EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ANNUAL REPORT 2025

The European Medicines Agency's contribution to science, medicines and health in 2025

An agency of the European Union

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Luxembourg: Publications Office of the European Union, 2026

Print	ISBN 978-92-9155-155-2	ISSN 1725-3225	doi:10.2809/6572911	TC-01-26-021-EN-C
PDF	ISBN 978-92-9155-154-5	ISSN 2467-2106	doi:10.2809/3465390	TC-01-26-021-EN-N
HTML	ISBN 978-92-9155-153-8	ISSN 2467-2106	doi:10.2809/5908586	TC-01-26-021-EN-Q

Table of contents

Foreword by Rui Santos Ivo

Chair of EMA Management Board

Welcome to EMA's annual report for 2025. In this report, you will find details about EMA's achievements and milestones during another important year for the Agency, the regulatory network and European healthcare systems.

This year marks my first as Chair of the Management Board, and I would like to express my sincere appreciation to my predecessor, Lorraine Nolan, for her steady and dedicated leadership and exemplary legacy.

I would also like to extend my warm congratulations to our Executive Director, Emer Cooke, on the extension of her mandate until the end of April 2027. Under her leadership, the Agency is well positioned to confidently and collectively navigate the opportunities and challenges ahead, particularly with the revision of the EU pharmaceutical legislation.

This report highlights the remarkable progress we are making in medicines regulation today. Among the many important developments highlighted in this report, the continued momentum in the field of veterinary medicines stands out. For the second consecutive year, EMA has recommended an unprecedented number of veterinary medicines for approval. This suggests the positive impact of the Veterinary Medicines Regulation, introduced in 2022, in fostering product innovation across the European Union (EU).

In 2025, we celebrated EMA's 30th anniversary and looked back over three decades of medicines regulation with our eyes on the future. EMA's scientific conference in Amsterdam in June was especially significant in celebrating the role of science in our societies, as well as the latest trends, innovations and challenges in the field of medicines regulation. I enjoyed meeting past and present EMA and network representatives during the event. We all share enduring values: collaboration, integrity, scientific excellence and an unwavering commitment to public and animal health.

These are also values being instilled in the newly formed African Medicines Agency (AMA), whose Governing Board and heads of African national

agencies attended a first-of-its-kind meeting with EMA's Management Board in June. This was a special and significant moment for the European and African regulatory networks, and it allowed our counterparts to gain insights into the governance and supervisory role of the Management Board across a broad range of activities, including strategic, financial and operational matters.

Currently, we are operating in a period of rapid transformation, defined by new ways of working and major legislative changes. These developments underscore how essential it is for EMA and the network to remain forward looking, agile, efficient and firmly committed to safeguarding the EU's high standards for human and animal health while serving all European citizens. They also highlight the need for ever-closer coordination and solidarity across the European medicines regulatory network as we respond to shared pressures on resources, expertise and capacity.

In 2025, we officially launched our EU Medicines Agencies Network Strategy (EMANS) to 2028. This strategy places greater emphasis on the competitiveness of the EU in the development and manufacture of medicines, as well as the use of data and artificial intelligence throughout the medicines lifecycle, and aims to foster innovation, access, emergency preparedness and sustainability. Preparation is underway for the implementation of the new EU pharmaceutical legislation, including significant investment in the development of staff across the European medicines regulatory network.

With so much change driven by rapid digitalisation, EMANS provides the strategic roadmap to ensure increased demand and manage structural changes effectively. It highlights the importance of continuous learning, upskilling and the development of new capabilities across our network, where the EU Network Training Centre provides comprehensive, high quality scientific and regulatory training, which is now more accessible than ever.

Bringing together assessors and experts from key scientific disciplines — clinical, non-clinical, quality and pharmacovigilance — and from across the EU/European Economic Area (EEA) national competent authorities, provides a unique opportunity to connect, network and share knowledge and experiences, developing a stronger sense of community and enhancing collaboration across the EU medicines regulatory network. Such initiatives are essential to building a truly integrated community of experts, able to respond consistently and effectively to emerging scientific and regulatory challenges.

Another key priority that gathered momentum in 2025 is our work to modernise clinical trials in the EU so it can be a leading destination for clinical research and innovation. I can see we have the tools and unity of purpose to deliver. Central to this transformation is the Clinical Trials Information System (CTIS), which serves as the single-entry point for sponsors and regulators to submit, assess and oversee trials across the EU. Since its launch in 2022, CTIS has received an increasing number of applications which, in conjunction with other initiatives, ensures a strong axis to this priority.

I believe we are ready as a network for the challenges the future brings, and as Chair of the Management Board, I will continue to focus on supporting the outstanding work of our scientists in Europe, together with my fellow Board members.

Looking ahead, we will focus on prioritising and reinforcing the valuable partnership EMA shares with national agencies and the European Commission, while jointly upholding the strong international reputation of EMA as a reference regulator.

Thank you for making my first year in this position so memorable. I would like to extend my sincere thanks also to our partners at the European Commission for their collaboration and continued support. My gratitude also goes to my fellow Board members and colleagues in our network, and to the EMA staff, whose commitment, drive and dedication to public health in the EU is exemplary and underpins our work every day.

Introduction by Emer Cooke

EMA Executive Director

This was a special year for EMA as it marked our 30th anniversary – three decades cultivating a world-class regulatory network and making medicines safe and effective for 450 million people and countless animals across the EU.

We commemorated this milestone through a series of activities. Our scientific conference — opened by King Willem-Alexander of the Netherlands and the European Commission – brought together past and present leaders, colleagues and partners who have shaped EMA's journey. The 30th anniversary also coincided with significant milestones in other policy areas. We celebrated 25 years of the orphan medicines regulation and 20 years of the small and medium-sized enterprises (SME) regulation.

Breakthroughs for humans and animals

At the heart of our work is the impact we make on people's lives. In 2025, EMA recommended 104 medicines for human use for marketing authorisation in the EU. This includes medicines representing important innovation or contributions to public health. Among them:

- A treatment for bladder cancer, one of the most common cancers in the EU, affecting over 200,000 people each year.
- A vaccine to protect young people from 12 years of age and adults against disease caused by the Chikungunya virus.
- The first oral medicine to treat postpartum depression following childbirth (Zurzuvae).

Out of the 104 recommended medicines, 16 were for the treatment of a rare disease. Our efforts extended to global public health, with three positive opinions for medicines intended for use outside the EU, including a medicine to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents.

Veterinary medicines also achieved new heights in 2025. For the second year in a row, EMA recommended a record number of veterinary medicines for approval, highlighting how the 2022 Veterinary Medicines Regulation fosters innovation. Thirty medicines in total were recommended for marketing authorisation, including 16 vaccines and 13 medicines with a new active substance, which had not previously been authorised in the EU.

Realising the opportunity of the new pharmaceutical legislation

Europe's life science landscape is transforming fast. The revision of the EU pharmaceutical legislation presents a once-in-a-generation opportunity to simplify, integrate and modernise the medicines framework. It offers us new scope to address availability and supply of medicines in Europe and support our commitment to build public trust in medicines regulation.

With the political agreement reached between the European Commission, Parliament and Council, we are set to realise our ambition to build a more streamlined, modern regulatory system that provides a fast path from innovation to safe and effective medicines.

The legislation introduces instruments fit for today's science: regulatory sandboxes, platform technology approaches, strengthened availability obligations and clearer pathways for advanced therapies. This modernisation is further bolstered by the upcoming EU Biotech Act, which aims to remove barriers to innovation and boost Europe's global competitiveness. EMA is ready to ensure these pieces of legislation translate into real-world results through our support for developers across the medicines lifecycle.

Unifying to address availability

Ensuring availability of medicines remains one of our most unifying challenges – and responsibilities. Over the past few years, the Agency's expanded mandate has positioned us as the central coordinator for the EU's response to medicines shortages, shifting from reactive mitigation to proactive, data-driven preparedness.

We maintain the Union List of Critical Medicines and operate the European Shortages Monitoring Platform (ESMP), which became operational in 2025, to ensure rapid information exchange on supply and demand with regulators and companies.

Working side-by-side with Member States, we activated the Voluntary Solidarity Mechanism on multiple occasions to resolve critical shortages, and we issued targeted recommendations to secure continuity of supply of certain medicines.

Looking ahead, the Critical Medicines Act will introduce complementary instruments that will help to fortify the EU's resilience and protect patients against medicine shortages. In many ways, this work shows Europe its best: coordinated, proactive and all invested in solving a common public health problem.

Turning data into decisions

Digitalisation and AI continued to transform our work in 2025 as we moved from exploration to implementation. In July, we published our first Observatory Report showcasing real AI use across the medicines network, including seven qualification procedures and four scientific advice processes related to AI tools. These included deep learning-based image analysis for liver disease, machine learning to assess radiographic progression in psoriatic arthritis, and digital twins in rare disease trials.

We also aligned with partners on how best to regulate this fast-developing technology. Together with the US Food and Drug Administration (US FDA) we developed principles for the use of AI in medicine development, from early research and clinical trials to manufacturing and safety monitoring. Across EMA, more than 100 AI use cases are being explored – from support in drafting assessment reports to improving signal detection and enhancing shortage management.

DARWIN EU reached a new scale in 2025 with a threefold rise in studies to support our understanding of medicines usage in Europe. It now includes 30 data partners across 16 countries, covering approximately 180 million patients. DARWIN EU studies in 2025 supported high-impact regulatory and public health questions, including: safety assessments such as suicidality risks linked to doxycycline and GLP-1 agonists, monitoring medicine shortages and evaluations of mpox vaccine effectiveness.

Contributing to public health globally

In an increasingly unpredictable world where public health challenges routinely cross national borders, our international partnerships have never been more vital. From further supporting the establishment of the AMA to continued work on harmonisation of scientific guidelines (ICH and VICH) and collaborations with the World Health Organization (WHO) and the International Coalition of Medicines Regulatory Authorities (ICMRA), 2025 was a year in which we continued to strengthen our global ties in response to a growing need for coordination and alignment.

In June, EMA hosted a landmark meeting at our Amsterdam office, bringing together the AMA Governing Board and the heads of several African national authorities as observers to meet with the EMA Management Board. It was the first meeting of its kind between the European and African regulatory networks. There is an abundant need for smart, effective, and coordinated medicines regulation, and collaboration is essential to finding sustainable solutions to shared regulatory challenges.

In October, my final ICMRA Summit as chair featured discussions on our evolving role as communicators and on key topics such as reliance and developing common approaches to AI. Even though EMA's two mandates at the helm of the coalition have now been completed, as a member of the Coalition, I remain deeply committed to supporting its work and objectives in the years ahead.

Last year also marked a decade of formal collaboration with the WHO. Together, we have tackled global health challenges through scientific cooperation, capacity-building and efforts to enhance regulatory efficiency. This long-standing partnership remains a cornerstone of our global engagement.

Making a difference for every patient

This year was a transformative year for all these reasons; it has provided us with stronger tools, deeper collaboration and clearer purpose to anticipate and act on behalf of European patients. These developments will help us turn scientific promise into innovative and accessible therapies. And our vision will endure: a fast path from innovation to safe and effective medicines – delivering with transparency, trust and collaboration.

Thank you to all our partners, colleagues and staff for their hard work and effort in 2025. As I told audiences at EMA's 30th anniversary scientific conference in June: every day that we make a difference is a day we can feel proud.

CHAPTER 1
Key achievements in 2025

Evaluation and monitoring of medicines: highlights

Human medicines

Medicines recommended for approval

In 2025, EMA recommended 104 medicines for marketing authorisation, including 38 with new active substances. Of those, the medicines selected in this overview represent significant progress in their therapeutic areas:

Anktiva, for the treatment of adults with a type of bladder cancer that affects the lining of the bladder (non-muscle invasive bladder cancer, NMIBC) and that is at high risk of growing and spreading. Bladder cancer is one of the most common cancers in the EU, affecting over 200,000 people each year, with most cases being NMIBC.

Aucatzyl, for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia, a type of cancer of the white blood cells.

Brinsupri, the first treatment for non-cystic fibrosis bronchiectasis, a serious, chronic, progressive lung disease resulting in damaged airways and severe pulmonary dysfunction, often leading to chronic cough and airflow obstruction due to abnormal mucus production.

Duvyzat, a treatment for Duchenne muscular dystrophy (DMD) in patients from the age of six who are still able to walk. DMD is a rare, ultimately lethal genetic disease in which the muscles progressively weaken and lose function.

Kisunla, for the treatment of early Alzheimer's disease. Patients have to be tested to exclude the presence of two copies of the ApoE ε4 gene.

Rezdiffra, for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), a serious disease where fat cells accumulate in the liver causing chronic inflammation. This is the first authorised treatment for MASH in the EU.

Teizeild, a first-in-class treatment to delay the onset of stage 3 type 1 diabetes in adults and in children from eight years of age with stage 2 type 1 diabetes.

Tepezza, for the treatment of adults with moderate-to-severe Thyroid Eye Disease (TED), also known as Graves' Eye Disease, a rare autoimmune disease that triggers inflammation of muscles, fat, and other tissues around and behind the eyes. Treatment options for moderate-to-severe TED are limited, most patients are treated with corticosteroids and some patients need multiple reconstructive surgeries.

Vimkunya, a vaccine to protect young people from 12 years of age and adults against disease caused by the Chikungunya virus.

Vyjuvek, to treat wounds in patients of all ages with dystrophic epidermolysis bullosa, a serious, ultra-rare genetic skin blistering disease caused by mutations in the collagen type VII alpha 1 chain (*COL7A1*) gene. Vyjuvek is expected to bring substantial therapeutic benefits and improve the quality of life for patients with this skin disorder.

Waskyra, the first medicine to treat Wiskott-Aldrich syndrome, a rare, inherited disease, seen almost exclusively in males, that affects blood cells and cells of the immune system.

Yeytuo (lenacapavir), for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents at high risk of becoming infected. Yeytuo will facilitate PrEP uptake and compliance because it only has to be administered twice a year via a subcutaneous injection. Lenacapavir was also approved as Lenacapavir Gilead under EU-Medicines for all (EU-M4All).

Zemcelpro, a stem cell therapy to treat patients with haematological malignancies (blood cancers) who need a blood stem cell transplant but have no suitable donor.

Biosimilars

In April 2025, EMA published a draft reflection paper on a **tailored clinical approach** in biosimilar medicines development. Building on extensive experience with biosimilar medicines, the paper suggested that demonstrated structural and functional comparability, together with comparative data on how the body interacts with the medicines (pharmacokinetic data), may be sufficient to demonstrate similarity with the reference medicine. This approach could potentially reduce the need for extensive clinical efficacy studies and would ultimately ensure wider availability of biosimilar medicines to patients in the EU. The approach has already opened the door to an increased number of biosimilar scientific advice requests.

Early access to medicines that address public health needs

In 2025, **three medicines** received a recommendation for marketing authorisation following an **accelerated assessment: Brinsupri, Vimkunya** and **Yeytu.** 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: **Anktiva, Aucatzyl, Duvyzat, Ezmekly, Lynozyfic, Rezdiffra, Zemcelpro** and **Ziihera.**

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 outweighs the potential risks of limited data. Marketing authorisation holders for these medicines are subject to specific post-authorisation obligations to generate complete data on the products.

Two medicines (Imreplys and **Maapliv)** 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.

© joyfotoliakid | stock.adobe.com

EMA's PRIority Medicines (PRIME) provides enhanced development support for promising medicines that target an unmet medical need. This year, **six medicines** with **PRIME designation** were recommended for approval (**Aucatzyl, Brinsupri, Teizeild, Vimkunya, Vyjuvek** and **Zemcelpro**).

Sixteen medicines under development were accepted in the scheme in 2025: Congenital, familial and genetic disorders (2), Neurology (2), Pneumology — Allergology (2), Vaccines (2), Cardiovascular diseases (1), Endocrinology — Gynaecology — Fertility — Metabolism (1), Immunology — Rheumatology — Transplantation (1), Infectious diseases (1), Musculoskeletal and connective tissue disorders (1), Oncology (1), Ophthalmology (1) and Uro-nephrology (1).

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 104 medicines recommended for marketing authorisation in 2025, **16 had their orphan designation confirmed** by the end of the year.

Five 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: Attroggy, Aucatzyl, Blenrep, Dawnzera and Oczyesa.

New uses for existing medicines

In 2025, **89** extensions of indication were recommended, including 40 for paediatric use. The extension of the use of a medicine that is already authorised for marketing in the EU can also offer new treatment opportunities for patients. Notable extensions of indication included:

Fabhalta, for the treatment of adults with complement 3 glomerulopathy, an ultra-rare kidney disease that previously had no treatment options. Fabhalta was initially approved for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia.

Ixchiq, for active immunisation of adolescents from 12 years of age against the disease caused by Chikungunya virus. This vaccine was initially approved to protect adults against the disease. Chikungunya is transmitted to humans by infected mosquitoes.

Kaftrio and Kalydeco, two cystic fibrosis medicines to be used in combination in patients aged two years and older who have at least one non-class I mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. This extended use for additional, rare mutations allows the treatment of about 95 % of all cystic fibrosis patients. Cystic fibrosis is an inherited disease that has severe effects on the lungs, the digestive system and other organs.

Mounjaro, for the treatment of adolescents and children from 10 years of age with insufficiently controlled type 2 diabetes, together with diet and physical activity. Mounjaro was initially approved for use in adults only.

Uplizna, for the treatment of active immunoglobulin G4-related disease, a rare autoimmune disease for which there were no authorised medicines in the EU. Uplizna was initially approved for neuromyelitis optica spectrum disorders.

Negative opinions

The Committee for Medicinal Products for Human Use (CHMP) adopted a **negative opinion for seven medicines** in 2025: **Atropine sulfate FGK, Blarcamesine Anavex, Elevidys, Jelrix, Kinselby, Nurzigma and Rezurock[1].**

[1]Rezurock received a positive opinion in January 2026 following a re-examination.

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. This is to optimise how the medicine is used by patients to achieve its full benefit and to protect patients from avoidable side effects. Regulatory measures range from a change to the product information to the suspension or withdrawal of a medicine or the recall of a limited number of batches.

The product information for 432 centrally authorised medicines was updated on the basis of new safety data in 2025. Every year, Pharmacovigilance Risk Assessment Committee (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 advice issued in 2025 included:

- **Azithromycin,** new recommendations on the way azithromycin is used, including the removal of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance.
- **Caspofungin,** new warning against the use of polyacrylonitrile-based membranes during continuous renal replacement therapy in critically ill patients receiving caspofungin.
- **Clozapine,** recommendation to ease risk minimisation measures based on new scientific evidence showing a markedly reduced risk of severe neutropenia over time; the frequencies of blood monitoring have been reduced, and absolute neutrophil count will now be the sole parameter required, replacing the previous need to also measure white blood cell count.
- **Crysvita** (burosumab), new recommendations to monitor blood calcium levels and parathyroid hormones due to risk of severe hypercalcaemia, and to add related possible side effects to the product information.
- **Finasteride** and **dutasteride tablets,** enhanced measures to minimise risk of suicidal thoughts alerting patients treated for androgenetic alopecia about the need to seek medical advice if they experience problems with sexual function (such as decreased sex drive or erectile dysfunction) known to contribute to mood alterations and suicidal ideation in some patients.
- **Injectable tranexamic acid,** a reminder to healthcare professionals to only administer injectable tranexamic acid intravenously (into a vein) and not by any other route.
- **Ixchiq** (live attenuated chikungunya vaccine), recommendation to only administer the vaccine when there is a significant risk of chikungunya infection and after careful consideration of the benefits and risks.
- **Mysimba** (naltrexone/bupropion), new measures to minimise potential cardiovascular risks with long-term use and an obligation on the company to provide more information from an ongoing study on the medicine's cardiovascular effects in patients treated for more than one year.
- **Oxbryta** (voxelotor), recommendation to maintain the marketing authorisation suspended, as recent clinical trials showed more sudden pain episodes and deaths in patients taking Oxbryta. This follows interim measures taken by the committee in September 2024, when it temporarily suspended the medicine to review emerging safety data.
- **Oxycodone,** new 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.
- **Remsima** (infliximab), instructions to healthcare professionals to confirm patients do not have hereditary fructose intolerance before using a new intravenous formulation, or contraindication of a new intravenous formulation in patients with hereditary fructose intolerance.
- **Semaglutide,** update of the product information to include non-arteritic anterior ischemic optic neuropathy (NAION) as a very rare side effect and to stop treatment with semaglutide if NAION is confirmed.
- **Tegretol** (carbamazepine), restriction on the use of Tegretol 100 mg/5 mL in neonates because the concentration of the excipient propylene glycol exceeds the recommended threshold.
- **Varilrix** and **Varivax** (varicella (chickenpox) vaccines), update to the product information to further describe the severity of the risk of encephalitis. People who receive the vaccine should seek immediate medical attention if they develop signs of infection or inflammation of the brain.

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

Veterinary medicines

New medicines to benefit animal health in Europe

In 2025, EMA recommended 30 veterinary medicines for marketing authorisation — the highest number of recommendations in a year for a second consecutive year. This suggests a sustained high interest in the development of veterinary medicines and the positive impact of the 2022 Veterinary Medicines Regulation in fostering innovation.

Among the 30 medicines recommended for marketing authorisation, 13 had a new active substance which had not previously been authorised in the EU. Sixteen were vaccines, including seven that were approved under exceptional circumstances to respond to animal health emergencies.

In January 2025, EMA's veterinary medicines committee, the Committee for Medicinal Products for Veterinary Use (CVMP), recommended the approval of the vaccines Bluevac-3 and Syvazul BTV 3 to protect sheep against bluetongue disease. Bluevac-3 is also approved for use in cattle. The disease is caused by the bluetongue virus. These vaccines are shown to protect against the newly emerged serotype-3 bluetongue virus (BTV3), responsible for recent outbreaks in Europe. The vaccines were recommended for approval under exceptional circumstances because already approved bluetongue vaccines show little protection against disease caused by the new serotype.

Five vaccines, which were recommended for marketing authorisation in 2025, were developed through a biotechnological process. These include:

- **Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A,** for the active immunisation of cattle to reduce viraemia (presence of viruses in the blood) and fever caused by epizootic haemorrhagic disease virus serotype 8.

- **Innovax-ND-IBD-ILT,** for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis virus, Marek's disease virus and infectious bursal disease virus.

- **Vaxxinact H5,** for the following indications associated with highly pathogenic avian influenza serotype 5, including the circulating clade 2.3.4.4b:

  - active immunisation to prevent mortality, clinical signs and to reduce viral excretion in chickens and mulard ducks;

  - to reduce mortality, clinical signs and viral excretion in muscovy ducks and turkeys;

  - to reduce viral excretion in pekin ducks.

- **Vaxxitek HVT+IBD+H5,** for:

  - active immunisation of one-day-old chicks or 18-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 subtype, including the circulating clade 2.3.4.4b;

  - active immunisation of one-day-old turkeys to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 subtype, including the circulating clade 2.3.4.4b.

- **Vectormune HVT-AIV,** for the active immunisation of one-day-old chickens to reduce mortality, clinical signs, and virus excretion due to infection with highly pathogenic avian influenza virus of the H5 subtype.

Optimising the safe and effective use of veterinary medicines

EMA and EU Member States continuously monitor the efficacy, safety and quality of the veterinary medicines on the market in the EU. The aim is to optimise their use to achieve full benefit, and to protect animals and users from avoidable adverse effects.

Important new safety advice issued in 2025

The product information for 13 medicines was updated based on new safety data, to help animal owners and healthcare professionals to make informed decisions when using or prescribing a medicine. These included:

- **Bravecto chewable tablets,** changes to the product information to include pruritus (itching) as potential side effects in dogs.

- **Bravecto spot-on solution for cats,** amendment to the product information to include pruritus and ataxia (incoordination) as potential side effects.

- **Bravecto spot-on solution for dogs,** changes to the product information to include diarrhoea and pruritus as potential side effects.

- **Divence IBR Marker Live, Divence Penta and Divence Tetra,** amendment to the product information to include milk production decrease, reduced food intake and decreased activity observed in dairy cows as potential side effects.

- **Eluracat,** changes to the product information to include anorexia (loss of appetite), behavioural disorder, dyspnoea (difficulty breathing), loss of consciousness, sedation, recumbency (lying down), muscle weakness and hiding as potential side effects in cats.

- **Felpreva,** amendment to the product information to change the frequency of application site reaction (e.g. scratching, erythema (reddening), hair loss, inflammation) from very rare to rare.

- **Librela,** changes to the product information to include diarrhoea, emesis (vomiting), joint pain, lameness and swelling in multiple joints (immune-mediated polyarthritis), weakness (paresis), loss of movement (paralysis) and convulsion (seizure) as potential side effects in dogs. In addition, special precautions should be taken when treating dogs with the following pre-existing conditions: low amounts of red blood cells (immune-mediated haemolytic anaemia), lameness and swelling in multiple joints (immune-mediated polyarthritis), low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia) or when treating dogs with preexisting convulsion (seizure) disorder.

- **Mhyosphere PCV ID,** amendment to the product information to change the frequency of elevated temperature from common to very common.

- **Neptra,** changes to the product information to include facial paralysis (loss of movement) as potential side effects in dogs.

- **Osurnia,** amendment to the product information to include new special precautions: in very rare cases, eye disorders such as neurogenic keratoconjunctivitis sicca, keratoconjunctivitis sicca, corneal ulcer, blepharospasm, eye redness and ocular discharge have been reported in treated dogs and ataxia (incoordination), internal ear disorder (mainly head tilt), facial paralysis and nystagmus (involuntary eye movements) have been reported in very rare cases in post-authorisation experience.

- **Yurvac RHD,** changes to the product information to include anorexia and intestinal stasis (inactivity) as potential side effects in rabbits.

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 2025, positive opinions were adopted recommending the extension of MRLs for the following active substances:

- **Fluralaner,** extension to salmonidae and other fin fish.
- **Lidocaine,** modification of the use restrictions in porcine.

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

© littlewolf1989 | stock.adobe.com

30 years of progress in science and medicines in the European Union

In 2025, EMA celebrated its 30th anniversary. Since the Agency's creation on 26 January 1995, the healthcare environment has undergone radical scientific, technological, legislative and societal change. Through it all, EMA's mission has been consistent: to ensure that humans and animals in the EU have access to high-quality, safe and effective medicines when they need them.

The past three decades have, among others, provided a regulatory framework to support the development of medicines for rare diseases, medicines for children and advanced therapies, such as cell and gene-therapies. EMA and the EU regulatory network have set standards for transparency, as well as stakeholder engagement, including with the stakeholders who matter most: citizens and patients in the EU.

Looking back at the progress of scientific, regulatory and therapeutic advancement, it is hard to imagine what the next 30 years will bring. One thing is certain: EMA is well prepared to face these challenges, guided by science, collaboration and an enduring commitment to public and animal health.

Emer Cooke, EMA's Executive Director

Over the years, the Agency has been given increasing responsibilities under EU legislation. Its role expanded significantly due to the COVID-19 pandemic, with a new extended mandate to tackle emerging challenges such as coordinating national responses to medicines shortages and supporting the development of innovative medicines – particularly in crisis situations, but also in preparation for emerging health threats.

Since its inception in 1995, EMA has served as the bedrock of medicine regulation in Europe. EMA's main contribution remains ensuring medicines in the EU are safe, effective and high quality. But EMA is now far more than just a regulatory body. It also drives innovation, fosters collaboration and supports healthcare systems in preparing for the challenges of tomorrow.

You are instrumental in getting new, innovative medicines to patients across the EU, and with the pharma reform, you should do it faster in the future.

Olivér Várhelyi, Commissioner for Health and Animal Welfare

Video: Overview of key milestones and achievements in the authorisation and safety monitoring of medicines for human and animal use in the EU.

This content is hosted by a third party. By viewing this external content, you accept the terms and conditions of youtube.com.

Celebrating 30 years of EMA

To mark its 30th anniversary, EMA organised a series of events in 2025 together with its stakeholders. The main anniversary event was a scientific conference hosted at the EMA building on 25 June 2025, which reflected on three decades of achievements in medicine and regulatory science, but also looked at trends, innovations and challenges for public and animal health.

The event was officially opened by His Majesty King Willem-Alexander of the Netherlands. Chaired by EMA's Chief Medical Officer, Steffen Thirstrup, the scientific conference featured keynote addresses, speeches and a panel discussion, which highlighted the Agency's pivotal role in safeguarding public health, mobilising Europe's best scientific minds and shaping the future of medicines regulation. It was attended by over 350 participants from the European institutions and agencies, the European medicines regulatory network, international partners, patient and healthcare professional organisations, industry organisations, the Dutch government and others.

Video: EMA's 30th anniversary scientific conference – Medicines, regulation and the future.

This content is hosted by a third party. By viewing this external content, you accept the terms and conditions of youtube.com.

In May 2025, EMA hosted its first-ever public open-door day. The event was held on 9 May to mark Europe Day and the anniversary of the Schuman Declaration. During the day, 120 visitors representing the general public, academia, patients, university students, industry stakeholders and healthcare professionals were guided around the EMA building by Agency staff members. The tour included presentations by EMA subject matter experts on the evaluation and authorisation of medicines, medicines safety monitoring, veterinary medicines and One Health, the construction of the EMA building, and more. The visitors also had the opportunity to see the rooms where committee meetings are held, the 30th anniversary archives exhibition and the Agency's 60-metre-high green wall.

A series of anniversary lunchtime talks for EMA staff members and delegates was organised throughout 2025. The sessions provided an opportunity for all participants to gain broader insights into EMA's contribution to innovative medicines development and scientific excellence, in collaboration with our partners and for the benefit of patients. They coincided with in-person committee meetings in the EMA building and featured speeches and presentations from topic experts, including committee chairs and EMA staff.

EMA also hosted the ICMRA summit and plenary meeting at its premises in Amsterdam from 21 to 24 October 2025. The meetings were attended by participants representing more than 40 international medicines regulatory authorities, as well as experts from the WHO as observers.

ICMRA is a voluntary, executive-level entity of worldwide medicines regulatory authorities set up to provide strategic coordination, advocacy and leadership. Every year, the summit programme is an opportunity for heads of medicines regulatory authorities from around the world to come together and discuss current and emerging issues facing medicines regulators and common global strategies to address them. Hosting the ICMRA summit and plenary meeting in Amsterdam underscored the Agency's commitment to strengthening global regulatory cooperation.

EMA's 30th anniversary coincided with anniversaries in a number of policy areas at EMA.

25 years of orphan medicines regulation

The year 2025 also marked the 25th anniversary of the EU Orphan Regulation. The Regulation has played a central role in facilitating the development and authorisation of medicines for rare diseases. These are often debilitating and life-threatening diseases that place a huge burden on patients and their families and carers and represent an enormous challenge for countries' public health systems.

The EU's orphan designation programme offers incentives to encourage companies to research and develop medicines that otherwise would not be developed, to help diagnose and treat patients with rare diseases. Since 2000, EMA has given orphan status to over 3,170 medicines. By the end of 2025, 278 medicines with orphan status received a marketing authorisation.

With the establishment of the Committee for Orphan Medicinal Products (COMP) in 2000, patient representatives were, for the first time, formally included in one of EMA's committees. Today, representatives of patients, healthcare professionals and civil society take part in most of EMA's scientific committees as full members, adding their unique perspective and experience to the debate. They play an increasingly important role in the assessment of the risks and benefits of medicines.

20 years of SME regulation

The 20th anniversary of the implementation of the SME Regulation was another policy milestone in 2025. Since 2005, EMA's SME Office has helped small and medium-sized enterprises (SMEs) bring innovative medicines to market by offering financial and regulatory support.

To mark this anniversary, EMA held a roundtable meeting with stakeholders on 17 October 2025. Representatives from the European Commission and the European medicines regulatory network joined EMA to present key achievements of the SME Regulation and share perspectives on EU support to SMEs in the pharmaceutical sector. Participants from SMEs, industry organisations, patients' organisations, life science incubators and public and private investors also exchanged views on current challenges and future opportunities to foster innovation and support SMEs in the pharmaceutical and MedTech sectors.

2025 was a year to celebrate science, share our stories and renew our purpose. Anniversaries are not endpoints; they are reflection points. With gratitude for all colleagues' contributions, and confidence in our shared purpose, we carry this legacy into the years ahead.

Emer Cooke, EMA's Executive Director

Accelerating and optimising the assessment of medicines

Streamlining and simplifying assessment processes

Throughout 2025, EMA made significant efforts to streamline and simplify medicines assessment processes, enhancing efficiency while maintaining the rigorous scientific standards on which regulatory decisions depend. Overall, these initiatives reflect the Agency's continued commitment to reducing administrative burden and improving predictability for all stakeholders, ultimately accelerating patient access to safe and effective medicines.

A cornerstone of these efforts has been the medicines assessment report **revamp project,** which has modernised the structure and content of assessment documentation to improve clarity for decision-makers and stakeholders. Specifically, key assessment templates were updated, and a more streamlined collaboration between assessment teams was introduced by enabling the co-authoring of documents. This initiative complements broader work to harmonise and optimise procedural aspects of the evaluation process.

In 2025, the **Group for Internal Rules on Extensions of Clock Stops** (GIREX) project achieved significant progress in shortening the time for applicants to respond to questions during the assessment process, or 'clock-stop' extension. The average clock-stop duration in 2025 was 159 days, down 46 days from the peak in 2022. This constitutes approximately a 22 % reduction from 2022.

In addition, the **pre-submission interaction group** (Pre-SIG) project is also in the process of reshaping interactions between EMA, rapporteur teams and applicants during the pre-submission phase. This initiative aims to enhance submission predictability and dossier maturity by fostering earlier dialogue and setting clearer expectations, through mechanisms including joint pre-submission meetings with the EMA product team and the rapporteurs, reducing the likelihood of procedural issues that could delay assessments. The work of this group will build towards the implementation of the new pharmaceutical legislation.

Additional streamlining measures implemented during 2025 include:

- A **single rapporteurship pilot programme** for biosimilar medicines: In 2025, EMA started piloting the appointment of a single CHMP rapporteur for less complex marketing authorisation applications for biosimilar medicines. The pilot was launched in March 2025 and will last for two years. The aim of the pilot is to make optimal use of the available expertise in the network, without lowering the quality of our assessment.

- New variations guidelines, developed with support from EMA and the national competent authorities in 2025, will facilitate quicker and more efficient processing of variations, benefiting both marketing authorisation holders and regulatory authorities. The guidelines will support the implementation of the new European Commission Variations Regulation that came into force in January 2025.

- The revamp of the **Good Pharmacovigilance Practices** (GVP) inspection programme has also enabled more efficient use of regulatory resources with the more extensive application of risk criteria when defining inspection frequency. The improved risk assessment model focuses inspection resources on high-

risk and high-impact areas, enabling faster responses to emerging safety concerns while maintaining robust oversight of pharmacovigilance systems. The project also delivered substantial simplification in the way information is exchanged between EMA and NCAs by moving the GVP Inspection programme onto a shared platform directly available to all NCAs. This change facilitates online collaboration and more efficient use of both network and EMA resources.

Collectively, these initiatives represent a comprehensive approach to simplifying the regulatory environment, ensuring that EMA's assessment processes remain fit-for-purpose in an evolving medicines landscape while upholding strict European Union safety standards.

A new era for clinical trials in the EU

The year 2025 marked the full implementation of the Clinical Trials Regulation (CTR), following a three-year transition from the Clinical Trials Directive. Since 31 January 2025, all clinical trials in the EU operate under a single, unified legal framework. The regulation streamlines processes for trial authorisation and supervision, ensuring all sponsors follow harmonised procedures regardless of the location in the EU where the trial will be conducted. This strengthens Europe's position as an attractive place for clinical research.

Central to this transformation is the CTIS, which serves as the single-entry point for sponsors and regulators to submit, assess, and oversee trials across the EU. Managed by EMA, CTIS has received more than 13,000 initial applications since its launch in 2022, (2,844 in 2025) with more than 10,600 trials authorised by EU Member States.

In April 2025, the WHO designated CTIS as a primary registry in its International Clinical Trials Registry Platform (ICTRP) Registry Network. This designation confirms that CTIS meets high standards for data quality, accessibility, and governance, supporting global data sharing and reinforcing trust in clinical research. It also aligns EU clinical trials with requirements for publication in leading medical journals, further integrating them into the global research ecosystem.

Throughout the year, work progressed on simplifying business rules and developing a long-term modernisation roadmap for the system.

CTIS is the single platform for information about ongoing trials. To improve access for doctors and patients to this information, EMA launched a new clinical trial map as part of the CTIS public website. With this interactive tool, users can search for ongoing trials by location and medical condition using lay language. Search results offer investigators' contact details, allowing patients to consult with their doctors and potentially enquire about enrolment on a trial. The trials map was initially launched in English and was expanded to 22 additional EU/EEA languages later in the year. Five more languages will be added in 2026.

The trials map was one of the initiatives developed under the Accelerating Clinical Trials in the EU (ACT EU) initiative. ACT EU is a collaboration between the European Commission, EMA, and NCAs, aimed at transforming how clinical trials are initiated, designed and run to promote the EU as a centre for clinical research. In 2025, the initiative published a three-year analysis of clinical trial applications in the EU/EEA which showed that the CTR transition was successfully completed, with 5,088 trials transferred to CTIS from the Clinical Trials Directive. The analysis also found that CTIS

received around 200 new initial applications per month between January 2023 and January 2025, including about 80 multinational trials.

Additional key achievements included:

- Training and support materials were simplified, including a revised CTIS sponsor handbook.
- To better assist non-commercial sponsors, a dedicated helpdesk was established and webinars were organised with Member States to broaden outreach at national level.
- The Multistakeholder Platform Advisory Group (MSP AG) continued to play a key role, contributing to updated recommendation papers on auxiliary medicinal products and focus groups to deliver solutions that are fit for purpose for stakeholders.
- A paper on decentralised trial elements was updated, and frequently raised requests for information were produced in consultation with the Clinical Trials Coordination and Advisory Group (CTAG).

Looking ahead, the EU has set ambitious targets: aiming to add an additional 500 multinational authorised clinical trials over five years, from January 2026 until the end of 2030, and ensuring two-thirds of trials start recruiting within 200 days of application submission, compared to 50 % today. These objectives build on ACT EU efforts and complementary initiatives such as CTR Collaborate, COMBINE, and MedEthicsEU, which aim to harmonise procedures and reduce administrative burden across the clinical research ecosystem.

A fast-track approach for authorising strategic multinational clinical trials, FAST-EU, was also launched under the leadership of the Heads of Medicines Agencies (HMA) at the end of 2025. This initiative is fully aligned with the shared goal of making Europe a more attractive destination for clinical research and improving timely access to innovative medicines for patients. EMA will support this effort with technical expertise and by facilitating processes through CTIS.

EMA continued piloting the use of individual patient-level data from clinical studies in marketing authorisation evaluations, aiming to gain a deeper understanding of the evidence, thereby improving its regulatory decisions. The pilot learnings will inform preparations in anticipation of systematic submissions of such data in the future.

Enhancing the 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 gained from clinical trials by enhancing their understanding of the use, safety and benefits of medicines.

In 2025, EMA continued to ramp up its efforts to generate robust evidence. EMA published its third report summarising the progress made to enable the use of real-world data and establish its value in regulatory decision-making. The report covers 59 regulator-led RWD studies conducted between February 2024 and February 2025, representing a 47.5 % increase from the previous year.

Studies were conducted via three pathways:

- the Data Analysis and Real-World Interrogation Network (DARWIN EU®);
- EMA's framework contract;
- in-house experts.

Fully operational since 2024, DARWIN EU® is now the main pathway to generate RWE. DARWIN EU® provides the structure, data and tools to access relevant and reliable RWE on diseases, populations

and medicine use and performance across Europe. In 2025, DARWIN EU® onboarded three new data partners, bringing the total to 33. These partners can provide data from over 180 million people across 16 European countries. Seven additional data partners were at an advanced stage of onboarding by the end of the year.

The number of studies conducted via DARWIN EU® continued to grow. In total, 67 studies were performed during the fourth year of operation of DARWIN EU®, which includes 52 studies newly initiated in 2025. Forty studies were completed in 2025. For example, a study on antibiotic prescribing practices across the EU helped inform and support the CHMP's May 2025 recommendations to revise how azithromycin is used, aiming to optimise its clinical use and minimise antimicrobial resistance. A study on respiratory syncytial virus (RSV) highlighted its impact on vulnerable populations such as infants and older adults and the unmet clinical need in certain groups, guiding EMA in preparing future vaccine effectiveness studies. Other notable work includes a study that supported the PRAC in confirming that the widely used antibiotic doxycycline is not associated with an increased risk of suicidality.

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

Overall, the RWD catalogues contain 272 registered data sources and 3,235 studies as of December 2025.

In 2025, substantial progress was made in strengthening the regulatory framework for real-world data and evidence at both EU and global levels. These advances represent key enablers for expanding and improving the use of RWE. Examples include:

- A reflection paper on the use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes, which was finalised and published in June 2025. It is aimed at all stakeholders involved in the planning, conduct and analysis of this type of non-interventional studies, including marketing authorisation holders and applicants.

- Internationally, ICH adopted the concept paper for the new ICH E23 guideline on RWD/RWE terminology, metadata and effectiveness-focused principles, and published the final ICH M14 Guideline, the first harmonised global standard for designing and reporting non-interventional RWD studies for safety assessment.

- Under the ICMRA Working Group on RWE for Public Health Emergencies, two collaborative studies were launched, focusing on the use of Glucagon-Like Peptide-1 receptor agonists (GLP-1 RAs) and on background incidence rates of adverse events of special interest to support early stages of vaccine safety signal evaluation.

Leveraging the power of data for public and animal health – empowering safe and responsible use of artificial intelligence

Artificial intelligence (AI) is a transformative technology with immense potential across the medicinal product lifecycle, from drug development to pharmacovigilance.

In March 2025, the CHMP issued the first Qualification Opinion (QO) on an innovative development methodology based on AI. The tool, called AIM-NASH, helps pathologists analyse liver biopsy scans to determine the severity of metabolic dysfunction associated steatohepatitis (MASH). This marked the first time that EMA considered data generated with the assistance of an AI-based tool to be scientifically valid to support an application for marketing authorisation.

> *In view of the technology-driven explosion of data, we need to be strategically aligned across the EU in terms of data governance, management and AI-powered analysis tools to transform data into tangible benefits for public and animal health.*
>
> Peter Arlett, EMA's Head of Data Analytics and Methods Task Force and co-chair of the Network Data Steering Group (NDSG)

In May 2025, HMA and EMA published a joint workplan, Data and AI in medicines regulation to 2028. It sets out how the European medicines regulatory network plans to maximise data use, exchange and interpretation, improve access to data and evidence generation, and leverage use of artificial intelligence for better decision-making. It also provides a framework to address new legislation and initiatives in the EU, notably the new pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act. A new Network Data Steering Group (NDSG), combining the former Big Data Steering Group and the Network Data Board, was set up to oversee the implementation of the workplan.

> *We are excited to join forces to harness data and AI to improve public and animal health across the EU and realise the vision of the network in its strategy to 2028. Through collaboration, stakeholder engagement, training and guidance, we aim to drive impactful outcomes throughout the workplan.*
>
> Karl Broich, president of the German Federal Institute for Drugs and Medical Devices (BfArM) and co-chair of the Network Data Steering Group (NDSG)

As regulators continue to deepen their understanding of how best to harness the potential of AI, significant effort was invested across the regulatory network in 2025 to collect and prioritise AI use cases and explore existing or potential solutions for implementation. This work will inform the development of the Knowledge Mining and AI use cases roadmap in 2026.

A group focused on AI with industry stakeholders was established to facilitate open dialogue with industry on the development and use of AI in the medicines lifecycle.

Collaboration with stakeholders and partners on AI continued in 2025 at the international level and under the umbrella of ICMRA. At the European Union level, EMA is chairing the EU Agencies Network Working Group (EUAN WG) on AI.

The NDSG worked with the US FDA on a set of ten guiding principles for good AI practice in the lifecycle of human and veterinary medicines. The principles give broad guidance on AI use in evidence generation and monitoring, from early research and clinical trials to manufacturing and safety monitoring. The principles were published in early January 2026.

Still in the area of AI, EMA published in July 2025 its first AI Observatory Report which compiles the European medicines regulatory network's experience with AI during 2024 in enhancing productivity, automating tasks, and supporting data-driven decisions across a medicines lifecycle. In addition, the Agency published a compilation of examples of AI use in medicine regulation, as well as a horizon scanning short report, based on the review of scientific literature and EU-funded projects, which helps identify gaps, challenges and opportunities for integrating AI in medicine regulation.

Product master data is essential for strengthening the interoperability of the Network's data assets. The NDSG recognised the Product Management Service (PMS) as the shared source of product master data for all EU medicinal products, supporting EU wide use cases (Medicinal Product Master Data for Better Regulation and Better Health – NDSG recommendations for human Product Master Data implementation and data management).

Facilitating the path to accessibility and strengthening the availability of medicines

Ensuring that patients get the medicines they need when they need them is one of EMA's core responsibilities. Medicine shortages can stem from a wide range of interconnected factors, including manufacturing constraints, supply chain disruptions and sudden increases in demand. Addressing them requires coordinated action across the EU regulatory network through groups such as the Medicine Shortages Single Point of Contact (SPOC) Working Party and, for potential and ongoing critical shortages, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). In 2025, EMA strengthened its role as the central hub for shortages management, advancing new tools for monitoring and coordination, improving preparedness and reinforcing long term supply resilience. Communication also remained a key pillar of this work, helping build a shared understanding of shortages management among patients, healthcare professionals and national authorities.

Strengthening shortages monitoring and rapid response

Throughout 2025, the MSSG oversaw several critical shortages, including GLP-1 RAs, Visudyne and Zypadhera. For GLP-1 RAs, the MSSG implemented regulatory flexibilities to accelerate the assessment of variations aimed at mitigating shortages and supported a drug utilisation study published in December 2025. The study provided insights into patient characteristics, prescribing trends over the past decade and factors driving the increased demand. Supply conditions improved steadily over the year. For Visudyne, a medicine to treat eye conditions such as age-related macular degeneration and pathologic myopia, which has been subject to shortages since 2020 due to reduced manufacturing capacity, the group agreed to continue regulatory support to accelerate variations needed to establish a new EU supply chain in 2026. For Zypadhera, a medicine to treat schizophrenia and in shortage since 2024 due to manufacturing issues, including quality defects, the marketing authorisation holder presented mitigation measures to the MSSG following a request for support from Finland through the voluntary solidarity mechanism. Beyond these product specific cases, as part of its preparedness activities the MSSG monitored the impact of Hurricane Helene on the availability of perfusion solutions and reviewed mitigation proposals.

Ahead of the 2025–2026 winter season, EMA and the SPOC Working Party closely monitored the supply of antibiotics commonly used to treat respiratory infections. EMA proactively engaged with key marketing authorisation holders to assess supply capacity and reached out to regulators in the southern hemisphere to identify trends from

their winter seasons. As of late December 2025, no critical shortages were identified in the EU.

A rapid and effective response to shortages depends on timely, high quality data. To centralise and streamline the reporting of shortages information across the EU, EMA launched the European Shortages Monitoring Platform (ESMP) on 29 January 2025. The platform enables marketing authorisation holders and NCAs to directly report information on supply, demand and availability of medicines during crises and preparedness actions led by the MSSG. Reporting of shortages for centrally authorised medicines is now mandatory via the ESMP, with further functionality expansion planned for 2026.

Reinforcing the supply chain for critical medicines

A major focus of EMA's long term work in 2025 was supporting the strengthening and resilience of supply chains for critical medicines. In April, the MSSG issued recommendations to reinforce the supply chain of radiopharmaceuticals, which are increasingly used in cancer diagnosis and treatment. Rising demand and limited European manufacturing capacity have led to periodic shortages. The recommendations emphasised the need to expand domestic capabilities and the consideration of EU-level solutions to address transport challenges.

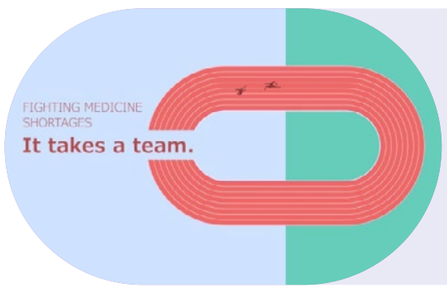
In July, the MSSG issued recommendations addressing vulnerabilities in the supply chain of antiD immunoglobulins, the only available treatment to prevent Rhesus immunisation during pregnancy. These medicines rely entirely on plasma donations containing antiD immunoglobulin, yet donor numbers are low and declining. The recommendations highlighted the need for more robust supply plans, reduced unnecessary use through non-invasive screening, investment in research and increased awareness of plasma donation.

The MSSG's recommendations are guided by the Union list of critical medicines, which identifies medicines essential to the functioning of EU healthcare systems. The list underwent a review in 2025, with an updated version published in December. It now includes nearly 300 active substances.

Communicating about shortages and supporting public understanding

In November 2025, EMA launched its first co-created communication campaign with European healthcare professional and consumer organisations to raise awareness of medicine shortages. The #ItTakesATeam campaign used videos, social media content and personal stories to highlight how different actors collaborate to support patients during shortages.

EMA also held a public webinar explaining the regulatory processes for managing shortages, how to access reliable information and how the public can contribute to prevention and mitigation efforts. Clear communication remains essential not only for public understanding but also for effective shortages management, helping reassure patients and reducing unnecessary pressure on supply chains during crises.



Video: Watch the YouTube playlist of #ItTakesATeam videos.

This content is hosted by a third party. By viewing this external content, you accept the terms and conditions of youtube.com.

New EU rules for health technology assessment

In January 2025, the new Health Technology Assessment (HTA) Regulation entered into force.

While EMA's role in the context of the Regulation is supportive in nature, the new framework enables enhanced collaboration across regulatory and health technology assessment decision-makers, reinforcing collective efforts to improve access to medicines for all patients across the EU. Throughout the year, EMA engaged closely with the European Commission and EU Member States to support the successful implementation of this landmark legislation.

Information exchange between EMA and HTA

The new HTA Regulation provides a robust legal basis for the exchange of information between EMA and HTA bodies. Since July 2025, EMA has provided relevant information to the HTA Coordination Group (HTACG) from the assessment of marketing authorisation applications, with regular updates shared at key milestones regarding assessment questions and timelines. Sharing of information from the regulatory assessment carried out by EMA with HTA bodies is critical to enable the ambitious timelines set for HTA Joint Clinical Assessments.

EMA is also conducting, together with colleagues from HTA bodies, parallel scientific advice through the parallel Joint Scientific Consultation (JSC) mechanism. This allows developers to obtain feedback from regulators and HTA bodies on their evidence-generation plans, thereby facilitating the quality and robustness of development plans. During 2025, the first three applications for parallel JSC were initiated and are currently at different stages of the process.

The Regulation also creates an EU framework for the assessment of selected high-risk medical devices to help national authorities make more timely and informed decisions on the pricing and reimbursement of such health technologies. In 2025, EMA initiated new activities related to evidence generation and review planning for medical devices in scope of the Regulation and these activities will be further developed in 2026.

Strengthening collaboration

At the interface between regulatory and HTA assessment, EMA maintains close working relationships with the HTACG, for which the European Commission provides the secretariat. A joint EMA/EC workshop on operational experience took place in September 2025, focusing on efficiency and effectiveness at the interface while preserving the respective remits of regulators and HTA bodies. In terms of evidence requirements, EMA, together with HTA bodies, published in April joint perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions. Through these close collaborative links, EMA continues to support the implementation of the HTA Regulation to deliver tangible value for patients throughout Europe.

> *EMA welcomes the new HTA regulation and is ready to do what it takes to support the European Commission and the Member States in its successful implementation. The new regulation will enable our collaboration across decision-makers reinforcing efforts to improve access to medicines for all patients in the EU.*
>
> *In our network strategy to 2028, facilitating the path to accessibility of new medicines for patients is a priority and the framework for cooperation and the exchange of information between regulators and HTA bodies provided by the new rules will help galvanise our efforts.*
>
> Emer Cooke,
> EMA Executive Director

Enhancing the sustainability of the network

The European medicines regulatory network is the backbone of medicines regulation in Europe, connecting NCAs, EMA and expert bodies in a collaborative system that protects public health across the continent. The sustainability of the network remains a key priority as EMA navigates an increasingly complex regulatory landscape. In 2025, EMA made significant progress in strengthening the network's resilience through targeted initiatives focused on simplification of processes, capacity building through training and enhanced collaboration.

EU Medicines Agencies Network Strategy (EMANS) to 2028

A cornerstone achievement of 2025 was the publication of the EU Medicines Agencies Network Strategy (EMANS) to 2028, following its adoption by HMA and the EMA Management Board. The strategy, titled 'Seizing opportunities in a changing medicines landscape', is a comprehensive update of the five-year strategy, which was developed in consultation with stakeholders to cover the period 2021 to 2025 (EMANS 2025). It will guide the network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance. The final report of EMANS 2025 will be published in March 2026.

The six focus areas of the strategy to 2028 build upon those in the EMANS to 2025, with the updated strategy placing more emphasis on the competitiveness of the EU in the development and manufacture of medicines, as well as the use of AI throughout the medicines lifecycle.

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**

> *With the strategy to 2028, our aim is to ensure a transparent, forward-looking and science-driven roadmap to managing the network's public health priorities. In the face of a new global framework, it is important that the European medicines regulatory agencies contribute to EU competitiveness. We are committed to catalysing the innovation of medicines and their manufacture by leveraging every opportunity to promote public and animal health.*
>
> Maria Lamas, Chair of the HMA Management Group

A key focus area of the strategy is **the sustainability of the network** - to ensure that it has available resources to support its scientific and regulatory decision-making, taking full advantage of technological advances. The strategy also highlights the need for simplicity in regulatory processes, recognising that administrative complexity drains valuable scientific resources which are better directed toward evaluating the safety and efficacy of medicines.

> *In these uncertain times, when our environment is evolving constantly, we need to be agile and able to anticipate transformative changes, as well as to better address supply chain security. This update to our network strategy enables us to seize opportunities across the entire medicines lifecycle – from innovation through to availability and access in the EU.*
>
> Emer Cooke, EMA's Executive Director

The EMANS to 2028 and its implementation were presented during EMA's 30th anniversary scientific conference in May: EMA's 30th anniversary scientific conference - medicines, regulation and the future.

Implementation of the EMANS has already yielded tangible benefits, including improvements in the assessment procedure and strengthening of work-sharing arrangements, which have resulted in additional capacity being freed up for assessment teams.

Through streamlined templates for common regulatory procedures, EMA has reduced duplication of effort and enabled rapporteurs and co-rapporteurs to focus on substantive scientific assessment rather than administrative formatting. Work-sharing arrangements have been strengthened, allowing centres of excellence within the network to lead on specific therapeutic areas or regulatory challenges, ensuring that appropriate expertise is applied to each evaluation while building capacity in participating authorities.

Capacity building through training

The sustainability of the network requires continuous investment in people and skills. In 2025, EMA continued to deliver coordinated training programmes through the EU Network Training Centre (EU NTC) to build regulatory expertise across Member States.

In 2025, EMA expanded its training programme in the area of Good Clinical Practice (GCP) inspections through targeted training initiatives for GCP inspectors. These included a specialised training day for GCP inspectors on ICH E6 (R3) implementation in June 2025 following the ACT EU workshop on ICH E6 (R3) (principles and Annex 1) in February 2025. In addition, in May 2025, the first online training course on GCP inspections for assessors of marketing authorisation applications submitted to the Agency was published.

These initiatives contributed to a significant increase in GCP inspections requested in 2025 (see section 3.1.2 GCP inspections) and have equipped GCP inspectors and assessors across the network with enhanced competencies in evaluating and inspecting clinical trials, ensuring the network can meet growing demands while maintaining the highest standards of scientific rigour.

EMA also pioneered innovative training methods. In October 2025, EMA hosted a data-integrity session for **good manufacturing practice (GMP)** inspectors, in collaboration with the EU4Health (EU4H) consortium. This was the first time the Agency offered a training session that incorporated virtual reality. The session was attended by inspectors from the EU network and, reflecting EMA's efforts to strengthen regulatory systems in Africa and supporting the establishment of the African Medicines Agency (AMA), 20 participants from five different African Regional Economic Communities.

Assessors' day @ EMA

In November 2025, EMA hosted an Assessors' Day, organised by the EU NTC. This event brought together assessors from four key scientific disciplines — clinical, non-clinical, quality and pharmacovigilance — and from across the EU/EEA NCAs. The event offered EU assessors a unique opportunity to connect, network, and share knowledge and experiences face-to-face, developing a stronger sense of community and enhancing collaboration across the EU medicines regulatory network. The key theme was the benefit-risk evaluation of medicines, with sessions dedicated to the critical scientific and regulatory aspects that shape these decisions. Additionally, a session on communication explored how assessors can effectively convey their scientific work to different audiences.

Reinforcing network crisis preparedness through a major event simulation exercise

In December 2025, EMA coordinated a major event simulation exercise together with partners from the European medicines regulatory network (EMRN) and the European Commission, to test the EMRN incident management plan for medicines for human use, as well as key processes in place to deal with major events which could have a serious impact on public health. The plan aims to prevent incidents from becoming major events and, where needed, to escalate them to EMA's MSSG. It was revised in November 2025 to include lessons learned from previous incidents and the COVID-19 pandemic. The revised plan also reflects the changes brought by the regulation reinforcing EMA's role (Regulation 2022/123).

The simulation focused on a fictitious human medicine safety incident with a root cause in quality. Based on the findings, EMA will consolidate relevant procedures and guidance. Key highlights of the exercise, including main findings and next steps, will be published in the coming months.

Key activities and events in 2025

JANUARY 2025

January 10, 2025

EMA confirms its readiness to support the implementation of the new Health Technology Assessment Regulation, applicable as of January 2025.
The regulation is an important step forward in accelerating and widening access to new medicines.

January 14, 2025

EMA publishes the revised version of its policies on the handling of competing interests of scientific committee members and experts and Management Board members.

January 26, 2025

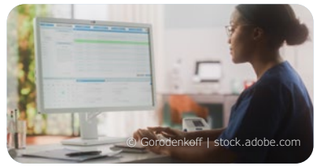
EMA marks 30 years of operation, celebrating its evolving role at the centre of the EU, assessing and authorising safe, high-quality medicines for 450 million people and countless animals in Europe.

January 29, 2025

The ESMP is now live with the full scope of functionalities. This will enable marketing authorisation holders (MAHs) and NCAs to directly report information on supply, demand, and availability of nationally and centrally authorised medicines during crises and preparedness actions led by EMA's MSSG.

January 30, 2025

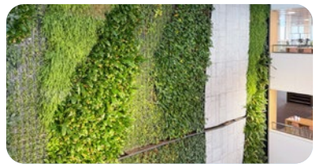
For the first time, the five EU health and environment agencies – EFSA (European Food Safety Authority), ECDC (European Centre for Disease Prevention and Control), ECHA (European Chemicals Agency), EEA (European Environment Agency) and EMA (European Medicines Agency) – supported by the JRC (Joint Research Centre), review how the use of azole substances outside human medicine affects public health.



January 31, 2025

From 31 January 2025, all clinical trials in the EU, including ongoing trials that were approved under the previous legal framework, the Clinical Trials Directive (CTD), are governed by the Clinical Trials Regulation.

FEBRUARY 2025



February 17, 2025

EMA's environmental management system has been certified with the Eco-Management and Audit Scheme (EMAS), recognising the Agency's commitment to environmental sustainability.

February 06, 2025

The Commissioner for Health and Animal Welfare, Olivér Várhelyi, visits EMA and emphasises the importance of close cooperation with EMA to support his goals in the area of medicines availability, boosting innovation and reducing complexities in the EU regulatory system, for the benefit of public and animal health.

March 13, 2025

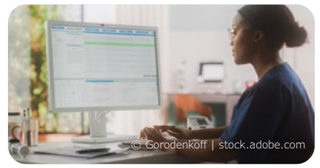
EMA's Management Board elects Rui Santos Ivo as chair of the Board for a three-year period.

March 18, 2025

EMA and HMA publish their joint EU medicines agencies' network strategy to 2028 (EMANS), which will guide the European medicines regulatory network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

March 3, 2025

EMA launches an interactive map on the CTIS public website, enabling patients and healthcare professionals to easily access comprehensive, real-time information about clinical trials conducted in their area, increasing access to clinical research in the EU.



MARCH 2025

March 24, 2025

EMA, in close collaboration with the European Commission, establishes a standard procedure for manufacturers of certain high-risk medical devices to request scientific advice on their intended clinical development strategy and proposals for clinical investigation.

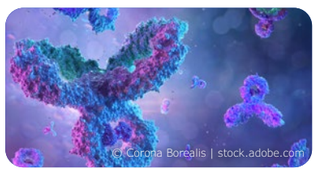
March 27, 2025

A delegation of the European Parliament Public Health (SANT) Committee visits EMA in Amsterdam to discuss EMA's activities related to antimicrobial resistance.

March 31, 2025

For the first time, all the 27 countries of the EU, together with Iceland and Norway, have collected and reported data on both sales and use of antimicrobials in animals in their countries. The findings are presented in the first European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance report.

APRIL 2025

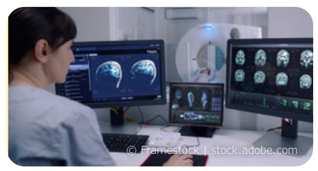


April 01, 2025

EMA opens a public consultation on a reflection paper outlining a new approach that would potentially reduce the amount of clinical data required for the development and approval of biosimilar medicines.

April 03, 2025

CTIS is designated as a primary registry by the World Health Organization within the ICTRP, formally recognising that it adheres to specific criteria for content, data quality and validity, accessibility, unique identification, technical capacity, and administration.



April 14, 2025

EMA and HMA, through the MSSG, issue recommendations to address supply chain vulnerabilities for radiopharmaceuticals.

MAY 2025

May 07, 2025

EMA and HMA publish a joint workplan "Data and AI in medicines regulation to 2028" outlining how the EMRN plans to leverage large volumes of regulatory and health data as well as new tools to encourage research, innovation, and to support regulatory decision making for better medicines that reach patients faster.

June 04, 2025

EMA releases a new draft ICH guideline on how to include and/or retain pregnant and breastfeeding people in clinical trials for public consultation.

June 17, 2025

EMA organises a workshop to explore the benefits and challenges of using Bayesian statistics in clinical development, gain insights into what should be included in upcoming guidance documents, and better understand current and emerging trial designs to ensure that future guidance is fit for purpose.

JUNE 2025

JULY 2025

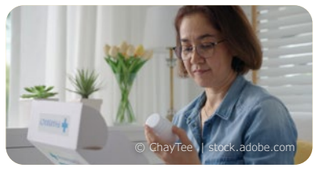
July 04, 2025

EMA and HMA, through the MSSG, issue recommendations to address supply chain vulnerabilities for anti-D immunoglobulins.

September 01, 2025

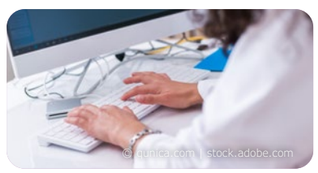
EMA and WHO celebrate a decade of formal collaboration and shared commitment to address global health challenges.

SEPTEMBER 2025



September 03, 2025

EMA and HMA warn the public about the growing threat of illegal medicines being advertised and sold online across the EU.



September 22, 2025

EMA welcomes the publication of the European Commission's new Variations Guidelines, which streamline the lifecycle management of medicines. They were developed with support from EMA and the EMRN.

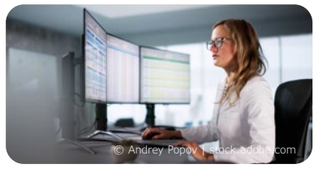
October 24, 2025

EMA's Executive Director Emer Cooke hands over her role of chair of ICMRA to Anthony Lawler from the Australian Therapeutic Goods Administration (TGA).

October 21, 2025

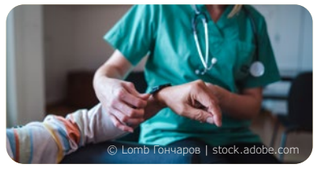
EMA launches its first social media campaign, #HealthNotHype, working with content creators across seven EU countries to raise awareness about the safe and responsible use of GLP-1 RAs.

OCTOBER 2025



September 23, 2025

The European Commission, HMA and EMA have jointly developed two new targets for clinical trials to monitor progress against the ambition to make the EU a more attractive destination for clinical research and improve timely access to innovative medicines for patients.



September 29, 2025

EMA releases a draft reflection paper on patient experience data for public consultation. These are data directly reflecting patients' experience or preferences on treatments or outcomes, without any interpretation by a clinician or anyone else.

NOVEMBER 2025

November 03, 2025

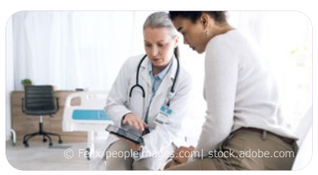
EMA organises a workshop to engage with external stakeholders to explore the opportunities and the potential use of external controls in the regulatory setting and to discuss related methodological challenges to draw causal conclusions.

November 04, 2025

EMA launches the #ItTakesATeam awareness campaign, co-created with EU healthcare professional and consumer organisations, to highlight shared efforts to prevent and manage medicine shortages across the EU, and the role of each actor in supporting patients faced with these shortages.

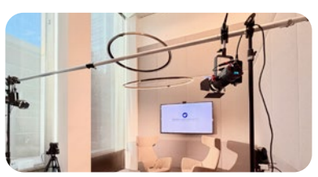
November 05, 2025

EMA and HMA host the first EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection to discuss the latest developments in adverse drug reaction case processing, signal management, and international guidance.



November 17, 2025

EMA's Emergency Task Force improves its approach to scientific advice for the most promising medicines and vaccines under development for public health threats.



November 18, 2025

EMA launches Inside EMA, a new podcast series about the science and the people behind medicines regulation in the EU.

November 20-21, 2025

EMA and HMA host a workshop on AI to provide keynotes on AI state-of-the-art, to update stakeholders on the evolving regulatory environment and HMA/EMA activities on AI, and to discuss progress on the Data and AI workplan as well as AI use cases across the medicines lifecycle.

DECEMBER 2025

December 11, 2025

EMA welcomes the landmark political agreement reached by the European Commission, the European Parliament, and the Council of the European Union on the comprehensive reform of the EU pharmaceutical legislation.

December 19, 2025

EMA publishes a Technology Capability Investment Plan that guides the technology choices that drive EMA's and the Network's digital transformation.

December 09, 2025

The second ESUAvet annual surveillance report is published, consolidating data from the EU including Iceland and Norway in 2024. Together with the report, a new dashboard is launched allowing public access to data on the sales of antimicrobial veterinary medicinal products across the EU.

CHAPTER 2
Key figures in 2025

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, support to research and development, inspections and compliance, medical devices, the EMRN, stakeholders, administration and communication. A more detailed overview of figures presenting EMA's activities in 2025 will be made available in the Agency's annual activity report.

Human medicines

In 2025, 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.

Activities supporting research and development

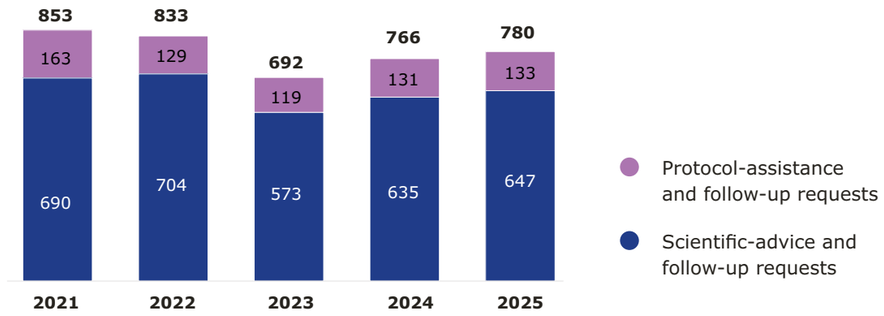
Scientific advice received

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.

In 2025, EMA received a total of 647 requests for scientific advice. Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases. The requests for protocol assistance amounted to 133 requests in 2025.

Scientific-advice and protocol-assistance requests received - total



PRIority Medicines (PRIME) recommendations adopted by EMA

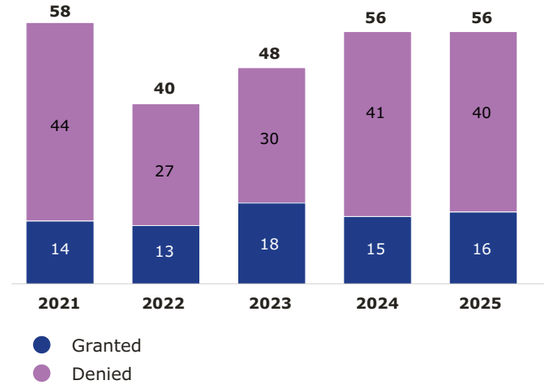
PRIME aims to support and optimise medicine development so that patients who have no or only unsatisfactory treatments for their disease have access to new medicines that have the potential to make a difference and enable them to live healthier lives. In 2025, EMA received 68 PRIME eligibility requests, 17 % more than in 2024, and adopted 56 recommendations. The Agency received 68 requests for scientific advice for PRIME products in 2025, a higher number than in 2024, when 42 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 2025 was 29 %, or 16 out of 56 medicines were accepted into the scheme.

Six PRIME-designated medicines were recommended for approval (Aucatzyl, Zemcelpro, Vyjuvek, Teizeild, Brinsupri, Vimkunya).

PRIME - eligibility recommendations



Support for clinical trials

On 31 January 2022, the CTR became applicable in the EU and the EEA. Its objective is to simplify and harmonise the authorisation of national and multinational clinical trials, making it easier for sponsors to initiate and conduct research in the EU/EEA.

Under the CTR, Member States remain responsible for the assessment, authorisation and supervision of clinical trials, and sponsors can now submit a single application for clinical trial authorisation in up to 30 European countries using the CTIS. The use of CTIS became mandatory in January 2023 for all new clinical trials applications, while ongoing trials authorised under the former CTD could transition to CTIS until 30 January 2025.

In 2025, a report analysing the three years of the CTR transition confirmed that the migration phase was successfully completed, with 5,088 clinical trials moved from EudraCT (under the CTD) to CTIS (under the CTR). CTIS is now the sole EU platform for clinical trial authorisation and oversight.

Between 31 January 2023 and 30 January 2025, CTIS received an average of 200 new initial clinical trial applications per month, including around 80 applications for multinational trials. While the number of multinational trials is expected to grow, these figures reflect a transitional period during which sponsors and other stakeholders continued adapting to the legal and procedural framework of the CTR.

With both the CTR and CTIS now being fully implemented and operational, the EU has established a more integrated and responsive clinical trial ecosystem—one characterised by greater transparency, efficiency, and collaboration to drive clinical research forward. Since its launch in 2022, CTIS has received nearly 13,000 initial applications, with more than 10,600 clinical trials authorised by EU Member States.

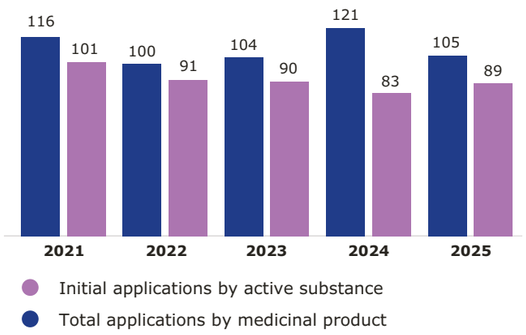
Recommendations for marketing authorisation

Applications for initial evaluation

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

Activities in the initial evaluation phase of human medicines range from pre-submission meetings with future applicants, through the evaluation by the CHMP to the granting of marketing authorisation by the European Commission. A total of 105 applications were received in 2025.

Initial-evaluation applications



Outcome of initial evaluation [2]

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
Cancer / Oncology									
Anktiva	•							•	
Aucatzyl	•	•		•				•	
Aumseqa	•								
Blenrep									
Datroway	•								
Dazublys					•				
Enzalutamide Accordpharma						•			
Ezmekly	•		•					•	
Inluriyo	•								
Itovebi	•								
Lynozyfic	•							•	
Ogsiveo	•		•						
Romvimza	•		•						
Tivdak	•								
Trabectedin Accord						•			
Voranigo	•		•						
Zemcelpro	•	•	•	•				•	
Ziihera	•		•					•	
Cardiovascular									
Macitentan Accord						•			
Macitentan AccordPharma *(duplicate of Macitentan Accord)*						•			
Myqorzo	•								
Rivaroxaban Koanaa						•			
Dermatology									
Vyjuvek	•	•	•	•					
Winlevi	•								
Diagnostic agents									
GalenVita									

[2]Some medicines might fall into more than one therapeutic area but have been reflected only in one.

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
Endocrinology									
Acvybra					•				
Bildyos					•				
Bilprevda					•				
Bomyntra					•				
Conexxence					•				
Degevma					•				
Denbrayce					•				
Enwylma					•				
Vevzuo					•				
Yaxwer					•				
Denosumab BBL					•				
Izamby					•				
Junod					•				
Zadenvi					•				
Denosumab Intas					•				
Jubereq					•				
Kefdensis					•				
Kyinsu									
Lynkuet	•								
Oczyesa									
Ondibta					•				
Osqay					•				
Osvyrti					•				
Ponlimsi					•				
Rolcya					•				
Teizeild	•	•							
Tepezza	•								
Xbonzy					•				
Zvogra					•				
Gastroenterology / Hepatology									
Teduglutide Viatris						•			

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
Haematology / Haemostaseology									
Dyrupeg					•				
Eltrombopag Accord						•			
Imreplys									•
Vivlipeg					•				
Wayrilz	•		•						
Immunology / Rheumatology / Transplantation									
Deqsiga									
Dawnzera	•								
Ekterly	•		•						
Gobivaz					•				
Gotenfia					•				
Qoyvolma					•				
Usgena					•				
Usrenty					•				
Usymro					•				
Waskyra	•		•	•					
Infections									
Emtricitabine/Tenofovir alafenamide Viatris						•			
Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatris						•			
Enflonsia	•								
Yeytuo							•		
Metabolism									
Aqneursa			•						
Maapliv			•						•
Rezdiffra	•							•	
Sephience	•		•						
Tryngolza	•		•						

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
Neurology									
Attrogy									
Austedo									
Duvyzat	•		•					•	
Imaavy	•								
Kisunla	•								
Riulvy									
Ophthalmology									
Eyluxvi					•				
Mynzepli					•				
Afiveg *(duplicate of Mynzepli)*					•				
Vgenfli					•				
Eiyzey *(duplicate of Vgenfli)*					•				
Pavblu					•				
Skojoy *(duplicate of Pavblu)*					•				
Ranluspec					•				
Ryjunea									
Pneumology / Allergology									
Alyftrek	•		•						
Brinsupri	•	•					•		
Exdensur	•								
Nintedanib Viatris						•			
Psychiatry									
Zurzuvae	•								
Uro-nephrology									
Xoanacyl									
Vaccines									
Capvaxive	•								
mNexspike	•								
Vacpertagen									
Vimkunya	•	•					•		

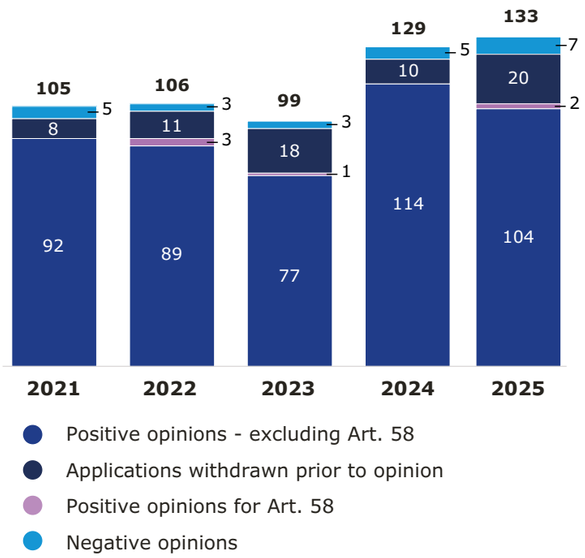
In 2025, EMA recommended 104 medicines for marketing authorisation. Of these, 38 had a new active substance which had never previously been authorised in the EU.

The CHMP adopted negative opinions for seven medicines in 2025:

- **Atropine sulfate FGK** (atropine), for the treatment of myopia in children aged three years and older.
- **Blarcamesine Anavex** (blarcamesine), for the treatment of Alzheimer's disease.
- **Elevidys** (delandistrogene moxeparvovec), for the treatment of Duchenne muscular dystrophy, a rare, ultimately lethal genetic disease in which the muscles progressively weaken and lose function.
- **Jelrix** (cartilage-forming cells, autologous), for the treatment of cartilage defects in the knee.
- **Kinselby** (resminostat), for the treatment of patients with advanced stage mycosis fungoides and Sezary syndrome, two cancers of blood cells that affect mainly the skin.
- **Nurzigma** (pridopidine), for the treatment of adults with Huntington's disease, an inherited condition that worsens over time and causes brain cells to die.
- **Rezurock** (belumosudil), for the treatment of chronic graft-versus-host disease, a condition in which donor cells attack the body's organs after a transplant. A re-examination was ongoing by the end of 2025, and Rezurock eventually received a positive opinion in January 2026.

Applications for 20 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.

Outcome of initial-evaluation applications



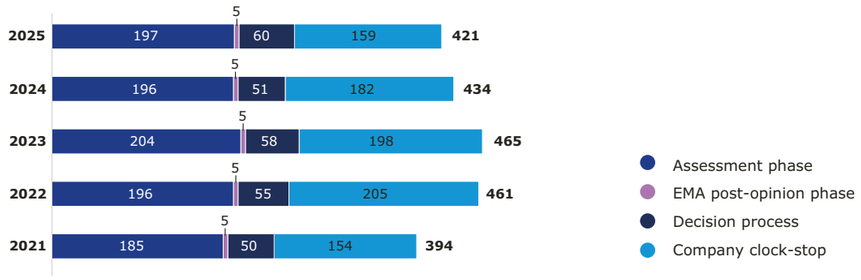
Average assessment time

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, questions or concerns with the application may be raised, requiring further information or clarification from the company. In this case, the clock is stopped to give the company time to reply to the Agency.

Once the reply is received, the active assessment timetable resumes.

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

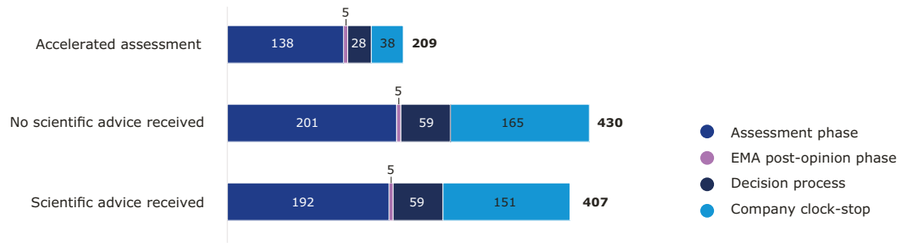
Average number of days for centralised procedure - positive opinions



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

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, averaged 421 days in 2025, lower than in 2024 (434 days).

Average number of days for centralised procedure - subset (2025)



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.

For medicines evaluated under accelerated assessment, the total time from the start of assessment until the granting of authorisation was reduced by seven days compared to 2024 (from 216 to 209 days).

Post-authorisation activities

In 2025, the CHMP gave 89 positive recommendations for an extension of the therapeutic indication of already authorised medicines, including 40 for paediatric use[3].

The product information for 432 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, provision of information on the safe and effective use of medicines, detecting new safety issues for centrally authorised products (CAPs), managing assessment procedures, e.g. for periodic safety update reports (PSURs), and the operation and maintenance of the EudraVigilance system.

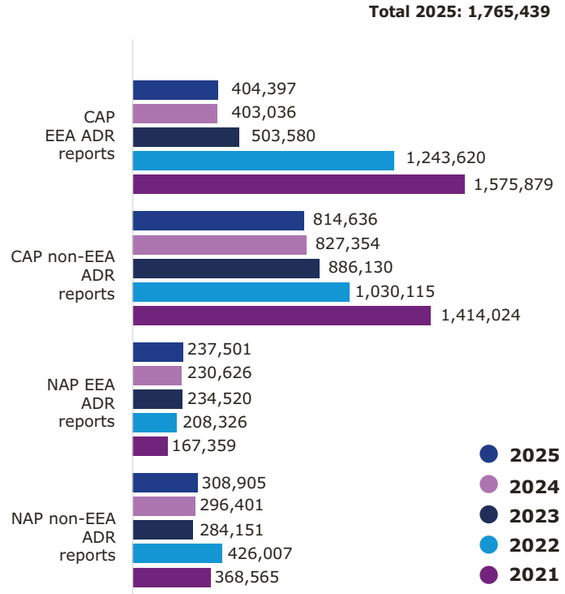
EudraVigilance

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

Over 1.7 million ADR reports were submitted to EudraVigilance in 2025, corresponding to almost the same number of reports received in 2024.

64 % of all reports in EudraVigilance originated outside the EEA.

EEA and non-EEA ADR reports received



[3]Most paediatric extensions of indication are based on the results of clinical studies agreed in the medicine's paediatric investigation plan (PIP).

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 2025, 1,201 potential signals were reviewed by EMA, a decrease of 4 % compared to 2024. Approximately 68 % of these signals originated from monitoring the EudraVigilance database, highlighting its central role for safety monitoring. The PRAC assessed 60 signals. Thirty-three of these were validated by EMA and 27 by Member States. In addition to signal detection activities and assessments at PRAC level, experts from the NCAs, in collaboration with EMA, contributed to the development of signal detection methods and continuous process improvement.

Outcome of signal assessment

1,201 potential signals were identified by EMA and underwent an initial confirmatory and prioritisation review;

60 confirmed signals were prioritised and assessed by the PRAC:

- Of these 60 signals, 33 were detected and validated by EMA.
- 27 were detected and validated by EU Member States.

Out of 60 confirmed and validated signals:

- 26 signals led to a product information update.
- 12 signals led to a recommendation for routine pharmacovigilance.
- 21 signals were undergoing review by the PRAC at the end of 2025 as further data were required.

Periodic safety update reports (PSURs)

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

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

In 2025, the PRAC started the assessment of 911 PSURs and PSUSAs, of which 32 % represent single assessments of active substances only contained in NAPs. In total, 906 recommendations were issued by the PRAC based on the assessment of PSURs and PSUSAs, of which 28 % consisted of single assessments of active substances only contained in NAPs.

PSURs and PSUSAs finalised

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

Veterinary medicines

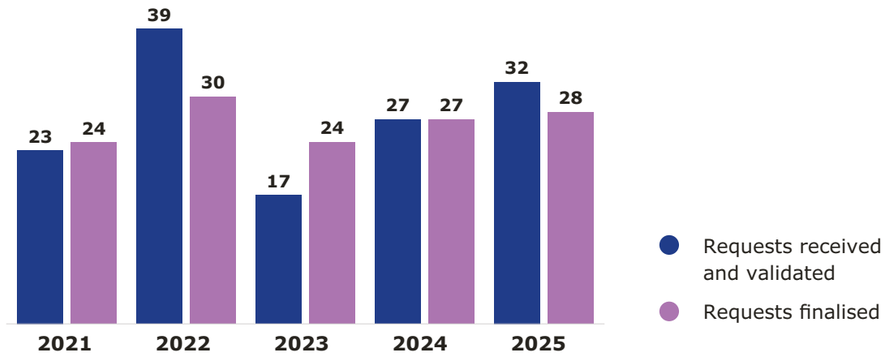
In 2025, EMA's work across the veterinary medicines lifecycle helped to guide innovative treatments to market that strengthen animal health and prevent the transmission of diseases in the EU. The Agency supports developers at every stage of veterinary medicine development, helping to boost innovation 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 2025, EMA received 32 requests for scientific advice and finalised 28. 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 2025, 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 based 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.

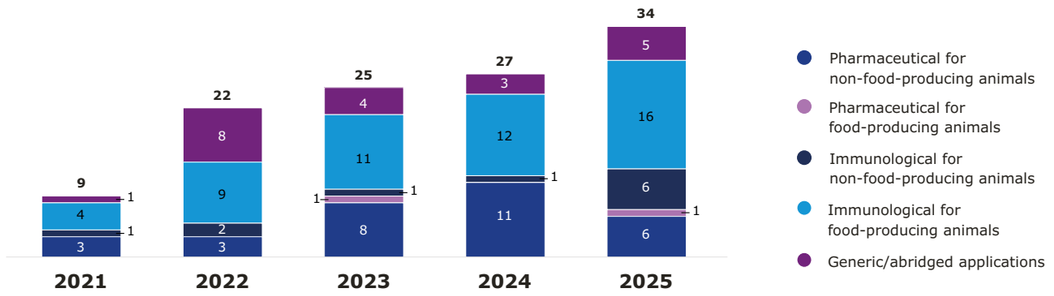
The Regulation aims to further stimulate the development of veterinary medicines for small markets, to increase the availability of treatments for serious or life-threatening animal diseases and unmet veterinary medical needs. The number of requests for limited market classification increased slightly last year, with 17 requests received in 2025 (compared to 14 in 2024). EMA also received four applications for initial marketing authorisation for limited market products in 2025, the same as in 2024.

Recommendations for marketing authorisation

Applications for initial evaluation

Activities in the initial evaluation phase of veterinary medicines include pre-submission meetings with future applicants, evaluation by the CVMP, and the decision on the granting of marketing authorisation by the European Commission. A total of 34 applications were received in 2025, an increase of 26 % compared to 2024, and continuing the trend seen since the new Veterinary Medicinal Products Regulation became applicable. Nearly two thirds of these applications were submitted for vaccines, 16 of which were for use in food-producing animals.

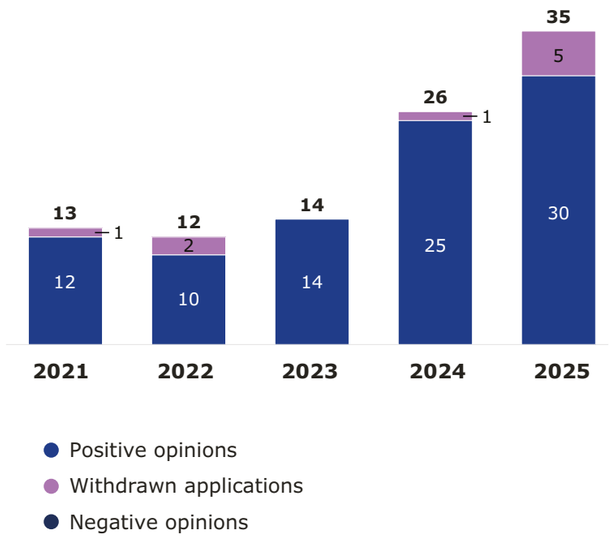
Applications for initial evaluation received



Recommendations for authorisation

In 2025, EMA recommended 30 veterinary medicines for marketing authorisation, the highest number of recommendations in a year for a second consecutive year. Of these, 13 had a new active substance that had not previously been authorised in the EU. Sixteen were vaccines, an increase of 14 % compared to 2024. Of these 16 vaccines, five had been developed through a biotechnological process. This demonstrates the animal health industry's continued strong interest in innovation and vaccines development.

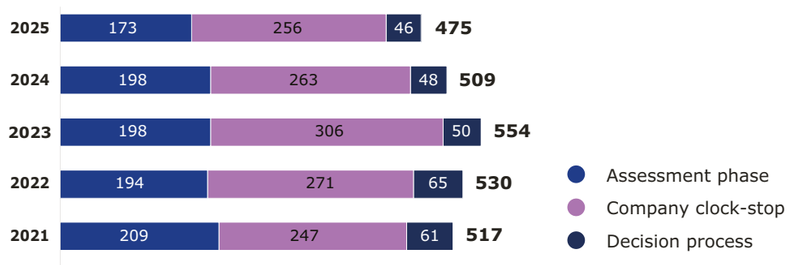
Outcome of initial-evaluation applications



PRODUCT NAME	New active substance	Cats	Cattle	Chickens	Dogs	Ducks	Goats	Horses	Pigs	Sea breams	Sheep	Turkeys
BioBhyo	•								•			
Bluevac-3			•								•	
BRAVECTO CombiUNO					•							
CEVAC REOMUNE				•								
Ecovaxxin MS	•			•								
Elmaro		•			•							
Emevet					•							
Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A.	•		•									
Firocoxib CP-Pharma					•							
Fluralaner Intervet					•							
Hemosyvet		•		•	•		•	•	•			
Hepizovac	•		•									
Innovax-ND-IBD-ILT	•			•								
Lenivia	•				•							
Nobilis Multriva Gm+REOm				•								
Nobilis Multriva IBm+ND				•								
Nobilis Multriva IBm+ND+EDS				•								
Nobilis Multriva				•								
Nobilis Multriva REOm				•								
Numelvi	•				•							
Omeprazole TriviumVet					•							
Portela	•	•										
Prazivetin										•		
Prevestrus vet	•				•							
Syvazul BTV 3			•								•	
Varenzin	•	•										
Vaxxinact H5	•			•		•						•
Vaxxitek HVT+IBD+H5	•			•								•
Vectormune HVT-AIV				•								
Zenrelia	•				•							

The average number of days taken for initial authorisations has decreased considerably compared to previous years, mainly due to the accelerated assessment procedures completed in 2025. Twenty per cent of all procedures were run on a reduced timetable because of the accelerated assessment requests submitted last year.

Average number of days for initial authorisations



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 11 known veterinary medicinal products was expanded in 2025.

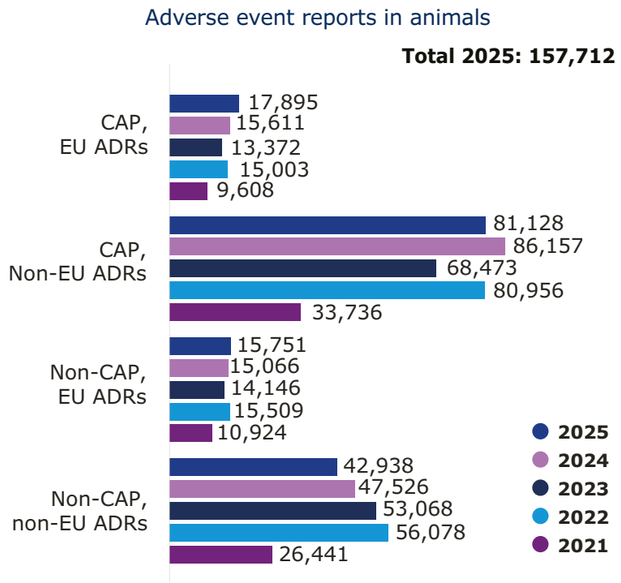
Safety monitoring of medicines

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). In 2025, the overall number of ADRs received in the EudraVigilance system remained stable.

Adverse event reports in animals



Inspections and compliance

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

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

- a programme of risk-based GMP inspections based on the results of inspections of pharmaceutical manufacturing sites by trusted authorities;
- a programme of risk-based routine GCP inspections at sites of clinical research organisations (CROs) most often used in the conduct of bioequivalence trials included in a marketing authorisation application in the mutual-recognition and decentralised procedures (in collaboration with NCAs/the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh));
- a programme of risk-based routine inspections of the pharmacovigilance systems in place for CAPs (in collaboration with NCAs);
- 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.

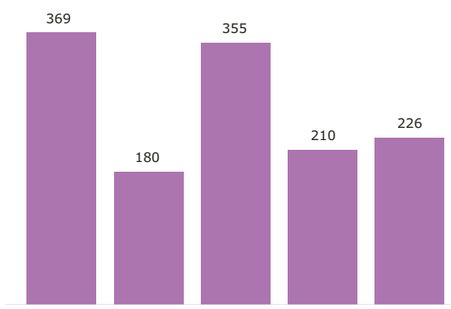
GMP inspections

The number of GMP inspections requests increased slightly last year, but the total was comparable to 2024. In total, 226 GMP inspections requested by the CHMP or the CVMP within the context of the centralised authorisation procedure were performed in 2025.

In 2025, 17 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.

When inspections lead to findings, companies must implement corrective action plans agreed with the inspecting authorities. 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.

Number of GMP inspections



GMP certificates and non-compliance statements issued by EEA authorities

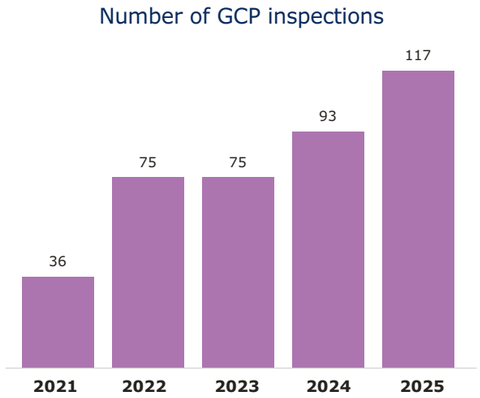
	2021		2022		2023		2024		2025	
	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement
EEA/EU	1,825	5	1,730	2	1,857	2	1,634	4	2,003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

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

GCP inspections

The number of GCP inspections increased last year by 26 % compared to 2024. The substantial capacity building initiatives put in place in the past couple of years have contributed to this significant increase in GCP inspections. For further details, please see section 5.2 Capacity building through training.

Number of GCP inspections



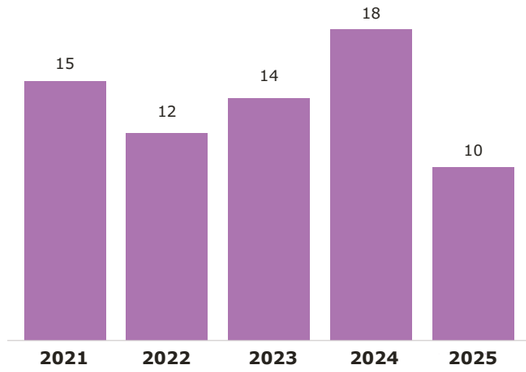
Pharmacovigilance inspections

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.

In 2025, 10 pharmacovigilance inspections were requested by the CHMP or the CVMP. Although there was a reduction in the number of pharmacovigilance inspections requested in 2025, the 2025 figure is comparable with the number of inspections requested in 2022. The fluctuation in the number of pharmacovigilance inspections requested by the CHMP or CVMP reflects the three-year cycle of the risk-based programme for routine pharmacovigilance inspections of MAHs of centrally authorised products rather than indicating a change in the number of inspections.

The pharmacovigilance inspections requested by the CHMP or CVMP are only a small part of the total number of pharmacovigilance inspections in the EU. 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).

Number of pharmacovigilance inspections



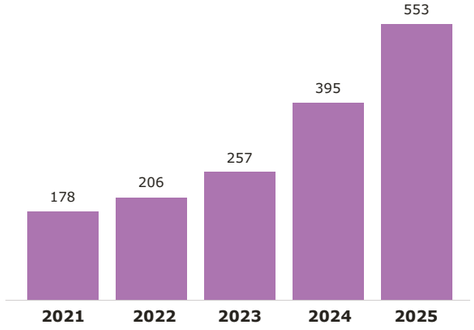
Market surveillance and quality defects

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.
- 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.

In 2025, the Agency received 553 suspected quality defect notifications, the highest number recorded in recent years. Of these, 167 cases were confirmed quality defects and led to batch recalls of 11 CAPs. None of the defects required a Class 1 recall.

Number of quality defect notifications received



Quality defects reported

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

*1 recall not classified
**2 recalls not classified

The main reasons for the recall of CAPs in 2025 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.

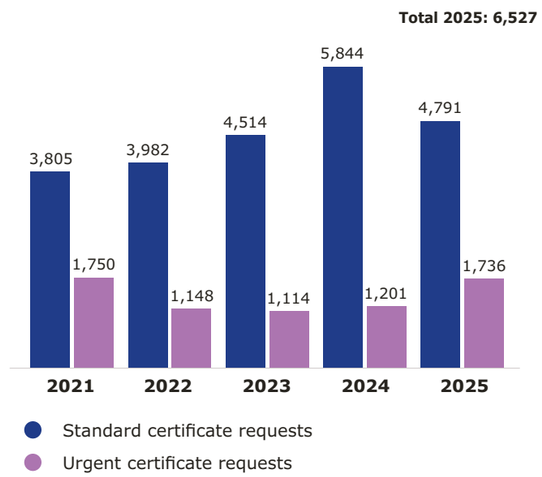
Parallel distribution notifications received

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

Certificates

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

Certificates



Medicine shortages

Medicine shortages arise for a wide range of reasons and are a result of complex global dynamics. Strengthening the reliable availability of medicines remains a priority for the EMRN. EMA contributes to this effort by closely monitoring the situation across the EU, coordinating actions to address critical shortages and maintaining clear communication with all key actors, from manufacturers and national regulators to healthcare professionals and patients.

Monitoring EU shortages

Shortages are monitored by the SPOC Working Party. This group allows representatives from all Member States to regularly report shortages in their countries and exchange information on mitigation measures. In 2025, the SPOC Working Party and its subgroups met 31 times. The group received 70 notifications of critical shortages for discussion and received 18 requests for information. In January 2025, the European Shortages Monitoring Platform, a digital platform that centralises and automates data collection from NCAs and MAHs, became fully operational. This will greatly support the work of the SPOC Working Party.

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 Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). The group met eight times in 2025. MAHs were invited to provide an oral explanation on shortages of the medicine Zypadhera as well as to present input on the methodology proposed by EMA to identify vulnerabilities in the supply chains of critical medicines.

The MSSG also coordinates requests for the voluntary solidarity mechanism. This tool allows Member States to support each other in the face of a critical medicine shortage. It 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 2025, six of these procedures were launched. 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.

A total of 115 applications for CECP were screened in 2025, nearly 60 % more than in 2024. The screening experts decided that an opinion was needed for 11 of these CECP applications.

In addition, the expert panels provide scientific advice for manufacturers of high-risk medical devices. In 2025, nine such procedures were finalised.

EMA continued the pilot on orphan medical devices in 2025. Five requests for orphan designation and two requests for clinical advice were finalised.

Figures on opinions by expert panels on high-risk medical devices

	2022	2023	2024	2025
Number of finalised screened applications for CECP	29	48	73	118
Number of finalised scientific opinions for CECP	7	1	6	14
Number of finalised PECP	1	2	4	0
Number of finalised advice procedures to Medical Device Coordination Group (MDCG)	-	3	2	0
Number of finalised Scientific Advice Pilot procedures	-	-	17	9
Number of finalised Orphan Device Designation Pilot procedures	-	-	-	5
Number of finalised Orphan Device Clinical Advice Pilot procedures	-	-	-	2

European medicines regulatory network

The EMRN is the cornerstone of EMA's work and success.

EMA plays a central role in this network, coordinating and facilitating collaboration between more than 50 national competent authorities across the EU and EEA for both human and veterinary medicines.

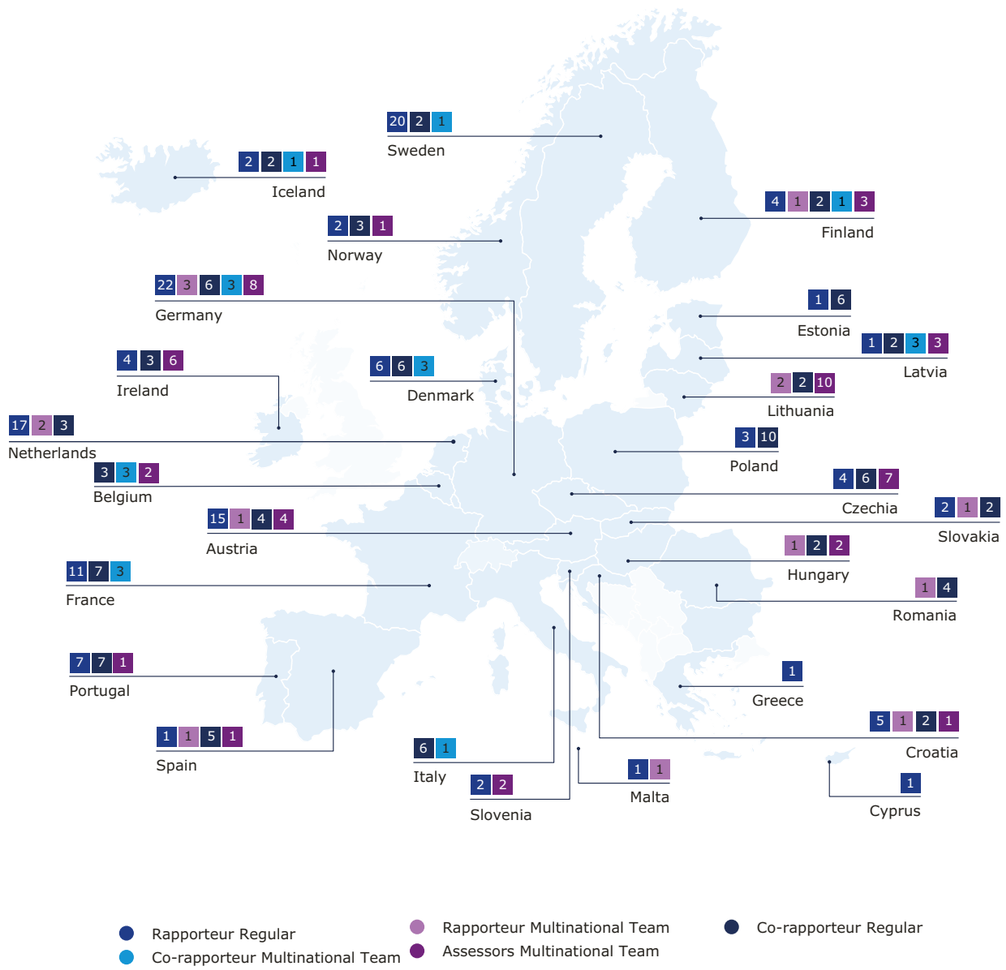
Through the network, EMA can draw from a pool of over 5,000 experts who provide the highest level of scientific expertise to the regulation of medicines in the EU. These experts contribute to EMA's scientific committees, working groups and other bodies, and are also involved in the evaluation teams that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

Rapporteurships and co-rapporteurships

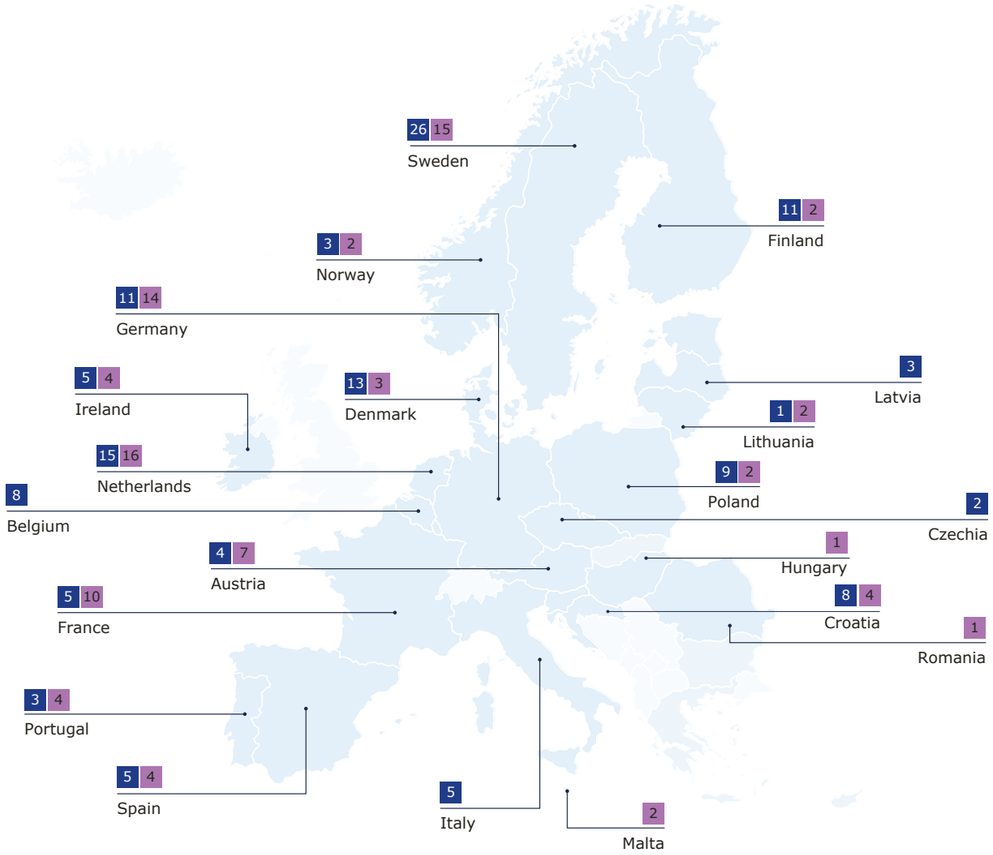
The assessment of a medicine by EMA's scientific committees is carried out by a rapporteur and a co-rapporteur, who prepare the assessment reports and lead discussions in the committees. The appointment is made on the basis of the best possible expertise for the particular product.

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

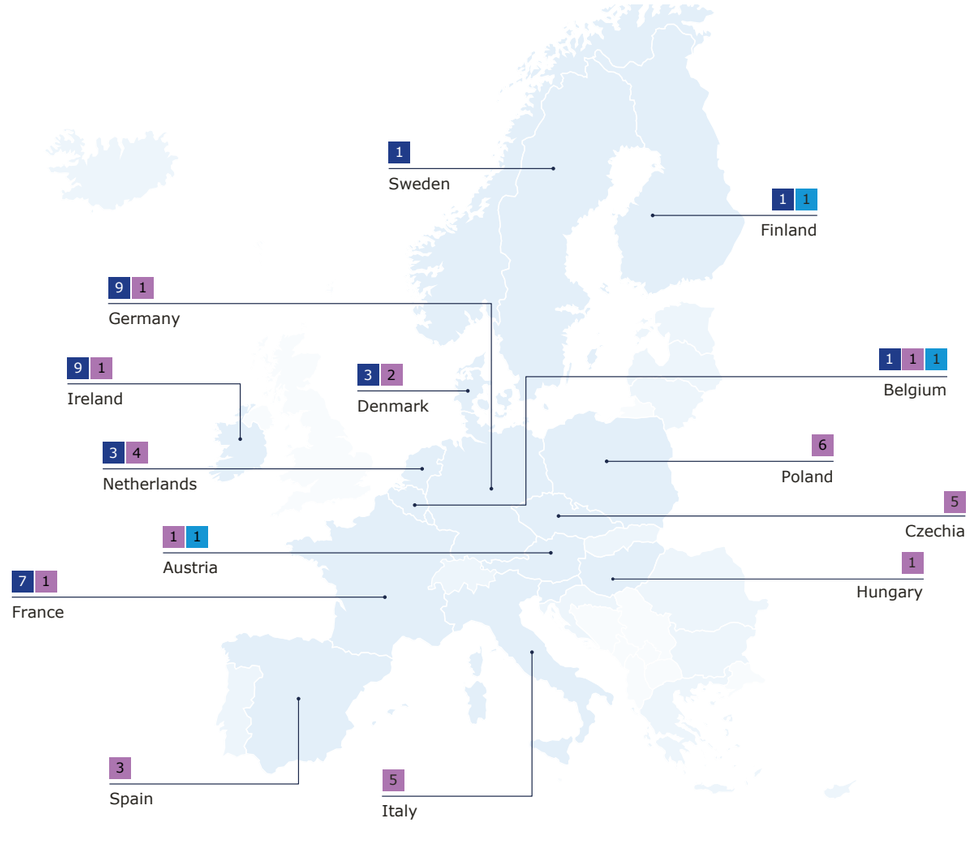
CHMP rapporteurs / co-rapporteurs appointed in 2025
(for initial marketing autorisation applications)



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



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



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 2025, EMA issued 119 press releases and news items to keep its audiences across the EU and beyond informed about key developments in the assessment of medicines and major achievements in both new and ongoing initiatives. EMA organised one press briefing on the human medicines highlights of 2024. In addition, EMA launched a new podcast, 'Inside EMA', targeted at science enthusiasts, which showcases the science and the people behind medicines regulation; the first two episodes were published in 2025.

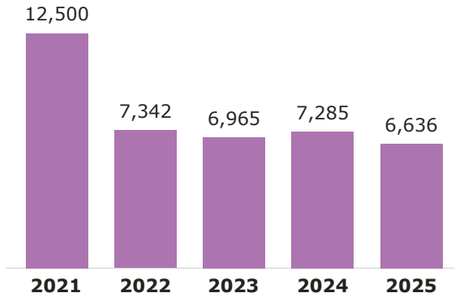
In its efforts to inform the public about new medicines or new uses of authorised medicines, EMA published 195 medicines overviews. It also communicated on safety concerns arising for some medicines through 13 public health communications. To keep the public and healthcare professionals up to date about specific actions required for some medicines, 18 direct healthcare professional communications and 16 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 2025, 3,382 webpages were added and updated, and 8,882 documents were published on the site. Additionally, EMA's social media presence kept expanding through experimenting with different tools to engage new audiences. In 2025, EMA conducted its first social media campaign working with content creators: the #HealthNotHype campaign aimed to raise awareness about the safe and responsible use of GLP-1 receptor agonists. By the end of the year, 479 posts and 52 videos were shared across social media platforms. Two LinkedIn live events were organised, one in June on 'Strengthening evidence generation in the EU' and the second in September, on the topic 'Smarter trials, stronger Europe. New targets for clinical research'. EMA staff and experts contributed 127 articles on scientific and regulatory subjects to international journals. Ninety per cent of all articles are publicly available under an open access licence.

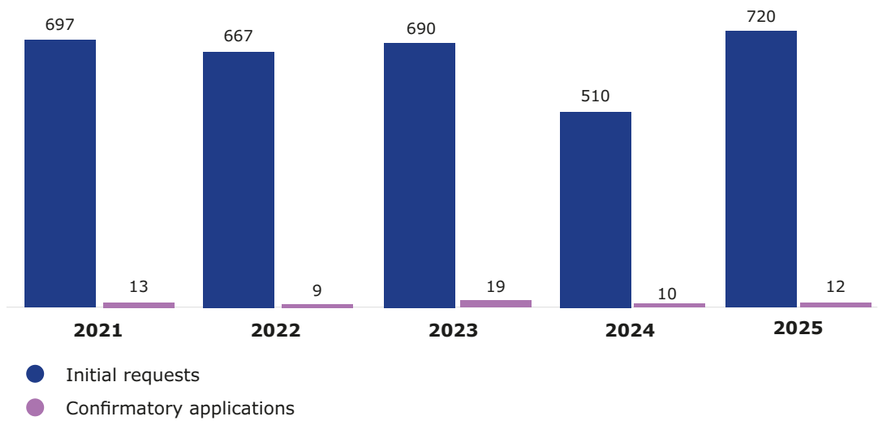
Requests for information and access to documents

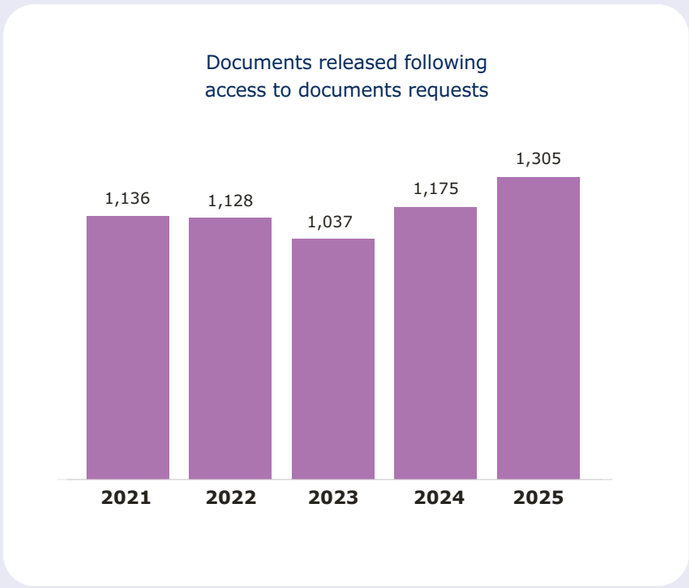
Providing citizens with clear, transparent information about its activities is a fundamental aspect of EMA's work. In 2025, the Agency received 6,636 requests for information. EU citizens have the right to access documents held by EU institutions, bodies, offices and agencies. EMA facilitates this access in accordance with the principles and conditions outlined in Regulation (EC) No 1049/2001 and the Agency's policy on document access. In 2025, EMA received 732 requests for access to documents (representing over 1,300 documents), with most of these requests originating from the pharmaceutical industry, followed by academia/research institutes.

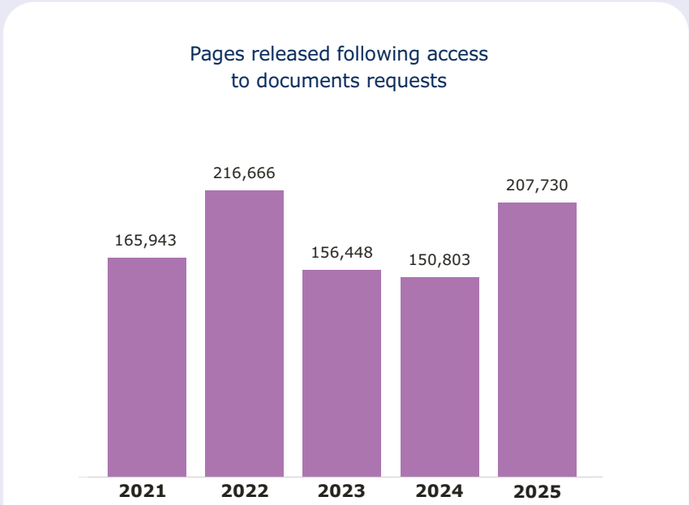
Requests for information received



Requests received for access to documents

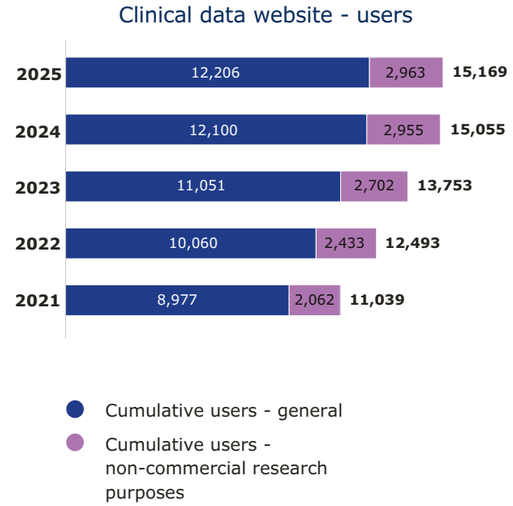






Publication of clinical data

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 2025, and following the completion of step 2 of the relaunch of Clinical Data Publication, 5,370 clinical data documents were published from 92 different procedures, which is in line with 2024. 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 led to an increase in the usage of the clinical data website in 2024, which then stabilised in 2025.



Exceptional transparency measures for Comirnaty and Spikevax

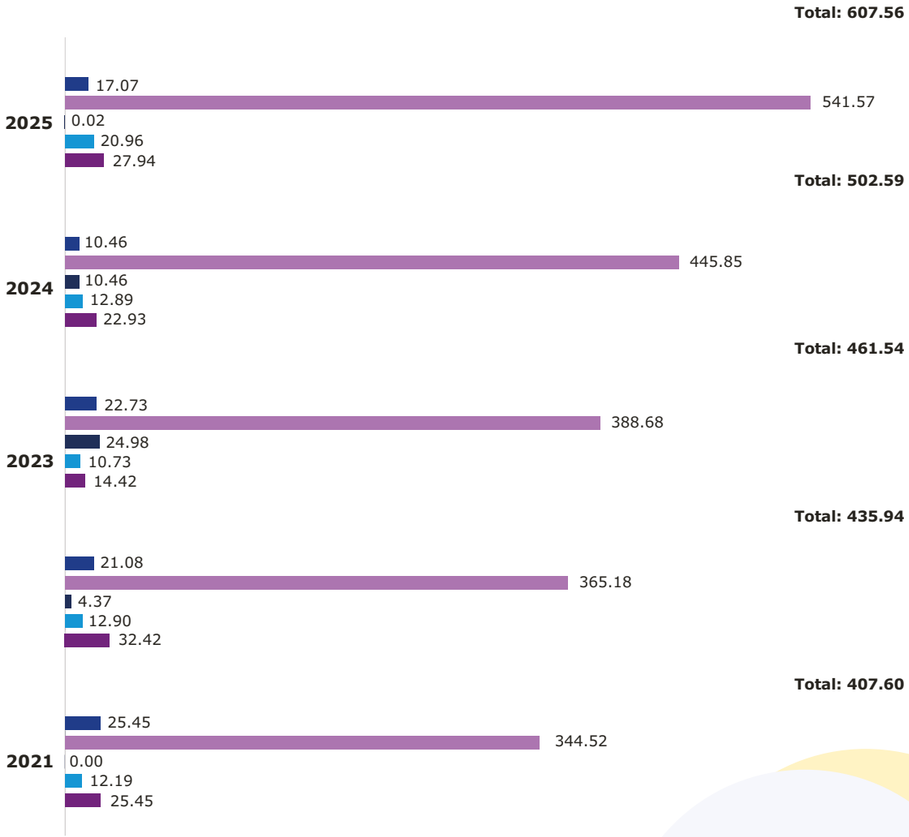
In line with the exceptional transparency measures that EMA adopted during the COVID-19 pandemic, the Agency is making data from the marketing authorisation applications for COVID-19 mRNA vaccines Comirnaty and Spikevax publicly available. This includes information on residual DNA measurements, as well as some quality and non-clinical aspects of the dossiers for these COVID-19 vaccines. The data are as presented in the dossiers on 12 June 2025. It also includes data released prior to 12 June 2025, under the EU regulation governing access to documents (Regulation (EC) 1049/2001). EMA is publishing these data gradually, in document format, in consultation with marketing authorisation holders. In total, 209 documents were published in 2025; 116 related to Comirnaty and 93 related to Spikevax.

Administrative aspects

Financial information

The Agency's total revenue in 2025 was EUR 607.56 million, a 21 % increase compared to EUR 502.59 million in 2024.

Revenue (in million €)



Implementation of the new fee regulation

Following adoption of a revised regulation on fees and charges payable to EMA (Regulation (EU) 2024/568), EMA implemented the new regulation as of 1 January 2025.

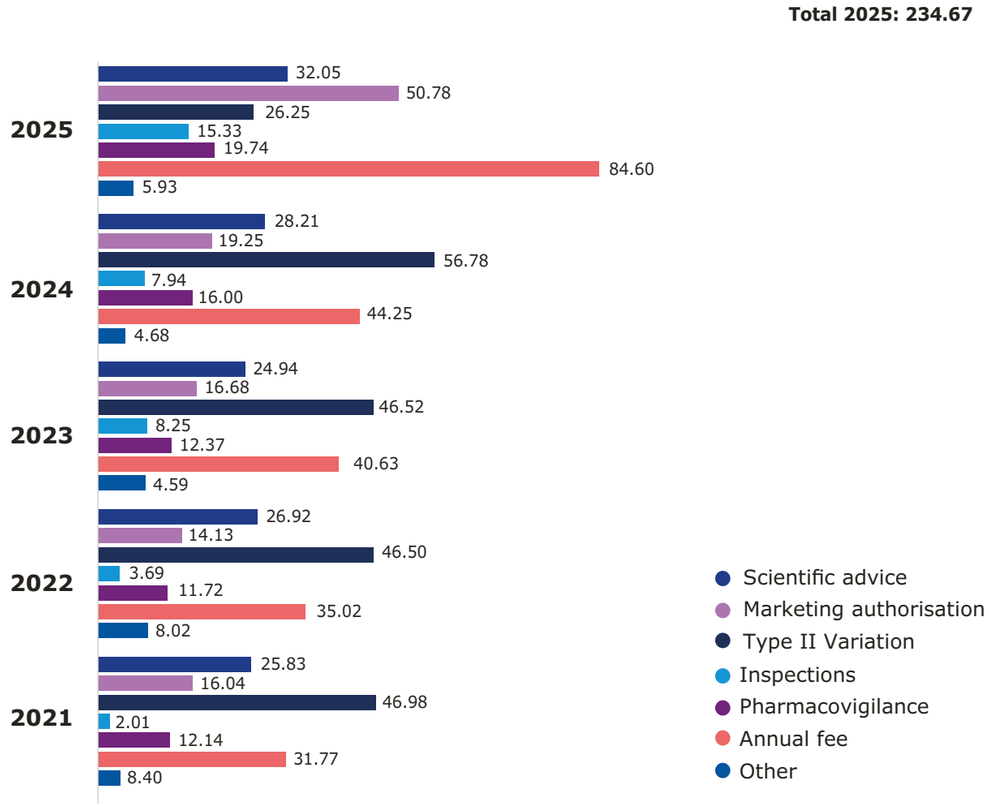
The regulation aims to ensure the sustainability of the EMRN, providing a sound financial basis to support its operations as well as the objectives outlined in the EMANS.

Remuneration to national competent authorities

NCAs in the EU Member States receive a share of EMA's revenue from fees for the assessments they carry out on behalf of the Agency. In 2025, EMA paid a total of EUR 234.67 million to the NCAs, a 33 % increase over 2024.

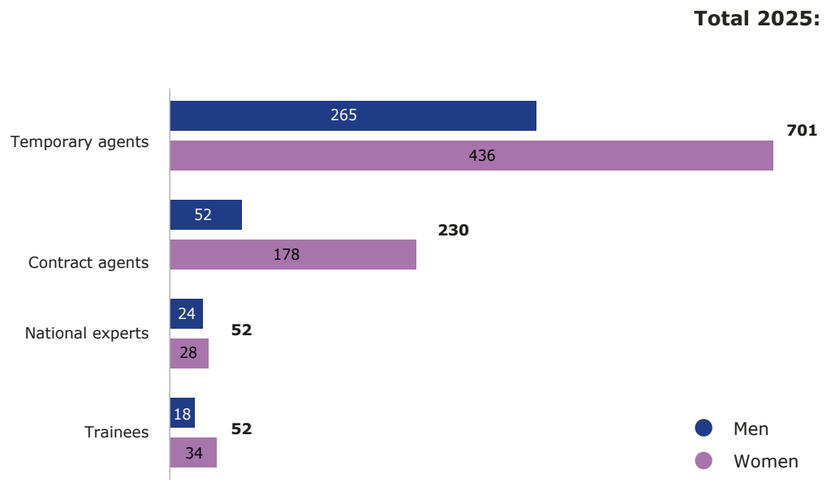
This figure includes payments for pharmacovigilance procedures, including the assessment of PSURs, PASS protocols and study results, and of pharmacovigilance-related referrals.

Remuneration to NCAs per fiscal year (in million €)



Agency staff

As of December 2025, the Agency had 1,035 staff members: 676 women and 359 men.



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 2025

Annex 11 – Guidelines and concept papers adopted by CHMP

Annex 12 – CVMP opinions on medicinal products for veterinary use in 2025

Annex 13 – Guidelines and concept papers adopted by CVMP in 2025

Annex 14 – COMP opinions on designation of orphan medicinal products in 2025

Annex 15 – HMPC European Union herbal monographs in 2025

Annex 16 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2025

Annex 17 – Referral procedures overview 2025 – human medicines

Annex 18 – Arbitrations and referrals in 2025 – veterinary medicines

Annex 19 – Budget summaries 2024-2025

Annex 20 – European Medicines Agency establishment plan

Annex 21 – Litigation activities of EMA in 2025

Annex 22 – Access to documents requests

Annex 23 – Clinical Data Publication

Annex 24 – Publications by Agency staff members and experts in 2025

The annexes are available on EMA's website.

Annual Report 2025

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

+31 (0)88 781 6000

Send a question:

www.ema.europa.eu

Annual report 2025

Publications Office
of the European Union