines and showed productive collaborations between regulators and industry. ICMRA published summary reports on each of the pilots in early 2025.



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# Key activities and events in 2024

## JANUARY 2024

**January 23, 2024**

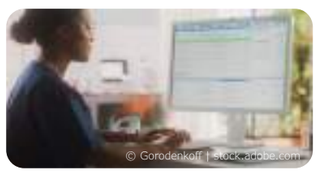
EMA has released a major revision of its user guide for micro, small and medium-sized enterprises (SMEs) in the pharmaceutical sector.


**January 26, 2024**

EMA has received a grant of ten million euros from the European Commission to help set up the AMA, in collaboration with African, European and international actors.


**January 29, 2024**

EMA has launched the ASU platform to support the collection of data by Member States on the sales and use of antimicrobials in animals.




**January 31, 2024**

All ongoing clinical trials in the EU must be transitioned to CTIS by 31 January 2025. This date marks the end of a three-year transition period that began when the Clinical Trials Regulation (CTR) became applicable in the EU.





## MARCH 2024


**March 6, 2024**

The Data Analysis and Real World Interrogation Network DARWIN EU continues working towards higher capacity for real-world data (RWD) studies and seeks to add ten new data partners in 2024.


**February 21, 2024**

Taking a One Health approach, which recognises the connection between the health of people and animals, a multi-agency report presents data primarily collected between 2019 and 2021 on antibiotic consumption and antimicrobial resistance in Europe. Countries that have decreased their consumption of antibiotics in both animals and humans have seen a reduction in antibiotic-resistant bacteria.

**February 15, 2024**

EMA and the Heads of Medicines Agencies (HMA) have launched two digital catalogues: one for real-world data (RWD) and one for RWD studies.


## FEBRUARY 2024


**February 08, 2024**

Following the launch in September 2022, EMA has accepted three academic and non-profit organisations developing advanced therapy medicinal products (ATMPs) into a pilot scheme, in which they benefit from enhanced support from the Agency.

## APRIL 2024


**March 20, 2024**

The Accelerating Clinical Trials in the EU (ACT EU) initiative has established a multi-stakeholder platform (MSP) aimed at improving the environment for clinical trials across the EU.

**April 17, 2024**

The International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO publish a report highlighting the outcomes of their discussions on key regulatory considerations and data requirements related to updated COVID-19 vaccine composition.



**April 23, 2024**

EMA has published a number of recommendations to address vulnerabilities in the production and delivery of medicines included in the Union list of critical medicines and strengthen their supply chain.


**April 26, 2024**

EMA and the European Commission's Directorate-General for Health and Food Safety (DG SANTE) have signed a working arrangement with the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea for the exchange of confidential information on medical and medicinal products.

## JUNE 2024


**June 10, 2024**

ACT EU has launched two advice pilots aimed at improving the quality of applications for clinical trials, the foundation for the development of safe and effective medicines in Europe.


**May 20, 2024**

The EMRN, composed of the European Commission, EMA and the 31 national authorities of the EEA Member States, were recognised as meeting international regulatory standards, guidelines and practices.

**May 07, 2024**

The European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA), and EMA have published a joint framework for action to strengthen cooperation to support the implementation of the One Health agenda in the EU.


**April 30, 2024**

EMA's Emergency Task Force has recommended updating COVID-19 vaccines to target the JN.1 variant for the 2024/2025 vaccination campaign.

## MAY 2024


**June 18, 2024**

EMA announces the launch of the updated Clinical Trials Information System, enhancing early access to clinical trial data for patients, healthcare professionals and stakeholders, in line with revised transparency rules.


**June 26, 2024**

The Medicines Shortages Steering Group (MSSG) has issued recommendations, including manufacturing capacity increases, supply chain monitoring, and prioritisation guidelines, to address shortages of GLP-1 receptor agonists.

**June 26, 2024**

EMA has organised a press briefing to discuss EU actions to tackle shortages of GLP-1 receptor agonists indicated for the treatment of diabetes and in some cases for weight management in patients with obesity or weight-related conditions.

## JULY 2024


**July 30, 2024**

EMA has awarded a grant to the African Medicines Regulatory Harmonisation (AMRH) initiative of the African Union Development Agency (AUDA-NEPAD) to support a pilot to test procedures for the joint continental evaluation and inspections of medicines in Africa.





## OCTOBER 2024


**October 2, 2024**

International regulators have published a report highlighting their considerations on the development, clinical trials and availability of vaccines and therapeutics for mpox. It presents the outcomes of a workshop that was organised by EMA under the umbrella of ICMRA.


**September 05, 2024**

EMA and the HMA have published high-level principles and recommendations for all staff across the EMRN using large language models (LLMs) in their work.

## SEPTEMBER 2024


**August 02, 2024**

EMA has launched a pilot programme for expert panels to support the development and assessment of orphan medical devices in the EU.

## AUGUST 2024

**October 9, 2024**

EMA and the HMA have published their draft joint EU network strategy to 2028 for an eight-week public consultation.

**October 10, 2024**

EMA has launched a public consultation on its draft revised policy on handling competing interests of scientific committee members and experts.

## NOVEMBER 2024

**November 08, 2024**

EMA's Committee for Veterinary Medicinal Products (CVMP) has issued the first certificate for a veterinary vaccine platform technology master file (vPTMF), which will support and accelerate the development and authorisation of new veterinary vaccines in the EU.


**November 13, 2024**

On 13 and 14 November, EMA co-hosted the 7th 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.

**December 11, 2024**

EMA has published a report highlighting the results of its fifth communication perception survey, which was conducted between May and June 2024.

**December 16, 2024**

EMA has published a report of a pilot exploring the creation and testing of electronic product information (ePI) in real regulatory procedures.

## DECEMBER 2024

**November 28, 2024**

The ESMP has gone live with a core set of functionalities. Marketing authorisation holders can now use the platform to report shortages of centrally authorised medicines.

**November 18, 2024**

To mark European Antibiotic Awareness Day (EAAD) in 2024, EMA has published an infosheet emphasising the urgent need to tackle antimicrobial resistance.

**November 21, 2024**

EMA endorses a joint ICMRA statement, which reiterates that preserving the effectiveness of antimicrobials is a top priority globally for the protection of public health and that regulators have an important role to play.

**December 17, 2024**

Emer Cooke looks back at 2024 and gives insights into the year ahead.


**December 18, 2024**

EMA and the HMA have published a comprehensive overhaul of their guidance on the identification of commercially confidential information (CCI) and personal data in marketing authorisation applications for human medicines.



# CHAPTER 2

# Key figures in 2024

Chapter 2 presents key figures highlighting statistics and trends illustrating more broadly the Agency's activities in the regulation of medicines in the EU.

The chapter covers: marketing authorisation and safety monitoring of medicines for human and veterinary use; inspections and compliance; medicine shortages; medical devices; the European medicines regulatory network, stakeholders, administration and communication. A more detailed overview of figures presenting EMA's activities in 2024 will be made available in the Agency's annual activity report.

# Human medicines

In 2024, EMA's work across the medicines' lifecycle helped to guide innovative treatments to market that strengthen public health. The Agency supports developers at every stage of medicine development, helping to boost innovation and research by offering expertise before, during and after marketing authorisation.

## Supporting research and development

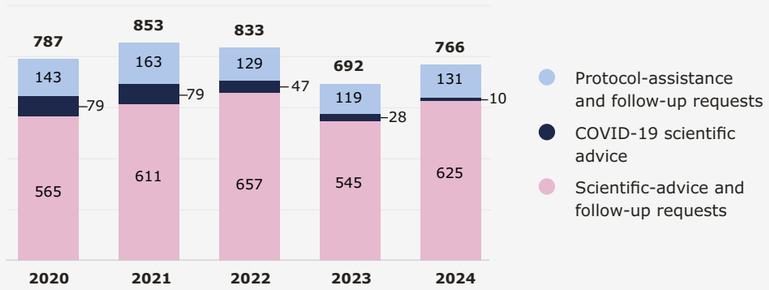
### Scientific advice

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.

**Scientific-advice and protocol-assistance requests received - total**








In 2024, EMA received a total of 635 requests for scientific advice. Among these, ten were for COVID-19 medicines or vaccines.

Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases. The requests for protocol assistance increased by 10 %, from 119 requests in 2023 to 131 in 2024.

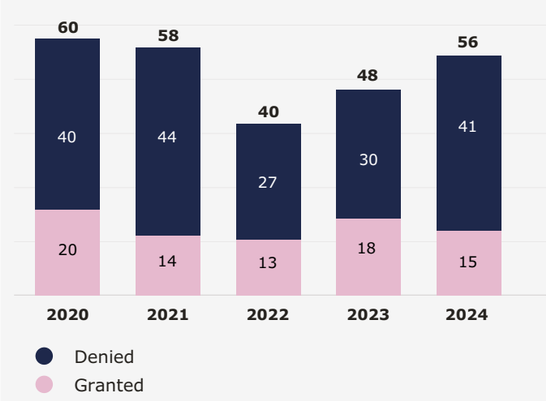
### PRIority Medicines (PRIME) programme

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. In 2024, EMA received 58 PRIME eligibility requests, 12 % more than in 2023, and adopted 56 recommendations, 17 % more than in 2023. The Agency received 42 requests for scientific advice for PRIME products, a higher number than in 2023, when 38 requests were received.

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. The acceptance rate in 2024 was 27 %, or 15 out of 56 requests.

Six PRIME-designated medicines were recommended for approval (Beqvez, Fabhalta, Ixchiq, Seladelpar Gilead, Voydeya and Winrevair).

**PRIME - eligibility recommendations**




# Recommendations for marketing authorisation

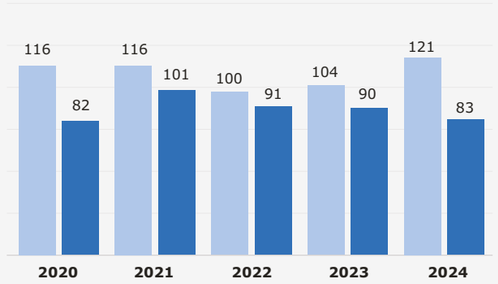
## Applications for initial evaluation

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.

A total of 121 applications were received in 2024.

**Initial-evaluation applications**










## Outcome of initial evaluation[1]

| Therapeutic area/ Product name | New active substance | PRIME | Orphan | ATMP | Biosimilar | Generic | Accelerated assesment | Conditional approval | Exceptional circumstances |
|---|---|---|---|---|---|---|---|---|---|
| **Cancer** | | | | | | | | | |
| Apexelsin | | | | | | ● | | | |
| Augtyro | ● | | | | | | | ● | |
| Avzivi | | | | | ● | | | | |
| Axitinib Accord | | | | | | ● | | | |
| Balversa | ● | | | | | | | | |
| Cejemly | ● | | | | | | | | |
| Dasatinib Accord Healthcare | | | | | | ● | | | |
| Elahere | ● | | ● | | | | | | |
| Enzalutamide Viatris | | | | | | ● | | | |
| Eribulin Baxter | | | | | | ● | | | |
| Fruzaqla | ● | | | | | | | | |
| Hetronifly | ● | | ● | | | | | | |
| Ituxredi | | | | | ● | | | | |
| Korjuny | | | | | | | | | |
| Lazcluze | ● | | | | | | | | |
| Loqtorzi | ● | | | | | | | | |
| Nilotinib Accord | | | | | | ● | | | |
| Ordspono | ● | | | | | | | ● | |
| Pomalidomide Accord | | | | | | ● | | | |
| Pomalidomide Krka | | | | | | ● | | | |
| Pomalidomide Teva | | | | | | ● | | | |
| Pomalidomide Zentiva | | | | | | ● | | | |
| Tizvenis[2] | | | | | | | | | |
| Truqap | ● | | | | | | | | |
| Tuznue | | | | | ● | | | | |
| Vyloy | ● | | ● | | | | | | |
| Welireg | ● | | | | | | | ● | |
| Zynyz | ● | | ● | | | | | | |
| **Cardiovascular** | | | | | | | | | |
| Beyonttra | ● | | | | | | | | |
| Jeraygo | ● | | | | | | | | |
| Neoatricon | | | | | | | | | |
| Winrevair | ● | ● | ● | | | | | | |
| Yuvanci | | | | | | | | | |

[1] Some medicines might fall into more than one therapeutic area but have been reflected only in one.
[2] The marketing authorisation holder withdrew this medicine on 5 July 2024.

| Therapeutic area/ Product name | New active substance | PRIME | Orphan | ATMP | Biosimilar | Generic | Accelerated assesment | Conditional approval | Exceptional circumstances |
|---|---|---|---|---|---|---|---|---|---|
| **Dermatology** | | | | | | | | | |
| Anzupgo | ● | | | | | | | | |
| Nemluvio | ● | | | | | | | | |
| **Diagnostic agents** | | | | | | | | | |
| GalliaPharm | | | | | | | | | |
| Siiltibcy | ● | | | | | | | | |
| Tauvid | ● | | | | | | | | |
| Theralugand | | | | | | | | | |
| **Endocrinology** | | | | | | | | | |
| Awiqli | ● | | | | | | | | |
| Emcitate | | | ● | | | | | | |
| Jubbonti | | | | | ● | | | | |
| Obodence | | | | | ● | | | | |
| Osenvelt | | | | | ● | | | | |
| Stoboclo | | | | | ● | | | | |
| Wyost | | | | | ● | | | | |
| Xbryk | | | | | ● | | | | |
| Zegalogue | ● | | | | | | | | |
| **Gastroenterology/Hepatology** | | | | | | | | | |
| Iqirvo | ● | | ● | | | | | ● | |
| Kayfanda | | | | | | | | | ● |
| Seladelpar Gilead | ● | ● | ● | | | | | ● | |
| **Haematology/Haemostaseology** | | | | | | | | | |
| Adzynma | ● | | ● | | | | | | ● |
| Alhemo | ● | | | | | | | | |
| Altuvoct | ● | | ● | | | | | | |
| Beqvez | ● | ● | | ● | | | | ● | |
| Eltrombopag Viatris | | | | | | ● | | | |
| Fabhalta | ● | ● | ● | | | | | | |
| Hympavzi | ● | | | | | | | | |
| Piasky | ● | | | | | | | | |
| Rytelo | ● | | | | | | | | |
| Ryzneuta | ● | | | | | | | | |
| Voydeya | ● | ● | ● | | | | | | |
| Zefylti | | | | | ● | | | | |

| Therapeutic area/ Product name | New active substance | PRIME | Orphan | ATMP | Biosimilar | Generic | Accelerated assesment | Conditional approval | Exceptional circumstances |
|---|---|---|---|---|---|---|---|---|---|
| **Immunology/Rheumatology/Transplantation** | | | | | | | | | |
| Absimky | | | | | ● | | | | |
| Andembry | ● | | | | | | | | |
| Apremilast Accord | | | | | | ● | | | |
| Avtozma | | | | | ● | | | | |
| Eksunbi | | | | | ● | | | | |
| Fymskina | | | | | ● | | | | |
| Imuldosa | | | | | ● | | | | |
| Otulfi | | | | | ● | | | | |
| Pyzchiva | | | | | ● | | | | |
| Steqeyma | | | | | ● | | | | |
| Tofidence | | | | | ● | | | | |
| Wezenla | | | | | ● | | | | |
| Yesintek | | | | | ● | | | | |
| **Infections** | | | | | | | | | |
| Akantior | | | ● | | | | | | |
| Emblaveo | | | | | | | ● | | |
| Exblifep | ● | | | | | | | | |
| Kavigale | ● | | | | | | ● | | |
| **Metabolism** | | | | | | | | | |
| Agilus | | | | | | | | | |
| **Neurology** | | | | | | | | | |
| Buprenorphine Neuraxpharm | | | | | | | | | |
| Dimethyl fumarate Accord | | | | | | ● | | | |
| Dimethyl fumarate Mylan | | | | | | ● | | | |
| Dimethyl fumarate Neuraxpharm | | | | | | ● | | | |
| Leqembi | ● | | | | | | | | |
| Qalsody | ● | | ● | | | | | | ● |
| Wainzua | ● | | | | | | | | |
| **Ophthalmology** | | | | | | | | | |
| Afqlir | | | | | ● | | | | |
| Ahzantive | | | | | ● | | | | |
| Baiama | | | | | ● | | | | |
| Eydenzelt | | | | | ● | | | | |

| Therapeutic area/ Product name | New active substance | PRIME | Orphan | ATMP | Biosimilar | Generic | Accelerated assesment | Conditional approval | Exceptional circumstances |
|---|---|---|---|---|---|---|---|---|---|
| Lytenava | | | | | | | | | |
| Opuviz | | | | | ● | | | | |
| Ranibizumab Midas | | | | | ● | | | | |
| Vevizye | | | | | | | | | |
| **Pneumology/Allergology** | | | | | | | | | |
| Eurneffy | | | | | | | | | |
| Gohibic | ● | | | | | | | | ● |
| Nintedanib Accord | | | | | | ● | | | |
| Omlyclo | | | | | ● | | | | |
| **Psychiatry** | | | | | | | | | |
| Niapelf | | | | | | ● | | | |
| Paxneury | | | | | | | | | |
| Tuzulby | | | | | | | | | |
| **Uro-nephrology** | | | | | | | | | |
| Filspari | ● | | ● | | | | | ● | |
| Obgemsa | ● | | | | | | | | |
| **Vaccines** | | | | | | | | | |
| Celldemic | | | | | | | | | |
| Fluad | | | | | | | | | |
| Flucelvax | | | | | | | | | |
| Fluenz | | | | | | | | | |
| Incellipan | | | | | | | | ● | |
| Ixchiq | ● | ● | | | | | ● | | |
| Kostaive | ● | | | | | | | | |
| mResvia | ● | | | | | | | | |
| Penbraya | | | | | | | | | |





In 2024, EMA recommended 114 medicines for marketing authorisation. Of these, 46 had a new active substance that had never previously been authorised in the EU.

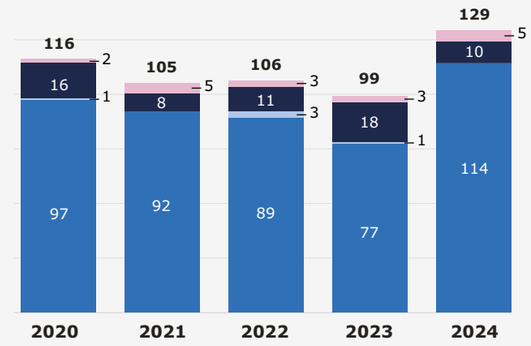
The CHMP adopted negative opinions for five medicines in 2024:

- **Cinainu,** for the treatment of moderate-to-severe alopecia areata, a disease causing hair loss of the scalp or other parts of the body;
- **Kizfizo,** for the treatment of neuroblastoma, a rare cancer that forms from immature nerve cells;
- **Masitinib AB Science,** for the treatment of amyotrophic lateral sclerosis, a rare disease of the nervous system leading to loss of muscle function and paralysis;
- **Nezglyal,** for the treatment of paediatric and adult male patients aged two years and older with cerebral adrenoleukodystrophy, a genetic condition that damages the membrane that covers nerve cells in the brain and spinal cord;
- **Syfovre,** for the treatment of geographic atrophy secondary to age-related macular degeneration, a progressive retinal macular disease causing gradual vision impairment mainly in elderly people.

The applications for eight medicines were withdrawn by the applicants prior to the CHMP adopting an opinion, in most cases because the data included in the application were insufficient to support a marketing authorisation.

Applicants for 60 % of the medicines granted a positive opinion by the CHMP in 2024 had received scientific advice during the development phase of their medicine. The figure rises to 79 % for medicines with a new active substance.

**Outcome of initial-evaluation applications**



## Average assessment time

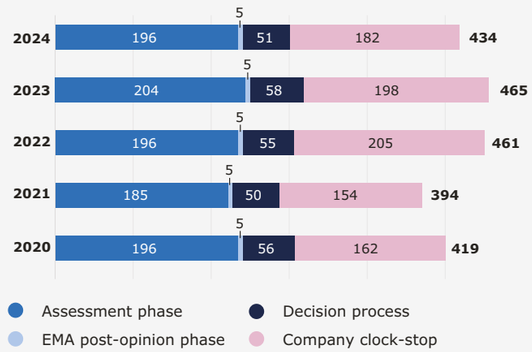
EMA has a maximum of 210 days to carry out its assessment. Within this time frame, the CHMP must issue a scientific opinion on whether the medicine under evaluation should be authorised. During the assessment, concerns with the application may be identified, requiring further information or clarification 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 countdown 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.

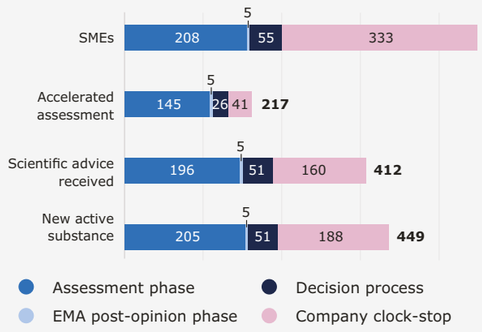
The overall total time required for the centralised procedure, from the start of the evaluation process to the adoption of a decision by the European Commission, was an average of 434 days in 2024, lower than in 2023 (465 days). The overall total time for medicines that had received scientific advice was 412 days.

For medicines evaluated under accelerated assessment, the total time from start of assessment until granting of authorisation was reduced by more than eight months (from 434 to 216 days).

### Average number of days for centralised procedure - positive opinions




### Average number of days for centralised procedure - subset (2024)




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, the CHMP gave 90 positive recommendations for an extension of the therapeutic indication of already authorised medicines. These included 39 medicines in the oncology area.

The product information for 401 authorised medicines was updated as new safety data were made available and assessed by EMA.





# 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, providing 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.

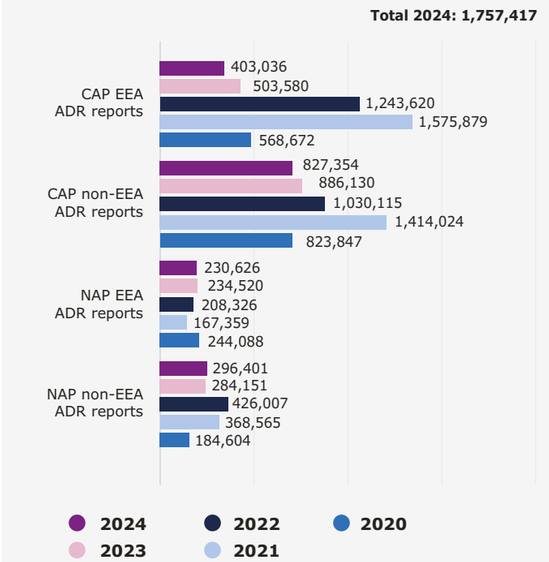
Over 1.7 million ADR reports were submitted to EudraVigilance in 2024, representing a slight decrease (8 %) compared with 2023.

63 % of all reports in EudraVigilance originated outside the EEA.

The share of reports submitted by European patients and consumers in 2024 also decreased considerably compared to 2022 and 2023, and is more in line with pre-pandemic figures.

The considerably higher rates of ADR reports, including from patient reporting, during the pandemic were a result of the mass vaccination campaigns and the heightened awareness of the importance of reporting any suspected side effects.

### EEA and non-EEA ADR reports received



## 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).

In 2024, 1,254 potential signals were reviewed by EMA, a decrease of 8 % compared to 2023. Approximately 74 % of these signals originated from monitoring the EudraVigilance database, highlighting its central role for safety monitoring. The PRAC assessed 71 signals. Thirty-nine of these were validated by EMA and 32 by Member States. In addition to signal detection activities and assessments at PRAC level, experts from the NCAs, in collaboration with EMA, provided major contributions to the development of signal detection methods and continuous process improvement.

### Outcome of signal assessment

**1,254 potential signals were identified by EMA and underwent an initial confirmatory and prioritisation review;**

**71 confirmed signals were prioritised and assessed by the PRAC:**

- Of these 71 signals, 39 were detected and validated by EMA,
- 32 were detected and validated by EU Member States;

**Out of 71 confirmed and validated signals**

- 32 signals led to a product information update;
- 14 signals led to a recommendation for routine pharmacovigilance; and
- 25 signals were undergoing review by the PRAC at the end of 2024 as further data were required.

## 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.

In 2024, the PRAC started the assessment of 910 PSURs and PSUR single assessment procedures (PSUSAs), of which 26 % represent single assessments of active substances only contained in NAPs. The PRAC issued 913 recommendations based on the assessment of PSURs and PSUSAs, of which 27 % consisted of single assessments of active substances only contained in NAPs. 19 % of assessments led to changes in the product information to optimise the safe and effective use of medicines by patients and healthcare professionals.





### PSURs and PSUSAs finalised

| | 2020 | 2021 | 2022 | 2023 | 2024 |
|---|---|---|---|---|---|
| PSURs - standalone (CAPs only) finalised | 516 | 575 | 542 | 584 | 627 |
| PSURs – single assessment finalised | 258 | 336 | 318 | 275 | 283 |
| PSURs – single assessment (CAPs with NAPs) finalised | 49 | 49 | 46 | 38 | 49 |
| PSURs – single assessment (NAPs only) finalised | 209 | 287 | 272 | 237 | 234 |
| **Total outcomes** | **774** | **911** | **860** | **859** | **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** |

# Veterinary medicines

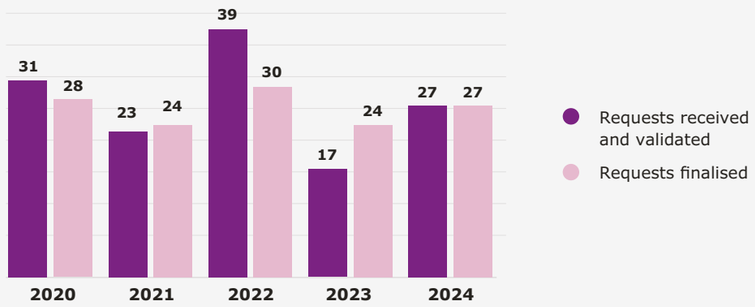
In 2024, EMA's work across the veterinary medicines lifecycle helped to guide innovative treatments to market that strengthen animal health and prevent the transmission of diseases in the EU. The Agency supports developers at every stage of veterinary medicine development, helping to boost innovation and research by offering expertise before, during and after marketing authorisation.

## 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. In 2024, EMA received 27 requests for scientific advice and also finalised 27. Almost a quarter of the finalised scientific advice requests were for immunological products, including vaccines. These types of medicines play a major role in protecting animal health by preventing and controlling serious epizootic diseases. They are also important for human health because they ensure safe food supplies and prevent animal-to-human transmission of infectious diseases. In addition, veterinary vaccines can be an effective tool in reducing the need to use antibiotics in animals, thereby contributing to the fight against antimicrobial resistance.

**Scientific-advice requests received and finalised**








### Veterinary limited markets

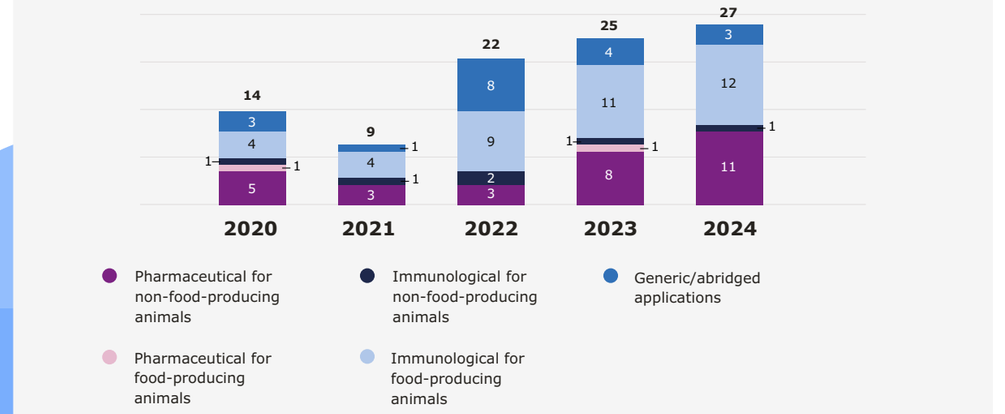
In 2024, companies developing medicines for small markets in the EU showed a steady interest in early engagement with EMA. The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) has established a specific authorisation route for medicines intended for veterinary limited markets in the 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. In 2024, EMA received 14 requests for limited market classification and four applications for initial marketing authorisation for limited market products.

## 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. A total of 27 applications were received in 2024, an increase of 8 % compared to 2023, and continuing the trend seen since the new Veterinary Medicinal Products Regulation became applicable. Approximately half of these applications were submitted for vaccines, 12 of which were for use in food-producing animals.

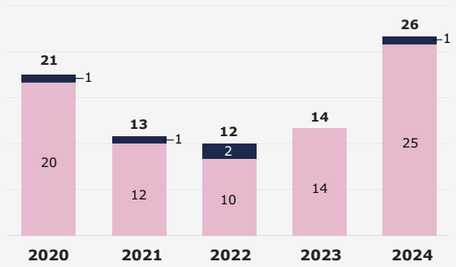
**Applications for initial evaluation received**



## Recommendations for authorisation

In 2024, EMA recommended 25 veterinary medicines for marketing authorisation, the highest number of recommendations in a year. Of these, two had a new active substance that had not previously been authorised in the EU. Fourteen were vaccines, an increase of 55 % compared to 2023. Of these 14 vaccines, seven had been developed through a biotechnological process. This demonstrates the animal health industry's continued strong interest in innovation and developing vaccines.

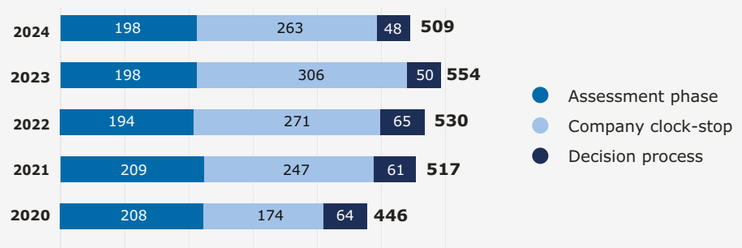
### Outcome of initial-evaluation applications






| PRODUCT NAME | New active substance | Atlantic salmon | Cattle | Cats | Chickens | Dogs | Pigs |
|---|---|---|---|---|---|---|---|
| Alcort | | | | | | ● | |
| ArthriCox | | | | | | ● | |
| BRAVECTO TriUNO | | | | | | ● | |
| CARPROFEN ORION | | | | ● | | ● | |
| Cepeloron | | | | | | ● | |
| Cevac Salmune ETI K | | | | | ● | | |
| Cirbloc M Hyo | | | | | | | ● |
| DIVENCE IBR Marker Live | | | ● | | | | |
| DIVENCE PENTA | ● | | ● | | | | |
| DIVENCE Tetra | | | ● | | | | |
| DuOtic | | | | | | ● | |
| Ichtiovac ERM | | ● | | | | | |
| Innovax-ND-H5 | ● | | | | ● | | |
| Lexylan | | | ● | | | ● | |
| Lotimax | | | | | | ● | |
| Nobilis Multriva RT+IBm+ND+EDS | | | | | ● | | |
| Nobilis Multriva RT+IBm+ND+Gm+REOm | | | | | ● | | |
| Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS | | | | | ● | | |
| Porcilis PCV M Hyo ID | | | | | | | ● |
| Poulvac Procerta HVT-IBD-ND | | | | | ● | | |
| RESPIVAC aMPV | | | | | ● | | |
| TOLFENAMIC ACID VMD | | | ● | ● | | ● | ● |
| Trilocur | | | | | | ● | |
| Trilorale | | | | | | ● | |
| VAXXON ND CLONE | | | | | ● | | |

**Average number of days for initial authorisations**




The average number of days taken for initial authorisations has decreased considerably compared with previous years, mainly due to a significant reduction of length of clock-stops taken by the companies to respond to questions from CVMP.

# 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. The use of four known veterinary medicinal products was expanded in 2024.

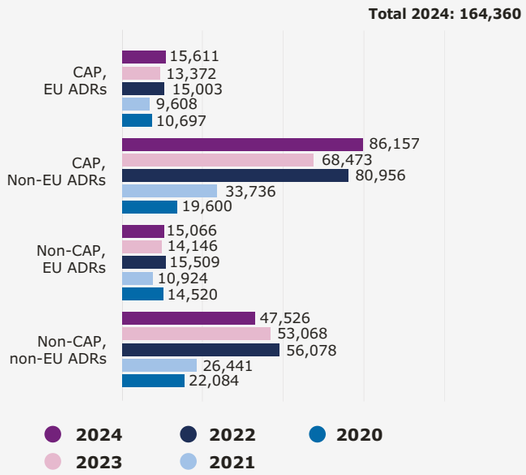
# Safety monitoring of medicines

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). The total number of reports rebounded in 2024, approaching the 2022 level when a backlog of reports was submitted by marketing authorisation holders. While ADRs reported from outside the EU continued to grow for centrally authorised products (CAPs), that trend seemed to be reversed for medicines authorised at national level (non-CAP, non-EU ADRs).

**Adverse event reports in animals**








# 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 from the CHMP or the CVMP in the context of assessing 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 Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh));
- a programme of risk-based routine inspections of the pharmacovigilance systems in place for CAPs (in collaboration with NCAs); and
- a two-year programme of routine GCP inspections based on risk factors and a random element to ensure that a diverse range of applications, trials, and sites and geographical locations are covered.

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

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

# Inspections

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

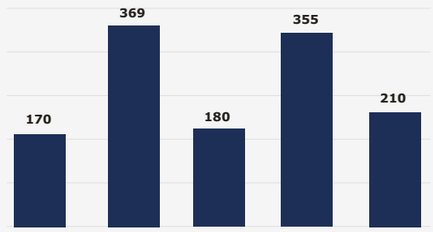
## GMP inspections

A total of 210 GMP inspections requested by the CHMP or the CVMP within the context of the centralised authorisation procedure were performed in 2024.

In 2024, ten GMP inspections conducted by EEA authorities led to the issuing of a non-compliance statement. This means that medicines manufactured at a site with such a non-compliance statement cannot be sold in the EU.

The EEA authorities issued one statement of GMP non-compliance relating to CAPs, either in connection with the active substance or the finished product; however, no recalls were necessary. When inspections lead to findings, companies must implement corrective action plans agreed with the inspecting authorities.

**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 either the CHMP or the CVMP.

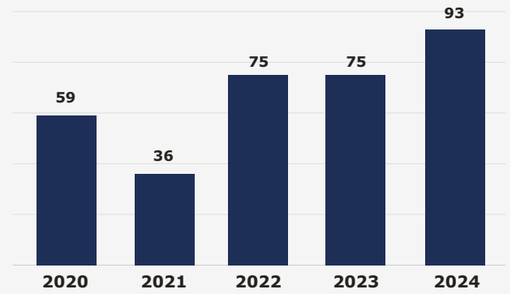




## GCP inspections

The number of GCP inspections increased by 24 % compared to 2023.

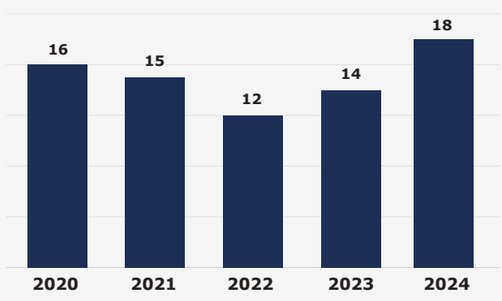
**GCP inspections**




## Pharmacovigilance inspections

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

**Number of pharmacovigilance inspections**



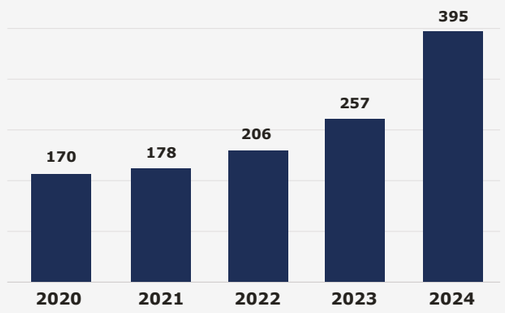

In 2024, 18 pharmacovigilance inspections were requested by the CHMP or the CVMP. Most EU/EEA pharmacovigilance inspections (over 90 %) are conducted under the national pharmacovigilance inspection programmes, which relate to marketing authorisation holders with product authorisations of all types (including CAPs).

# Market surveillance and quality defects

Manufacturers are required to inform the authorities of quality defects in a manufactured product. This can lead to a recall of batches from the market or a prevention of their release by the manufacturer. Where a defect is considered to be a risk to public or animal health, the marketing authorisation holder is requested to withdraw the affected batches of the CAP from the EU market and the supervisory authority issues a rapid alert. The alert is classified from 1 to 3, depending on the expected risk to public or animal health posed by the defective product:

- Class 1 recall: the defect presents a life-threatening or serious risk to health;
- Class 2 recall: the defect may cause mistreatment or harm to the patient or animal, but is not life-threatening or serious; and
- Class 3 recall: the defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

**Number of quality defect notifications received**




In 2024, the Agency received 395 suspected quality defect notifications, the highest number recorded in recent years. Of these, 221 cases were confirmed quality defects and led to batch recalls of nine CAPs. None of the defects required a Class 1 recall.

| | 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





The main reasons for the recall of CAPs in 2024 included:

**Manufacturing laboratory control issues:** These include out-of-specification results obtained during quality control testing;

**Product contamination and sterility issues:** These include chemical, microbiological or physical contamination of the medicinal product;

**Product label issues**: These include issues related to labelling of the medicinal products (e.g. a missing or incorrect batch number);

**Product packaging issues:** These relate to physical issues (e.g. a mix-up or a damaged container);

**Product physical issues:** These relate to incorrect product physical properties (e.g. friability, size/shape, leakage).

# 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.

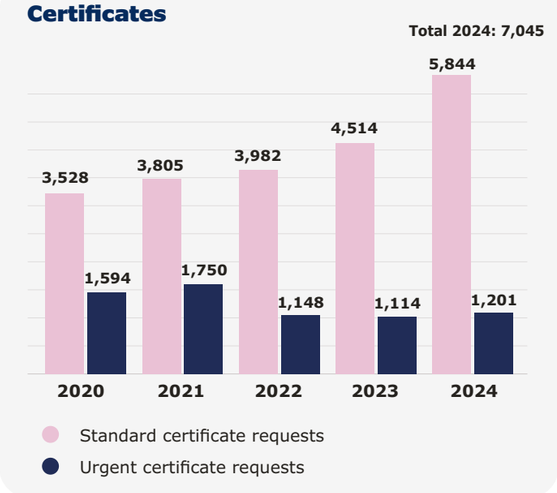
**Parallel distribution notifications received**

| | 2020 | 2021 | 2022 | 2023 | 2024 |
|---|---|---|---|---|---|
| Initial notifications | 3,172 | 2,555 | 1,816 | 2,092 | 2,656 |
| Notifications of change | 0 | 0 | 0 | 0 | 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.

**Certificates**



# Medicine shortages

Medicine shortages can happen for many reasons, from supply disruptions to public health emergencies. They are a burden on healthcare systems and put patients at risk. Improving the availability of medicines is a priority for the EU medicines regulatory network. EMA plays an important role in this by monitoring the EU situation, coordinating the response to critical shortages and communicating with all relevant stakeholders, from industry to healthcare professionals and patients.

## Monitoring EU shortages

Shortages are monitored by the Medicine Shortages Single Point of Contact (SPOC) working party. This group allows representatives from all Member States to regularly report shortages in their countries and exchange information on mitigation measures.

To support the SPOC working party with the monitoring of shortages, in November 2024, EMA launched the European Shortages Monitoring Platform, a digital platform that will centralise and automate data collection from NCAs and marketing authorisation holders.

## Preventing and managing critical shortages

The SPOC working party can escalate critical shortages or flag events that might lead to shortages to a group composed of heads of NCAs, patient and healthcare professional representatives, the European Commission and EMA. This is the Medicines Shortages Steering Group (MSSG). The group met 11 times in 2024. In this context, six oral explanations with marketing authorisations holders took place.

The main topics discussed were the ongoing shortages of Visudyne (verteporfin) and GLP-1 receptor agonists. For Visudyne, the MSSG supervised the allocation of available stock in the ongoing shortage. It worked with the marketing authorisation holder of the product to accelerate the implementation of a new supply chain in Europe and recommend additional mitigation mechanisms. For GLP-1 receptor agonists, recommendations to all stakeholders on managing the ongoing shortages were issued in July. A multi-stakeholder workshop was also then held to understand the needs of all relevant actors. In December, a real-world study characterising patients prescribed GLP-1 receptor agonists in five European countries was published to try and further understand how these medicines are used.

The MSSG also followed the supply situation for antibiotics used to treat respiratory infections throughout autumn/winter 2023-2024 and agreed on actions in preparation for autumn/winter 2024-2025. Additional supplies of antibiotics were identified and made available to Member States for the autumn/winter 2024-2025 season.





An analysis of vulnerabilities of the supply chain of insulins was initiated in 2024, with the aim of identifying prevention and mitigation measures to secure the availability of these important medicines.

Throughout the year, the MSSG continued to monitor events that could lead to public health emergencies, including the impact of the hurricane Helene on the availability of medicinal products in the EU/EEA.

## New tool for coordinated EU response to shortages

At the end of 2023, the MSSG created the voluntary solidarity mechanism, to complement the existing tools included in the MSSG toolkit. This allows Member States to support each other in the face of a critical medicine shortage. The tool enables any Member State facing a critical shortage to request assistance from other Member States in obtaining stocks for a period of time.

This mechanism can only be used under limited conditions and was developed as a last resort for Member States after they have exhausted all other possibilities. In 2024, seven of these procedures were launched. All of these involved oncology medicines. In all cases at least one Member State was able to provide support.

# 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.

Seventy-three applications for CECP were screened in 2024, over 50 % more than in 2023. The screening experts decided that an opinion was needed for six of these CECP applications.

When it comes to PECPs, in 2024 expert panels issued opinions for four applications.

In addition, EMA is running a pilot that enables the expert panels to provide scientific advice for manufacturers of high-risk medical devices. In 2024, 17 such procedures were finalised.

In line with EU legislation, the expert panels provided two advice reports upon request of the Medical Device Coordination Group (MDCG).

**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 CECP | 3 | 7 | 1 | 6 |
| Number of finalised PECP | 15 | 1 | 2 | 4 |
| Number of finalised advice procedures to MDCG | - | - | 3 | 2 |
| Number of finalised scientific advice pilot procedures | - | - | 3 | 17 |

EMA also launched a pilot on orphan medical devices in August 2024, which is scheduled to run until the end of 2025. As of December 2024, six applications have been received.





# European medicines regulatory network

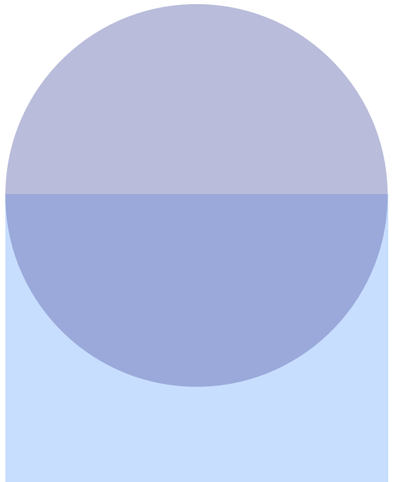
The European medicines regulatory network is the cornerstone of EMA's work and success. EMA plays a central role in this network, coordinating and facilitating collaboration between more than 50 national competent authorities across the EU and EEA for both human and veterinary medicines.

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

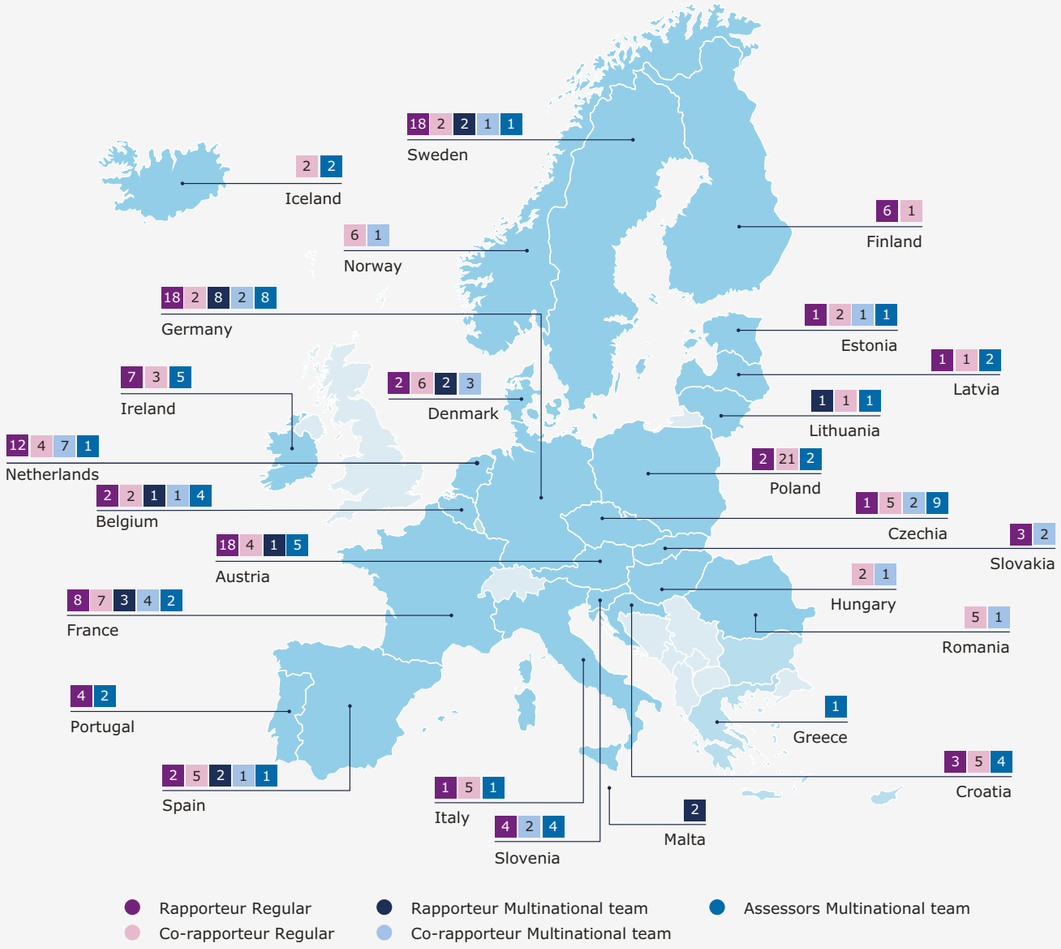
The assessment of a medicine by EMA's scientific committees is carried out by a rapporteur and a co-rapporteur, who prepare the assessment reports and lead discussions in the committees. The appointment is made on the basis of the best possible expertise for the particular product. Rapporteurs work through assessment procedures and take the lead in evaluating any new information on the medicine that may become available.

EMA and its regulatory network partners run a scheme to enable multinational teams to assess applications for human and veterinary medicines. The aim is to mobilise the best expertise for medicines evaluation, regardless of where experts are based. The concept enables rapporteurs and co-rapporteurs for EMA's scientific committees to include experts from other Member States in their assessment teams. This helps to optimise resource use across the regulatory network and encourage cross-border fertilisation of scientific expertise.



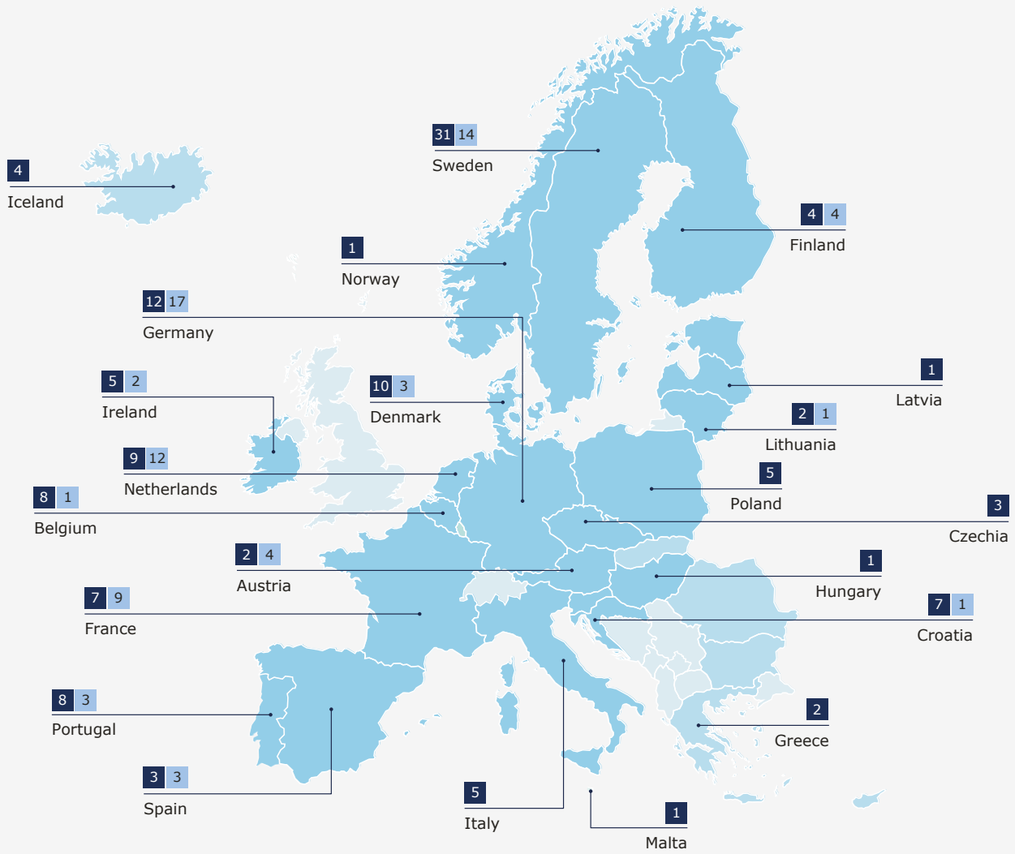
## CHMP rapporteurs / co-rapporteurs appointed in 2024

(for initial marketing autorisation applications, including generics)

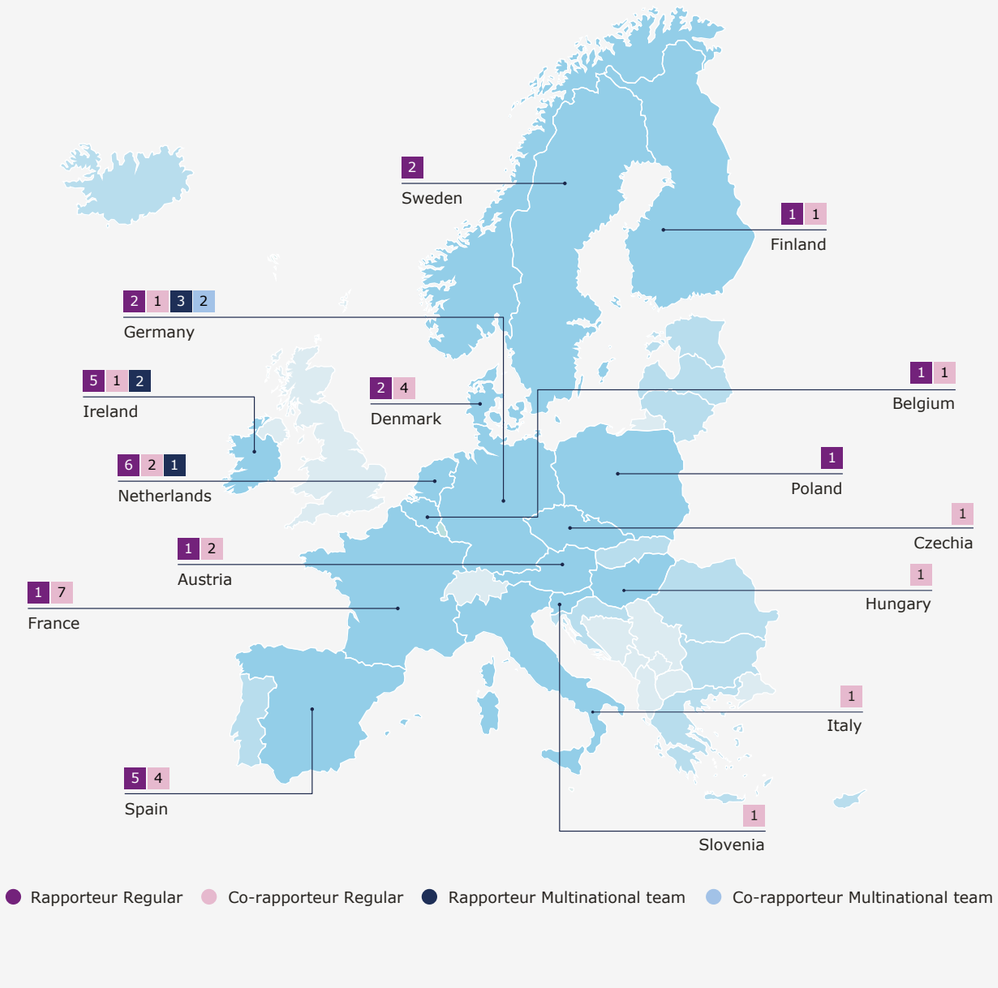



## PRAC rapporteurs / co-rapporteurs appointed in 2024

(for initial marketing authorisation applications)



**CVMP rapporteurs / co-rapporteurs appointed in 2024**
(for initial marketing authorisation applications, including generics)








# Communication and stakeholders

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. We work closely with our regulatory partners and stakeholders both within the EU and globally. We also use many different channels to disseminate this information: we contribute articles to relevant scientific journals, we maintain regular communication with media and we engage with diverse audiences across different social media platforms.

## External communication

In 2024, EMA issued 115 press releases and news items to keep our audiences across the EU and beyond informed about key developments in the assessment of medicines and major achievements in both new and ongoing initiatives. Two press briefings were organised on human medicines highlights and measures to manage shortages of GLP-1 receptor agonists. In addition, a media seminar on medicine shortages took place on EMA premises, attended by 27 members of the press.

In its efforts to inform the public about new medicines or new uses of authorised medicines, EMA published 214 medicines overviews. It also communicated on safety concerns arising for some medicines through 24 public health communications. To keep the public and healthcare professionals up to date about specific actions required for some medicines, 28 direct healthcare professional communications and 17 shortage catalogue entries were also published.

The EMA website remains the primary communication platform, offering a thorough source of information and guidance on centrally authorised 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 with 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 85 articles on scientific and regulatory subjects to international journals. Over 80 % of all articles are publicly available under an open access licence.

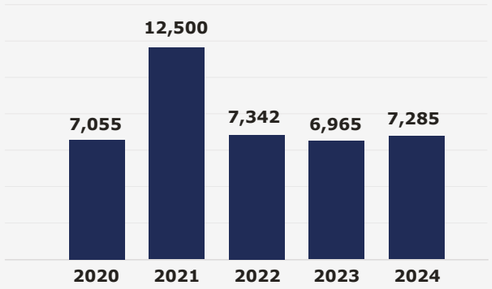
# Requests for information and access to documents

Providing citizens with clear, transparent information about its activities is a fundamental aspect of EMA's work. In 2024, the Agency received 7,285 requests for information.

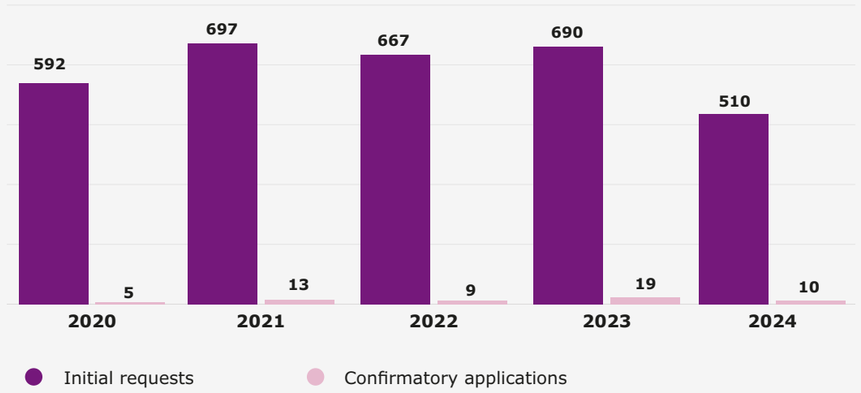
EU citizens have the right to access documents held by EU institutions, bodies, offices and agencies. EMA facilitates this access in accordance with the principles and conditions outlined in Regulation (EC) No 1049/2001 and the Agency's policy on document access.

In 2024, EMA received 520 requests for access to documents (representing over 1,000 documents), with most of these requests originating from the pharmaceutical industry, followed by patients and consumers.

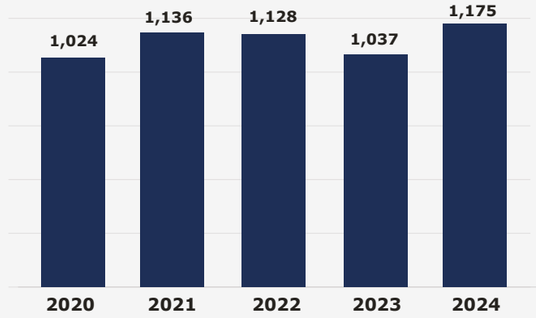
### Requests for information received



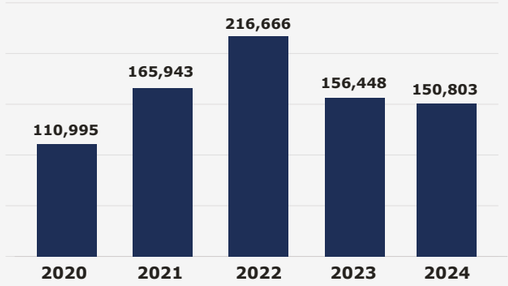

### Requests received for access to documents




### Documents released following access to documents requests




### Pages released following access to documents requests

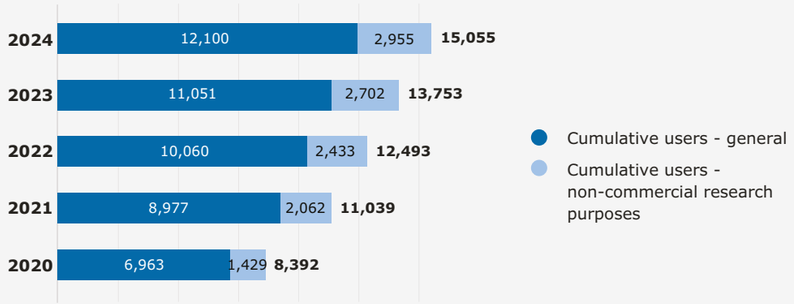


# Publication of clinical data

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.

In 2024, 5,817 clinical data documents were published from 73 different procedures. The publication of clinical data for non-COVID medicines containing new active substances resumed in 2023, following its interruption at the end of 2018 because of the business continuity measures introduced for the Agency's relocation to the Netherlands and subsequently due to the COVID-19 pandemic. This year, this has led to an increase in the usage of the clinical data website.

**Clinical data website - users**





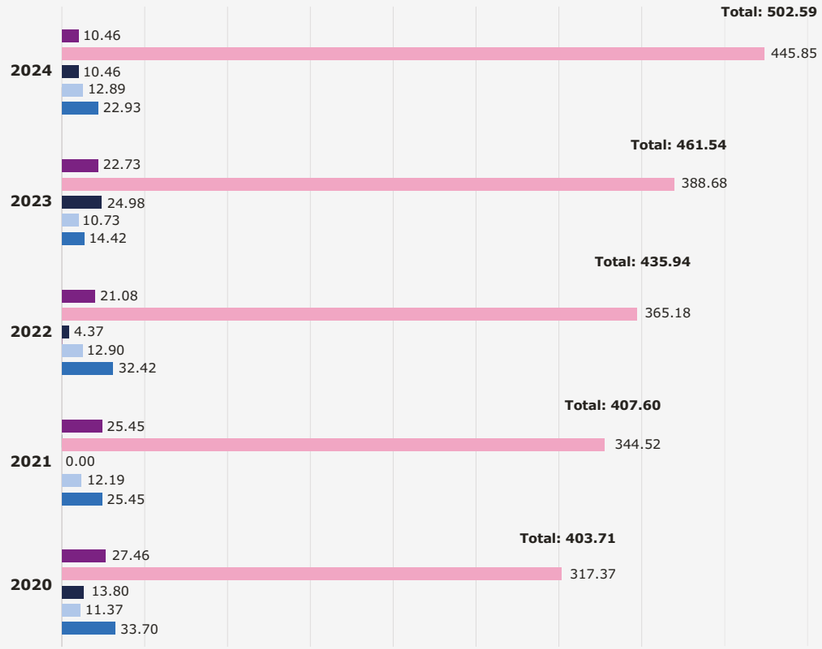



# Administrative aspects

## Financial information

The Agency's total revenue in 2024 was EUR 502.59 million, a 9 % increase compared to EUR 461.54 million in 2023. In addition, the Agency operates with fund sources for assigned revenue, mainly CL for internal assigned revenue (rent and building charges received from the Agency's subtenant in London) and R0 for external assigned revenue. In 2024, assigned revenue (funding sources R0 and CL) amounted to EUR 10.46 million.

**Revenue (in million € )**



## Preparing for the new fee regulation

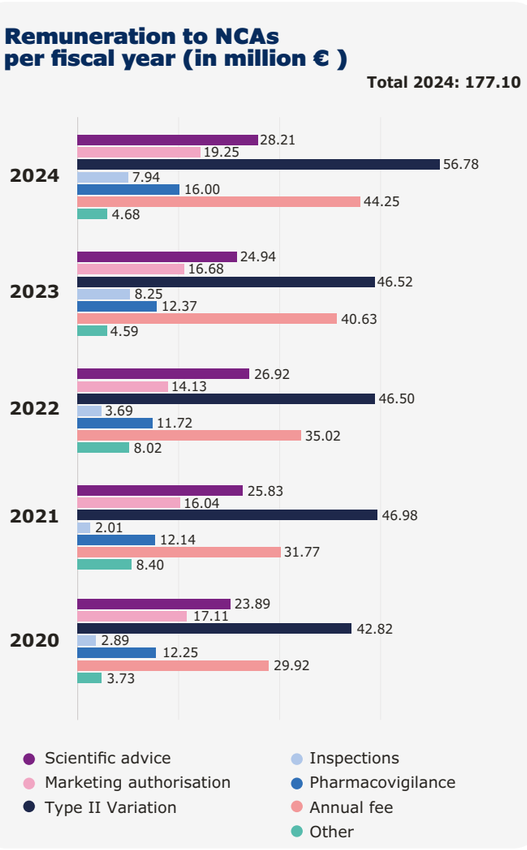
Following the adoption of a revised regulation on fees and charges payable to EMA (Regulation (EU) 2024/568), the Agency focused on preparing for the implementation of the new regulation throughout 2024, to be ready for its implementation on 1 January 2025. The regulation aims to ensure the sustainability 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.

Preparations included the drafting and updating of all relevant regulatory and legal documentation, such as the cooperation agreement with NCAs, Working Arrangements and Management Board decisions that replaced the previous fee implementing rules. In parallel, the Agency was involved in several technical developments, adapting and improving existing systems and launching new ones. The implementation was further supported by communication measures, such as webinars and the publication of Q&A documents, to guide stakeholders through the new regulation.

# Remuneration to national competent authorities

The 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. In 2024, EMA paid a total of EUR 177.10 million to the NCAs, a 15 % increase over 2023. This figure includes payments for pharmacovigilance procedures, including the assessment of PSURs, PASS protocols and study results, and of pharmacovigilance-related referrals.

**Remuneration to NCAs per fiscal year (in million € )**



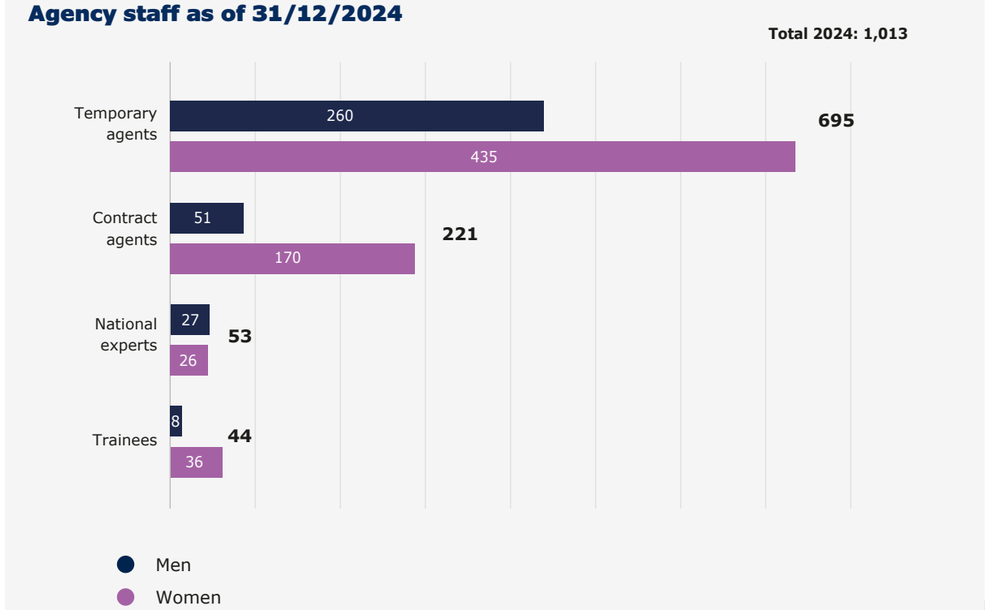





# Agency staff

As of December 2024, the Agency had 1,013 staff members: 667 women and 346 men.

**Agency staff as of 31/12/2024**



# Annexes

**Annex 1** – Members of the Management Board

**Annex 2** - Members of the Committee for Medicinal Products for Human Use

**Annex 3 –** Members of the Pharmacovigilance Risk Assessment Committee

**Annex 4** – Members of the Committee for Medicinal Products for Veterinary Use

**Annex 5** – Members of the Committee on Orphan Medicinal Products

**Annex 6** – Members of the Committee on Herbal Medicinal Products

**Annex 7** – Committee for Advanced Therapies

**Annex 8** – Members of the Paediatric Committee

**Annex 9** – Working parties and working groups

**Annex 10** – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2024

**Annex 11** – Guidelines and concept papers adopted by CHMP

**Annex 12** – CVMP opinions on medicinal products for veterinary use in 2024

**Annex 13** – Guidelines and concept papers adopted by CVMP in 2024

**Annex 14** – COMP opinions on designation of orphan medicinal products in 2024

**Annex 15** – HMPC European Union herbal monographs in 2024

**Annex 16** – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2024

**Annex 17** – Referral procedures overview 2024 – human medicines

**Annex 18** – Arbitrations and referrals in 2024 – veterinary medicines

**Annex 19** – Budget summaries 2023-2024

**Annex 20** – European Medicines Agency establishment plan

**Annex 21** – Litigation activities of EMA in 2024

**Annex 22** – Access to documents requests

**Annex 23** – Clinical Data Publication

**Annex 24** – Publications by Agency staff members and experts in 2024

The annexes are available on EMA's website.

**European Medicines Agency**

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**Send a question:**

**www.ema.europa.eu**

**Annual report 2024**



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