1 March 2023
EMA/527628/2011 Rev. 4
European Medicines Agency

Frequently asked questions

This document provides answers to the most frequently asked questions received by the European Medicines Agency (EMA).

If the information you're looking for is not here, please send a question to EMA.

If you're a journalist or other media representative EMA invites you to contact the Agency's press office.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

Languages

What information is available on this website in languages other than English?

Currently, most of the information on this website is only available in English. Much of this content provides regulatory guidance to the pharmaceutical industry, which mainly operates in English.

Information intended for a wider audience is translated into **all official European Union (EU) languages**.

For **medicines evaluated by EMA**, the following resources are available in all EU languages:

- Human medicines overviews
- Q&A on refusals and withdrawals of marketing authorisation applications
- Product information including the package leaflets for patients
- Major reviews of medicines (known as referrals), explaining EMA's recommendations about issues such as a safety concern

This website also provides core **institutional information** in official EU languages, such as these frequently asked questions (FAQs) and the 'About us' section.

Citizens can submit questions to EMA in any official EU language. EMA will reply in the same language.

For more information:

- Languages on this website
- What we publish on medicines and when

How can I identify which information is available in all EU languages?

You can identify the documents that are translated into all **official European Union (EU) languages** through the box below:

Information featured on this page is available in all official EU languages, plus Icelandic and Norwegian.

Select 'available languages' to access the language you need.

COVID-19

Where can I find information on COVID-19 vaccines and treatments on this website?

You can find information on **COVID-19 vaccines** and **treatments** on:

- COVID-19 vaccines
- COVID-19 treatments

EMA publishes **information in lay-language** about the most important topics related to COVID-19 here:

- COVID-19 vaccines: key facts as Link

You can find information translated to all EU languages on the respective medicine pages.

How can I find updated information on the safety of COVID-19 vaccines?

You can find more information on EMA's role in monitoring the **safety** of COVID-19 vaccines on the dedicated webpage:

- Safety of COVID-19 vaccines

You can also find information on the safety of COVID-19 vaccines on their respective medicine pages.

How can I learn about the authorisation of COVID-19 vaccines and treatments?

There's a description of the **authorisation process** for COVID-19 vaccines and treatments on these pages:

- COVID-19 vaccines: development, evaluation, approval and monitoring
- COVID-19 vaccines: studies for approval
- COVID-19 vaccines
- COVID-19 treatments

Medicines and their evaluation

What type of information is available on a medicine evaluated by EMA?

EMA publishes information about all the medicines it assesses as a European public assessment report (EPAR). This is a set of documents that explains the scientific conclusion reached by EMA's Committees at the end of the evaluation process. Each EPAR includes an **overview for the public** and the **product information**.

You can also find information on medicines at various stages of their life cycles, including the early developmental stages through to post-authorisation changes, safety reviews and suspensions and withdrawals of authorisation.

For more information:

- Search human medicines
- Search veterinary medicines
- What we publish on medicines and when

Why can I not find information about a particular medicine on your website?

The medicine you are looking for may be:

- authorised through **national procedures** and not centrally through EMA. To find information on nationally authorised medicines, contact the medicines regulatory agency in your country;
- still **in development** and not yet authorised;
- **not classified as a medicine** but as a medical device or a nutritional supplement.

For more information:

- National competent authorities (human)
- National competent authorities (veterinary)
- Medicines under evaluation (human)

Can EMA tell me when a medicine will be approved?

EMA publishes the names of the active substances of medicines currently under evaluation but cannot say when the medicines will be authorised. **EMA takes around a year to evaluate a medicine**, at the end of which it issues a recommendation on whether the medicine should be authorised. EMA then sends this recommendation to the European Commission, which takes a binding decision on whether to grant a marketing authorisation.

Following a positive recommendation from EMA, the **European Commission takes around two months to authorise a medicine.** The European Commission follows the opinion of EMA in almost all cases.

EMA publishes information on the medicines it evaluates at the time it makes a recommendation as well as after the European Commission has issued a marketing authorisation.

During the evaluation procedure, EMA publishes information relevant to the evaluation timetable in the agenda and minutes of the meetings of its relevant scientific committees.

For more information:

- Medicines under evaluation (human)
- Summaries of opinion (human)
- Summaries of opinion (veterinary)

How can I keep up to date with EMA's opinions?

For the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), EMA publishes **meeting highlights** with evaluation outcomes of major public interest on the Friday following their monthly plenary meetings. These are also published on EMA's homepage.

For the Committee for Advanced Therapies, the Committee (CAT) for Orphan Medicinal Products (COMP) and the Paediatric Committee (PDCO), EMA publishes monthly **meeting reports** in the week following the committee's plenary meeting. These documents can be found on the webpages of the respective committees.

To stay up to date with the latest news, features, and publications from EMA, you can subscribe to our RSS feeds or follow EMA on Twitter.

EMA also publishes a **monthly newsletter** called 'human medicines highlights', which provides key information on EMA's recent activities on human medicines.

For more information:

- Committees, working parties and other groups
- RSS feeds
- Human medicines highlights
- What's new

Availability of medicines

How can I get hold of a medicine that is not yet authorised?

Medicines cannot be placed on the market without authorisation. However, some medicines can be supplied to individual patients under special conditions before they have been authorised. These include **clinical trials** and **compassionate-use programmes**, which Member States regulate.

To find out if a medicine is currently available in your country through a compassionate-use programme, check with your national medicines regulatory authority or the company responsible for the medicine.

In addition, you may be eligible to take part in a clinical trial. For information on clinical trials, talk to your doctor or nurse.

For more information:

- What we do
- National competent authorities (human)
- Clinical trials in human medicines

My medicine has been evaluated by EMA but is not available in my country. Why not?

Although medicines evaluated by EMA receive an authorisation valid in the whole of the EU, **decisions on where a medicine is marketed** are made by the **company that markets the medicine** (the marketing-authorisation holder). The EMA has no control over these decisions. This means that medicines that have received a central marketing authorisation via EMA may not be available in all European Union (EU) Member States.

A medicine that is authorised in the EU might not be authorised or marketed in countries outside the EU. Contact the medicines regulatory authorities in these countries to get more information on the availability of medicines in their territories.

For more information:

- What we do
- National competent authorities (human)
- National competent authorities (veterinary)

Does EMA have information on the availability of medicines in Member States?

No. EMA does not have up-to-date information on the availability of medicines in Member States. Medicines **regulatory authorities** in Member States may be able to provide you with this information.

For more information:

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

Can you help me to get hold of a medicine?

No. EMA does not have any commercial interests and does not get involved in the distribution of medicines. **EMA's responsibilities are limited to the evaluation of medicines** for authorisation purposes and their supervision once they are authorised.

EMA is also unable to give any financial assistance to patients who are trying to get hold of a medicine.

EMA suggests that you discuss your treatment with a healthcare professional, such as a doctor or pharmacist.

For more information:

- What we do

Reporting suspected side effects

I am experiencing a side effect from a medicine. What should I do?

If you are experiencing a side effect or think you may be experiencing one, you should **seek advice from a doctor or pharmacist**. You can also find information on side effects seen with a medicine in the package leaflet.

EMA also recommends that you **report any suspected side effects** to the national competent authority. You can do this either by talking to a healthcare professional, or in some cases, you can report the side effects directly to the national competent authority using online patient reporting forms or by telephone. For information on how to report a side effect in your country, please consult the appropriate authority.

These **spontaneous reports** of suspected side effects by healthcare professionals, patients or carers are used to continuously monitor the safety of medicines on the market and to ensure that their benefits continue to outweigh their risks.

EMA cannot accept side effect reports directly from patients. EMA is also not in a position to provide medical advice or to confirm whether your symptoms are being caused by your medicine.

For more information:

- European database of suspected adverse drug reaction reports
- Search human medicines
- Leaflet: Did you know? You can report side effects yourself

Medical advice

Can EMA give me any advice on my treatment or medical condition?

No. EMA cannot advise individual patients on their treatment or condition. EMA suggests that you discuss these issues with a **healthcare professional**, such as your doctor or pharmacist.

Can you recommend a medical specialist for my condition?

No. EMA does not maintain a list of medical specialists and is **unable to advise individual patients** on where to seek treatment.

Clinical trials

How can I get onto a clinical trial?

EMA is not involved in recruiting volunteers for clinical trials. If you would like to take part in a clinical trial, you should **discuss it with your doctor or nurse**, who may be able to refer you for a suitable trial.

For more information:

- Clinical trials in human medicines

Medical devices

What is the role of EMA in the evaluation of certain categories of medical devices?

EMA has **distinct regulatory roles** per category of medical device, including in vitro diagnostics.

- Medicines used in combination with a medical device
- Medical devices with an ancillary medicinal substance
- Companion diagnostics ('in vitro diagnostics')
- Medical devices made of substances that are systemically absorbed
- High-risk medical devices — EMA supports the medical device expert panels that provide opinions and views to notified bodies on the scientific assessment of certain high-risk medical devices and in vitro diagnostics.

For more information:

- Medical devices

What is the role of EMA in crisis preparedness and management for medicinal products and medical devices?

EMA has a central role in monitoring and mitigating **shortages of critical medical devices** and **in vitro diagnostics** in the context of a public health emergency.

For more information:

- Crisis preparedness and management
- Medical devices
- Availability of medicines

Herbal medicines

How are herbal medicines evaluated?

In the European Union (EU), **herbal medicines** are authorised by medicines regulatory authorities in Member States.

EMA has a role in preparing scientific opinions on the quality, safety, and efficacy of herbal medicines, to help harmonise this information across the EU. These **'Community herbal monographs'** are prepared by the Committee on Herbal Medicinal Products (HMPC) and contain information about what a herbal medicine is used for, restrictions on its use, its undesirable effects and its interactions with other medicines.

For more information:

- Search herbal medicines
- Herbal Medicinal Products Committee
- National competent authorities (human)
- European Commission: Herbal medicinal products

Food supplements and cosmetics

How are food supplements evaluated?

Food supplements are evaluated at **national level**, usually by the authorities that deal with food safety and labelling. They are not usually evaluated by medicines regulatory authorities, unless they contain a substance that has pharmacological activity or make a medicinal claim.

For more information:

- European Commission: food supplements
- European Food Safety Authority

How are cosmetics evaluated?

Cosmetics are evaluated by **authorities** in each **Member State**. They are not evaluated by EMA.

For more information:

- National competent authorities (human)

EMA’s fees

What fees does EMA charge?

EMA charges fees to pharmaceutical companies for the **services it provides**. EMA publishes the rules on these fees, including a list of the fees charged for each type of procedure. Fees are adjusted each year for inflation.

For more information:

- Fees payable to the EMA

Transparency and competing interests

How are the EMA's committee members selected?

Most of the members of EMA's scientific committees are **nominated** by the **Member States** or the **European Commission**. EMA's Management Board is also made up of representatives of Member States and members nominated by the European Commission.

For more information:

- Committees
- Management Board

How are competing interests monitored?

The members of EMA's Management Board and scientific committees, and its experts and staff are not permitted to have financial or other interests in the pharmaceutical industry that could affect their impartiality. Each member and expert make an **annual declaration** of their **financial interests**. These are publicly available.

For more information:

- Handling competing interest
- Management Board
- Committees
- European experts

How is the financial transparency of patient and consumer organisations evaluated?

EMA requires every patient and consumer organisation that it works with to provide **financial statements**, including details on donors and their contributions. Each organisation is re-evaluated every two years.

For more information:

- Working with patients and consumers

Pricing, advertising, sales and patents

Does EMA have any information on the price or reimbursement of medicines in Member States?

No. Decisions on **pricing and reimbursement** are made at a **national level** following negotiations between governments and marketing authorisation holders. EMA is not involved in these decisions and does not have any information on pricing or reimbursement arrangements in Member States.

For more information:

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

Does EMA control advertising of medicines?

No. Advertising of medicines is controlled by medicines **regulatory authorities** in Member States and **other national regulatory bodies**, together with **self-regulation** by the pharmaceutical industry.

In the European Union (EU), advertising of prescription-only medicines directly to patients and consumers is forbidden.

For more information:

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

How can I get sales figures for a medicine?

EMA does not have information on sales figures or prescription numbers for any medicine. Sales are dealt with at a **national level**. The medicines regulatory authorities in Member States may be able to provide information on sales of a medicine.

For more information:

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

Can EMA provide me with information on patents on medicines?

No. EMA is not responsible for **patents** on medicines: issues regarding patent law are not within EMA's remit. The European Patent Office may be able to provide information on a specific patent.

The European Medicines Agency

What does EMA do?

EMA's main responsibility is the protection and promotion of **public and animal health**, by carrying out **scientific evaluations** of medicines for human and veterinary use.

The outcome of EMA's evaluation is used by the European Commission to decide whether a medicine can be authorised for marketing in the European Union (EU). The company producing a medicine can only market it once the medicine has received a marketing authorisation from the European Commission.

EMA also supervises the **safety of medicines** in the EU after they have been authorised. It can also give scientific opinions on medicines at the request of Member States or the European Commission.

For more information:

- What we do

What does EMA not control?

EMA does **not control**:

- the pricing of medicines;
- patents on medicines;
- the availability of medicines;
- medical devices. However, EMA is involved in the assessment of certain categories of medical devices;
- homeopathic medicines;
- herbal supplements;
- food supplements;
- cosmetics.

For more information:

- What we do

Are all medicines approved via EMA?

No. In the European Union (EU), there are two ways of getting a marketing authorisation for a medicine:

- the **centralised procedure**, via EMA, which results in a single marketing authorisation valid throughout the EU;
- **national authorisation procedures**, where individual EU Member States authorise medicines for use in their own territory.

There are also two routes to allow companies to gain authorisation in more than one country: the **mutual-recognition procedure** and the **decentralised procedure**.

For more information:

- Authorisation of medicines

When is EMA open?

EMA's normal business hours are **Monday to Friday**, **08:30 to 18:00 (Central European Time, CET)**.

EMA is closed for holidays on various days throughout the year. These are not always on the same days as the national holidays in the Netherlands or other Member States.

For more information:

- Business hours and holidays

Can EMA help to fund my work?

No. EMA does not directly **fund research**.

Can EMA recommend academic courses?

No. EMA is unable to recommend **academic courses** in regulatory affairs, medicine, or any other discipline.

Can EMA supply me with branded merchandise?

No. EMA is **unable to supply** pens, mugs or other items branded with EMA's logo.

This website

How can I search for information on EMA's website?

A general **'Site-wide search' bar** is featured at the top right of every page on the EMA website. It allows you to perform a full text search across web pages and documents on the EMA website.

A **medicines 'Quick search' bar** is featured on the **homepage** under 'Search for medicines'. If you are looking for information on a specific medicine assessed by EMA, you can use this feature to search our full database of human medicines, veterinary medicines, and herbal medicines.

The main medicines search provides more options. It may be useful if you are looking for medicines for a particular disease area or therapeutic indication or if you are looking for specific types of medicines such as generics, biosimilars or orphan medicines.

Only medicines evaluated by EMA are available on the website. Information on medicines authorised in individual Member States through national procedures can only be obtained through the national medicines regulatory authorities. You may not be able to obtain a complete list of available treatment options for a specific condition by searching on EMA's website.

The search is currently only available in English. For more help with using the search functionalities, check our Search tips.

How can I report an issue with EMA's website?

If your experience issues with this website, such as opening a link or a document, send us a message.

You can also rate a page and **leave a comment** under the section 'How useful was this page?' at the bottom of most pages of this website.