



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



# ANNUAL REPORT 2023

The European Medicines Agency's  
contribution to science,  
medicines and health in 2023

An agency of the European Union



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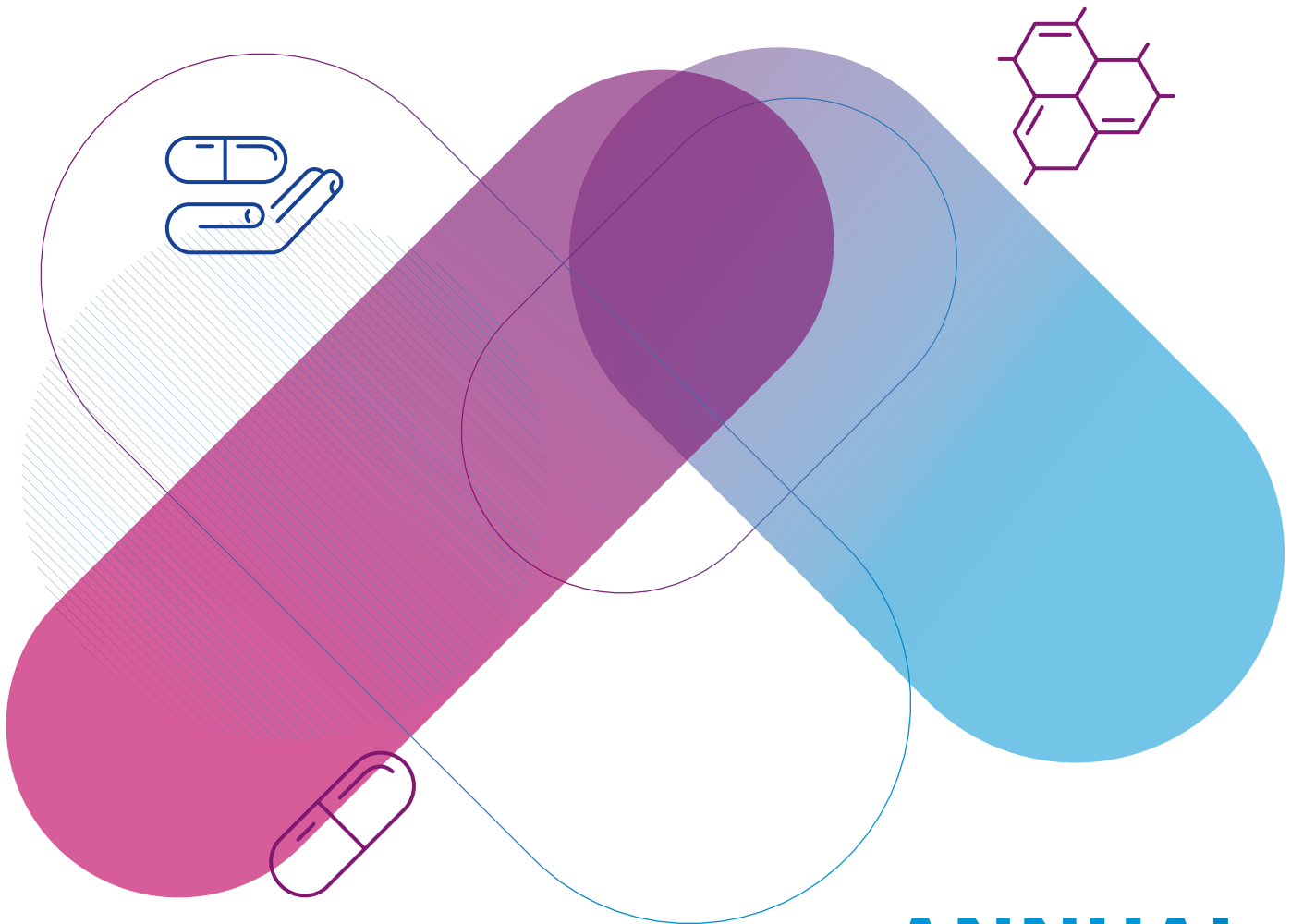
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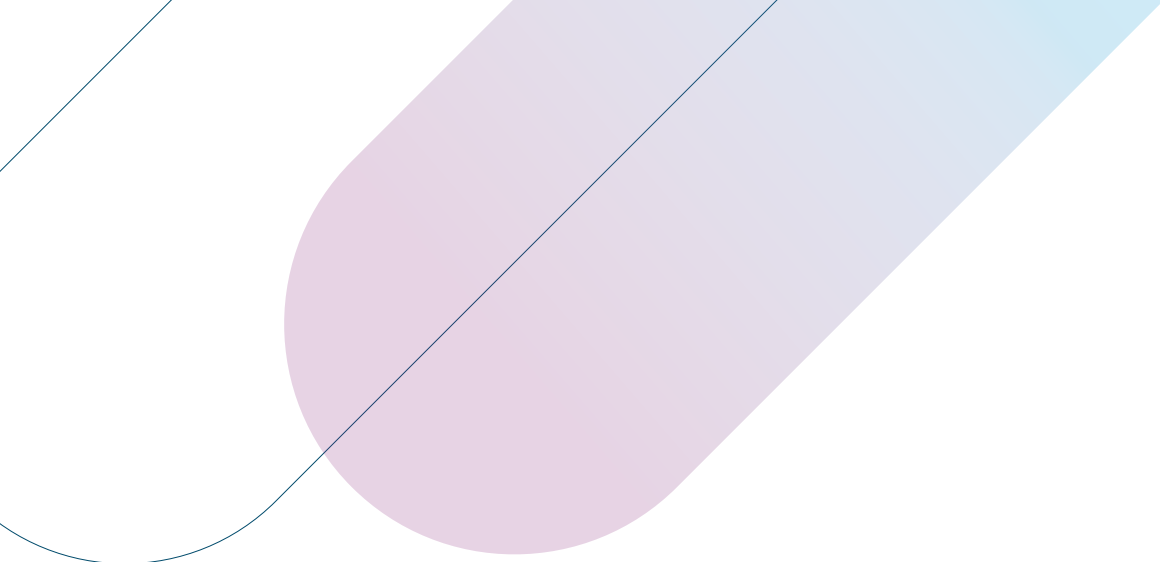


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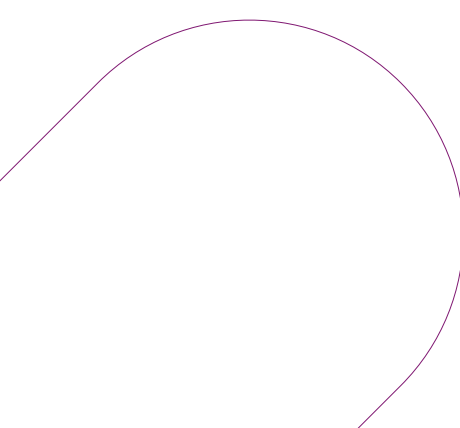
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# Foreword by Lorraine Nolan

## Chair of EMA Management Board

Welcome to the European Medicines Agency's (EMA) annual report for 2023. On behalf of the Management Board, I invite you to explore the wealth of information in the following pages, which details the Agency's important work to promote public health in the European Union (EU).

In 2023, the World Health Organization declared the end of the COVID-19 pandemic. Over these

three years we as a network collaborated, pooled our scientific and regulatory expertise across Europe, and together dealt with a crisis of gargantuan proportions. They were difficult times for health systems and while there are many lessons to learn – covered in the joint report issued by EMA and the Heads of Medicines Agencies (HMA) – our network is more robust and our mission more relevant than ever.

### Midterm report: lessons beyond COVID-19

Alongside the COVID-19 lessons, we also published the midterm report of the European Medicines Agencies Network Strategy (EMANS). Adopted in 2020, the EMANS identified shared challenges, goals, and priorities for a five-year period, to give strategic direction to the work of the European medicines regulatory network (EMRN).

The pandemic and its unprecedented challenges absorbed large amounts of resources from the medicines regulatory network, but it strengthened the network and supported transformative change in the European system across key strategic areas.

Today, we are on course and in good shape for the next challenges to come. For example, the structures, processes, and new technologies built throughout the COVID-19 pandemic will help implement the upcoming revision of the EU's pharmaceutical legislation.

## Systemic challenges in 2023

The Management Board's oversight role covers the full range of EMA programmes and activities, making sure that the Agency works effectively and co-operates successfully with partner organisations across the EU and beyond. In 2023, our attention was focused on ongoing initiatives to address medicines shortages and the implementation of the Clinical Trials Information System (CTIS).

The CTIS was made mandatory on 31 January and, over the course of the year, the Board was pleased to see the number of clinical trial submissions grow from 100 new initial clinical trials in February 2023

to over 190 in October 2023. This is a testament to the hard work done to improve the performance of the system and enhance user experience.

On shortages, the Board noted the significant progress made to strengthen the existing framework. There are now a range of tools and measures available to Member States, including EMA Medicines Shortages Steering Group (MSSG) Toolkit, which sets out a wide range of actions Member States can take to manage medicine supply issues. We also welcomed the first version of the Union list of critical medicines.

## Launching the audits and risks group

In 2023, we launched the Management Board Audits and Risks Group (MBRG) as a new subgroup of the Management Board. Its role is to provide objective and independent review, advice, impact

assessment and oversight of EMA's strategic processes in relation to risk, internal control and governance.

## Transformation across the Network

The pace of development of Artificial Intelligence (AI) also sent ripples through the network in 2023. The Board fully supported EMA's public consultation on its draft [AI Reflection Paper](#), which sets out the parameters for this technology in the context of medicines regulation. I believe we have a responsibility as a network to leverage digital innovation where it can help improve our processes and get safe medicines to the patient faster. I also welcome the EMA and HMA's AI workplan to 2028 that sets out a collaborative and coordinated strategy to make the most of the benefits of AI to stakeholders, while managing the risks.

Our work in medicines regulation relies on scientific talent and purposeful collaboration across 27 Member States. This is in the DNA of the EMRN and the cornerstone of EMA's work and success

and I welcome all of the effort and progress made by EMA in partnership with the network to ensure it is prepared and ready for new health challenges, as well as the constant demands of technological change and transformation.

On that note, I would like to thank all my colleagues and fellow Board members for their enthusiasm and support in 2023. I appreciate the great effort and participation of members of the various topic coordination groups that enrich the thinking of the Management Board, and indeed all aspects of our work.

Thank you all for your dedication and the trust you place in me as Chair.



# Introduction by Emer Cooke

## EMA Executive Director

It is an honour to introduce our 2023 annual report, which details EMA's contribution to public health in the EU: supporting the approval of new medicines to the market to bring new opportunities for patient care, driving innovation in medicines development and promoting the value of science in our societies.

In 2023, EMA recommended 77 medicines for marketing authorisation, 39 of which had a new active substance; many represent noteworthy progress in their therapeutic areas. We recommended two vaccines to protect against lower respiratory tract disease caused by respiratory syncytial virus (RSV), a common respiratory virus.

### **COVID lessons: preparedness**

Our work in the field of human medicines was shaped by the long tail of the COVID-19 pandemic in 2023. We continued to carefully monitor and evaluate the safety, efficacy and quality of treatments and vaccines against the changing nature of the virus.

We also recommended for approval the first advanced therapy medicinal product using a ground-breaking gene-editing technology known as CRISPR/Cas9 to treat two rare blood disorders, beta thalassemia and severe sickle cell disease.

EMA also adopted two positive opinions for medicines for use in countries outside the EU: a new treatment option for the estimated 50 million young children with schistosomiasis, and a medicine used to treat sleeping sickness caused by trypanosoma rhodesiense.

We have embedded its important lessons in our work and mission: you can now read the main COVID-19 learnings report, which was published by EMA and the Heads of Medicines Agencies (HMA) in 2023. Several of its recommendations have already been implemented as part of EMA's extended mandate, with the Agency assuming an enhanced role on preparedness to be more proactive on public health threats.



## Veterinary medicines highlights

In 2023, we recommended 14 veterinary medicines for marketing authorisation. Of these, nine had a new active substance, which had not previously been authorised in the EU – a threefold increase compared to 2022. Nine were vaccines, including six new biotechnological vaccines (compared to one in 2022).

We have come a long way in our fight against antimicrobial resistance (AMR) in the veterinary area. We brought the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project to a successful conclusion in 2023. The final report, published in November 2023, shows that the sales of antibiotics for animal use more than halved

(53 %) between 2011 and 2022, according to data from 25 participating countries. The ESVAC concept has now been integrated into EU legislation, making the collection of data on sales and use of veterinary antimicrobials mandatory for all EU countries.

The fight against AMR continues, e.g. by looking at alternatives to antibiotics. The Committee for Veterinary Medicinal Products (CVMP) adopted a guideline to encourage the development of new phage therapy products to treat bacterial infections. It is another fundamental step towards the promotion of animal and human health as envisaged by the One Health approach.

## Medicines shortages in the EU

Throughout the year, we made significant progress in managing the ongoing challenge of shortages throughout the EU. We saw the need for a coordinated approach between Member States during the winter season 2022/2023, with shortages of antibiotics and other critical medicines.

The changes we made to achieve a more proactive approach to this systemic challenge are now bearing fruit. In addition to an extensive supply and demand exercise on key antibiotics, we launched a series of co-ordinated actions across the EU throughout 2023. The **Medicines Shortages Steering Group (MSSG)** created a solidarity mechanism which allows Member States to support each other in the face of a critical medicine shortage. The group also published a toolkit with comprehensive recommendations for Member States to tackle shortages in their territory.

In December 2023, the EU regulatory network published the first version of the Union list of critical medicines to support efforts to ensure supply security and prevent shortages of more than 200 substances.

In addition, there were also significant communication efforts to promote best practices by industry, healthcare professionals and patients to contribute to the prevention of shortages.

The results of these actions are noticeable. In January 2023, around 17 Member States reported critical shortages of antibiotics, down to seven Member States in January 2024. In most cases these shortages affect individual products only. We will continue to monitor and act where the need arises in the EU.

## Strategic focus areas in 2023

In this report, we focus on three strategic areas in 2023: cancer medicines, data-driven medicine regulation and transparency and communication. In 2023, we stepped up our support for the EU Beating Cancer Plan with the launch of a new initiative, which has become known as the 'Cancer Medicines Pathfinder.'

This initiative explores how EMA can enable high-quality, robust and rapid assessment of key medicines overall, applying the learnings from the COVID-19 pandemic. Cancer was selected as a pathfinder for this initiative because it is a therapeutic area with a high rate of innovation and scientific progress, but also a high unmet medical need.

In 2023, we made significant progress in creating and using better data to translate innovation into medicines that reach patients. The work of the Big Data Steering Group explores the best ways to integrate data analysis into its assessment processes to improve our decision making.

Two years into its operation, the Data Analysis and Real World Interrogation Network EU (DARWIN EU) now boasts a network of 20 data partners from 12 EU Member States that together provide access to data from 130 million patients.

We also launched a draft Reflection Paper on Artificial Intelligence, which sets out our thinking around this huge technological shift in our societies.

Furthermore, we continue to strengthen the EU as a destination for clinical trials. The Accelerating Clinical Trials in the EU initiative (ACT EU) is now in full swing. We have initiated a new multi-stakeholder platform to step up the dialogue with all key stakeholders in EU clinical trials.

## Collaboration beyond the EU

The COVID-19 pandemic has clearly demonstrated that public health can only be thought of in global terms. International collaboration is integral to medicines regulation, because we can better solve challenges by working together.

In 2023, we celebrated the 10th anniversary of the International Coalition of Medicines Regulatory Authorities (ICMRA), a network that was conceived to help tackle new and emerging human medicine, regulatory and safety challenges at the global level. ICMRA, which brings together the heads of 38 regulators, with the WHO as an observer, proved its value many times over during the COVID-19 pandemic.

Last year, EMA received a grant of ten million euros from the European Commission to support regulatory systems at national and regional level in Africa, and the setting up of the African

## Opportunity in transformation

Alongside all of these developments, in 2023 we welcomed the EU Pharma Review. This is a once-in-a-generation opportunity to transform and improve the way we do things to benefit the patients we serve. We are committed to using the momentum this creates to help ensure the EU regulatory framework is fit for new, innovative medicines, support better access to medicines for patients and help address major public health threats like AMR.

The future for medicine regulation in the EU is exciting, but we must stay in front of change and always be prepared for new challenges – not as they emerge, but long before that. We are continuously looking at how we can ensure that we have the right skills and expertise to deal with rapid scientific advancements within the network.

Finally, we outline the role of trust, transparency and communication in this report. We always aim to be as open as possible about the data that informs the decisions EMA makes. This is why I am so pleased that EMA has resumed its clinical data publication initiative in 2023 beyond COVID-19 medicines, after several years of suspension linked to business continuity measures.

Medicines Agency (AMA), in collaboration with African, European and international actors. This is an exciting collaboration. We will support the AMA, its technical committees, and regulators by sharing our experience in pooling resources and coordinating work to regulate medicines.

In 2023, we also expanded the scope of the OPEN initiative from COVID-19 vaccines and treatments to a wider range of medicines. OPEN was one of our success stories of the pandemic. It was established as a pilot in December 2020 to increase international collaboration and share scientific expertise on the evaluation of COVID-19 vaccines and therapeutics. Its expansion will facilitate patient access globally to medicines with the potential to address AMR, respiratory syncytial virus (RSV) infections, or newly diagnosed myelodysplastic syndromes (and other hereditary diseases).

Finally, I would like to thank my many colleagues – EMA staff, experts from the Member States and partners in the EU institutions and sister agencies – for their work and dedication to the network. Behind all of the numbers in this annual report are people; and behind them is a network which has come out of one of the greatest healthcare challenges of our lifetime more proactive, resilient and better prepared.

I invite you to delve into these pages and look forward to your continued collaboration across our network to support the EU's public health goals in 2024. Let the achievements documented here be a reminder of the real value of our scientific work. EMA is always committed to its mission to promote public health, drive scientific innovation and safeguard the well-being of patients across Europe. Thank you all for your continued support.

# CHAPTER 1

## Key achievements in 2023



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# Evaluation and monitoring of medicines: highlights

## Human medicines

### Medicines recommended for approval

Authorisation of new medicines is essential to advancing public health as they bring new treatment opportunities for patients. In 2023, EMA recommended 77 medicines for marketing authorisation, 39 of which had a new active substance. Many of these represented significant progress in their therapeutic areas, including:



**Abrysvo**, a vaccine to protect small infants, via immunisation of the mother during pregnancy, and adults from the age of 60 and older people against lower respiratory tract disease caused by respiratory syncytial virus (RSV). RSV is a common respiratory virus that usually causes mild, cold-like symptoms that can be serious in vulnerable people, including older adults and those with lung or heart disease and diabetes.



**Aqumeldi**, for the treatment of heart failure in children from birth to less than 18 years.



**Arexvy**, a vaccine for active immunisation of adults aged 60 years and older against lower respiratory tract disease caused by respiratory syncytial virus (RSV).



**Camzyos**, for the treatment of symptomatic obstructive hypertrophic cardiomyopathy, a disease in which the heart muscle becomes thickened and can make it harder for the heart to pump blood.



**Casgevy**, for the treatment of transfusion dependent beta-thalassemia and severe sickle cell disease, two inherited rare diseases caused by genetic mutations that affect the production or function of haemoglobin, the protein found in red blood cells that carries oxygen around the body. This is the first medicine using CRISPR/Cas9, a novel gene-editing technology.



**Columvi**, for the treatment of diffuse large B-cell lymphoma, an aggressive type of non-Hodgkin lymphoma, a cancer of the lymphatic system that can arise in lymph nodes or outside of the lymphatic system.



**Elrexio**, for the treatment of adult patients with relapsed or refractory multiple myeloma, a rare cancer of the bone marrow that affects plasma cells, a type of white blood cell that produces antibodies.



**Finlee**, in combination with Spexotras, for the treatment of paediatric patients aged one year and older with glioma, a type of brain tumour that begins in glial cells, the cells that surround and support nerve cells.



**Jaypirca**, for the treatment of relapsed or refractory mantle cell lymphoma which develops when B-cells, a type of white blood cell that makes antibodies, become abnormal.



**Krazati**, for the treatment of adults with advanced non-small cell lung cancer with a G12C mutation in the KRAS gene whose disease has worsened after at least one systemic treatment.



**Loargys**, treatment of hyperargininaemia, a rare disease with neurological clinical signs including spasticity, ataxia, hyperreflexia, incoordination, and seizures.



**Lytgobi**, for the treatment of cholangiocarcinoma or bile duct cancer, a type of cancer that forms in the slender tubes that carry the digestive fluid.



**Omjjara**, the first treatment for myelofibrosis, a rare blood cancer that affects the bone marrow, in patients with moderate-to-severe anaemia.



**Pedmarqsi**, for the prevention of ototoxicity induced by cisplatin chemotherapy in children from one month up to 18 years of age with localised, non-metastatic, solid tumours. Ototoxicity is the development of hearing or balance problems due to a medicine.



**Skyclarys**, for the treatment of Friedreich's ataxia, an inherited disease causing a range of symptoms that worsen over time, including difficulty walking, inability to co-ordinate movements, muscle weakness, speech problems, damage to the heart muscle and diabetes.



**Talvey**, for the treatment of adult patients with relapsed and refractory multiple myeloma, a rare cancer of the bone marrow that affects plasma cells, a type of white blood cell that produces antibodies.



**Tepkinly**, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, a fast-growing cancer of the lymphatic system.

## Early access to medicines that address public health needs

In 2023, **three medicines** received a recommendation for marketing authorisation following an **accelerated assessment**: **Abrysvo**, **Arexvy** and **Talvey**. 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: **Casgevy**, **Columvi**, **Elrexio**, **Jaypirca**, **Krazati**, **Lytgobi**, **Talvey** and **Tepkinly**.

The conditional authorisation allows for early approval on the basis of less complete clinical data than normally required because the benefits of earlier patient access outweigh the potential risks of limited data. These authorisations are subject to specific post-authorisation obligations to generate complete data on the medicines.

**One medicine (Loargys)** was 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.

## Medicines for rare diseases

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

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 for maintaining the medicine's orphan status and granting the medicine ten years of market exclusivity. Among the 77 medicines recommended for marketing authorisation in 2023, **17 had an orphan designation that was confirmed** by the end of the year.

The enhanced development support provided by EMA's **PRIority Medicines (PRIME)** aims to help patients benefit as early as possible from promising medicines that target an unmet medical need. This is done by optimising the generation of robust data and enabling accelerated assessment. This year, **three medicines with PRIME designation were recommended for approval (Casgevy, Elrexio and Talvey)**.

**Eighteen medicines under development were accepted in the scheme in 2023: endocrinology-gynaecology-fertility-metabolism (4), cardiovascular diseases (3), oncology (3), ophthalmology (3), vaccines for infectious diseases (2), gastroenterology – hepatology (1), neurology (1) and other, congenital, familial and genetic disorders (1).**

Eight 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, and thus no longer benefit from the incentives. These are: Elfabrio, Elrexio, Inaqovi, Jaypirca, Lytgobi, Pombiliti, Vanflyta and Zilbrysq.

## Medicines for children

Two medicines, Aqumeldi and Pedmarqsi, received a paediatric use marketing authorisation (PUMA), a process established in 2007 as part of the EU paediatric regulation intended to make it more profitable for pharmaceutical companies to develop and market medicines for children.

EMA issued a recommendation for Arpraziquantel, a new treatment option for the estimated 50 million young children with schistosomiasis, a neglected tropical disease caused by parasitic blood worms. Arpraziquantel was assessed under a regulatory



procedure known as **EU-Medicines for all (EU-M4All)** that enables EMA, in cooperation with the World Health Organization, to support global regulatory capacity building and contribute to the protection and promotion of public health beyond the EU.

In addition, half of the extensions of indication that received a positive recommendation were for paediatric use. Extensions of indication included:



**Soliris**, for the treatment of paediatric patients from 6 years of age with refractory generalised myasthenia gravis.



**Spexotras**, for the treatment of children aged 1 year and older with high grade and low grade glioma, having a specific mutation (V600E) in the BRAF gene. It is used together with another cancer medicine, dabrafenib.



**Bezlotoxumab**, for the treatment of paediatric patients from 1 to 18 years of age with *Clostridioides difficile* infection (CDI).

## New uses for existing medicines

In 2023, **77** extensions of indication were recommended. 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.



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## Negative opinions

The Committee for Medical Products for Human Use (CHMP) adopted a **negative opinion for three medicines** in 2023: **Albrioza**, **Lagevrio** and **Sohonos**.

**94 % of all opinions (positive and negative) were reached by consensus among the CHMP members, which means that, following in-depth discussions, the experts agreed on all aspects of the marketing authorisations and there were no divergent opinions.**

**Over 65 % of all applicants that were granted a positive opinion for their medicine had received scientific advice or protocol assistance from EMA during their product's development phase. The figure increases to 88 % for applicants for medicines with new active substances. Early engagement with developers allows EMA to clarify what kind of evidence is required to later evaluate a medicine for authorisation. This encourages generation of more robust data for regulatory assessment and thus protects patients from taking part in unnecessary or poorly designed clinical trials.**

## Keeping patients safe

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

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

**The product information for 387 centrally authorised medicines was updated on the basis of new safety data in 2023. Every year, PRAC recommendations on safety warnings are also included in the product information of many thousands of nationally authorised products (NAPs). The revised information is expected to help patients and healthcare professionals to make informed decisions when using or prescribing a specific medicine.**

Important new advice issued in 2023 included:

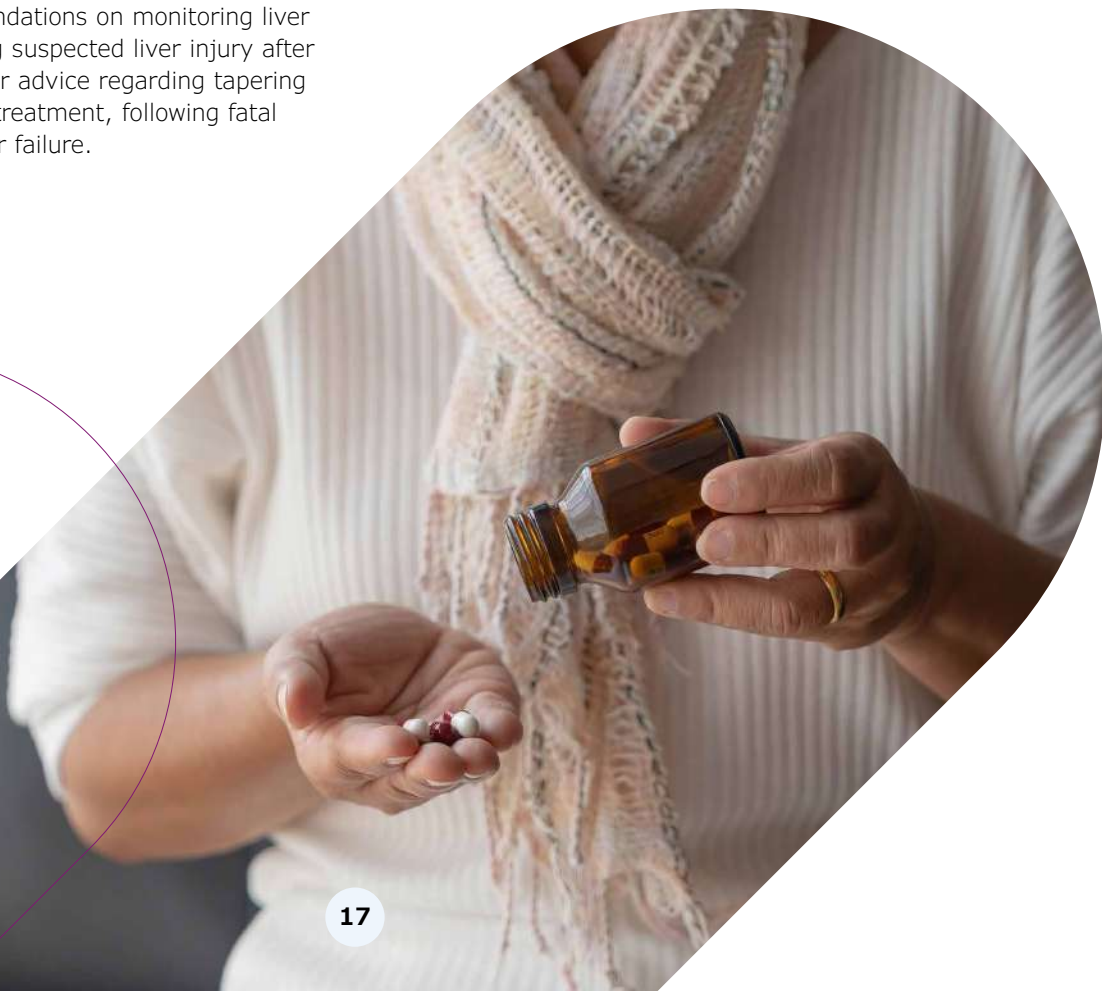
- **Adakveo** (crizanlizumab), recommendation to no longer use Adakveo to prevent painful crises in patients aged 16 years and older with sickle cell disease, a genetic condition in which the red blood cells become rigid and sticky and change from being disc-shaped to being crescent-shaped (like a sickle). The recommendation followed a review by the CHMP of the results of the STAND study which showed that Adakveo did not reduce the number of painful crises leading to a healthcare visit when compared to placebo (a dummy treatment).
- **Fluoroquinolone** antibiotics: reminder of measures to reduce the risk of long-lasting, disabling and potentially irreversible side effects. These restrictions were introduced in 2019 following an **EU-wide review** of these very rare, but serious side effects. An EMA-funded study (**EUPAS37856**) has shown that although the use of fluoroquinolone antibiotics has decreased over time, these medicines are still prescribed outside of their recommended uses.
- **Gavreto** (pralsetinib), recommendation to evaluate patients for active and inactive ('latent') tuberculosis before starting treatment and to initiate standard antimycobacterial therapy in patients with active or latent tuberculosis before treatment with Gavreto. Also, avoid co-administration of pralsetinib with strong CYP3A4 inducers, or increase the dose of pralsetinib if co-administration cannot be avoided.
- **Olumiant** (baricitinib), recommendation to use a lower dose in patients at higher risk of blood clots, cardiovascular conditions, and cancer in line with the dosing recommendations for other JAK inhibitors used to treat several chronic inflammatory disorders.

- **Omega-3-acid ethyl esters**, recommendation to update the product information to add atrial fibrillation as a common side effect, to inform healthcare professionals and patients of the risk of atrial fibrillation, and to permanently discontinue treatment if atrial fibrillation develops.
- **Pseudoephedrine-containing medicines**, recommendation to not use pseudoephedrine in patients with severe or uncontrolled high blood pressure, or with severe acute or chronic kidney disease or failure, to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). In addition, healthcare professionals should advise patients to stop using these medicines immediately and seek treatment if they develop symptoms of PRES or RCVS, such as severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures, and visual disturbances.
- **Topiramate-containing medicines**, recommendation to not use topiramate for the treatment of epilepsy during pregnancy unless there is no other suitable treatment available, and to reassess at least annually the need for topiramate treatment in line with a new pregnancy prevention programme.
- **Zolgensma** (onasemnogene abeparvovec), updated recommendations on monitoring liver function, assessing suspected liver injury after infusion and further advice regarding tapering the corticosteroid treatment, following fatal cases of acute liver failure.

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

Medicine development and manufacturing is global. It is important for regulators to ensure that EU standards are adhered to, no matter where clinical trials or manufacturing takes place.

In December, EMA recommended suspending the marketing authorisations of more than 350 generic medicines tested by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Pune, India. The recommendation followed a good clinical practice (GCP) inspection which showed that supporting data were lacking or insufficient to show bioequivalence. The [list](#) of the medicines concerned is available on EMA's website.



# Veterinary medicines

## New medicines to benefit animal health in Europe

In 2023, EMA recommended 14 veterinary medicines for marketing authorisation. Of these, nine had a new active substance which had not previously been authorised in the EU – a threefold increase compared to 2022. Among the 14 medicines recommended for marketing authorisation, nine were vaccines, including six that had been developed by means of a biotechnological process (compared to one in 2022). This demonstrates the animal health industry's continued strong interest in developing vaccines. The new biotechnological vaccines include:

- **Bovilis Cryptium**, a new vaccine for the active immunisation of pregnant heifers and cows to raise antibodies in their colostrum against Gp40 of *Cryptosporidium parvum*. This is expected to provide passive immunisation of calves to reduce clinical signs (i.e. diarrhoea) caused by *C. parvum*.
- **Innovax ILT-IBD**, a new vaccine for the active immunisation of one-day-old chicks or 18-19-day-old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease virus and to prevent mortality and reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus.
- **Newflend ND H9**, a new vaccine for the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV) and to reduce mortality, clinical signs, lesions, and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9).
- **Poulvac Procerta HVT-IBD**, a new vaccine for the active immunisation of one-day-old chicks and 18-19 day-old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease virus, and prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease virus.
- **Prevexxion RN+HVT**, a new vaccine for the active immunisation of one-day-old chicks to prevent mortality and reduce clinical signs and lesions caused by Marek's disease virus, including very virulent Marek's disease virus.
- **YURVAC RHD**, a new vaccine for the active immunisation of rabbits from 30 days of age to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains.

## Optimising the safe and effective use of veterinary medicines

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



## Important new safety advice issued in 2023

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

- **Apoquel (oclacitinib maleate)**: Amendment to the product information on potential side effects following administration of Apoquel, to include convulsion.
- **Cimalgex (cimicoxib)**: Amendment to the product information on potential side effects following the administration of Cimalgex, to include frequent urination and/or excessive thirst. A statement was also added to reflect that severe adverse events in the gastrointestinal tract and kidneys may be fatal.
- **Galliprant (grapiprant)**: Amendment to the product information on potential side effects following the administration of Galliprant, to include pancreatic inflammation.
- **Injectable veterinary medicines containing procaine benzylpenicillin**: Recommendation not to use these veterinary medicines for the treatment of infections caused by certain pathogens. In addition, recommendation to update the product information to add potential side effects following the administration of these medicines in young piglets and new warnings to ensure their efficacious use. For some of these medicines, the dose and treatment duration were increased, and consequently the meat and offal withdrawal periods for all target species to ensure consumer safety.
- **Neptra (florfenicol/terbinafine hydrochloride/mometasone furoate)**: Amendment to the product information for Neptra to include new special precautions for use in cats as it can be associated with neurological signs (including ataxia (incoordination), Horner's syndrome with protrusion of membrane nictitans (translucent third eyelid), miosis (constricted pupil), anisocoria (unequal pupil size), internal ear disorders (head tilt), anorexia and lethargy.
- **Solensia (frunevetmab)**: Amendment to the product information on potential side effects following the administration of Solensia, to include anaphylaxis (severe allergic reaction) and skin disorders (e.g. skin scab, skin sore). In case of anaphylaxis, appropriate symptomatic treatment should be administered.

## Protecting consumers of 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 consumption. The MRL is established before a medicine can be authorised for food-producing animals in the EU.

If a marketing authorisation holder intends to apply for an extension of their marketing authorisation to another species, they must first obtain an extension to their MRL.

In 2023, positive opinions were adopted recommending the extension of MRLs for the following active substances:

- **Sodium salicylate** extension to poultry except turkey.
- **Ketoprofen** extension to poultry.
- **Rafoxanide** extrapolation to bovine, ovine and other ruminants' milk.

More information and figures on veterinary medicines are available in [chapter 2](#).

# Better data to translate innovation into medicines

Data underpin everything in healthcare and fuel the decisions regulators take every day. The evidence we gather from analysing data is how we can tell whether a medicine works and whether it is safe, how the balance of benefits and risks is weighed. In 2023, new possibilities for data-driven decision-making surfaced that have the potential to transform medicines regulation.

With emerging technologies such as artificial intelligence (AI) and machine learning, a much more proactive and responsive regulatory system is within view. These digital advancements make it possible to use data in new ways and explore the full potential of new analytic tools to make sense of them. Traditionally, clinical trials represent the foundation of data-driven medicines regulation, but increasingly, data generated by patients and healthcare professionals as part of daily healthcare activities can complement evidence from clinical trials. This can help medicines regulators better characterise diseases, treatments and assess the benefits and risks of medicines across their entire life cycle.

In 2023, understanding how we can efficiently analyse and use data to inform medicines regulation has been a key priority for the Agency and the European medicines regulatory network (EMRN). This year was important in ensuring the EU's regulatory system is more prepared to embrace the full potential of data. The Accelerating Clinical Trials in the EU initiative (ACT EU) is in full swing, with its [workplan](#) to 2026 published in November. At the same time, the work of the [Big Data Steering Group](#) (BDSG) continued exploring the best ways to strengthen the regulatory system by integrating data analysis into its assessment processes to improve decision making.



## [Video](#)

[LinkedIn live interview with Peter Arlett: Real-world evidence in medicines regulation](#)

# ACT EU and innovating clinical trials



## Video

What is Accelerating Clinical Trials in the EU (ACT EU) and how is the Network supporting innovative clinical trials?

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Clinical trials are the gold standard to generate evidence about medicines. They are the cornerstone of medicines regulation and, for this reason, the Network has committed to supporting clinical research and ensuring that the EU is a global hub in this field. A dynamic and efficient clinical trial environment is an engine for development, attracting innovation and research to Europe, guaranteeing representative trials and supporting early access for European patients to new treatments.

While 2022 saw many regulatory changes to the EU clinical trials environment, like the new Clinical Trials Regulation coming into force, the rollout of the Clinical Trials Information System (CTIS) and the launch of ACT EU, 2023 was a year of consolidation. CTIS became mandatory in **January**, with the Agency continuing to provide support and **guidance** to applicants on the new system, which enables centralised submission and access to clinical data in the EU. Enabling this transition is vital, as creating streamlined infrastructures across the EU is one of the main goals of the Network, and one of the pillars of the ACT EU initiative. In addition, guidance is being updated to ensure that it reflects technological change and encourages innovation by including, for example, technologies that allow decentralised studies at patients' homes or more powerful analytical tools.

Publishing information on clinical studies helps build trust and support clinical research. A **consultation** launched in May collected stakeholders' views on

how to enable timely transparency in the new CTIS. The consultation resulted in the publication of the **revised CTIS transparency rules** in October.

EMA and HMA organised two important occasions for exchange in 2023: in July, a workshop explored the **revision of the ICH E6** guideline on the conduct of clinical trials with all relevant stakeholders and, in November, a **multi-stakeholder workshop on clinical trial methodology** looked at the available know-how at EU level and where further guidance is needed. In April, a **reflection paper on single-arm trials was published**.

None of this would be possible without a forum for discussion with all the relevant parties involved in clinical trials: from regulators and developers, to academia, healthcare professionals, patients and consumers. For this reason, 2023 also saw the creation of the **ACT EU multi-stakeholder platform**, which was launched in June. The platform includes representatives from all groups mentioned and meets regularly to discuss ACT EU priorities.

Keep informed about ACT EU: check out the [website](#), launched in November

# The potential of data: beyond clinical trials

Data-driven regulation goes beyond clinical trials. As previously noted, the analysis of real-world data (RWD) can complement evidence from clinical trials and support regulatory decisions. In June, the publication of the [first report on the use of real-world evidence in regulatory decision making](#) was a considerable milestone towards integrating regulator-led studies using RWD in regulatory activities.

The report assessed the use of RWD in regulator-led pilot studies during an 18-month period. It highlighted areas like safety monitoring, evaluation of orphan designations, assessment of paediatric investigation plans and provision of scientific advice to developers as key areas where the generation of real-world evidence (RWE) can address knowledge gaps. Some of the studies looked at how diseases manifest in different populations, how medicines are used by patients and how patients may react to specific treatments. This can be particularly helpful when treating rare conditions or special populations like children, elderly individuals and pregnant people, that are less represented and studied in clinical trials.

To ensure that we exploit the full potential of data-driven medicines regulation, the BDSG is working towards creating a framework that is ready to adapt to and exploit future innovation.

Learn more about the work of the BDSG: check out the [2023 report](#)

In April, EMA organised a [multi-stakeholder workshop on qualification of novel technologies](#) to discuss the first point of dialogue between regulators and developers on new technological advancements. In June, the [reflection paper on proposed international harmonisation of real-world evidence terminology](#) was published. With this paper, global regulators are taking an important step towards a more standardised use of terms such as RWD and RWE.

## Sources of real-world data: DARWIN EU

Generating data is simple. We do it every day as we sleep, eat, walk and go about our lives. But how does data get fed into regulatory decision making? How is it analysed so it can become valid and reliable evidence rather than raw, unfiltered information?

EMA has three ways to access and analyse data: 1) through direct access to several European primary healthcare databases, 2) through studies commissioned to research organisations that use more specialised sources, and 3) through a federated network of data partners known as DARWIN EU®.

[DARWIN EU](#), which will celebrate its second year in February 2024, is a network of 20 partners from 12 EU Member States to date. Together they provide access to data from millions of patients in Europe. By the end of 2023, the initiative ran 18 studies to support the work of EMA's committees. These studies are looking into a variety of questions: from how opioids are used in the EU, to investigating deaths and severe adverse events linked to severe asthma, and understanding the disease progression of multiple myeloma and rare conditions like dermatomyositis and polymyositis.

[Info sheet on real world evidence data studies](#)



### **Innovative manufacturing**

**Innovation is not only about development of new medicines. It's also about how medicines are made. Ultramodern factories, quality batch-testing using AI, 'mini-pods' that can produce medicines for patients directly at point-of-care ... How do we promote trust in the quality of all these technologies?**

**The Quality Innovation Group was created at the end of 2022 to support the translation of innovative approaches to the design, manufacture and quality control of medicines. Its work plan, published in February 2023, focuses on providing developers with advice from proof-of-concept through to product development, helping clarify regulatory expectations, speeding up regulatory timelines and reducing the regulatory burden. Four listen-and-learn focus groups were held with industry stakeholders this year, to understand the regulatory needs of developers. At the same time, the group met with the US FDA in November to ensure that these efforts are aligned internationally.**

In December 2023, EMA finalised the Data Quality Framework for EU medicines regulation, following discussions with stakeholders, the Methodology Working Party and public consultation. This sets common standards for data sources to ensure they are accurate and reliable. The HMA-EMA Big Data Forum, an annual fixture in EMA's calendar of events, brought all

stakeholders together in December to discuss the state of play of the work towards data-driven regulation. A similar event took place in the veterinary community in November, to discuss the implementation of the Veterinary Big Data Plan to 2025 following the establishment of the Veterinary Data Hub in June.

### **Embracing the opportunities of artificial intelligence**

**There is no doubt that 2023 was the year of artificial intelligence (AI). Everyone is starting to explore and understand how to use AI in day-to-day life, and regulators make no exception. EMA and the Network have been working to enable the potential of AI for medicines regulation and to assess its risks.**

**In July, EMA published a draft reflection paper outlining the current thinking on the regulatory use of AI for public consultation. This paper reflects on principles relevant to the application of AI and machine learning at any step of a medicine's lifecycle, from drug discovery to the post-authorisation setting.**

**To encourage stakeholders to bring in their views on this topic, which may have important repercussions on medicines regulation at global, European and national level, a multi-stakeholder workshop was organised in November. This work led, in December, to the publication of the HMA-EMA AI Workplan that aims to ensure the Network remains at the forefront of benefiting from AI in medicines regulation.**

# Cancer as a pathfinder

The burden of cancer is increasing in the EU. The estimated number of new cancers diagnosed in 2022 was 2.7 million, and 1.3 million people lost their lives to it <sup>1</sup>. Cancer is the second leading cause of mortality after cardiovascular disease. However, there still remains an area of high unmet medical need in Europe. In 2023, EMA launched a new initiative to help develop cancer medicines and build up valuable expertise in line with the aims of the Europe's Beating Cancer Plan.

For many years now, oncology has been the therapeutic area that has had the highest number of new approvals. In 2023 alone, the CHMP gave positive opinions to 25 new cancer medicines, which represents one third of all the new medicines reviewed positively by EMA. But there are still many unmet medical needs to address.

In the last few years, significant breakthroughs such as targeted therapies and immunotherapies have transformed the treatment of many types of cancer, including more common cancers like breast cancer, lung cancer and less frequent cancers like leukaemias.

In 2023, EMA launched a new initiative, called '**Cancer Medicines Pathfinder**', to further support the development and approval of cancer medicines which could have a meaningful impact on transforming patient care.

**The Cancer Medicines Pathfinder builds strategically on the EU network's experience during the pandemic and leverages available tools and processes to proactively help advance and refine cancer treatments.**

**Francesco Pignatti,**  
Scientific Adviser Oncology



## Video

Francesco Pignatti presents the Cancer Medicines Pathfinder initiative at EMA's press briefing on human medicines highlights.

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<sup>1</sup> An overview of the cancer disease burden in the EU is available in the European Cancer Information System: [https://ecis.jrc.ec.europa.eu/factsheets\\_2022.php](https://ecis.jrc.ec.europa.eu/factsheets_2022.php).

This new initiative explores how EMA can improve medicine evaluation overall, including by applying some of the learnings from the COVID-19 pandemic. Cancer was chosen for this initiative because it is a therapeutic area with a high rate of innovation and scientific progress, but also a high unmet medical need. Ultimately, this work will pave the way for other therapeutic areas,

to support patients' swift access to the most innovative therapies.

The Cancer Medicines Pathfinder rests on three pillars: accelerating assessments of medicines, strengthening dialogue with stakeholders and communicating benefits and risks.

## Accelerating assessment of medicines critical to patient care

In 2023, EMA explored how it can further expedite and refine its processes in the evaluation of cancer medicines which have a significant potential to address unmet medical needs, focussing on those designated as PRIME (PRIority MEDicines) products. The objective is to maximise efficiency in the assessment of medicines critical to patient care, while keeping the high-quality standards applied

to all the medicines approved. EMA took further steps to guide developers in their submissions and build capacity within the multinational assessment framework. It has started to analyse challenges in the development and submissions to inform new developments, focussing on conditional approval and real-world data as an external comparator.

### Building oncology expertise across Europe

EMA has re-shaped its expert communities through the **Oncology European Specialised Expert Community (ESEC)**, a platform to promote information sharing among European experts on scientific and regulatory topics.

The ESEC is composed of over 150 experts: assessors working for a National Competent Authority (NCA), members of EMA working parties and advisory groups, and European experts with a special interest or expertise in oncology. Its tasks include mapping competences across the European network of experts, providing training and upskilling to the European medicines regulatory network and connecting experts from multidisciplinary teams and across topics of expertise. In March 2023, EMA organised a dedicated webinar for ESEC experts on challenges in drug development, regulation and clinical practice in Acute Myeloid Leukaemia.

In addition, EMA took steps to further enable clinical-oncology scientists to participate in medicines regulation. In May 2023, EMA launched a **pilot educational program in oncology** which consists of live and recorded webinars that provide an overview of the regulatory requirements for medicines' evaluation, with a focus on oncology. The general training curriculum was delivered in 2023 and a specific curriculum for oncology is planned for 2024. One of the goals of this pilot is to encourage scientists to contribute to regulatory activities, should the opportunity arise and, more generally, to increase collaboration between regulatory authorities and stakeholders in healthcare and academia.

# Strengthening multi-stakeholder dialogue and international collaboration

EMA has a long track record of multi-stakeholder dialogue in cancer, involving researchers, developers, payers, patients, and other regulators. These partnerships were further strengthened in 2023 to enhance research and access to innovative treatments.

EMA continued its work through the **Cancer Medicines Forum**, established in 2022 in collaboration with the **European Organisation for Research and Treatment of Cancer (EORTC)**.

In the Forum, academics and regulators can discuss specific challenges around research into optimising cancer treatments. The Forum met three times in 2023. Topics discussed included experience with pragmatic trials and real-world data, which treatment optimisation questions should be prioritised, and how EMA can support efforts to optimise treatments with oncology medicines.

Addressing unmet medical needs often requires a global effort. EMA has a lot of experience with international collaboration in oncology, e.g. through the **'cluster'** meetings with SwissMedic, the US FDA, Health Canada, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), the Australian Therapeutic Goods Administration (TGA), which are organised each month to share clinical review information. In 2023, EMA reinforced global collaboration with the view to further expand the level of interactions earlier in the assessment.

## **Conversations on Cancer: hearing the patient's voice**

EMA works closely with patients to ensure their views and preferences are understood and taken on board in the evaluation of medicines. In October 2023, EMA joined for the first time as a co-organiser the **FDA's Conversations on Cancer**, a public panel discussion. For the first edition of this new joint initiative, a range of speakers from the US and the EU highlighted the day-to-day, year-to-year experience of patients living with metastatic breast cancer.

# Communicating benefits and risks with patients

Patients and healthcare professionals need access to clear information to make informed decisions. In 2023, EMA continued to explore ways to refine its approaches to ensure the benefits and risks of cancer medicines are not only better assessed, but also **better explained and communicated**. This goes hand in hand with efforts to improve evidence generation in the regulatory process.

Actions include structured templates for benefit risk communication, advancing endpoint methodology to measure the benefits of cancer drugs using different sources of data, exploring the role of patient preference studies to inform regulatory decisions, and new international guidance on patient preference studies. Work in these areas is expected to continue during 2024.

## Perception of progression-free survival as a clinical endpoint

In December 2023, academics and EMA experts published an [article in the European Journal of Cancer](#) which describes the attitudes of healthcare professionals and drug regulators to progression-free survival (PFS) as an efficacy endpoint in clinical trials with patients with advanced cancer. It also explores to what extent these attitudes influence the willingness to trade between PFS and toxicity. The study highlighted the need to improve communication to patients about meaning, strengths and limitations of improvements in PFS.



# Building trust through transparency and communication

EU medicines regulation involves our partners in the Member States and other institutions and a range of stakeholders, from patients, healthcare professionals, academia, pharmaceutical companies and the broader public. They all rely on timely and trusted communication. Good communication and transparency go a long way to building trust in medicines regulation and public health.

In 2023, EMA provided European citizens with comprehensive information on medicines by publishing product information, European public assessment reports, as well as clinical trial data but also through direct patient, healthcare and industry outreach and proactive media engagement.

Throughout the year, all of our communications activities supported the strategic priorities outlined in the [European medicines network strategy to 2025](#) and the [Regulatory Science Strategy to 2025](#).

## Transparency: clinical studies in the EU

The Agency aims to be as open as possible about the data that informs the decisions it makes. This is why EMA became the first regulatory authority in the world in 2016 to give open access to clinical data that companies submit to support their marketing authorisation applications for human medicines.

One of the aims of this initiative was to build confidence in our decision-making processes. At the end of 2018, EMA temporarily suspended all new activities related to clinical data publication to ensure business continuity during the Agency's relocation to the Netherlands. This suspension

was lifted to allow EMA to respond appropriately to the COVID-19 pandemic as part of its exceptional transparency measures.

In addition to continuing publication of clinical data on COVID-19 related medicinal products, in September 2023, the publication was restarted in a phased approach, beginning with non-COVID medicines with new active substance (initial marketing authorisation applications).

As of early 2024, clinical data packages are being published on the clinical data website.

## Publication of electronic product information

In 2023, the Heads of Medicines Agencies (HMA), the European Commission and EMA published for the first time **electronic product information (ePI) for selected human medicines** harmonised across the EU. Digital platforms open new possibilities to share this information electronically, keep it constantly updated and make it more accessible to end users, including patients and healthcare professionals.

The creation and testing of ePI in real regulatory procedures was explored through a one-year **pilot initiative by HMA**, the European Commission and EMA to enable the transition to the electronic system for medicines evaluated both nationally and at European level. The ePI initiative is an action under the Pharmaceutical Strategy for Europe supported by the EU funding programme **EU4Health**.

## Patient, healthcare professional and industry engagement

Understanding the views of **patients** and their carers on the use of medicines through the work of the Patients' and Consumers' Working Party (PCWP), and their benefits and risks, is of great value for EMA and the network's decision-making. In 2023, work intensified to increase the use of 'patient experience data' in medicines development and regulatory decision making.

2023 marked the tenth anniversary of the establishment of EMA's Healthcare Professionals' Working Party (HCPWP). In June, the HCPWP plenary meeting brought together former co-chairs to reflect with all members on the past, present and future of the working party and set the foundation for its focus in the coming years.



The Healthcare Professionals Working Party with past and current co-chairs

**You are the EU model on stakeholder engagement. Thank you!**

Representative of patient or consumer organisation (providing a comment in EMA's latest communication perception survey)

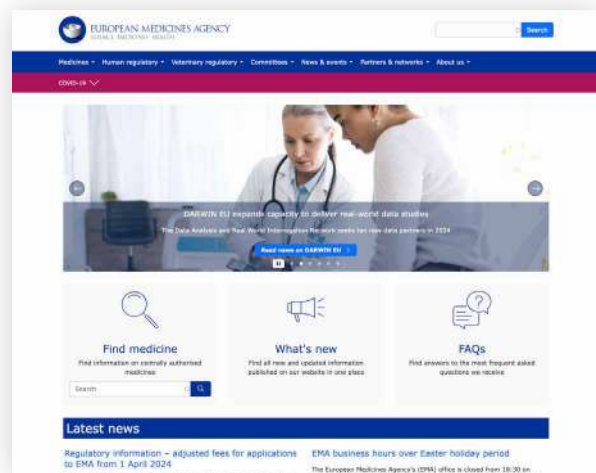


**Read more** about our engagement with stakeholders in the 'EMA's stakeholder engagement report for 2022-2023'

The Industry Standing Group (ISG) continued to provide a platform for the regular exchange of views, promote dialogue and receive feedback from industry stakeholders on issues of strategic interest related to human medicines within the European legal framework and facilitate implementation of the European Commission's new legislative proposals.

## Relaunch of EMA's website

As EMA's primary communication channel, and a first point of contact for many, the corporate website is a comprehensive source of information and guidance on centrally authorised medicines and on medicines regulation in the EU. In 2023, the website underwent a major revamp, providing people with a trusted platform for information on medicines, with clearer navigation and a revamped 'what's new' page.



## Proactive media engagement

Our interactions with broadcasters, print journalists and online reporters is crucial to ensuring scientific information finds its way into the public domain. In the aftermath of the pandemic, with vaccine technologies and medicines shortages still in the headlines, there was high demand for EMA experts and their insights.

In 2023, we built on the proactive media strategies we adopted during the pandemic to keep media informed about EMA decisions and developments in medicines regulation. On any given day, EMA's press team handled detailed requests from a range of media – specialist, local and international – all in search of reliable scientific information.



**In 2023, EMA's press office responded to 1,100 media queries and organised 35 interviews with media.**

Alongside key news announcements throughout the year, in 2023 we collaborated with other EU agencies and the European Commission to co-ordinate additional public health updates. These included the state of respiratory diseases and treatments in the EU at a joint **press briefing** with the European Centre for Disease Prevention and Control (ECDC) in September, and the **Union critical list of medicines** in November.



**Video**

Joint EMA-ECDC press briefing on current state of respiratory diseases and treatments in the EU/EEA

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**COVID-19: lessons from a health crisis**

In December, a **joint report** issued by EMA and HMA reviewed the network's response to the COVID-19 pandemic and highlighted the main learnings for any future health crises. Areas where lessons learned have been identified include transparency, stakeholder engagement and communication.



## New approaches to social content

As the influence and impact of social media grows, so too do our efforts to engage audiences with new types of content about medicines regulation. In 2023, the Agency created high-quality and engaging audiovisual material in formats that resonate with different audiences and across platforms: from simple explainer videos that break down complex topics, to live expert interviews and campaigns on high priority public health issues.

We actively use three social media channels: LinkedIn, Instagram and X (former Twitter). X is mainly used to connect with journalists to publish and share the latest news. Increasingly, LinkedIn has grown as a channel that can connect EMA to healthcare, research, technology and academic audiences. A LinkedIn influencer

account for EMA's Executive Director now attracts over 22,000 followers. EMA's corporate account has over 200,000 followers. To ensure better engagement with its audiences, EMA organised three LinkedIn Live interviews in 2023: one through a partnership with LinkedIn News Europe on RNA technologies, and two on EMA's own LinkedIn page covering the **first anniversary of DARWIN EU** and **veterinary medicines**. All three sessions featured EMA experts addressing audience questions in real time.

Social media also allow us to proactively respond to public health issues. We ran short campaigns on antibiotic shortages and how to buy medicines safely online.



### Video

LinkedIn Live interview with Ivo Claassen: Tomorrow's veterinary medicines for healthy animals and humans

# Perception of EMA communication

In 2023, EMA published the results of its fourth **communication perception survey**, which was carried out in September 2022. According to the survey, 93 % of respondents value EMA's communication as 'important' or 'indispensable'.

EMA's communication materials are mostly disseminated internally within respondents' organisations (82 %), or externally through social media (36 %) or the organisations' websites (34 %).



**My experience says that EMA is really open and transparent. I have been using EMA's communication materials for many years. EMA's communication is also honest and timely.**

Patient or carer  
(providing a comment in EMA's latest communication perception survey)

# Key activities and events in 2023

## JANUARY 2023



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### **January 16, 2023**

A Big Data Steering Group (BDSG) report provides a summary of its key activities and achievements in 2022.



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### **January 19, 2023**

EMA and the European Food Safety Authority (EFSA) publish a joint report on the development of a harmonised approach for the assessment of dietary exposure of people to residues of veterinary medicines, feed additives and pesticides in food of animal origin in the EU.



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### **January 20, 2023**

EMA, the European Commission and the Heads of Medicines Agencies (HMA), through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), closely monitor and respond to current shortages of antibiotics affecting the EU.



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### **January 26, 2023**

EMA's steering group on shortages meets to discuss the progress in our response to shortages of antibiotics containing amoxicillin.



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### **January 31, 2023**

From 31 January 2023, all initial clinical trial applications in the EU must be submitted via the Clinical Trials Information System (CTIS).

## MARCH 2023



### **February 27, 2023**

EMA launches a pilot to give scientific advice on the intended clinical development strategy and proposals for clinical investigation for certain high-risk medical devices.



### **February 06, 2023**

Closing report of EMA and European Commission action plan on paediatrics highlights key initiatives in the past four years to increase the efficiency of paediatric regulatory processes and boost the development of medicines for children.

### **February 03, 2023**

EMA, the **Heads of Medicines Agencies (HMA)** and the European Commission launch a public consultation on the establishment of a multi-stakeholder platform to improve clinical trials in the EU. The multi-stakeholder platform is a deliverable of the joint initiative **Accelerating Clinical Trials in the EU (ACT EU)**.



### **February 02, 2023**

EMA's additional responsibilities regarding the monitoring and mitigation of shortages of critical medical devices during public health emergencies apply.

## FEBRUARY 2023



**March 22, 2023**

EMA publishes a report summarising the mid-term achievements of its Regulatory Science Strategy (RSS) to 2025.



**March 28, 2023**

DARWIN EU® completes its first studies and calls for new data partners.

**March 30, 2023**

EMA's human medicines committee (CHMP) recommends authorising the COVID-19 vaccine Bimervax (previously COVID-19 Vaccine HIPRA) as a booster in people aged 16 years and above who have been vaccinated with an mRNA COVID-19 vaccine.



## APRIL 2023



**April 04, 2023**

EMA introduces a number of new features to the PRIority Medicines (PRIME) scheme to strengthen its support for the development of medicines in areas of unmet medical needs.



**April 21, 2023**

EMA opens a public consultation on a reflection paper that discusses key concepts for single-arm clinical trials that are submitted as pivotal evidence in support of marketing authorisation applications for medicines in the EU.



**May 10, 2023**

EMA and the European medicines regulatory network lift their respective COVID-19 business continuity measures after successfully handling the unprecedented operational challenges posed by the pandemic.



**May 17, 2023**

EMA publishes recommendations for industry on good practices to ensure continuity in the supply of human medicines, prevent shortages and reduce their impact.



**May 08, 2023**

EMA's Executive Director Emer Cooke shares her reflections on the end of the COVID-19 public health emergency and what this means for the Agency.



**May 03, 2023**

EMA opens a public consultation to review the transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System (CTIS) in the EU.



**April 24, 2023**

EMA publishes a statement by Executive Director Emer Cooke to mark European Immunization Week, which takes place every year in the final week of April.

**MAY 2023**



**May 30, 2023**

International Coalition of Medicines Regulatory Authorities (ICMRA) publishes a report highlighting the outcomes of their discussions on COVID-19 vaccines and the need for and strategy to update their composition based on the emerging evidence on coronavirus SARS-CoV-2 variants and lessons learned from previous vaccine updates.



**May 31, 2023**

The EU and the US make important progress towards enabling mutual recognition of inspections of manufacturing facilities of certain veterinary products.

**JUNE 2023**



**June 06, 2023**

The European Centre for Disease Prevention and Control (ECDC) and EMA issue a joint statement on adapted COVID-19 vaccines and considerations for their use during the autumn 2023 vaccination campaigns.



**June 22, 2023**

EMA publishes a report on pharmacovigilance tasks from EU Member States and EMA from 2019 to 2022.





**July 17, 2023**

The European Commission, the Heads of Medicines Agencies (HMA) and EMA issue recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the next winter season.



**July 19, 2023**

EMA publishes a draft reflection paper outlining the current thinking on the use of artificial intelligence to support the safe and effective development, regulation and use of human and veterinary medicines.



**July 06, 2023**

EMA, the European Commission and the Heads of Medicines Agencies (HMA) phase out the extraordinary regulatory flexibilities for medicines put in place during the COVID-19 pandemic to help address regulatory and supply challenges arising from the pandemic.

**July 05, 2023**

EMA joins with other regulators in ICMRA in a statement on the supporting the safety of COVID-19 vaccines.



**JULY 2023**



**June 22, 2023**

The Accelerating Clinical Trials in the EU (ACT EU) initiative organises the kick-off workshop for a new multi-stakeholder platform to improve clinical trials in the EU.



**June 23, 2023**

EMA publishes a report on the experience gained with regulator-led studies from September 2021 to February 2023.



**July 20, 2023**

EMA expands the scope of the OPEN initiative from COVID-19 vaccines and treatments to a wider range of medicines, such as medicines with the potential to address antimicrobial resistance (AMR), unmet medical needs such as respiratory syncytial virus (RSV) infections or newly diagnosed myelodysplastic syndromes (and other hereditary diseases).

**July 25, 2023**

EMA publishes a report from a workshop that collected insights and suggestions for possible EU-level actions to improve the way clinical trials are set up and conducted in Europe during public health emergencies.



## AUGUST 2023



**August 10, 2023**

Noël Wathion, EMA's former Deputy Executive Director who was at the forefront of the Agency's response when COVID-19 hit, shares his reflections on the steps and measures taken by EMA to fight the pandemic, and on how the Agency dealt with uncertainties.



**August 30, 2023**

EMA's human medicines committee (CHMP) recommends authorising an adapted Comirnaty vaccine targeting the Omicron XBB.1.5 subvariant.

## OCTOBER 2023



### **October 06, 2023**

EMA adopts revised transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System (CTIS).



### **September 15, 2023**

Over the past three years, EMA and the EUnetHTA 21 (European Network for Health Technology Assessment) consortium have delivered a number of milestones to prepare the EU for the entry into application of the Regulation on Health Technology Assessment. As of September 2023, EUnetHTA 21 ceased to operate, but preparations will continue for the implementation of the Regulation, under the direction of the HTA Coordination Group.



### **September 14, 2023**

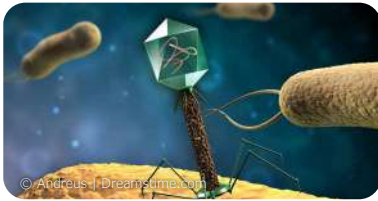
EMA's human medicines committee (CHMP) recommends authorising an adapted Spikevax vaccine targeting the Omicron XBB.1.5 subvariant.



### **September 12, 2023**

EMA and the US FDA mark 20 years working together to promote public and animal health and protect EU and US patients.

## SEPTEMBER 2023



**October 16, 2023**

EMA's Committee for Veterinary Medicinal Products (CVMP) adopts a guideline on quality, safety and efficacy of bacteriophages as veterinary products. The document aims to facilitate and guide the authorisation path of bacteriophage products.



**October 24, 2023**

EMA publishes details of the newly created solidarity mechanism developed by EMA Medicines Shortages Steering Group (MSSG). This voluntary mechanism allows Member States to support each other in the face of a critical medicine shortage.

**October 31, 2023**

EMA's human medicines committee (CHMP) recommends authorising an adapted Nuvaxovid vaccine targeting the Omicron XBB.1.5 subvariant of the SARS-CoV-2 virus.



## NOVEMBER 2023



**November 08, 2023**

The Heads of Medicines Agencies (HMA), the European Commission and EMA publish for the first time electronic product information (ePI) for selected human medicines harmonised across the EU.



**November 09, 2023**

Global regulators celebrate 10 years of strategic leadership and cooperation under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).



**December 05, 2023**

EMA relaunches its website with a refreshed overall look and feel.



**December 08, 2023**

Close collaboration between medicines regulators worldwide paves the way towards the development of a global Pharmaceutical Quality Knowledge Management System (PQ KMS).



**December 01, 2023**

The European medicines regulatory network (EMRN) issues a joint report, which reviews the Network's response and highlights the main learnings for any future health crises.

**DECEMBER 2023**



**November 20, 2023**

European countries have substantially reduced sales of veterinary antibiotics, which translates into a lower risk of bacteria becoming resistant in people and animals, according to the thirteenth annual report on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC).



**December 12, 2023**

The European Commission, the Heads of Medicines Agencies (HMA) and EMA publish the first version of the Union list of critical medicines to help avoid potential shortages in the EU.



**December 18, 2023**

EMA and the Heads of Medicines Agencies (HMA) publish an AI workplan to 2028.



**December 19, 2023**

EMA's Executive Director looks back at 2023 and takes stock of the Agency's work throughout the year.



**December 20, 2023**

The midterm report of the European Medicines Agencies Network Strategy highlights good progress during a critical period of the pandemic.

# CHAPTER 2

## Key figures in 2023

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

The chapter covers: marketing authorisation and safety monitoring of medicines for human and veterinary use; inspections and compliance; medical devices; the European medicines regulatory network, stakeholders, administration and communication. A more detailed overview of figures presenting EMA's activities in 2023 will be made available in the Agency's annual activity report.



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# Human medicines

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

## Supporting research and development

### Scientific advice

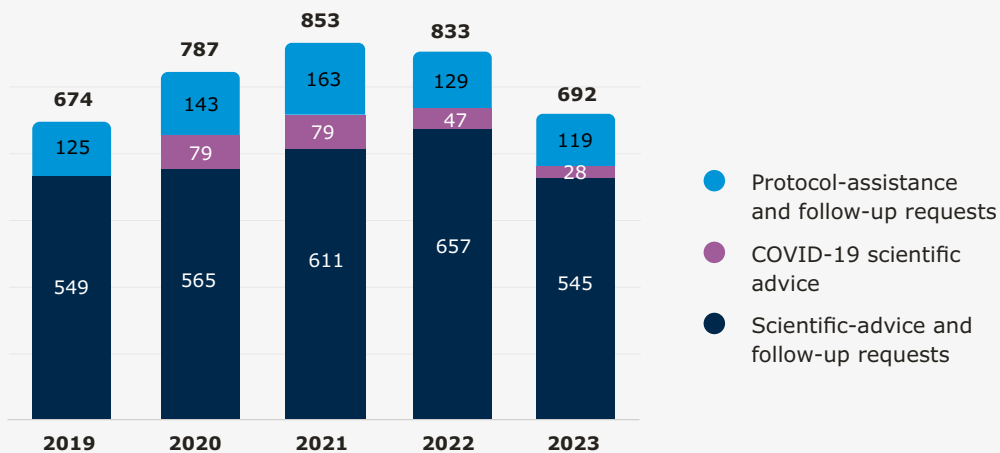
During a medicine’s development, a developer can request guidance and direction from EMA on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. This is known as scientific advice.

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

In 2023, EMA received a total of 573 requests for scientific advice. Among these, 28 were for COVID-19 medicines or vaccines. The Agency received 38 requests for scientific advice for PRIority Medicines (PRIME) products in 2023, a similar number to 2022.

Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases. The requests for protocol assistance decreased by 8 %, from 129 requests in 2022 to 119 in 2023.

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



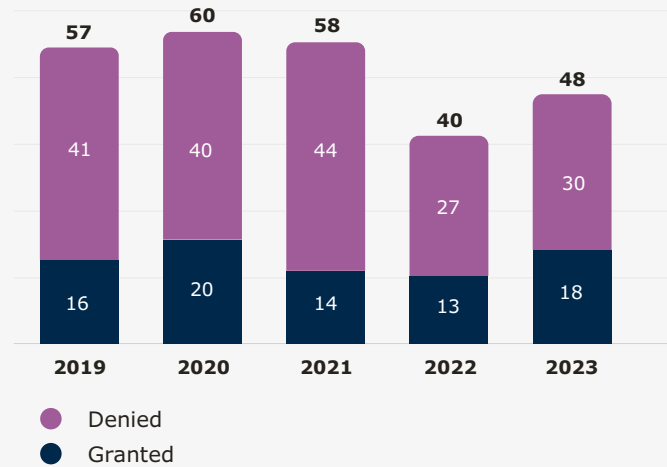
## PRIME

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 enable them to live healthier lives. In 2023, EMA received 52 PRIME eligibility requests, 16 % more than in 2022, and adopted 48 recommendations, 20 % more than in 2022.

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 2023 was 37.5 %, or 18 out of 48 recommendations.

Three PRIME-designated medicines were recommended for approval (Casgevy, Elrexio and Talvey).

### PRIME - eligibility recommendations



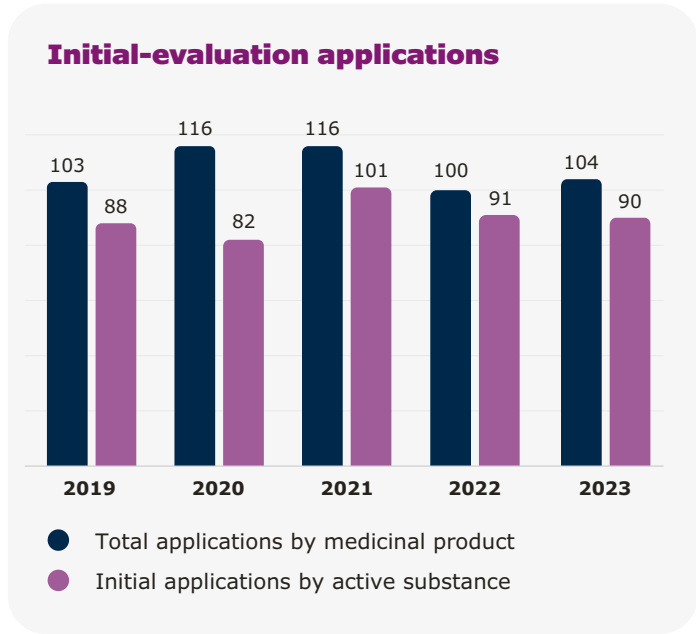
# Recommendations for marketing authorisation

## Applications for initial evaluation



EMA's scientific committees carry out robust scientific evaluations of medicines and issue recommendations for the European Commission, which ultimately decides whether or not to authorise a medicine for marketing throughout the EU.

The initial evaluation covers all activities relating to the processing of marketing authorisation applications for new medicines which have never been authorised before, from the pre-submission discussion with future applicants, through to the evaluation by the CHMP and the granting of the marketing authorisation by the European Commission.

A total of 104 applications were received in 2023.









Outcome of initial evaluation<sup>2</sup>

Therapeutic area/ Product name	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
 <b>Cancer</b>									
Akeega									
Azacididine Kabi						•			
Columvi	•		•					•	
Degarelix Accord						•			
Elrexio	•	•						•	
Enrylaze									
Finlee			•						
Herwenda					•				
Inaqovi	•								
Jaypirca	•							•	
Krazati	•							•	
Lytgobi	•							•	
Mevlyq						•			
Naveruclif						•			
Omjjara	•		•						
Orserdu	•								
Pedmarqsi									
Pomalidomide Viatris						•			
Spexotras			•						
Talvey	•	•	•				•	•	
Tepkinly	•		•					•	
Tevimbra <sup>3</sup>	•		•						
Tibsovo	•		•						
Tidhesco <sup>4</sup>									
Vanflyta	•								
 <b>Cardiovascular</b>									
Aqumeldi									
Camzyos	•								
Dabigatran Etxilate Accord						•			
Dabigatran Etxilate Leon Farma						•			
Ibuprofen Gen.Orph						•			
Qaialdo									







<sup>2</sup> Some medicines might fall into more than one therapeutic area but have been reflected only in one.

<sup>3</sup> The orphan status was removed after authorisation at the request of the marketing authorisation holder.

<sup>4</sup> Duplicate of Tibsovo. The marketing authorisation application was withdrawn after the positive CHMP opinion.

Therapeutic area/ Product name	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
 <b>Dermatology</b>									
Ebglyss	•								
Hyftor			•						
Opzelura									
Litfulo	•								
Sotyktu	•								
 <b>Diagnostic agents</b>									
Elucirem	•								
Pylclari	•								
Vueway <sup>5</sup>									
 <b>Endocrinology</b>									
Dapagliflozin Viatris						•			
Sitagliptin/Metformin hydrochloride Sun						•			
Tolvaptan Accord						•			
Yorvipath	•		•						
Veozza	•								
 <b>Gastroenterology/ Hepatology</b>									
Omvoh	•								
Velsipity	•								
 <b>Haematology/ Haemostaseology</b>									
Bekemv					•				
Casgevy	•	•	•	•				•	
Épysqli					•				
Jesduvroq	•								
Vafseo	•								
 <b>Immunology/ Rheumatology/ Transplantation</b>									
Tyenne					•				
Uzpruvo					•				

<sup>5</sup> Duplicate of Elucirem

Therapeutic area/ Product name	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assessment	Conditional approval	Exceptional circumstances
 <b>Infections</b>									
Apretude									
Rezzayo	•		•						
 <b>Metabolism</b>									
Elfabrio									
Loargys	•		•						
Opfolda									•
 <b>Neurology</b>									
Agamree	•		•						
Aquipta	•								
Briumvi	•								
Lacosamide Adroiq						•			
Rystiggo	•		•						
Skyclarys	•		•						
Sugammadex Adroiq						•			
Sugammadex Piramal						•			
Tyruko					•				
Zilbrysq	•								
Ztalmy	•		•						
 <b>Ophthalmology</b>									
Catiolanze									
Rimmyrah					•				
Yesafili					•				
 <b>Pneumology/Allergology</b>									
Lyfnua	•								
 <b>Vaccines</b>									
Abrysv0	•						•		
Arexvy	•						•		
Bimervax	•								
Zoonotic Influenza Vaccine Seqirus									

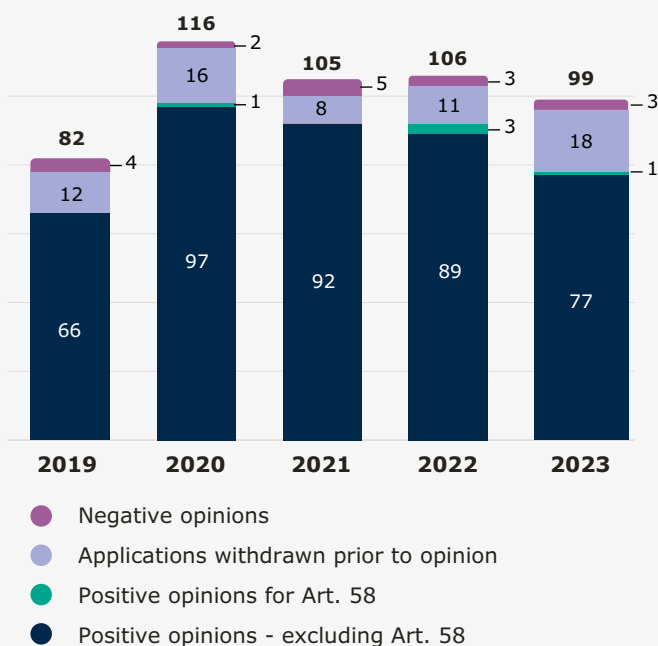
In 2023, EMA recommended 77 medicines for marketing authorisation. Of these, 39 had a new active substance which had never previously been authorised in the EU.

The CHMP adopted negative opinions for three medicines in 2023:

- **Albrioza**, for the treatment of amyotrophic lateral sclerosis, a rare neurological disease affecting nerve cells in the brain and spinal cord that control voluntary muscle movement;
- **Lagevrio**, for the treatment of COVID-19 in adults; and
- **Sohonos**, to treat fibrodysplasia ossificans progressiva, a rare genetic disease that causes extra bone to form in places outside the skeleton, such as in joints, muscles, tendons and ligaments, leading to progressively decreasing mobility and other severe impairments.

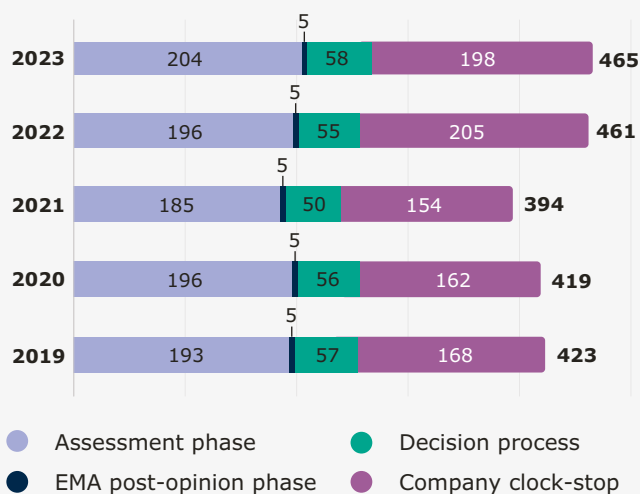
The applications for 18 medicines were withdrawn by the applicants prior to the CHMP adopting an opinion, in most cases because the data included in the application were insufficient to support a marketing authorisation.

### Outcome of initial-evaluation applications



Applicants for 67 % of the medicines granted a positive opinion by the CHMP in 2023 had received scientific advice during the development phase of their medicine. The figure rises to 88 % for medicines with a new active substance.

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



### Average assessment time

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

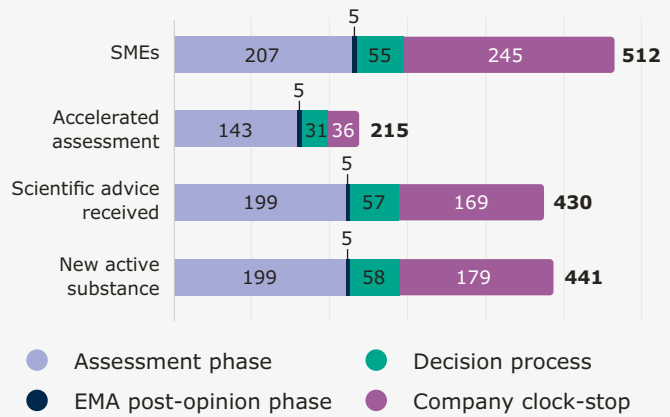
Once issued, the CHMP opinion is transmitted to the European Commission, which has the ultimate authority to grant a marketing authorisation and will take a decision within 67 days of receipt of the CHMP opinion.



The overall total time required for the centralised procedure, from start of the evaluation process to the adoption of a decision by the European Commission, was an average of 465 days in 2023, similar to 2022 (461 days). The overall total time for medicines that had received scientific advice was 430 days.

For medicines evaluated under accelerated assessment, the total time from start of assessment until granting of authorisation was reduced by more than 8 months (from 465 to 215 days), potentially facilitating the subsequent decision-making steps at a national level and, ultimately, patient access.

**Average number of days for centralised procedure - subset (2023)**



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

**Post-authorisation activities**

In 2023, the CHMP gave 77 positive recommendations for extension of the therapeutic indication of already authorised medicines. These included 38 medicines for paediatric use<sup>6</sup>.

The product information for 387 authorised medicines was updated as new safety data were made available and assessed by EMA.

<sup>6</sup> Most paediatric extensions of indication are based on the results of clinical studies agreed in the medicine's paediatric investigation plan (PIP).



# Safety monitoring of medicines

EMA and EU Member States are responsible for coordinating the EU’s safety monitoring of medicines, also known as pharmacovigilance. The regulatory authorities constantly monitor the safety of medicines and can take action on an indication 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 as it covers 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.

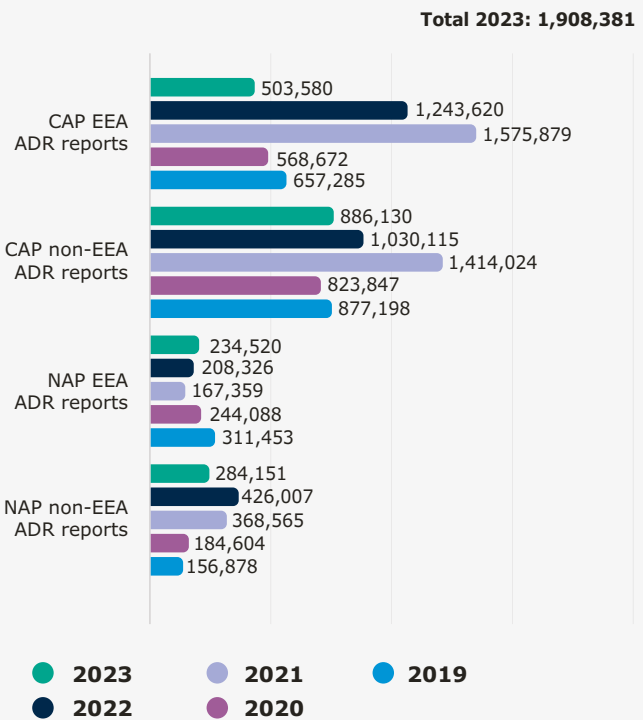
Over 1.9 million ADR reports were submitted to EudraVigilance in 2023, representing a substantial decrease (34 %) compared with 2022.

Over 60 % of all reports in EudraVigilance originated outside the EEA.

The share of reports submitted by European patients and consumers in 2023 also decreased considerably compared to 2021 and 2022, and is more in line with pre-pandemic figures.

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

### EEA and non-EEA ADR reports received



## Signal detection

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

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

In 2023, 1,364 potential signals were reviewed by EMA, a decrease of 15 % compared to 2022. Approximately 74 % of these signals originated from monitoring the EudraVigilance database, highlighting its central role for safety monitoring. The PRAC assessed 71 signals and, of these, EMA validated 39. The number of signals validated by Member States and assessed by the PRAC increased to 32, from 25. In addition to signal detection activities and assessments at PRAC level, experts from the NCAs, in collaboration with EMA, provided a major contribution to the development of signal detection methods and continuous process improvement.

## Periodic safety update reports (PSURs)

Marketing authorisation holders are required to submit a report on the evaluation of a medicine's benefit-risk balance to the regulatory authorities at regular, predefined intervals following the authorisation of a medicine. These reports summarise data on the benefits and risks of a medicine and take into consideration all studies carried out with it, both in authorised and unauthorised indications.

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

## Outcome of signal assessment

**1,364 potential signals reviewed by EMA**



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

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



**Out of 71 confirmed signals**

- 19 signals led to a product information update;
- 13 signals led to a recommendation for routine pharmacovigilance; and
- 39 signals were undergoing review by the PRAC at the end of 2022 as further data were required.

**PSURs and PSUSAs finalised**

	2019	2020	2021	2022	2023
PSURs - standalone (CAPs only) finalised	558	516	575	542	570
PSURs - single assessment finalised	270	258	336	318	276
PSURs - single assessment (CAPs with NAPs) finalised	48	49	49	46	37
PSURs - single assessment (NAPs only) finalised	222	209	287	272	239
<b>Total outcomes</b>	<b>828</b>	<b>774</b>	<b>911</b>	<b>860</b>	<b>846</b>

**PRAC outcomes of PSURs and PSUSAs**

	2019	2020	2021	2022	2023
<b>Maintenance</b>	<b>655</b>	<b>630</b>	<b>748</b>	<b>720</b>	<b>718</b>
NAPs only	166	161	226	216	196
CAPs/NAPs and CAPs only	489	469	522	504	522
<b>CHMP variation</b>	<b>173</b>	<b>144</b>	<b>163</b>	<b>140</b>	<b>128</b>
NAPs only	56	48	61	56	43
CAPs/NAPs and CAPs only	117	96	102	84	85
<b>Total outcomes</b>	<b>828</b>	<b>774</b>	<b>911</b>	<b>860</b>	<b>846</b>

# Veterinary medicines

In 2023, EMA's work across the veterinary medicines lifecycle helped to guide innovative treatments to market that protect and prevent the transmission of diseases in the EU. The Agency supports developers at every stage of the veterinary medicines development: helping to boost innovation and research by offering expertise before, during and after marketing authorisation. This begins at the earliest stage of the medicine development process and continues throughout the lifecycle of the medicine.

## Activities supporting research and development

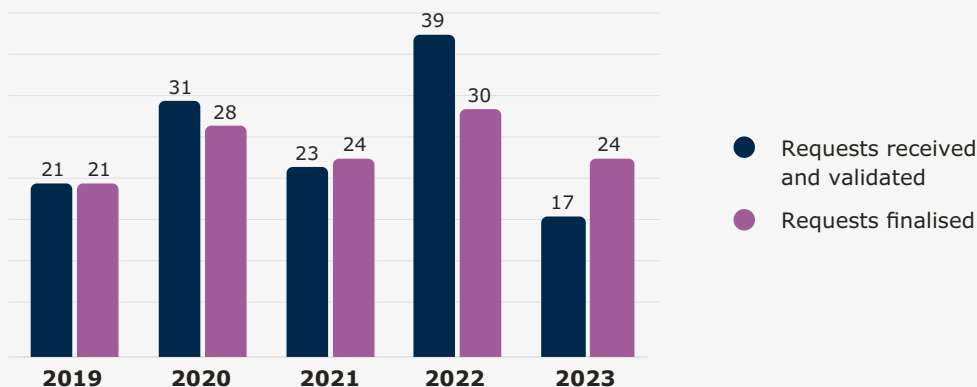
### Scientific advice

EMA offers scientific advice to companies on the appropriate tests and studies in the development of a veterinary medicine. This aims to facilitate the development and availability of high-quality, effective and acceptably safe medicines. In 2023, EMA received 17 requests for scientific advice and finalised 24. Almost a quarter of the finalised scientific advice requests were for immunologicals, 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 AMR.

In 2023, there was continued strong interest in early engagement with EMA by companies developing medicines for small markets in the EU. The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) introduced a specific authorisation route for medicines intended for veterinary limited markets in the EU when it

### Scientific-advice requests received and finalised



became applicable on 28 January 2022. It enables the CVMP to recommend granting a marketing authorisation for such medicines based on less comprehensive data than normally required, where the benefit for animal or public health of placing the medicine on the market is greater than the

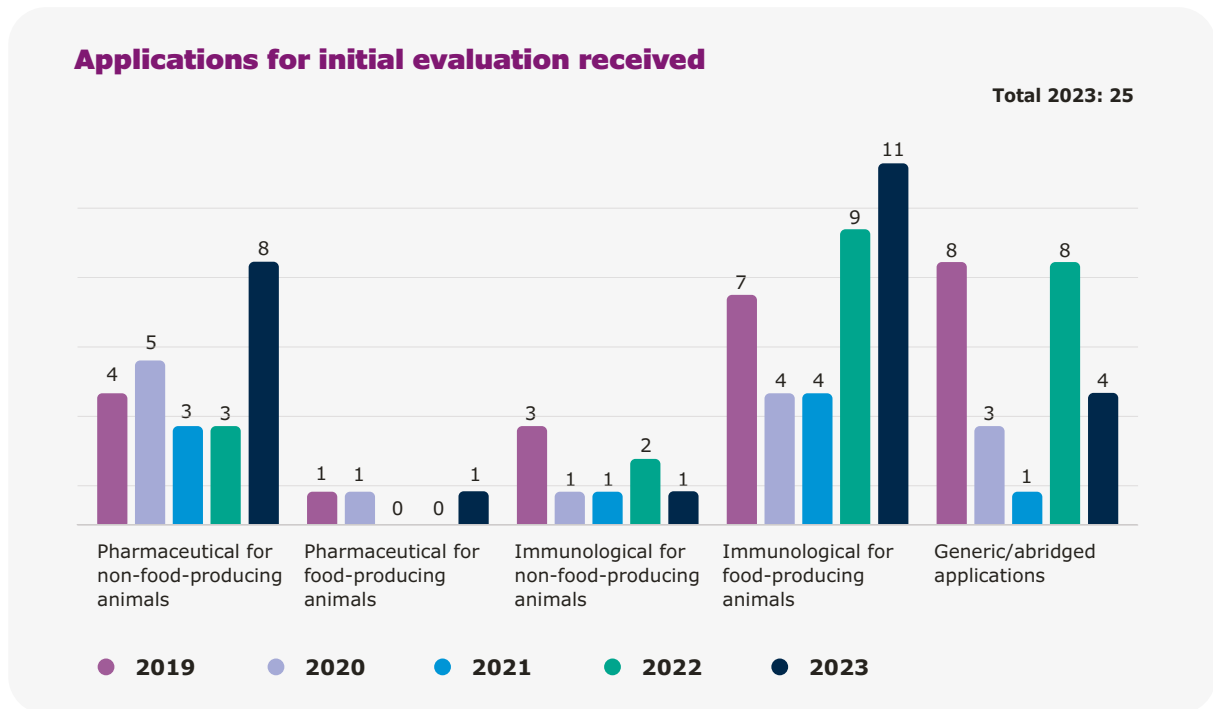
inherent risk of a reduced data package on the medicine. The Regulation aims to further stimulate the development of veterinary medicines for small markets, in order to increase the availability of treatments for serious or life-threatening animal diseases and unmet veterinary medical needs.

## Recommendations for marketing authorisation

### Applications for initial evaluation

The initial evaluation phase covers activities relating to the processing of marketing authorisation applications for veterinary medicines, ranging from pre-submission meetings with future applicants, through evaluation by the CVMP to the granting of marketing authorisation by the

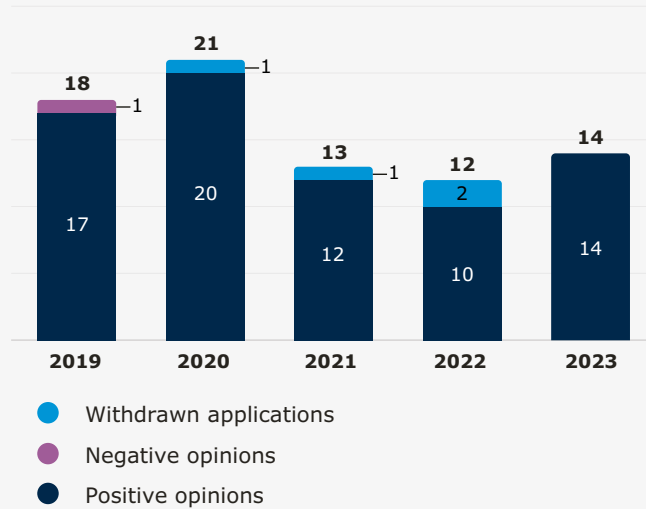
European Commission. A total of 25 applications were received in 2023, an increase of 14 % compared to 2022. Approximately half of these applications were submitted for vaccines, 11 of which were for use in food-producing animals.



## Recommendations for authorisation

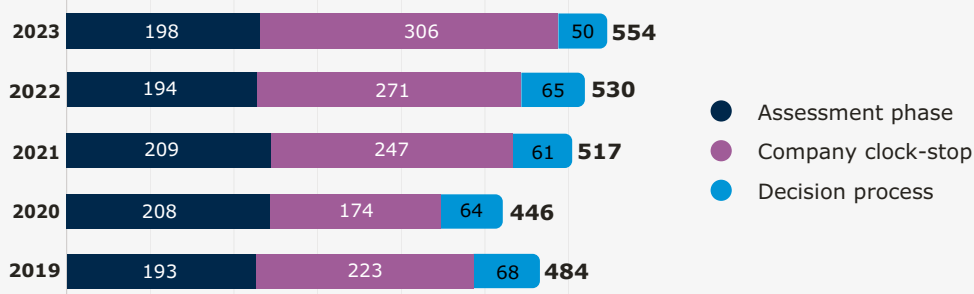
In 2023, EMA recommended 14 veterinary medicines for marketing authorisation. Of these, nine had a new active substance which had not previously been authorised in the EU – a threefold increase compared to 2022. Among the 14 medicines recommended for marketing authorisation, nine were vaccines, six of which had been developed by means of a biotechnological process. This demonstrates the animal health industry’s continued strong interest in innovation and developing vaccines.

### Outcome of initial-evaluation applications



Product name	New active substance	Cattle	Cats	Chickens	Dogs	Rabbits
Bovilis Cryptium	•	•				
Bovilis Nasalgen-C	•	•				
Eluracat	•		•			
Eurican L4	•				•	
Innovax-ILT-IBD	•			•		
Loxitab					•	
Newflend ND H9	•			•		
Nobivac LoVo L4					•	
Oxmax	•				•	
Poulvac Procerta HVT-IBD				•		
Prevexxion RN+HVT				•		
Prolevare					•	
Senvelgo	•		•			
YURVAC RHD	•					•

### Average number of days for initial authorisations



The average number of days taken for initial evaluations increased compared to previous years,

mostly due to longer clock-stops taken by the companies to respond to questions from CVMP.

## Post-authorisation activities

Post-authorisation activities relate to variations, extensions and transfers of marketing authorisations.

The use of an already-authorised medicine in a new species or a new indication offers new treatment opportunities. The use of eight known products was expanded in 2023.

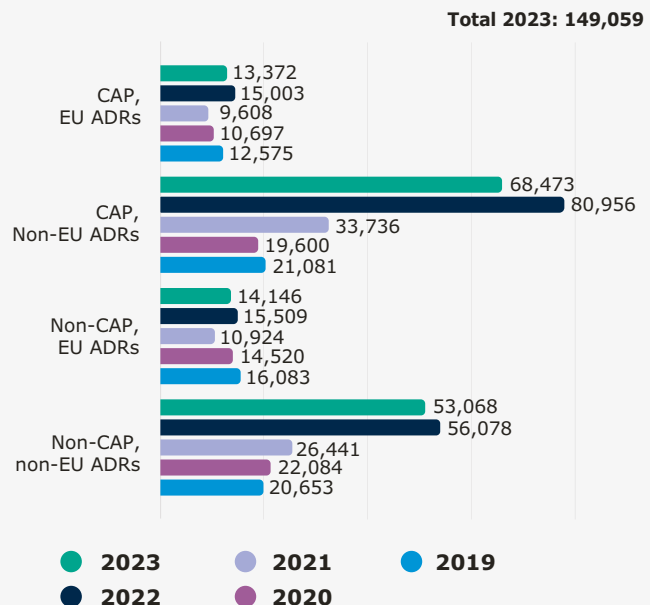
## Safety monitoring of medicines

Pharmacovigilance covers activities related to the detection, reporting, assessment, understanding and prevention of adverse events (AEs) 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 both serious and non-serious AE reports. In 2023, the overall number of AE reports received in the EudraVigilance system was slightly lower than 2022, when a backlog of reports was submitted by marketing authorisation holders.

### Adverse event reports in animals





# Inspections and compliance

In the European medicines regulatory network, the responsibility for carrying out inspections rests with EU NCAs, but EMA plays an important role.

The Agency coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP), good pharmacovigilance practices (GVP) and certain aspects of the supervision of authorised medicinal products in the EU. The main verification tool is inspections. Some are carried out routinely, while others are triggered by request of the CHMP or CVMP in the context of the assessment of marketing authorisation applications and/or matters referred to these committees in accordance with EU legislation.

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

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

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

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

# Inspections

GMP, GCP, GLP and pharmacovigilance inspections requested by the CHMP or CVMP for medicines that are subject to centralised authorisation procedures take place worldwide. However, they represent

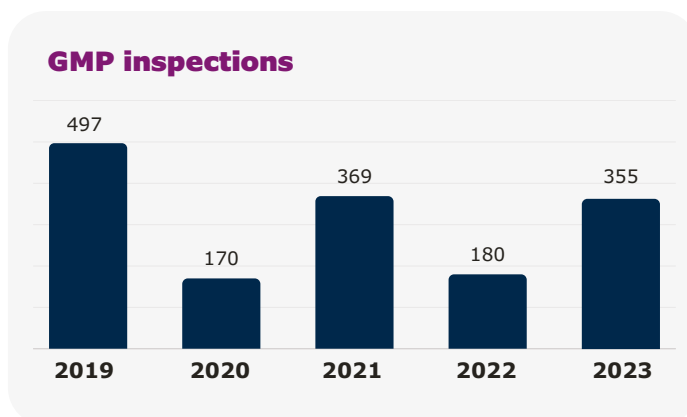
just a small part of the total number of inspections performed by the EU/EEA inspectors, who also carry out inspections as part of their national programmes.

## GMP inspections

The number of GMP inspection requests in 2023 rose to levels comparable to those of 2021.

Seven GMP inspections conducted by EEA authorities led to the issuing of a non-compliance statement. Medicines manufactured at a site with such a non-compliance statement cannot be sold in the EU.

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



## GMP certificates and non-compliance statements issued by EEA authorities

	2019		2020		2021		2022		2023	
	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	2,235	11	1,695	1	1,825	5	1,730	2	1,857	2
China	51	4	11	0	24	0	15	0	44	
India	105	1	64	0	29	0	81	2	101	4
USA	127	0	35	0	52	0	118	0	155	
Rest of the world	108	0	38	0	52	0	187	2	231	1
<b>Total</b>	<b>2,626</b>	<b>16</b>	<b>1,843</b>	<b>1</b>	<b>1,982</b>	<b>5</b>	<b>2,131</b>	<b>6</b>	<b>2,388</b>	<b>7</b>

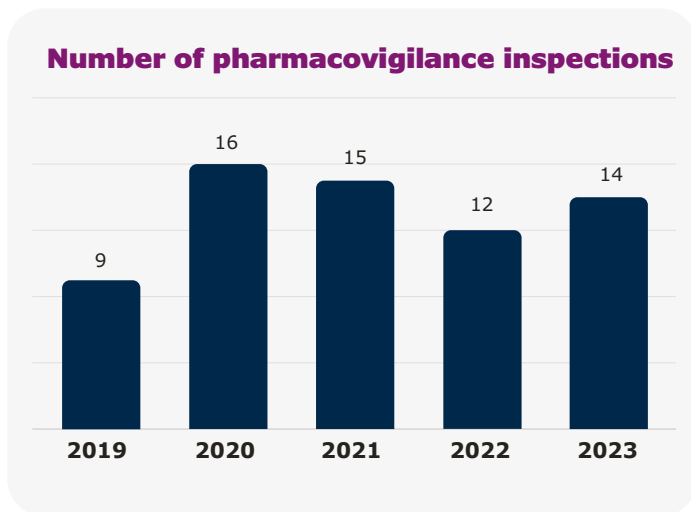
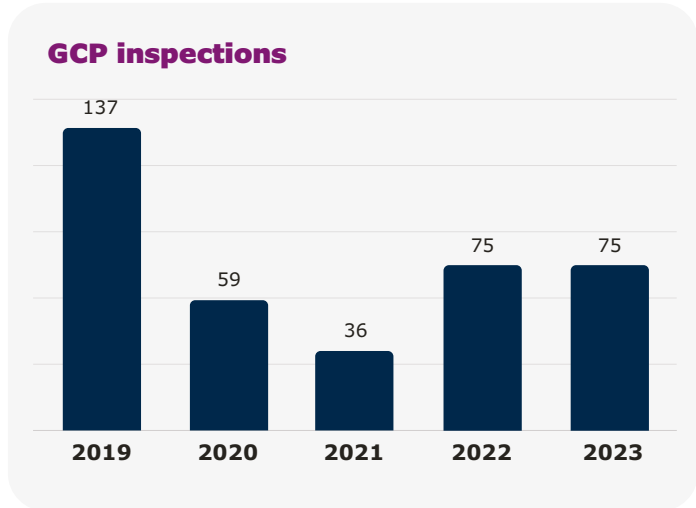
Note: This table shows the number of GMP certificates and non-compliance statements issued by EEA authorities as an outcome of GMP inspections conducted between 2019 and 2023. It includes GMP inspections requested by the CHMP or the CVMP.

## GCP inspections

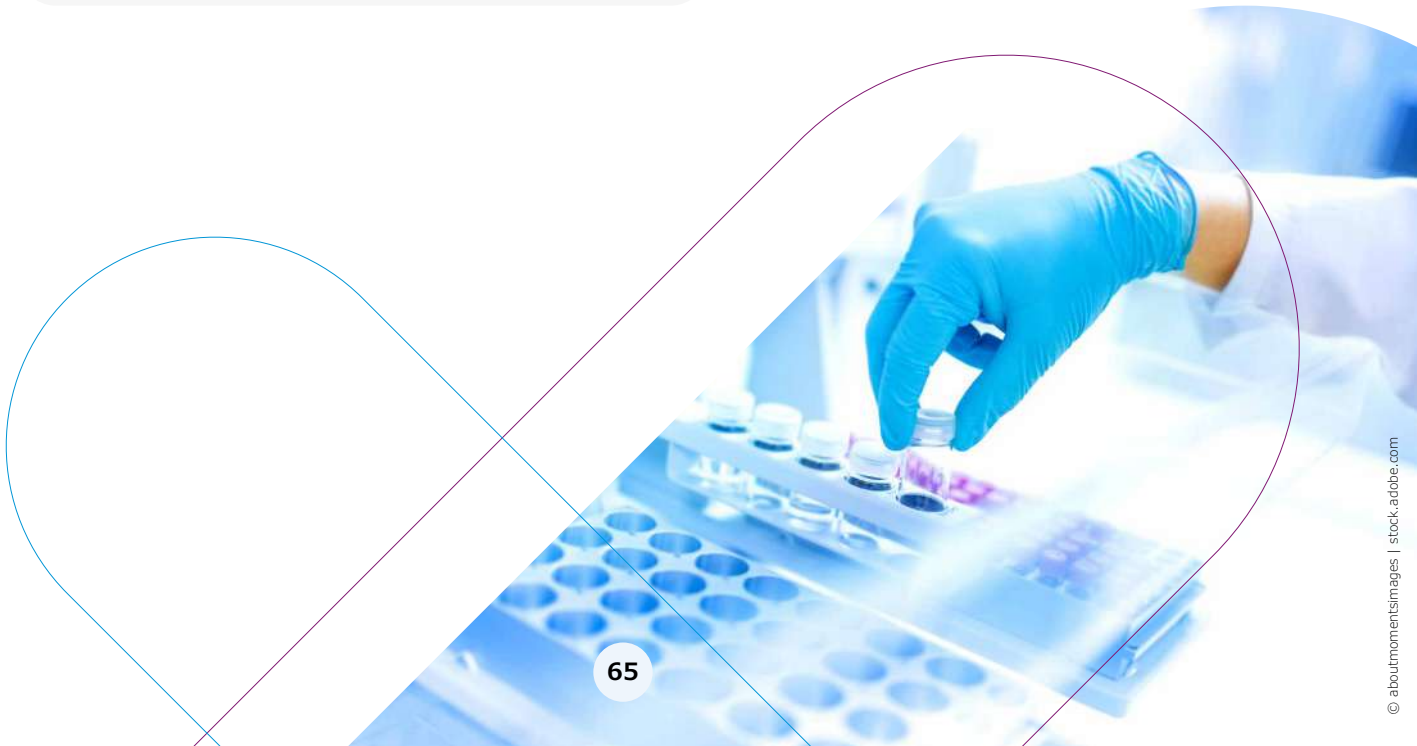
The number of GCP inspections is 75, exactly the same as in 2022. These activities are not yet back to the levels recorded before the pandemic.

## Pharmacovigilance inspections

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



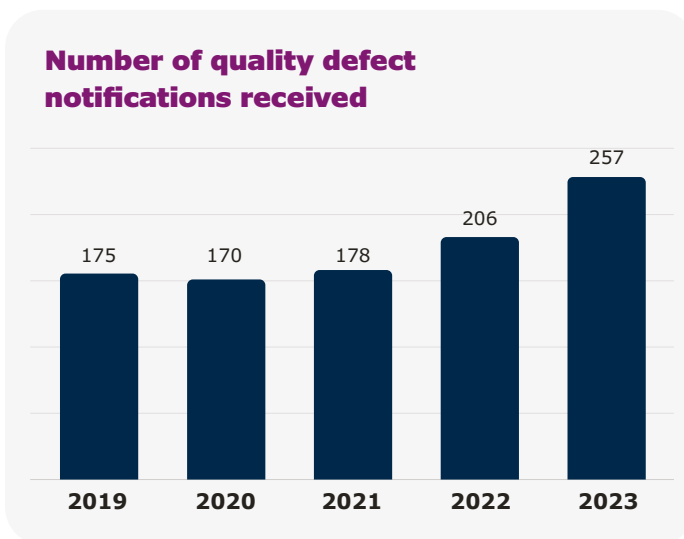
In 2023, 14 pharmacovigilance inspections were requested by the CHMP or CVMP. Most EU/EEA pharmacovigilance inspections (over 90 %) are conducted under the national pharmacovigilance inspection programmes, which relate to marketing authorisation holders with product authorisations of all types (including CAPs).



# Market surveillance and quality defects

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

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



In 2023, the Agency received 257 suspected quality defect notifications, the highest number recorded in recent years. Of these, 188 cases were confirmed quality defects and led to batch recalls of 9 CAPs.

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

\*1 recall not classified

The main reasons for recall of CAPs in 2023 included:

**Manufacturing laboratory control issues** include out-of-specification results obtained during quality control testing.

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

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

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

**Product physical issues** 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

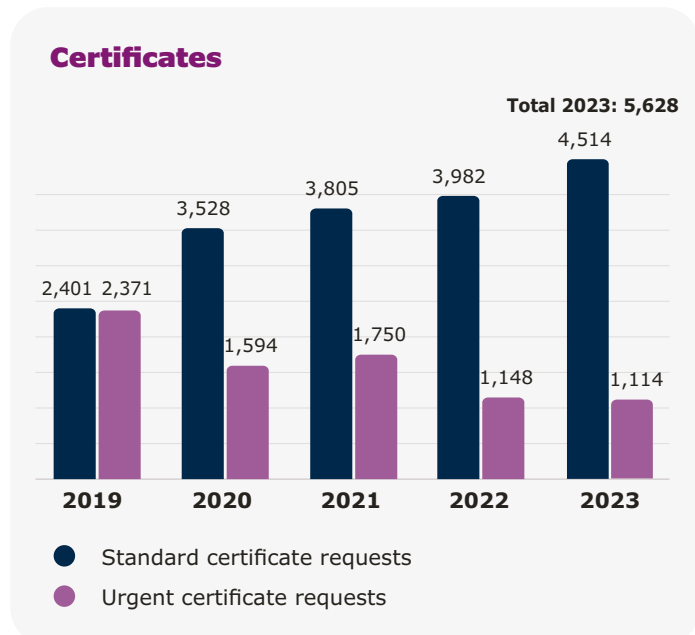
independent of the marketing authorisation holder is compliant with the rules.

### Parallel distribution notifications received

	2019	2020	2021	2022	2023
Initial notifications	2,468	3,172	2,555	1,816	2,092
Notifications of bulk change	12	10	19	32	21
Annual updates	4,270	11,624	4,816	5,509	5,477
<b>Total</b>	<b>8,853</b>	<b>14,806</b>	<b>7,390</b>	<b>7,357</b>	<b>7,590</b>

## Certificates

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



# Medical devices

In the EU, medical devices must undergo assessments to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. They are regulated at EU Member State level, but EMA, through panels of experts in medical devices, is involved in the regulatory process for some types of devices.

For certain high-risk devices, EU legislation requires notified bodies to consult the expert panels before issuing a CE certificate.

These high-risk medical devices 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 should be provided on the clinical evaluation assessment report.

48 applications for CECP were screened in 2023, over 60 % more than in 2022. The screening experts decided that an opinion was needed for one of these CECP applications.

When it comes to PECPs, in 2023 expert panels issued opinions for two applications.

In addition, **EMA is running a pilot** that enables the expert panels to provide scientific advice for manufacturers of high-risk medical devices. In 2023, three such procedures were finalised.

In line with EU legislation, the expert panels provide advice to the **Medical Device Coordination Group (MDCG)**, which finalised three advice procedures in 2023.

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

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

# European medicines regulatory network

The European medicines regulatory network is the cornerstone of EMA's work and success. EMA operates at the heart of this network, coordinating and supporting interactions between over 50 national competent authorities in the EU and the EEA for both human and veterinary medicines.

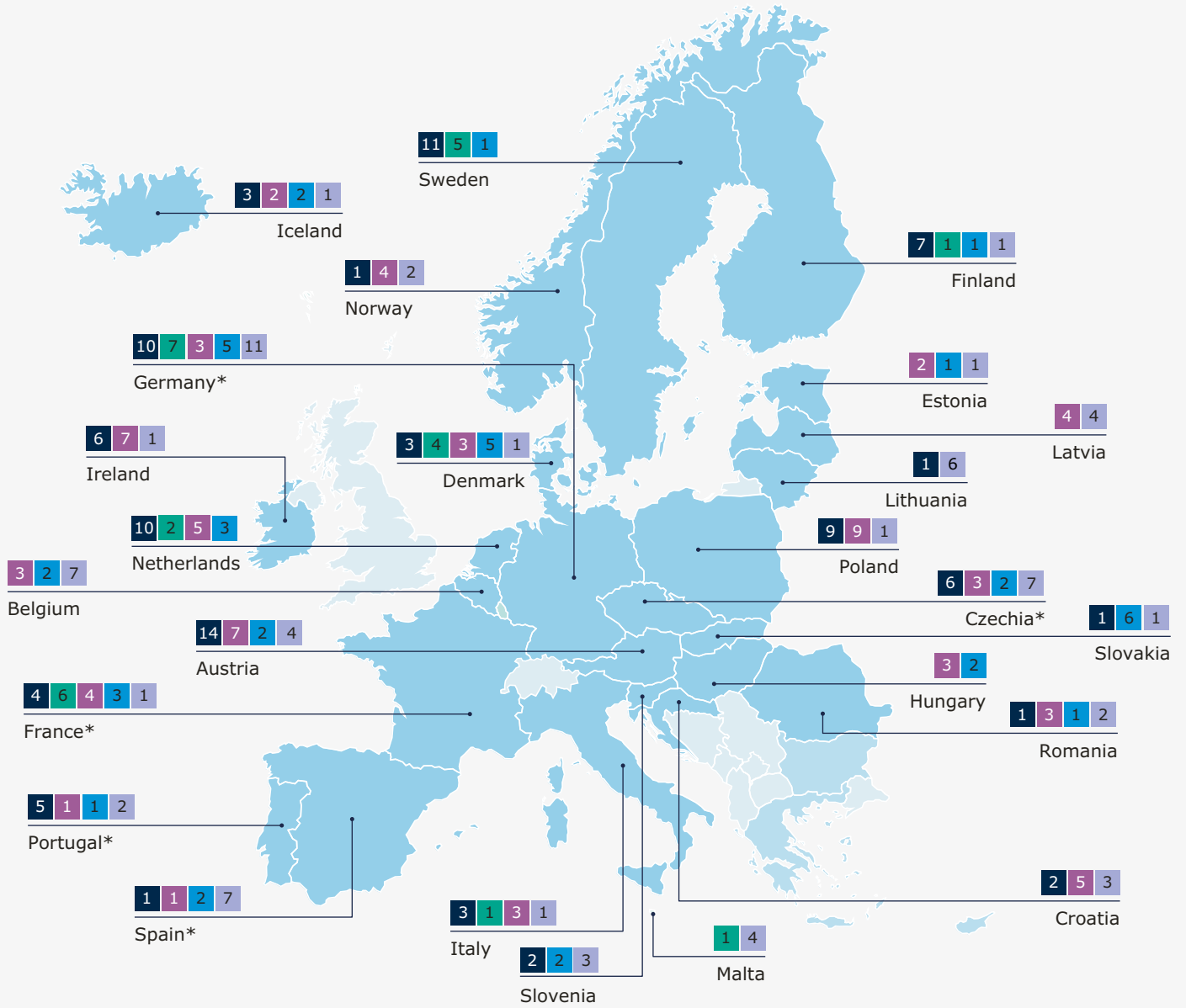
The network gives EMA access to a pool of over 4,000 experts, who provide the best available scientific expertise for the regulation of medicines in the EU by participating in EMA's scientific

committees, working parties and other groups as well as members of the assessment teams carrying 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.

**CHMP rapporteurs/co-rapporteurs appointed in 2023**  
 (for initial marketing authorisation applications, including generics)



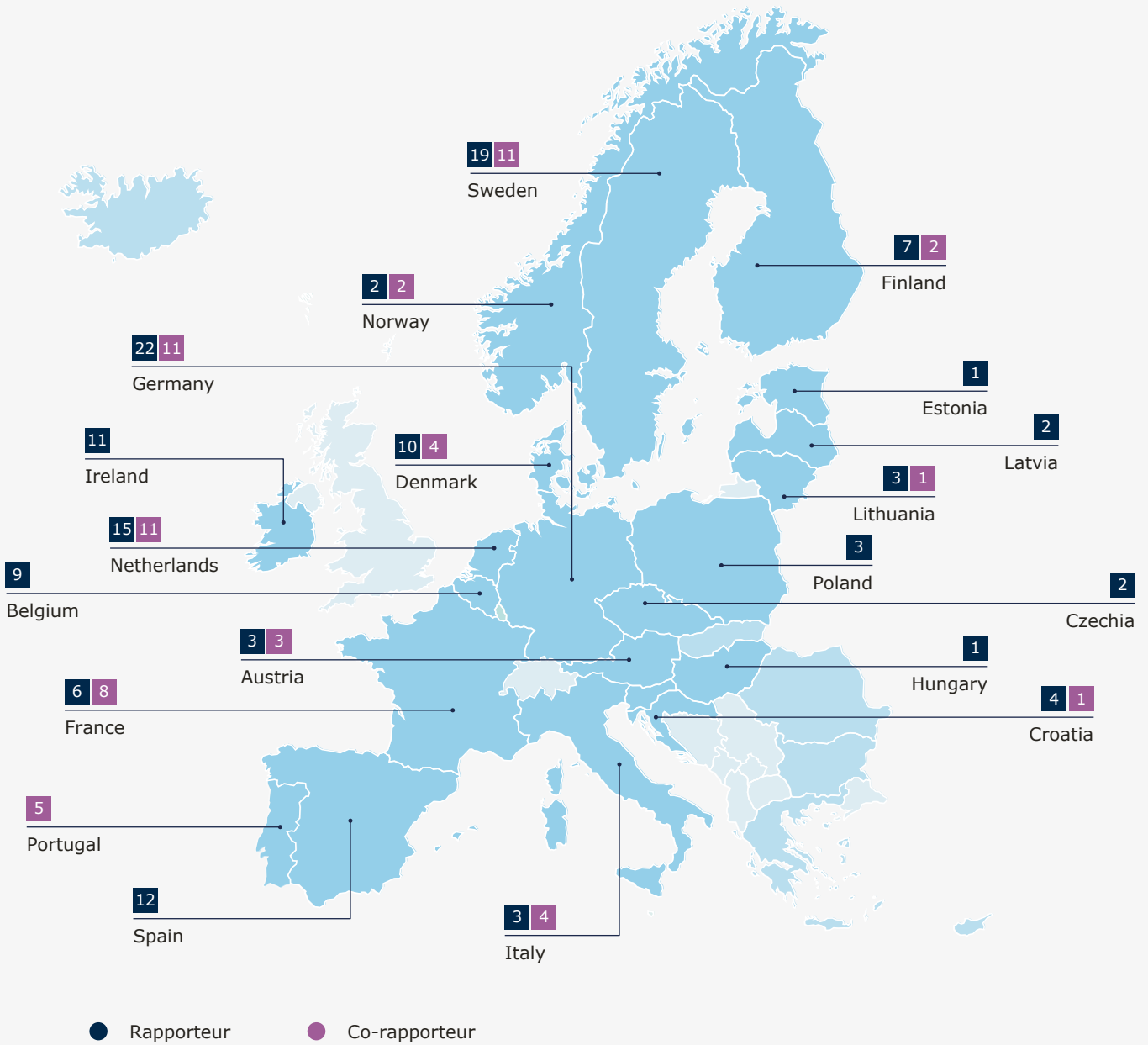
- Rapporteur Regular
- Co-rapporteur Regular
- Rapporteur Multinational team
- Co-rapporteur Multinational team
- Assessors Multinational team

\* co-opted members included under the country of affiliation/provenance

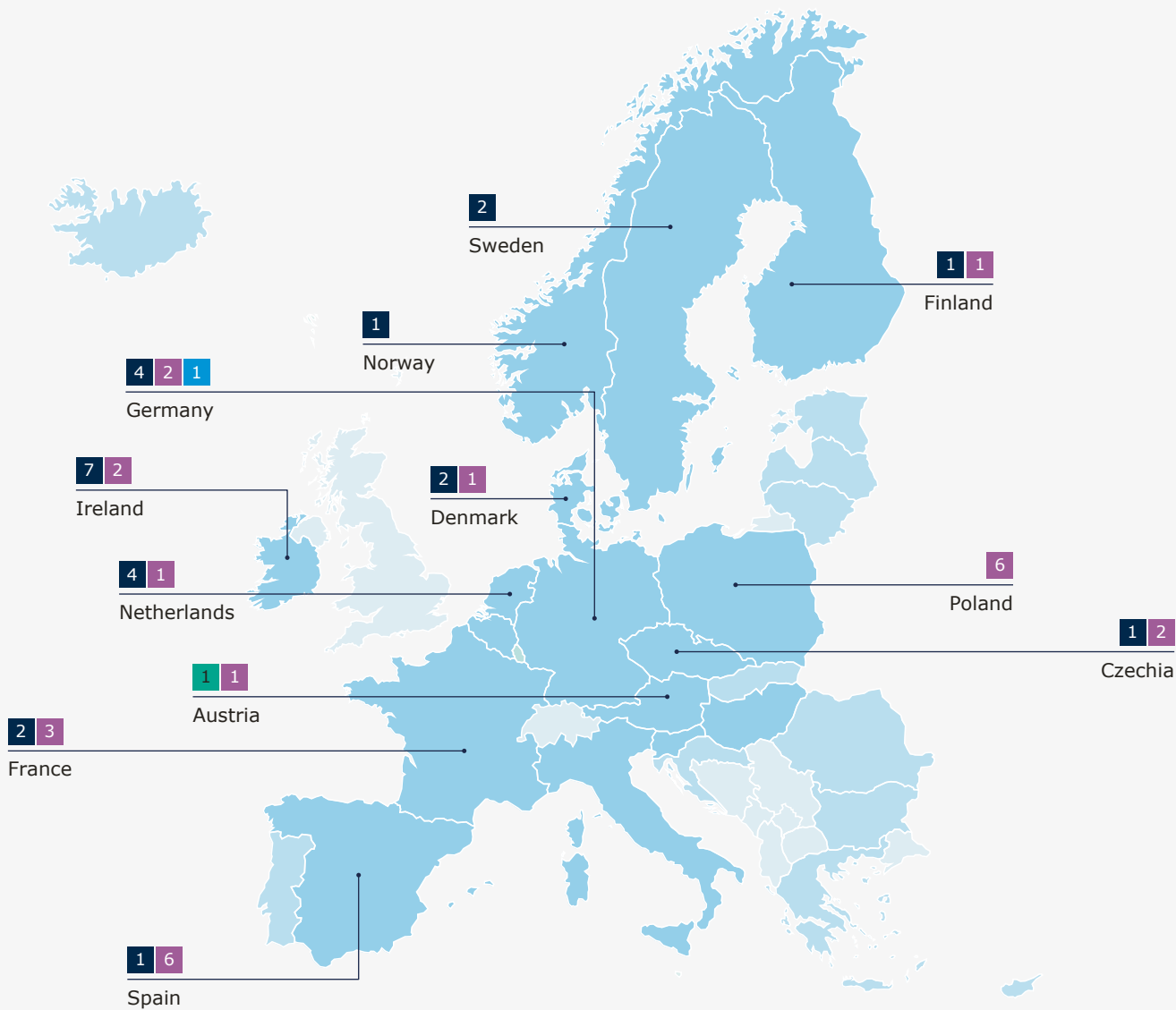


**PRAC rapporteurs/co-rapporteurs appointed in 2023**

(for initial marketing authorisation applications)



**CVMP rapporteurs/co-rapporteurs appointed in 2023**  
 (for initial marketing authorisation applications, including generics)



● Rapporteur Regular  
 ● Co-rapporteur Regular  
 ● Rapporteur Multinational team  
 ● Co-rapporteur Multinational team

# Communication and stakeholders

Access to and promotion of clear and accurate information on medicines to our audiences and stakeholders, including patients, healthcare professionals, researchers, academia, industry and citizens, is part of EMA's public health mandate. We collaborate extensively with our regulatory partners and our stakeholders across the EU and at international level. Additionally, we publish articles in relevant journals and regularly engage with international, local and specialist media on a wide range of topics related to medicines regulation.

## External communication

In 2023, EMA published 124 press releases and news items informing our audiences in the EU and beyond about important developments in relation to the assessment of medicines or significant milestones reached in new and existing initiatives. We continued our interaction with journalists by replying to 1,242 requests for comments and interviews.

As our primary communication channel, the EMA website is a comprehensive source of information and guidance on centrally authorised medicines and medicine regulation in the EU. In 2023,

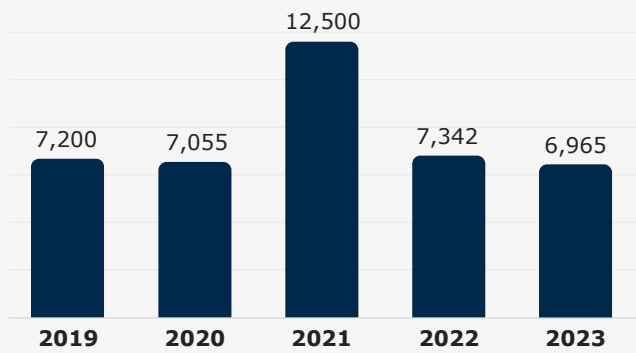
we published and updated 5,105 webpages and published 6,611 documents on the EMA website.

Furthermore, we extended our activities on social media and piloted creative approaches to reach new audiences. By the end of 2023, we had shared 1,016 posts and 24 videos on our social media channels.

EMA's staff and experts published 80 articles on scientific and regulatory topics in international journals.

# Requests for information and access to documents

## Requests for information received

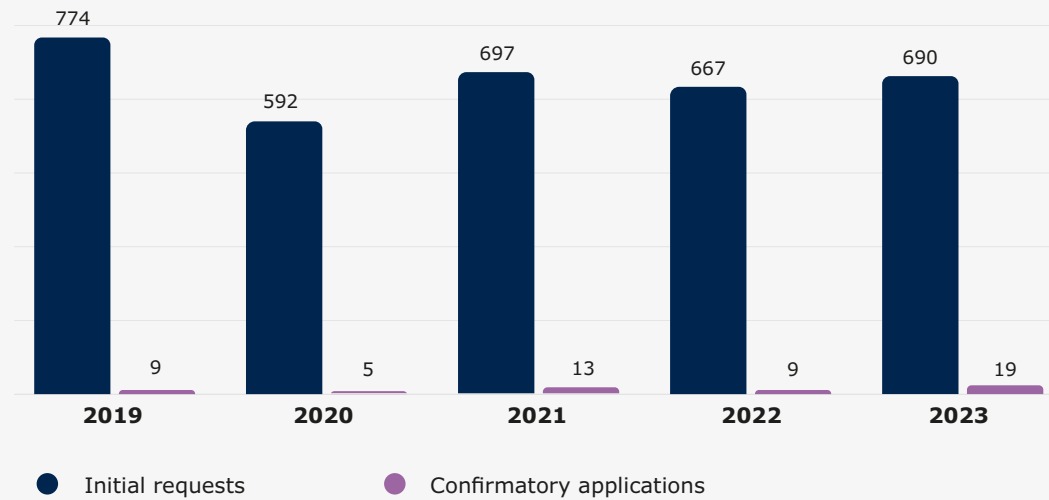


Providing citizens with good, transparent information about its work is a key part of EMA's work. In 2023, 6,965 requests for information were received.

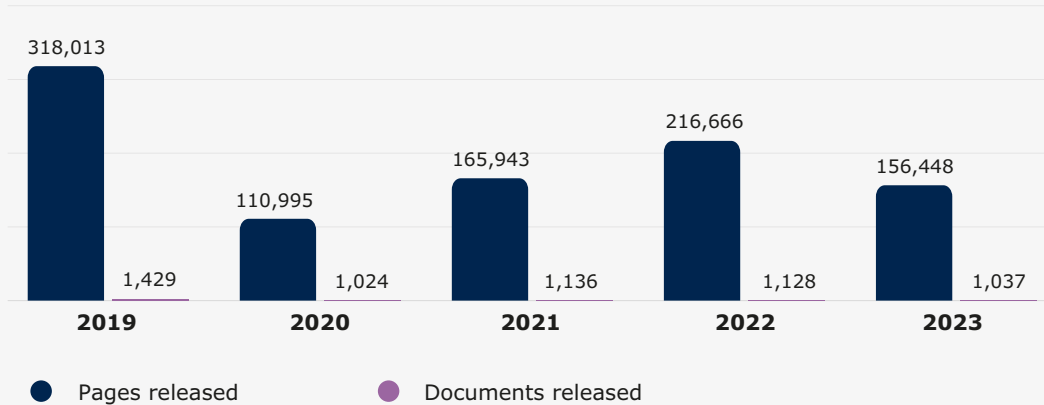
EU citizens have the right to access documents held by EU institutions, bodies, offices and agencies. EMA grants this access according to the principles and conditions defined by Regulation (EC) No 1049/2001 and the Agency's policy on access to documents.

EMA received 690 requests for access to documents in 2023. The majority of these requests came from the pharmaceutical industry.

## Requests received for access to documents



### Documents and pages released following access to document requests



## Publication of clinical data

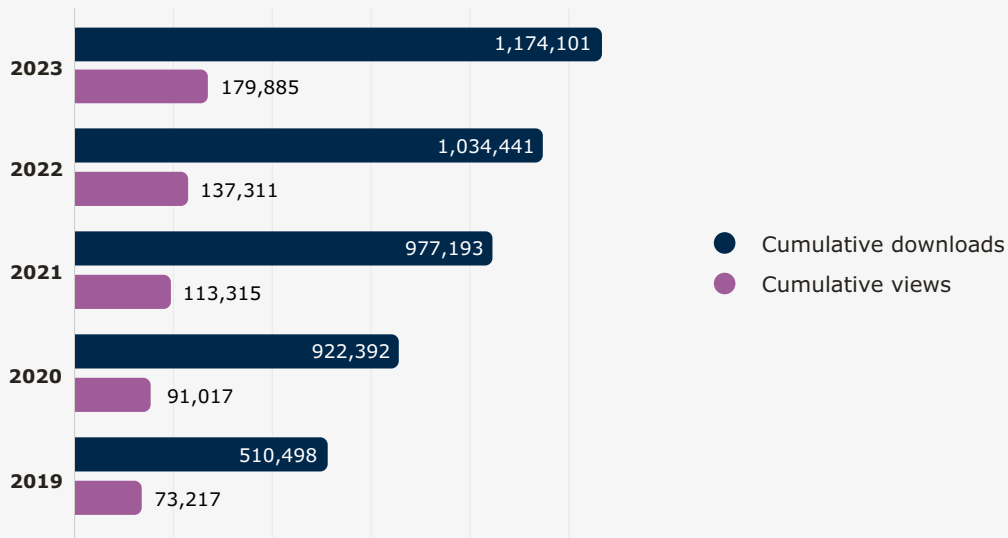
EMA publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. This is based on EMA's flagship policy on the publication of clinical data.

Agency's relocation to the Netherlands, and then due to the COVID-19 pandemic. As of early 2024, clinical data packages of marketing authorisation applications for new active substances are being published on the clinical data website.

In September 2023, EMA restarted the publication of clinical data for non-COVID medicines after it had been temporarily suspended at the end of 2018, first to ensure business continuity during the

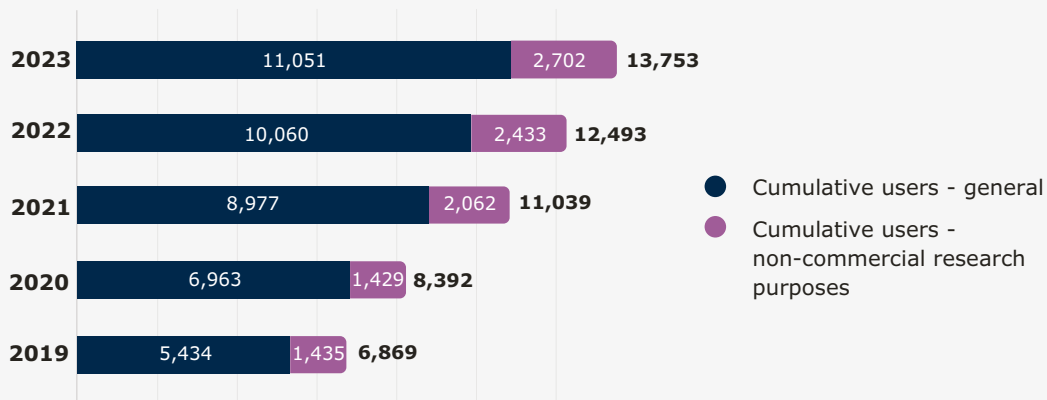
Usage of the clinical data website is expected to continue to rise with the full restart of the flagship policy.

### Clinical data website - usage





### Clinical data website - users



### Cumulative data

	2018	2019	2020	2021	2022	2023
Products	133	133	134	140	147	151
Procedures	142	142	143	154	200	241
Documents	7,089	7,089	7,153	7,368	8,110	8,824
Pages	3,393,170	3,393,170	3,404,171	3,483,496	3,690,267	4,071,151

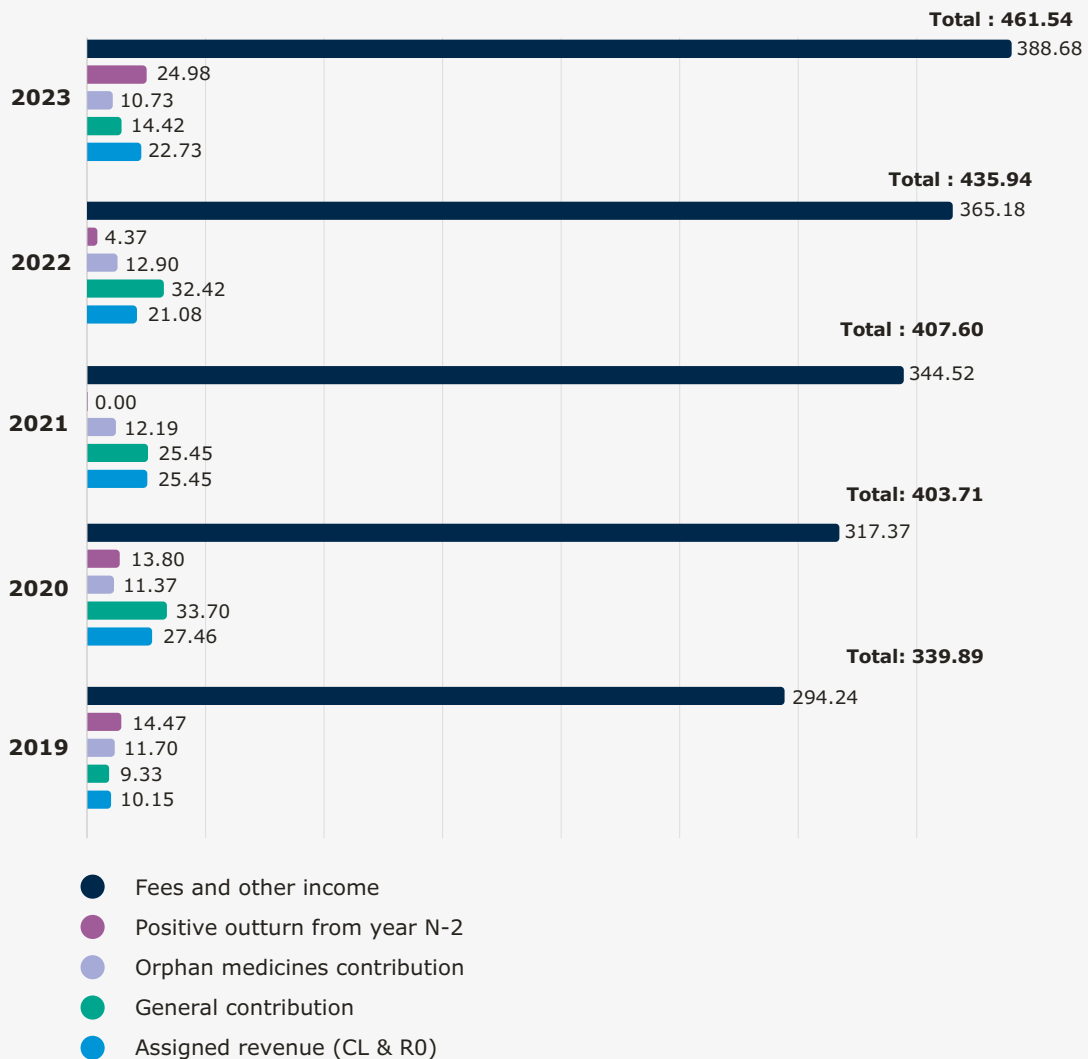
# Administrative aspects

## Financial information

The Agency's total revenue in 2023 was EUR 461.54 million. In addition, the Agency operated with fund sources for assigned revenue, mainly CL for internal assigned revenue (rent and building charges received from the

Agency's subtenant in London) but also for R0 for external assigned revenue. In 2023, assigned revenue (funding sources R0 and CL) amounted to EUR 22.73 million.

### Revenue (in million €)

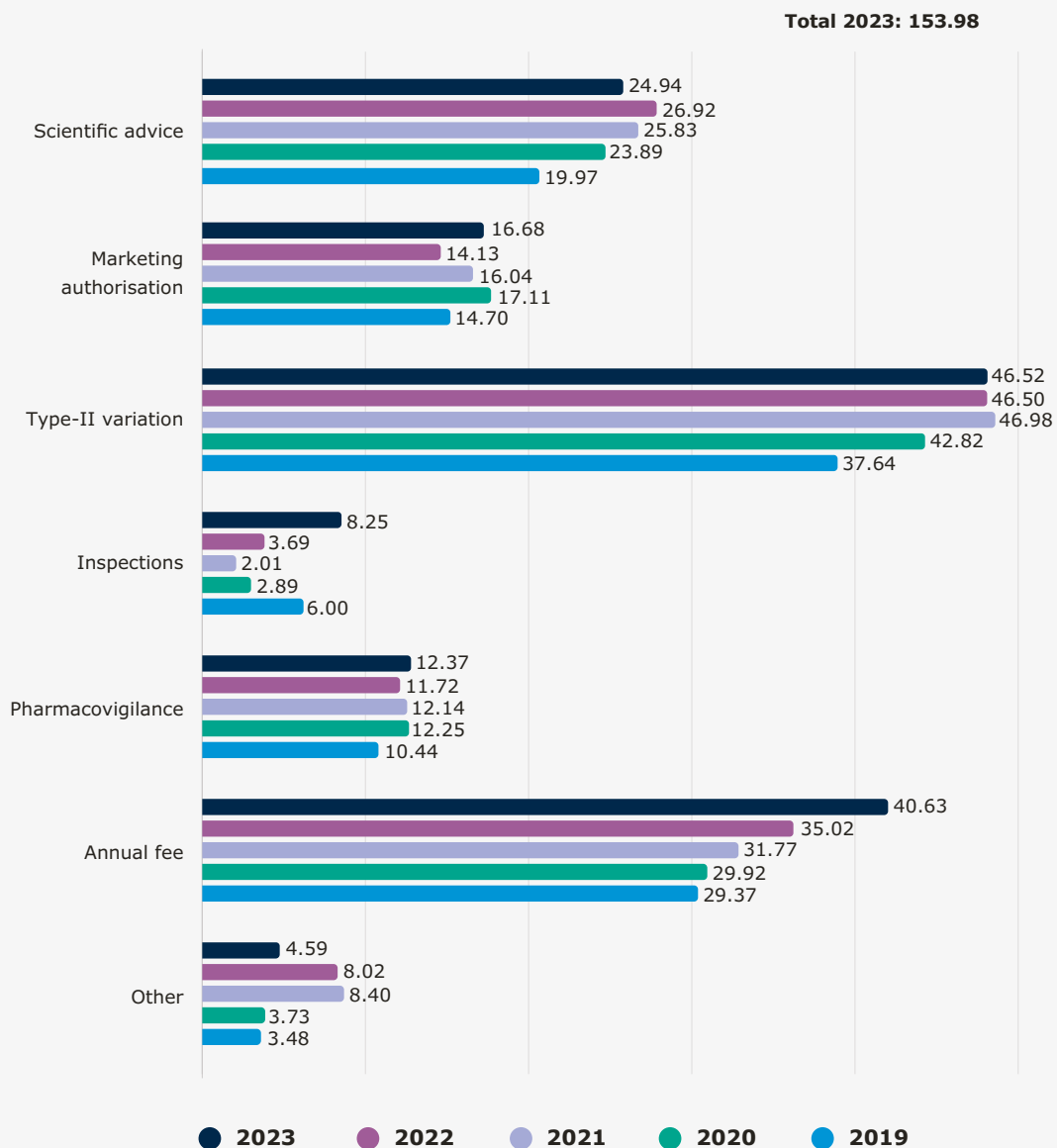


# Remuneration to national competent authorities

NCA's 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 2023, EMA paid a total of EUR 153.97 million to the NCAs, compared to EUR 145.99 million

in 2022. This figure includes payments for pharmacovigilance procedures, including the assessment of PSURs, PASS protocols and study results, and of pharmacovigilance-related referrals.

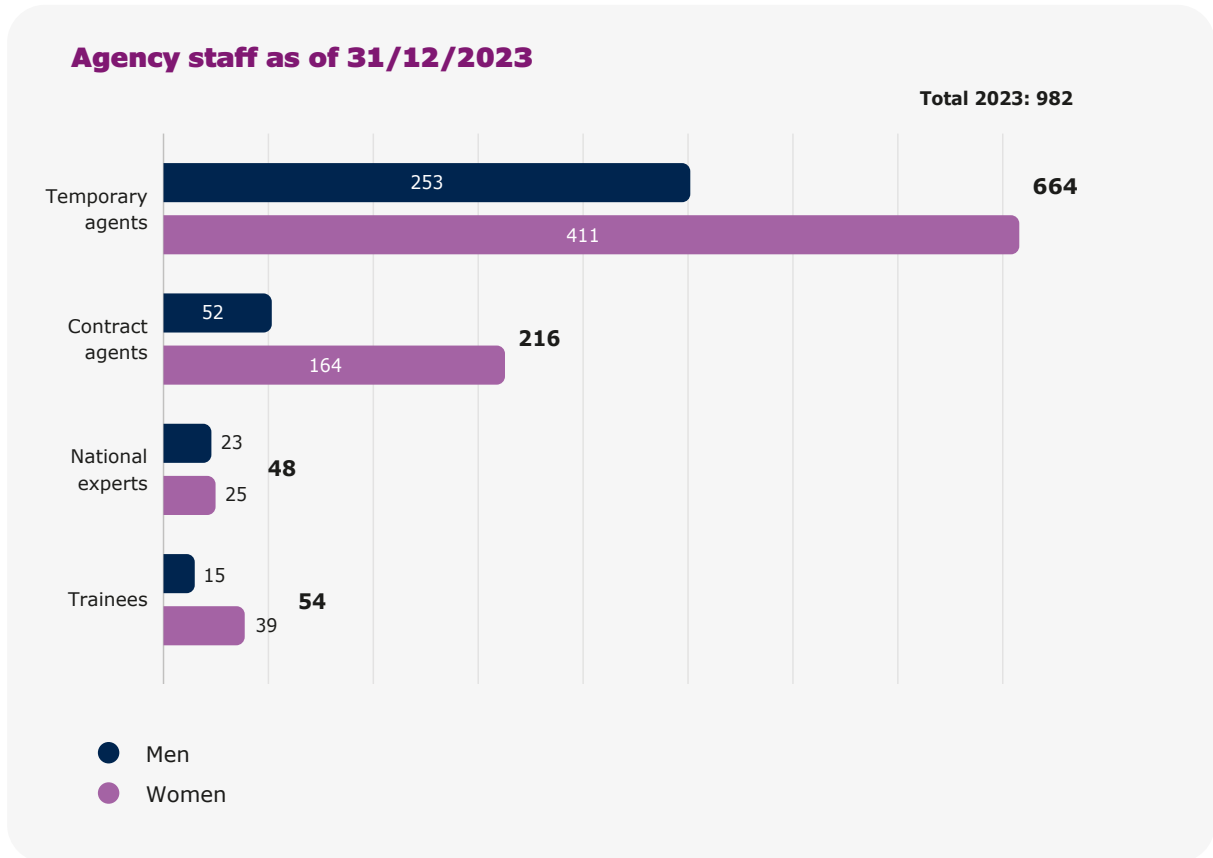
Remuneration to NCAs per fiscal year (in € millions)





# Agency staff

As of December 2023, the Agency had 982 staff members: 639 women and 343 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 2023
- Annex 11** – Guidelines and concept papers adopted by CHMP
- Annex 12** – CVMP opinions on medicinal products for veterinary use in 2023
- Annex 13** – Guidelines and concept papers adopted by CVMP in 2023
- Annex 14** – COMP opinions on designation of orphan medicinal products in 2023
- Annex 15** – HMPC European Union herbal monographs in 2023
- Annex 16** – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2023
- Annex 17** – Referral procedures overview 2023 – human medicines
- Annex 18** – Arbitrations and referrals in 2023 – veterinary medicines
- Annex 19** – Budget summaries 2022-2023
- Annex 20** – European Medicines Agency establishment plan
- Annex 21** – Litigation activities of EMA in 2023
- Annex 22** – Access to documents requests
- Annex 23** – Clinical Data Publication
- Annex 24** – Publications by Agency staff members and experts in 2023

The annexes are available on EMA's [website](#).





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**Send a question:**



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