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 Amsterdam. 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 the 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.

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.

Who does initial research on medicines?

The initial research on medicines is usually done by **pharmaceutical and biotechnology companies** – some big companies develop many medicines, while others are small companies who may only be researching one or two.

Doctors and academics also perform research, and may get together to research either new medicines or new uses of old medicines. Such researchers, either in public institutions or private companies, investigate vast numbers of substances for their potential as medicines each year.

However, only a small proportion of the compounds investigated will ever be promising enough to progress to further development

Did you know..?

Developers of **innovative treatments** can discuss the scientific, legal and regulatory aspects of their medicine with EMA early in the development through the Innovation Task Force. In 2018, 9 of 22 such requests for early discussions came from university-based or academic groups.

How are potential new medicines tested?

Potential new medicines are tested first in the laboratory and then in human volunteers, in studies called clinical trials. These tests help us to understand how the medicines work and to evaluate their **benefits and side effects**.

Medicine developers who wish to conduct clinical trials in the EU need to submit applications to the national competent authorities of the countries where they want to conduct the trials.

EMA does not have a role in the authorisation of clinical trials in the EU; this is the responsibility of the national competent authorities.

However, EMA, in cooperation with the EU Member States, plays a key role in ensuring that medicine developers follow **EU and international standards**.

Whether they conduct these studies within or outside the EU, developers conducting studies to support the marketing authorisation of a medicine in the EU have to comply with strict rules. These rules, called Good clinical practice, apply to the way they design the studies, how they record their results and how they report these results. These rules are in place to ensure that studies are scientifically sound and conducted in an ethical manner.

Can EMA influence which medicines should be developed?

EMA **cannot sponsor medicines or fund research studies** for a specific medicine, nor can it force companies to research particular medicines or treatments for a particular condition.

Being a medicines regulator, EMA has to be neutral and cannot have a financial or other interest in any medicine being developed.

However, EMA can, and does, publicise areas where there is a need for new medicines – for example, new antibiotics – to **encourage interested parties** to research them. In addition, the EU legislation provides measures to encourage companies to develop medicines for rare diseases. These include for example fee reductions when obtaining scientific advice from EMA.

Also provided by the EU legislation is a system of obligations, rewards and incentives to encourage manufacturers to research and develop medicines for children.

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.** Medical devices are regulated by national competent authorities in Europe. EMA is involved in the assessment of certain categories of medical devices. For more information, see 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.

Who makes decisions on patient access to medicines?

Medicines that are granted a marketing authorisation by the European Commission can be marketed throughout the EU.

However, before a medicine is made available to patients in a particular EU country, decisions about **pricing** and **reimbursement** take place at national and regional level in the context of the national health system of the country.

EMA has no role in decisions on pricing and reimbursement. However, to facilitate these processes, the Agency collaborates with health technology assessment (HTA) bodies, which assess the relative effectiveness of the new medicine in comparison with existing medicines, and EU **healthcare payers**, who look at the medicine's cost effectiveness, its impact on healthcare budgets and the seriousness of the disease.

The aim of this collaboration is to find ways for developers to address the data needs of medicines regulators as well as those of HTA bodies and EU healthcare payers during the development of a medicine, rather than generating new data after its authorisation. If one set of evidence addressing the needs of all these groups can be generated early during the development of a medicine, it should make decisions on pricing and reimbursement at national level quicker and easier.

To achieve this, EMA and the European Network for Health Technology Assessment (EUnetHTA) offer medicine developers the possibility to receive simultaneous, coordinated advice on their development plans.

Patient representatives are involved in these consultations on a routine basis so that their views and experiences can be incorporated into the discussions.

Did you know..?

In 2019, simultaneous advice from EMA and HTA bodies was provided upon request during the development of 27 medicines. Patients were involved in two thirds of these cases.

How is the safety of a medicine ensured once on the market?

Once a medicine has been authorised for use in the EU, EMA and the EU Member States **constantly monitor** its safety and take action if new information indicates that the medicine is no longer as safe and effective as previously thought.

- the safety monitoring of medicines involves a number of **routine activities** ranging from:
- assessing the way risks associated with a medicine will be managed and monitored once it is authorised;
- continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications;
- regularly assessing reports submitted by the company holding the marketing authorisation on the benefit-risk balance of a medicine in real life;
- assessing the design and results of post-authorisation safety studies which were required at the time of authorisation.

EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission. These are called EU **referral procedures**; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimisation measures or the benefit-risk balance of the medicine.

EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee (PRAC). This ensures that EMA and the EU Member States can move very quickly once an issue is detected and **take any necessary action**, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

For more information, see Pharmacovigilance: Overview.

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. How EMA evaluates medicines for human use

The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications for centralised marketing authorisations in the European Union. This authorisation procedure allows pharmaceutical companies to market the medicine and make it available to patients and healthcare professionals throughout the European Economic Area on the basis of a single marketing authorisation.

Preparing an application

What happens before a medicine assessment starts?

A few months before the assessment starts, EMA provides guidance to medicine developers to ensure that their applications for marketing authorisation comply with legal and regulatory requirements to avoid unnecessary delays.

To obtain marketing authorisation, medicine developers need to submit specific data on their medicine. EMA then carries out a thorough assessment of these data to decide whether or not the medicine is safe, effective and of good quality and is therefore suitable for use in patients.

EMA provides companies with guidance on the type of information that needs to be included in a marketing authorisation application.

About 6 to 7 months before submitting an application, medicine developers can meet with EMA to ensure that their application complies with legal and regulatory requirements. This means that the application includes all the different aspects required by EU legislation and needed to demonstrate that a medicine works as intended.

These meetings involve a range of EMA staff responsible for various areas such as quality, safety and efficacy, risk management or paediatric aspects, who will follow the application throughout the assessment.

EMA encourages developers to request such pre-submission meetings as they aim to increase the quality of the applications and avoid unnecessary delays.

Who bears the cost of medicine evaluation?

European legislation requires that pharmaceutical companies contribute to the costs of regulation of medicines. As the companies will earn revenues from the sales of medicines, it is fair that they should bear most of the financial costs of regulating them. This means that EU taxpayers do not have to support all the costs of ensuring the safety and effectiveness of medicines.

Companies pay an administrative fee upfront before EMA assessment starts. The administrative fee applicable for each procedure is defined by EU legislation.

What information needs to be submitted in a marketing authorisation application?

The data submitted by medicine developers in their application for marketing authorisation must comply with EU legislation and include information on:

- the group of patients the medicine is proposed to treat, and whether there is an unmet medical need addressed by the medicine;
- the quality of the medicine including its chemical and physical properties, such as its stability, its purity and biological activity;
- compliance with international requirements for laboratory testing, medicine manufacture and conduct of clinical trials ('good laboratory practice', 'good clinical practice' and 'good manufacturing practice');
- the medicine's mechanism of action, as investigated in laboratory studies;
- how the medicine is distributed in, and eliminated by, the body;
- the benefits observed in the patient group at whom the medicine is aimed;
- the medicine's side effects observed in patients, including in special populations such as children or the elderly;
- the way risks will be managed and monitored once the medicine is authorised;
- what information is intended to be gathered from follow-up studies after authorisation.

Information about any possible (known or potential) safety concerns with the medicine, the way risks will be managed and monitored once the medicine is authorised and what information is intended to be gathered from follow-up studies after authorisation is described in detail in a document called the 'risk

management plan' (RMP). The RMP is evaluated by EMA's safety committee, PRAC, to ensure its suitability.

The information to be provided to patients and healthcare professionals (i.e. the summary or product characteristics or SmPC, labelling and package leaflet) must also be supplied by the developer and is reviewed and agreed by the CHMP.

Where do data on the medicine come from?

Most of the evidence collected on a medicine during its development comes from studies funded by the medicine developer. Any other data available on the medicine (for example from existing studies in the medical literature) must also be submitted by the applicant and will be assessed.

Studies that support the marketing authorisation of a medicine have to comply with strict rules and are conducted in a regulated setting. International standards, called good clinical practice, apply to the study design, recording and reporting to ensure that studies are scientifically sound and conducted in an ethical manner. The type of evidence needed to determine the benefits and risks of a medicine are defined by EU law and must be adhered to by medicine developers. Inspections can be requested by EMA to verify compliance with these standards.

EMA supports the conduct of high-quality studies through initiatives such as the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) which bring together expertise from independent academic centres across Europe. Thanks to these initiatives additional sources of evidence can complement the evidence provided by medicine developers, in particular in the context of the continuous safety monitoring of a medicine after its authorisation.

Assessment process

What is the key principle underpinning a medicine's assessment?

The balance between the benefits and risks of a medicine is the key principle guiding a medicine's assessment. A medicine can only be authorised if its benefits outweigh the risks.

All medicines have benefits as well as risks. When assessing the evidence gathered on a medicine, EMA determines whether the benefits of the medicine outweigh its risks in the group of patients for whom the medicine is intended.

In addition, since not everything is known about a medicine's safety at the time of its initial authorisation, the way risks will be minimised, managed and monitored once the medicine is more widely used is also an integral part of the assessment and is agreed at the time of authorisation.

While the authorisation of a medicine is based on an overall **positive balance between the benefits and risks** at population level, each patient is different and before a medicine is used, doctors and their patient should judge whether this is the right treatment option for them based on the information available on the medicine and on the patient's specific situation.

Did you know..?

In some cases, for example when a medicine is intended to treat a life-threatening disease for which there is no satisfactory treatment or if the disease targeted is very rare, EMA can recommend marketing authorisation on the basis of less complete or limited evidence on the medicine, provided that further data are provided at a later stage.

As for all marketing authorisations, it must still be demonstrated that the benefits of the medicine outweigh the risks.

For more information, see:

- Conditional marketing authorisation
- Guideline on procedures for granting marketing authorisation under exceptional circumstances

Who is involved in the assessment of marketing authorisation applications?

A **committee of experts**, each supported by a team of assessors, evaluates the applications.

EMA's Committee for Medicinal Products for Human Use (CHMP) assesses applications submitted by medicine developers and recommends whether or not a medicine should be granted marketing authorisation. The committee is composed of one member and an alternate from each EU Member State, as well as from Iceland and Norway. It also has up to five EU experts in relevant fields such as statistics and quality of medicines, who are nominated by the European Commission.

When conducting an assessment, the CHMP members are each supported by a team of assessors in the national agencies, who have a range of expertise and will look at the various aspects of the medicine, such as its safety, quality and the way it works.

The CHMP also works with other EMA committees during the assessment. These include the:

- Committee for Advanced Therapies (CAT) which leads the assessment of advanced therapy medicines (gene therapy, tissue engineering and cell-based medicines);
- Pharmacovigilance Risk Assessment Committee (PRAC) for aspects related to the medicine's safety and risk management;
- Paediatric Committee (PDCO) for aspects related to the medicine's use in children;
- Committee for Orphan Medicinal Products (COMP) for orphan-designated medicines.

How does the CHMP work?

Peer review and collegial decisions are at the heart of the CHMP assessments.

For each application for a new medicine, two committee members – known as rapporteur and co-rapporteur – from different countries are appointed to lead the assessment (for generics only one rapporteur is appointed). They are appointed according to objective criteria to make best use of the available expertise in the EU.

The role of the rapporteur and co-rapporteur is to conduct the scientific evaluation of the medicine independently from each other. They each form an **assessment team** with assessors from their national agency and sometimes from other national agencies.

In their assessment reports, each team summarises the data from the application, presents its judgments of the medicine's effects and its views on any uncertainties and limitations of the data. They also identify questions that will have to be answered by the applicant. The two separate assessments take into account regulatory requirements, relevant scientific guidelines and experience in the evaluation of similar medicines.

In addition to the rapporteur and co-rapporteur, the CHMP also appoints one or more **peer reviewers** from amongst the CHMP members. Their role is to look at the way the two assessments are performed and ensure that the scientific argumentation is sound, clear and robust.

All the CHMP members, in discussion with colleagues and experts in their national agencies, also contribute actively to the evaluation process. They review the assessments made by the rapporteurs, provide comments and identify additional questions to be addressed by the applicant. The initial assessment and the comments received from peer reviewers and other committee members are then discussed during a plenary meeting of the CHMP.

As a result of the discussions and as new information becomes available during the assessment, either from additional experts or from clarifications provided by the applicant, the scientific arguments are refined so that a final recommendation, representing the committee's analysis and opinion on the data, is developed. This can sometimes mean, for example, that the committee's view on the benefit and risk of the medicine may change during the evaluation and diverge from the initial assessments performed by the rapporteurs.

Can the CHMP request more information during the evaluation?

During the evaluation, the CHMP raises questions on the evidence provided in the application and asks the applicant to provide **clarifications or additional analyses** to address these questions. Responses have to be provided within an agreed timeframe.

The CHMP can raise objections or concerns which can relate to any aspect of the medicine. If unresolved, major objections **preclude marketing authorisation**.

Major objections can relate for example to the way the medicine was studied, the way it is manufactured, or to the effects seen in patients such as the magnitude of the benefits or the seriousness of the side effects.

Additional experts involved

What additional expertise can the CHMP rely on?

Experts with specialised scientific knowledge or clinical experience are often consulted during the evaluation to enrich the scientific discussion.

Additional experts can be called upon by the CHMP at any time during the assessment to provide advice on specific aspects raised during the evaluation.

Did you know..?

External experts are consulted in about a quarter of the assessments of new medicines (excluding generics).

The CHMP can request the support of and ask specific questions to its working parties which have expertise in a particular field such as biostatistics, or a therapeutic area such as cancer. The members of EMA's working parties have an in-depth knowledge of the latest scientific developments in their field of expertise.

The committee can also call upon external experts through its scientific advisory groups or ad-hoc expert groups. These groups, which include healthcare professionals and patients, are asked to respond to specific questions on the potential use and value of the medicine in clinical practice.

Did you know..?

EMA regularly exchanges views on ongoing medicines' assessments with other regulatory agencies such as the United States Food and Drug Administration, Health Canada and the Japanese regulatory authorities. These discussions can relate for example to clinical and statistical issues, strategies to manage the risks and studies to be conducted after authorisation.

For more information, see:

- Cluster activities

How are patients and healthcare professionals involved?

Patients and healthcare professionals are involved as experts and provide their views on whether the medicine can address their needs.

Patients and healthcare professionals are invited to take part as experts in scientific advisory groups or ad-hoc expert groups. Patients contribute to discussions by highlighting, for example, their **experience of the disease**, their needs and what risks they would consider acceptable in view of the expected benefits. Healthcare professionals may advise on groups of patients with unmet needs or the feasibility of measures proposed to minimise the risks associated with a medicine in clinical practice.

In addition, individual patients can be invited to CHMP plenary meetings in person or via teleconference or consulted in writing (The outcome report of a pilot is available).

Did you know..?

In 2018, patients and healthcare professionals were involved in the assessment of about one in four new medicines (excluding generics).

What are the measures to safeguard experts' independence?

Independence is safeguarded by a **high level of transparency** and the application of restrictions if certain interests are considered to potentially impact impartiality.

EMA policies on handling competing interests have been put in place to restrict the involvement of members, experts and staff with possible competing interests in the Agency's work while maintaining EMA's ability to access the best available expertise.

Members and experts of committees, working parties and scientific advisory groups or ad hoc expert groups submit a **declaration of interests** prior to any involvement in EMA activities.

The Agency assigns each declaration of interests a level of risk based on whether the expert has any direct or indirect interests (financial or other) that could affect their impartiality. Prior to involvement in a specific EMA activity, EMA checks the declaration of interests. If a competing interest is identified, the member or expert will have restricted rights.

Restrictions include no participation in the discussion on a particular topic or exclusion from voting on the topic. Members' and experts' declarations of interests and information on restrictions applied during scientific committee meetings are publicly available in the meeting minutes.

Rules for experts who are members of scientific committees are stricter than for those participating in advisory bodies and ad-hoc expert groups. This way EMA can call on the best expertise in the context of advisory groups in order to gather the most relevant and complete information, and apply stricter rules when it comes to decision making.

Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than requirements for other committee members.

In addition, members of the committees, working parties, scientific advisory groups (and experts attending these meetings), and EMA staff have to abide by the principles set out in the EMA code of conduct .

Did you know..?

The declarations of interests of all the experts, including patients and healthcare professionals, who take part in EMA activities are published on the EMA website. EMA also publishes annual reports on its independence which include facts and figures on declared interests and resulting restrictions.

Outcome

How does the CHMP make its final recommendation?

The final CHMP recommendation is reached by a **formal vote**. Ideally, the CHMP will come to a consensus and unanimously recommend either the approval or refusal of the marketing authorisation; such a consensus is reached in 90% of cases. However, when a final recommendation by consensus cannot be reached, the committee's final recommendation will represent the majority view.

What information is publicly available during the evaluation of a new medicine and once a decision has been made?

EMA provides a high level of transparency about its medicine assessment by publishing of meeting agendas and minutes, reports describing how the medicine was assessed and the clinical study results submitted by medicine developers in their applications.

The list of new medicines that are being evaluated by the CHMP is available on the EMA website and updated every month.

EMA also publishes the agendas and minutes of all its committees' meetings, where information on the stage of the assessment can be found.

Once a decision has been taken on the authorisation or refusal of a marketing authorisation, EMA publishes a comprehensive set of documents called the European public assessment report (EPAR). This includes the public CHMP assessment report, which describes in detail the data assessed and why the CHMP recommended authorising or refusing authorisation.

For applications received after 1 January 2015, EMA also publishes the clinical study results submitted by medicine developers in support of their marketing authorisation applications. For older applications, clinical study results can be obtained through a request for access to the document.

Detailed information on what EMA publishes and when on human medicines from the early development to the initial evaluation and the post-authorisation changes can be found in EMA's guide to information on human medicines evaluated by EMA.

Did you know..?

As of October 2018, EMA had published the clinical study results submitted by medicine developers in their applications for over 100 medicines recently assessed by EMA. These are available for public scrutiny on EMA's dedicated website on clinical data

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5. 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 Amsterdam, 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.

6. 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 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.

7. 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.

8. 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 optimise 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.

9. 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.