



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European regulatory system for medicines

Bringing new safe and
effective medicines
to patients across the
European Union



EUROPEAN REGULATORY SYSTEM FOR MEDICINES

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This booklet explains how the European regulatory system for medicines operates.

It describes how medicines¹ are authorised and monitored in the European Union (EU) and how the European medicines regulatory network - a partnership between the European Commission, the medicines regulatory authorities in EU Member States (MSs) and the European Economic Area (EEA), and the European Medicines Agency (EMA) - works to ensure that patients in the EU have access to high-quality, effective and safe medicines.

THE EU REGULATORY SYSTEM FOR MEDICINES

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network is what makes the EU regulatory system unique.

The network is supported by a pool of over 4,000 experts drawn from across Europe, allowing it to source the best possible scientific expertise and to provide scientific advice of the highest quality.

The diversity of experts involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas, first-hand experience and best practice between scientists striving for the highest standards for medicines' regulation.



EMA and the Member States cooperate and share expertise in the assessment of new medicinal products, the monitoring of their safety and the response to public health emergencies. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials, conducting inspections of medicine manufacturers, and ensuring medicine manufacturers' compliance with good clinical practice (GCP), good manufacturing practice (GMP), good distribution practice (GDP) and good pharmacovigilance practice (GVP).

¹ The regulation of medical devices does not fall within the scope of the European regulatory system for medicines. For information on EMA's role in the regulation of medical devices, see <https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices>

This works because EU legislation requires that each Member State operates to the same rules and requirements regarding the authorisation and monitoring of medicines.

IT systems which connect all parties in the network facilitate the exchange of information on aspects such as safety monitoring of medicines, authorisation and supervision of clinical trials, and compliance with good manufacturing and distribution practices.

By working closely together, Member States reduce duplication, share the workload and ensure the efficient and effective regulation of medicines across the EU.

MARKETING AUTHORISATIONS

To protect public health and ensure the availability of high-quality, safe and effective medicines for European citizens, all medicines must be authorised before they can be placed on the market in the EU. The European system offers different routes for such an [authorisation](#).

The **centralised procedure** allows the marketing of a medicine on the basis of a single EU-wide assessment and marketing authorisation which is valid throughout the EU. Pharmaceutical companies submit a single authorisation application to EMA.

The Agency's Committee for Medicinal Products for Human Use (CHMP) or Committee for Veterinary Medicinal Products (CVMP) then carries out a scientific assessment of the application and gives a recommendation to the European Commission on whether or not to grant a marketing authorisation. Once granted by the European Commission, the centralised marketing authorisation is automatically valid in all EU Member States. The use of the centralised procedure is compulsory for most innovative medicines, including medicines for rare diseases and advanced-therapy medicines.



Not all medicines authorised in the EU fall within the scope of the centralised procedure, as most are authorised by national competent authorities (NCAs) in the Member States.

EMA enables one application, one assessment, one market authorisation for the whole of the EU.

When a company wants to have a medicine authorised in several Member States, it can use one of the following procedures:

- **the decentralised procedure**, where companies can apply for the simultaneous authorisation of a medicine in more than one EU Member State if it has not yet been authorised in any EU country and does not fall within the scope of the centralised procedure;
- **the mutual recognition procedure**, where companies that have a medicine authorised in one EU Member State can apply for this authorisation to be recognised in other EU countries. This process allows Member States to rely on each other's scientific assessments.

Different authorisation routes: one set of common rules.

Rules and requirements applicable to pharmaceuticals in the EU are the same, irrespective of the authorisation route for a medicine.

Transparency about how the system works and how it reaches its decisions is an important feature of the EU regulatory system for medicines.

A European Public Assessment Report, or [EPAR](#), is published for every human or veterinary medicine that has been granted or refused a marketing authorisation following an assessment by EMA. For a medicine that is authorised by a Member State, details on the assessment of the medicine are also available in a Public Assessment Report. All EPARs are translated into all 24 official EU languages.

EMA also publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. Proactive publication of clinical data on EMA's [clinical data website](#) builds public trust and confidence in EMA's scientific and decision-making processes, avoids duplication of clinical trials, and enables academics and researchers to re-assess clinical data.

PRICING AND REIMBURSEMENT

Once a marketing authorisation has been granted, decisions on price and reimbursement take place at the level of each Member State considering the potential role and use of the medicine in the context of the national health system of that country.

THE ROLE OF THE EUROPEAN COMMISSION

The European Commission plays an important role in the regulation of medicines in the EU. On the basis of scientific assessments carried out by EMA, it grants or refuses, amends or suspends marketing authorisations for medicines evaluated via the centralised procedure. It can also take EU-wide action when a safety issue has been identified for a nationally authorised product and when harmonised regulatory measures in all MSs are considered necessary following assessment by EMA's safety committee, the PRAC.

The European Commission can also take action concerning other aspects of medicine regulation:

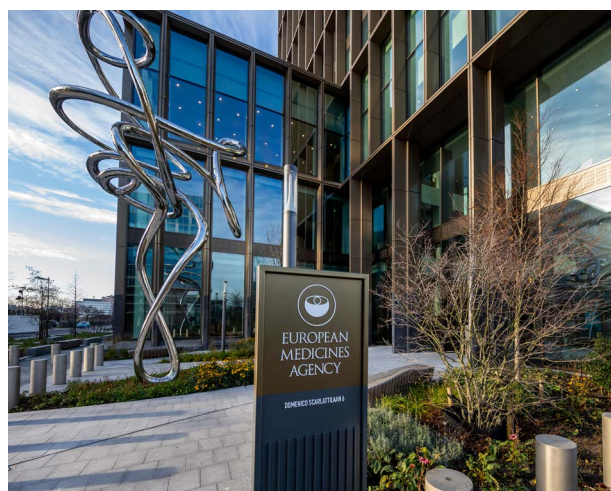
- **Right of initiative** - it can propose new or amended legislation for the pharmaceutical sector;
- **Implementation** - it can adopt implementing measures as well as oversee the correct application of EU law on pharmaceuticals;
- **Global outreach** - it ensures appropriate collaboration with relevant international partners and promotes the EU regulatory system globally.

THE ROLE OF EMA

EMA is responsible for the scientific evaluation, primarily of innovative and high-technology medicines developed by pharmaceutical companies for use in the EU. EMA was established in 1995 to ensure the best use of scientific resources across Europe for the evaluation, supervision and pharmacovigilance of medicines.

Experts participate in the work of EMA as members of its scientific committees, working parties, scientific advisory groups and other ad hoc advisory groups, or as members of the national assessment teams that evaluate medicines.

The experts are chosen on the basis of their scientific expertise and/or their experience with a specific disease and many of them are made available to EMA by the NCAs in Member States.



EMA experts cannot have any financial or other interests in the pharmaceutical and medical device industry that could affect their impartiality.

Their signed declarations of interests are publicly available.

EMA'S SCIENTIFIC COMMITTEES

The EMA currently has seven scientific committees that carry out its scientific assessments:

- Committee for Medicinal Products for Human Use (CHMP)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- Committee for Veterinary Medicinal Products (CVMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Committee for Advanced Therapies (CAT)
- Paediatric Committee (PDCO)

NATIONAL COMPETENT AUTHORITIES

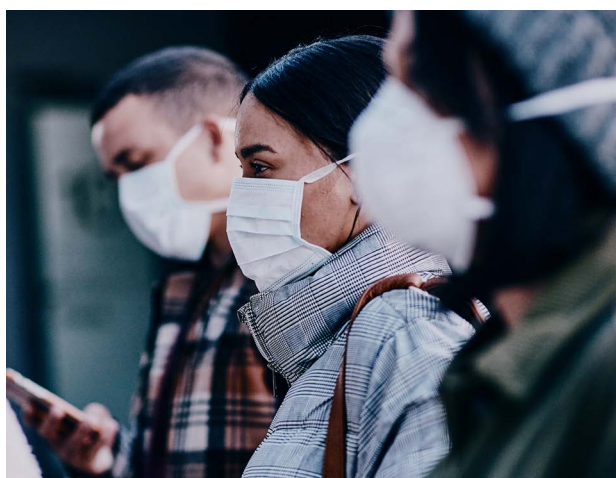
The national competent authorities (NCAs), responsible for the regulation of human and veterinary medicines in EU Member States, coordinate their work in a forum called **Heads of Medicines Agencies (HMA)**.

HMA work closely with EMA and the European Commission to maximise cooperation and ensure the European medicines regulatory network functions efficiently. The HMA meets four times per year to address key strategic issues, such as exchange of information, IT developments and sharing of best practices, and to streamline mutual recognition and decentralised procedures.

PREPARING FOR AND MANAGING PUBLIC HEALTH EMERGENCIES

EMA plays a key role in the preparation for and during **major events and public health emergencies**, such as a pandemic, in line with the [Regulation \(EU\) 2022/123](#) on EMA's reinforced role in crisis preparedness and management.

EMA's [Emergency Task Force](#) (ETF) is an advisory and support body and is the cornerstone of EMA's crisis preparedness and emergency response.



It provides advice to developers of vaccines and therapeutics that could address the public health emergency or that are directed against pathogens with potential to cause public health emergencies, and offers scientific support to facilitate clinical trials in the EU for the most promising medicines. It also issues scientific recommendations to EMA's human medicines committee (CHMP) on the use of medicines prior to their authorisation, such as compassionate use programmes or national emergency use authorisations, and conducts scientific reviews of data on medicinal products which may be used to address a public health emergency.

EMA's [Executive Steering Group on Shortages and Safety of Medicinal Products](#) (MSSG) ensures a robust response to issues impacting the quality, safety, efficacy and supply of medicines during major events and public health emergencies².

The MSSG monitors the supply and demand of critical medicines to identify any potential or actual shortages of these medicines, and provides recommendations and coordinating actions, at EU level, that aim to prevent shortages or mitigate their effects. In addition, where the public health emergency or the major event may affect the quality, safety or efficacy of medicinal products, the MSSG is responsible for evaluating the information, and for considering the need for urgent and EU-coordinated actions.

The MSSG is supported by the Medicine Shortages Single Point of Contact (SPOC) Working Party consisting of representatives of the national competent authorities for medicinal products, who are responsible for sharing information on ongoing or potential shortages with EMA and the network.

SUPPORT FOR THE DEVELOPMENT OF MEDICINES

The Agency supports the development of regulatory mechanisms to help promising new medicines reach patients as early as possible. The Agency can also give advice on data requirements to ensure that a mature dossier is in place at the time of the marketing authorisation application.

Guidelines

EMA prepares [scientific guidelines](#) in cooperation with experts from its scientific committees and working groups, and in consultation with patients and healthcare professionals. These guidelines reflect the latest thinking on developments in biomedical science. They are available to guide the development programmes of all medicine developers who wish to submit an application for a marketing authorisation in the EU, and to ensure that medicines are developed consistently and to the highest quality.

Innovation Task Force

The [Innovation Task Force](#) (ITF) is a multidisciplinary group that includes scientific, technical, methodological, regulatory and legal competences.

² As of February 2023, EMA is also responsible for monitoring events, reporting shortages and coordinating responses of EU countries to shortages of critical medical devices and in-vitro diagnostic medical devices during public health emergencies

ITF briefing meetings allow medicine developers, in particular small and medium-sized enterprises and academics, to engage in very early dialogue on scientific, technical and methodological aspects related to the development of innovative medicines.

This facilitates the informal exchange of information and guidance in the development process, complementing, reinforcing and preparing for existing formal procedures such as qualification of novel methodologies and scientific advice.

SME office

The [SME office](#) provides incentives and support for micro, small and medium-sized enterprises (SMEs) that are developing medicines for human or veterinary use, in order to promote innovation and the development of new medicines. This support is open to all companies and enterprises that have SME status assigned by EMA.

Scientific advice

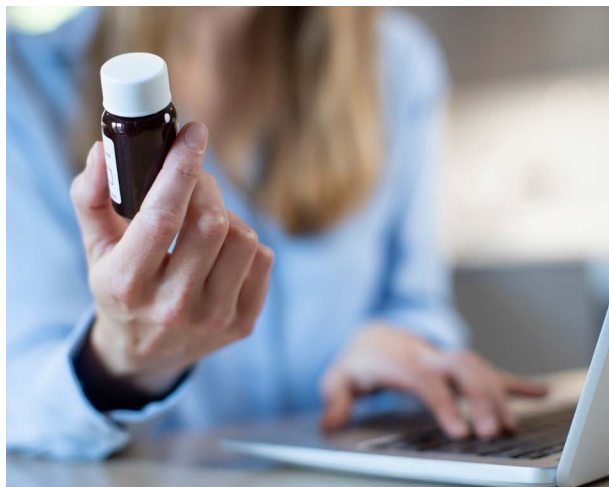
EMA gives product-specific [scientific advice](#) to companies for the development of medicines. This is an important tool to help develop and make available high-quality, effective and safe medicines, for the benefit of patients. Scientific advice can also be given by NCAs.

PRIME

[PRIME](#) is a voluntary scheme to support the development of medicines that target an unmet medical need. It allows medicine developers to engage in early dialogue and enhances the interaction with EMA to optimise their development plans. This helps companies to generate more robust data and accelerates the assessment of these medicines so they can reach patients earlier.

INVOLVEMENT OF PATIENTS AND HEALTHCARE PROFESSIONALS

Patients and healthcare professionals are part of EMA's Management Board and are involved in the evaluation of medicines throughout their regulatory lifecycle. They bring clinical-practice experience and real-life perspective of living with a condition into medicine-specific discussions.



Patients and healthcare professionals are members of EMA's scientific committees (CAT, COMP, PDCO, PRAC), the Emergency Task Force (ETF) and the Medicine Shortages Steering Group (MSSG), and contribute as individual experts in scientific advice and scientific advisory groups. They also review documents prior to their publication and provide input in the drafting of scientific guidelines. Scientific committees can consult patients and healthcare professionals on disease-specific issues. As an example, EMA's safety committee, the PRAC, can hold [public hearings](#) during safety reviews of medicines to gather perspectives, knowledge and insights into the way medicines are used in clinical practice.

EMA also works closely with European organisations representing patients, consumers, healthcare professionals and learned societies, and has dedicated working parties to exchange views with healthcare professionals (HCPWP) and with patients and consumers (PCWP). These bodies provide input into EMA's wider consultations on scientific guidelines and on policies and strategic objectives (e.g. regulatory science strategy, antimicrobial resistance).

ENGAGEMENT WITH ACADEMICS

The academic sector represents an important source of innovation and nurtures the product pipelines of small and medium-sized enterprises and larger companies. EMA collaborates with academia to support opportunities offered by advances in science and technology and to ensure regulators' preparedness for future challenges.

EMA offers **fee incentives** to the academic sector to encourage the development of priority medicines and medicines for patients with rare diseases. It also provides regulatory and scientific support to facilitate development of new and innovative medicines.

EMA is also involved in a number of research projects with the academic sector, learned societies and research groups as part of its mission to foster scientific excellence in regulatory science.

AUTHORISATION AND SUPERVISION OF MANUFACTURERS

Manufacturers, importers and distributors of medicines in the EU must be licensed before they can carry out medicine-related activities.



The regulatory authorities of each Member State are responsible for granting licences for such activities taking place within their respective territories. All manufacturing and importing licenses are entered into [EudraGMDP](#), the publicly-available European database operated by EMA.

Manufacturers listed in the application of a medicine to be marketed in the EU are inspected by an EU competent authority. This includes manufacturers located outside the EU unless a mutual recognition agreement (MRA) is in place between the European Union and the country of manufacture which allows EU authorities and their counterparts to rely on each other's inspections.

Inspection outcomes can be accessed by all Member States and are made publicly available across the EU through EudraGMDP.

Equivalence between Member States' inspectorates is ensured and maintained in a variety of ways, including common legislation, common good manufacturing practice (GMP), common procedures for inspectorates, technical support, meetings, trainings, and internal and external audits.

In order to be imported into the EU, an active pharmaceutical ingredient needs to be accompanied by a Written Confirmation issued by the competent authority of the country where it is produced, confirming that the good manufacturing practice (GMP) applied is at least equivalent to the recognised EU GMP standards.

A waiver applies for some countries which have applied to have their regulatory systems for the supervision of manufacturers of active pharmaceutical ingredients assessed by the EU and have been found to be equivalent to the EU.

Every batch of medicines must be certified as having been manufactured and tested in accordance with GMP and in conformance with the marketing authorisation before it can be released onto the market in the EU. If the product is manufactured outside the EU and has been imported, it needs to undergo full analytical testing in the EU, unless a mutual recognition agreement (MRA) is in place between the EU and the exporting country.

SAFETY MONITORING OF MEDICINES

The European regulatory system for medicines monitors the safety of all medicines that are available on the European market throughout their life span.

All suspected side effects that are reported by patients and healthcare professionals must be entered into EudraVigilance, the EU database operated by EMA to collect, manage and analyse reports of suspected side effects of medicines. These data are continuously monitored by EMA and the Member States in order to identify any new safety information.

EMA provides public access to reports of suspected side effects for authorised medicines in the EEA in the European [database](#) of suspected drug-reaction reports. This website allows users to view data from all suspected side effect reports submitted to EudraVigilance.

EMA has a committee dedicated to the safety of medicines for human use - the Pharmacovigilance Risk Assessment Committee, or PRAC. The PRAC has a broad remit covering all aspects of pharmacovigilance. In addition to its role in risk assessment, the committee provides advice and recommendations to the European medicines regulatory network on risk management planning and benefit-risk assessment for medicines after marketing.

If there is a safety issue with a medicine that is authorised in more than one Member State, the same regulatory action agreed by the PRAC is taken across the EU and patients and healthcare professionals in all Member States are provided with the same guidance.

CLINICAL TRIALS

The authorisation and oversight of a clinical trial is the responsibility of the Member State in which the trial is taking place. The [Clinical Trials Information System](#) (CTIS) is an online system that supports the regulatory submission, authorisation and supervision of clinical trials in the EU and the EEA. It allows clinical trial sponsors to submit an application to run a trial in one or more EU Member States, and national competent authorities (NCAs) to process the application and oversee the authorised trials. Clinical trial protocols and results are publicly available.

The [Accelerating Clinical Trials in the EU](#) (ACT EU) initiative aims to develop the EU further as a competitive centre for innovative clinical research. It builds on the Clinical Trials Regulation and the launch of CTIS and aims to promote larger, multinational trials specifically in the academic setting, enable innovative trial methods, and develop and publish guidance on key methodologies.

ACT EU also supports the modernisation of Good Clinical Practice (GCP) and a multi-stakeholder platform to facilitate a more holistic discussion across the clinical research landscape.



REAL-WORLD DATA

Data generated in real-world healthcare settings, such as data from electronic health records and health insurance claims, can complement evidence from clinical trials in medicines assessment.

EMA manages the Data Analysis and Real World Interrogation Network ([DARWIN EU®](#)), a federated network which gives the European regulatory network access to results from analysis of data from real-world healthcare databases across the EU. These results inform regulatory decision making and support the development, authorisation and safe and effective use of medicines by patients.

INTERNATIONAL COOPERATION

The European Commission and EMA, in close cooperation with Member States, work to forge close ties with partner organisations around the world. These activities aim to foster the timely exchange of regulatory and scientific expertise and the development of best practices in the regulatory field across the world.

The European Commission and EMA work with the World Health Organization (WHO) on a range of issues, including high-priority medicines intended for markets outside the EU (medicines reviewed under EMA's so-called '[EU-Medicines for all procedure](#)' or EU-M4all), the quality of medicines and the development of international non-proprietary names.

SUPPORTING ACCESS TO HIGH-PRIORITY MEDICINES FOR PATIENTS OUTSIDE THE EU — EU-M4ALL

EMA's human medicines committee, the CHMP, can carry out scientific assessments and give opinions on medicines for use exclusively outside the EU. When assessing these medicines, the CHMP cooperates with WHO and national regulators in the countries where the products are expected to be used and applies the same rigorous standards as for medicines intended for use inside the EU. Medicines eligible for this procedure are used to prevent or treat diseases that impact global public health. This includes vaccines used in the WHO Expanded Programme on Immunization, or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria, dengue and tuberculosis.

Cooperation with WHO and regulators from target countries enriches the epidemiology and local disease expertise, facilitates a benefit-risk assessment tailored to the intended non-EU population, streamlines the WHO prequalification programme and facilitates national registration of medicines in target countries.

The [OPEN Initiative](#) allows WHO and some medicines regulators from outside the EU to take part in selected EMA scientific evaluations. The initiative aims to facilitate sharing of scientific expertise, tackle common challenges and enhance transparency on regulatory decisions.

For the EU, one of the main forums for multilateral international cooperation is the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which brings together medicines regulatory authorities and pharmaceutical industry from around the world. ICH is dedicated to harmonisation in safety, quality and efficacy as the main criteria for approving and authorising new medicines. The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products is the equivalent forum for veterinary medicines.

EMA and many national competent authorities are also involved in the Pharmaceutical Inspection

Convention and the Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S), a close international cooperation between pharmaceutical inspection authorities in the field of GMP.

Regulatory cooperation and exchange of information with international regulators is also assured through the International Pharmaceutical Regulators Programme (IPRP).

A strategic forum at the level of global agencies, the International Coalition of Medicines Regulatory Authorities (ICMRA), was established in 2013. ICMRA is a voluntary, executive-level entity of medicines regulatory authorities worldwide providing strategic coordination, advocacy and leadership.

There are also a number of bilateral cooperation agreements in place that facilitate the exchange of important information on medicines between regulators inside and outside the EU.

THE EUROPEAN UNION – KEY FACTS



Population

>477 Million



Medicines regulatory authorities

50+



GDP

€ 14.5 Trillion



Official languages

24

The EU has developed a single market through a standardised system of laws that apply to all its Member States. The same rules and harmonised procedures apply to all the **27 Member States** regarding the authorisation of medicines and the supervision of their safety.

Accession to the EU means a commitment to apply the “**acquis communautaire**” (the body of EU legislation and guidance) to ensure that all EU Member States operate to the same standards.



■ **27 EU Member States:** Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden

■ **European Economic Area (EEA):** 27 EU Member States plus Iceland, Liechtenstein and Norway



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