EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

About us

This document provides an overview of the main responsibilities of the European Medicines Agency (EMA). It is based on the 'About us' section of EMA's corporate website.

Please note that the document contains links to sections of the EMA website, some of which are only available in English.

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1. About us

EMA is a decentralised agency of the European Union (EU), located in London. It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.

EMA protects public and animal health in 28 EU Member States, as well as the countries of the European Economic Area (EEA), by ensuring that all medicines available on the EU market are safe, effective and of high quality.

EMA serves a market of over 500 million people living in the EU.

2. What we do

The mission of the EMA is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.

Facilitate development and access to medicines

EMA is committed to enabling **timely patient access** to new medicines, and plays a vital role in supporting medicine development for the benefit of patients.

The Agency uses a wide range of **regulatory mechanisms** to achieve these aims, which are continuously reviewed and improved. For more information, see:

- support for early access;
- scientific advice and protocol assistance;
- paediatric procedures;
- scientific support for advanced-therapy medicines;
- orphan designation of medicines for rare diseases;
- scientific guidelines on requirements for the quality, safety and efficacy testing of medicines;
- the Innovation Task Force, a forum for early dialogue with applicants.

EMA also plays a role in supporting research and innovation in the pharmaceutical sector, and promotes innovation and development of new medicines by European micro-, small- and medium-sized-enterprises.

Evaluate applications for marketing authorisation

EMA's scientific committees provide independent recommendations on medicines for human and veterinary use, based on a comprehensive **scientific evaluation of data.**

The Agency's evaluations of marketing-authorisation applications submitted through the **centralised procedure** provide the basis for the authorisation of medicines in Europe.

They also underpin important decisions about medicines marketed in Europe, referred to EMA through referral procedures. EMA coordinates inspections in connection with the assessment of marketing-authorisation applications or matters referred to its committees.

Monitor the safety of medicines across their lifecycle

EMA **continuously monitors** and supervises the safety of medicines that have been authorised in the EU, to ensure that their **benefits outweigh their risks**. The Agency works by:

- developing guidelines and setting standards;
- coordinating the monitoring of pharmaceutical companies' compliance with their pharmacovigilance obligations;
- contributing to international pharmacovigilance activities with authorities outside the EU;
- informing the public on the safety of medicines and cooperating with external parties, in particular representatives of patients and healthcare professionals.

For more information see Pharmacovigilance.

Provide information to healthcare professionals and patients

The Agency publishes **clear and impartial information** about medicines and their approved uses. This includes public versions of scientific assessment reports and summaries written in lay language.

For more information, see:

- Transparency
- Search human medicines
- Search veterinary medicines

What we don't do

Not all aspects of medicine regulation in the EU fall under the remit of the Agency. EMA does not:

- **evaluate the initial marketing authorisation application of all medicines in the EU.** The vast majority of medicines available in the EU are authorised at national level.For more information on the authorisation routes of medicines in the EU, see Chapter 2 of this document on the Authorisation of medicines;
- **evaluate applications for the authorisation of clinical trials.** The authorisation of clinical trials occurs at Member State level, although the Agency plays a key role in ensuring that the standards of good clinical practice are applied in cooperation with the Member States and manages a database of clinical trials carried out in the EU.
- **evaluate medical devices, food supplements and cosmetics.** These devices and substances are evaluated at national level. In some cases, EMA can be consulted on ancillary medicinal substances contained in medical devices;
- **carry out research or develop medicines.** Pharmaceutical companies or other medicines developers carry out the research and development of medicines, who then submit the findings and test results for their products to the Agency for evaluation;
- **take decisions on the price or availability of medicines.** Decisions about 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. For more information, see Health-technology-assessment bodies;

- **control the advertising of medicines.** The control of the advertising of non-prescription medicines in the EU is primarily conducted on a self-regulatory basis by industry bodies, supported by the statutory role of the national regulatory authorities in the Member States;
- **control or have information on pharmaceutical patents.** Patents having effect in most European countries may be obtained either nationally, via national patent offices, or via a centralised process at the European Patent Office;
- **develop treatment guidelines.** National governments or the health authorities of individual EU Member States develop guidelines for decisions regarding diagnosis, management, and treatment in specific areas of healthcare (sometimes known as clinical guidelines);
- **provide medical advice.** Healthcare professionals can provide individual patients advice on medical conditions, treatments or side effects with a medicine;
- **develop laws concerning medicines.** The European Commission develops EU legislation concerning medicines and the European Parliament together with the Council of the European Union adopt it. The European Commission also develops EU policies in the field of human or veterinary medicines and public health. For more information see European Commission: Medicinal products for human use;
- **issue marketing authorisations.** The legal decision to grant, suspend or revoke a marketing authorisation for any medicine falls under the remit of the European Commission for centrally authorised products, and the national competent authorities of the EU Member States for nationally authorised products.

3. Authorisation of medicines

All medicines must be authorised before they can be marketed and made available to patients. In the EU, there are two main routes for authorising medicines: a centralised route and a national route.

Centralised authorisation procedure

Under the centralised authorisation procedure, pharmaceutical companies submit a **single marketing-authorisation application** to EMA.

This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation.

EMA's Committee for Medicinal products for Human Use (CHMP) or Committee for Medicinal products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not.

Once granted by the European Commission, the centralised marketing authorisation is **valid in all EU Member States** as well as in the EEA countries Iceland, Liechtenstein and Norway.

Benefits for EU citizens

- Medicines are authorised for all EU citizens at the same time.
- Single evaluation by European experts.
- Product information available in all EU languages at the same time.

Scope of the centralised authorisation procedure

The centralised procedure is **compulsory** for:

- human medicines containing a new active substance to treat:
  - human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS);
  - cancer;
  - diabetes;
  - neurodegenerative diseases;
  - auto-immune and other immune dysfunctions;
  - viral diseases.
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- orphan medicines (medicines for rare diseases);
- veterinary medicines for use as growth or yield enhancers.

It is **optional** for other medicines:

- containing new active substances for indications other than those stated above;
- that are a significant therapeutic, scientific or technical innovation;
- whose authorisation would be in the interest of public or animal health at EU level.

Today, **the great majority of new, innovative medicines** pass through the centralised authorisation procedure in order to be marketed in the EU.

National authorisation procedures

The majority of medicines available in the EU were authorised at national level, either because they were authorised before EMA's creation or they were not in the scope of the centralised procedure.

Each EU Member State has its own national authorisation procedures. Information about these can normally be found on the websites of the national competent authorities:

- National competent authorities (human)
- National competent authorities (veterinary)

If a company wishes to request marketing authorisation in several EU Member States for a medicine that is outside the scope of the centralised procedure, it may use one of the following routes:

- the **mutual-recognition procedure**, whereby a marketing authorisation granted in one Member State can be recognised in other EU countries;
- the **decentralised procedure**, whereby a medicine that has not yet been authorised in the EU can be simultaneously authorised in several EU Member States.

For more information see:

- Coordination Group for Mutual Recognition and Decentralised Procedures – Human

- Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

The **data requirements** and standards governing the authorisation of medicines are the same in the EU, irrespective of the authorisation route.

4. Who we are

The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.

EMA is governed by an independent Management Board. Its day-to-day operations are carried out by the EMA staff, based in London, overseen by EMA's Executive Director.

EMA is a networking organisation whose activities involve thousands of experts from across Europe. These experts carry out the work of EMA's scientific committees.

Management Board

The Management Board consists of 35 members, appointed to act in the public interest, who do not represent any government, organisation or sector.

The Board sets the Agency's budget, approves the annual work programme and is responsible for ensuring that the Agency works effectively and co-operates successfully with partner organisations across the EU and beyond.

For more information, see Section 3.1.

Executive Director

The Agency's Executive Director is the legal representative of the Agency. He is responsible for all operational matters, staffing issues and drawing up the annual work programme.

Agency staff

The Agency's staff support the Executive Director in carrying out his responsibilities, including administrative and procedural aspects of EU law related to the evaluation and safety-monitoring of medicines in the EU.

Organisation chart of the European Medicines Agency

Scientific Committees

EMA has seven scientific committees that evaluate medicines along their lifecycle from early stages of development, through marketing authorisation to safety monitoring once they are on the market.

In addition, the Agency has a number of working parties and related groups, which the committees can consult on scientific issues relating to their particular field of expertise.

These bodies are composed of European experts made available by national competent authorities of the EU Member States, which work closely with EMA in the European medicines regulatory network.

5. Management Board

The Management Board is the European Medicines Agency's integral governance body. It has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.

The Board's **operational tasks** range from adopting legally binding implementing rules, to setting strategic directions for scientific networks, to reporting on the use of European Union (EU) contributions for the Agency's activities:

It has legally enforceable rule-making authority for implementation of certain parts of the **fee regulation**. It adopts the Agency's financial regulation and its implementing rules, which are binding texts for the Agency, the Board and the Executive Director.

It has a key role to play in the 'discharge' (sign-off) process of the Agency's **accounts** by the European Union's budgetary authority. As part of this process, the Board conducts an analysis and assessment of the Executive Director's annual activity report. This forms part of the package of controls and reports that lead to Executive Director receiving discharge for the Agency's budget. The Board also gives its opinion on the Agency's annual accounts.

It has close ties with the Agency's **accounting officer**, who is appointed by the Board, and with the **internal auditor**, who reports to the Board and to the Executive Director on audit findings.

It is consulted on the rules of procedure and the membership of the Agency's committees.

It is responsible for adopting the **implementing provisions** for the practical application of the rules and regulations applicable to officials and other EU staff.

The tasks and responsibilities of the Management Board are set out in the Agency's legal background.

Composition

The members of the Management Board are appointed on the basis of their expertise in management and, if appropriate, experience in the field of human or veterinary medicines. They are selected to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographical spread within the EU.

The Management Board is made up of the following **members**:

- one representative of each of the 28 EU Member States;
- two representatives of the European Commission;
- two representatives of the European Parliament;
- two representatives of patients' organisations;
- one representative of doctors' organisations;
- one representative of veterinarians' organisations.

In addition to the members, the Management Board also has one **observer** each from Iceland, Liechtenstein and Norway.

The representatives of the Member States, European Commission and European Parliament are appointed directly by the Member State and institution concerned. The four 'civil society' Board

members (patients', doctors' and veterinarians' representatives) are appointed by the Council of the European Union, after consultation of the European Parliament.

The representatives of the Member States and of the Commission may have alternates.

Board members are appointed for a three-year term, which may be renewed.

6. How we work

To fulfil its mission, the EMA works closely with national competent authorities in a regulatory network. The Agency also implements policies and procedures to ensure its works independently, openly and transparently and upholds the highest standards in its scientific recommendations.

EMA brings together scientific experts from across Europe by working closely with the national regulatory authorities in European Union (EU) Member States, in a partnership known as the European medicines regulatory network (For more information, see Chapter 5).

The network **pools resources and expertise** in the EU and gives EMA access to thousands of European scientific experts who take part in the regulation of medicines.

Ensuring the **independence** of its scientific assessments is a high priority for EMA. The Agency takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests that could affect their impartiality.

EMA strives towards being as **open and transparent** as possible about how it reaches its scientific conclusions. EMA's European public assessment reports describe the scientific basis for EMA's recommendations on all centrally authorised medicines.

EMA also publishes a large amount of information in **lay language** about its work and about medicines. For more information, see Transparency.

The Agency also seeks to publish clear and up-to-date information on how it operates, including **planning and reporting** documents and information on funding, financial management and budgetary reporting.

7. European medicines regulatory network

The system for regulating medicines in Europe is unique in the world. It is based on a closely-coordinated regulatory network of national competent authorities in the Member States of the EEA working together with the EMA and the European Commission.

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

These national authorities supply thousands of European experts to take part in EMA's scientific committees, working parties and other groups.

The regulatory network also includes the European Commission, whose principal role in the European system is to take binding decisions based on the scientific recommendations delivered by EMA.

By working closely together, this network ensures that safe, effective and high-quality medicines are authorised throughout the European Union (EU), and that patients, healthcare professionals and citizens are provided with adequate and consistent information about medicines.

Benefits of the network for EU citizens

- Enables Member States to pool resources and coordinate work to regulate medicines efficiently and effectively;
- Creates certainty for patients, healthcare professionals, industry and governments by ensuring consistent standards and use of best available expertise;
- Reduces the administrative burden through the centralised authorisation procedure, helping medicines to reach patients faster;
- Accelerates the exchange of information on important issues, such as the safety of medicines.

Pooling expertise

The European medicines regulatory network gives EMA access to experts from across the EU, allowing it to bring together the best-available scientific expertise in the EU for the regulation of medicines.

The diversity of the experts involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas and best practices between scientists striving for the highest standards for medicines regulation.

These European experts serve as members of the Agency's scientific committees, working parties or in assessment teams supporting their members. They can be nominated by Member States or by the Agency itself and are made available by the national competent authorities.

The Agency maintains a public European expert list containing details on all experts who can be involved in EMA work. Experts can only be involved once the Agency has assessed their declaration of interests.

Multinational assessment teams

EMA and its regulatory network partners run a scheme to enable multinational teams to assess applications for human and veterinary medicines. The aim is to **mobilise the best expertise** for medicines evaluation, regardless of where experts are based.

EMA has encouraged the formation of multinational assessment teams since 2013 for **initial marketing authorisation** applications.

The concept enables rapporteurs and co-rapporteurs for EMA's scientific committees to include experts from other Member States in their assessment teams. This helps to optimse resource use across the regulatory network and encourage cross-border fertilisation of scientific expertise.

The scheme began with co-rapporteur assessment teams for human medicines (CHMP and CAT), then expanded to rapporteur assessment teams, veterinary medicines (CVMP) and scientific advice procedures.

From April 2017, multinational teams can also evaluate certain **post-authorisation** applications to extend existing marketing authorisations.

Pooling information

EMA and the national authorities depend on standards, processes and Information Technology (IT) systems that allow important information on medicines to be shared between European countries and analysed together.

Some of the data are supplied by the Member States and centrally managed by EMA. This supports an exchange of information on a number of issues, including:

- suspected side effects reported with medicines;
- the oversight of clinical trials;
- inspections to check compliance with good practice in the clinical development, manufacturing and distribution, and safety monitoring of medicines.

This helps to reduce duplication and supports efficient and effective regulation of medicines across the EU.

For more information on the IT systems EMA manages together with the EU Member States, see EU Telematics.

8. Handling competing interests

The European Medicines Agency (EMA) takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests that could affect their impartiality. The Agency has separate policies in place for these groups.

Scientific experts

The Agency's policy on the handling of competing interests of scientific experts, including committee members allows the Agency to identify cases where the potential involvement of an expert as a member of a committee, working party or other group or in any other Agency activity needs to be **restricted or excluded** due to interests in the pharmaceutical industry.

The Agency screens each expert's declaration of interests (DoI) and assigns each DoI an interest level based on whether the expert has any interests, and whether these are direct or indirect.

After assigning an interest level, the Agency uses the information provided to determine if an expert's involvement should be restricted or excluded in specific activities of the Agency, such as the evaluation of a particular medicine. It bases these decisions on:

- the nature of the interests declared;
- the time since the interest occurred;
- the type of activity that the expert will be undertaking.

The current revised policy reflects a balanced approach to handling competing interests that aims to effectively restrict the involvement of experts with possible competing interests in the Agency's work while maintaining EMA's ability to access the best available expertise.

It includes a number of **measures** which take into account the nature of the declared interest before determining the length of time any restrictions may apply:

- an executive role, or a lead role in the development of a medicine during previous employment with a pharmaceutical company will result in **non-involvement** with the concerned company or product during the term of the mandate;
- for the majority of declared interests a **three-year cooling-off period** is foreseen. Restrictions to involvement decrease over time and make a distinction between current interests and interests within the last three years;

- for some interests, such as financial interests, there continues to be **no cooling-off period** required when the interest is no longer present.

Requirements for experts who are members of scientific committees are stricter than for those participating in advisory bodies and ad-hoc expert groups. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than requirements for the other committee members.

The revised policy entered into force on 30 January 2015. EMA subsequently updated the policy:

- to **restrict involvement** of experts in the assessment of medicines if they plan to take up a job in the pharmaceutical industry in May 2015. This restriction is reflected in the guidance document.
- to **clarify the restrictions** if an expert takes up a job in industry and to align the rules on close family members for committee and working party members interests with those for Management Board members in October 2016.

The revised policy takes into account **input from stakeholders** at the Agency's September 2013 public workshop Best expertise vs conflicts of interests: striking the right balance.

Breach-of-trust procedure

EMA has in place a breach-of-trust procedure, which sets out how the Agency deals with incorrect or incomplete DoIs by experts and committee members.

The Agency updated the procedure in April 2015 to align it with the current version of the policy on handling competing interests and to take into account experience gained since it was first endorsed by EMA's Management Board in 2012.

Staff members

The Agency's code of conduct extends the requirements for impartiality and the submission of annual DoIs to all staff members working at the Agency.

New staff must **get rid of any interests** they have before they can start to work at the Agency.

The completed DoIs for management staff are available on the EMA website under Agency structure. All other DoIs are available on request.

Tthe Management Board revised its rules on how the Agency handles potential competing interests of staff members in October 2016. The revised rules are similar to the principles adopted for committee members and experts. They explain the allowable and non-allowable interests for staff, and include controls on the appointment of individuals as responsible for managing the evaluation of medicines.

Management Board members

The policy on handling competing interests for Management Board members and breach-of-trust procedure aligns with the policy on handling competing interests and breach-of-trust procedure for scientific committee members and experts.

EMA's Management Board adopted the current version of the policy and trust of-breach procedure in December 2015. This policy entered into force on 1 May 2016 and was subsequently updated in

October 2016 to **clarify restrictions** for positions in a governing body of a professional organisation and to align the rules on grants or other funding with those for committee members and experts.

All Management Board members must submit a DoI every year. These are available on the EMA website under Management Board members.

Annual review of policies on independence

As of 2015, EMA reviews all of its policies on independence and rules for handling competing interests and their implementation on an annual basis and publishes an annual report. The report includes results of breach-of-trust procedures, any controls carried out, initiatives planned for the following year and recommendations for improvement.