EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Directorate

Frequently asked questions

This document provides answers to the most frequently asked questions received by the European Medicines Agency (EMA). If the answer to your question is not here, please use our online form**:** Send a question to EMA.

Please give as much background information as possible to help us answer your query effectively.

To help us direct your query to the right people within the Agency, please indicate whether you are making your enquiry for personal reasons (e.g. a patient or carer, a student, a researcher, a healthcare professional, etc.) or on behalf of an organisation.

If appropriate, please give the type of organisation you represent (e.g. patient organisation, pharmaceutical company, etc.)

Journalists and other representatives of the press should contact our press office directly at press@ema.europa.eu.

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Questions about the Agency

What does the Agency do?

The Agency'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 the Agency'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.

The Agency 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.

What does the Agency not control?

The European Medicines Agency does not control:

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

Are all medicines approved via the Agency?

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

the centralised procedure, via the Agency, 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.

How are herbal medicines evaluated?

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

The Agency 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.

What acronym should I use for the Agency?

If you wish to use an acronym for the Agency, use 'EMA'. Please note that this is an unofficial acronym.

The Agency's old acronym of 'EMEA' should not be used any longer.

When is the Agency open?

The Agency's normal business hours are 9.00am to 5.30pm, Monday to Friday.

The Agency is closed for holidays on various days throughout the year. These are not always on the same days as the national holidays in the United Kingdom or other Member States.

Can the Agency fund my work?

No, EMA does not directly fund research.

Can the Agency recommend academic courses?

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

Can the Agency supply me with branded merchandise?

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

Questions about the Agency’s website

Is the Agency’s website available in languages other than English?

Currently, most of the information on the Agency's website is only available in English. Some content is translated into other official European Union (EU) languages, including public summaries and product information in European public assessment reports (EPARs), question-and-answer documents for the public, information on recruitment, work programmes and summaries of the annual report. These frequently asked questions are also available in all EU languages.

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

How can I search for information on the Agency’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 the Agency, 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 the Agency 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 the Agency's website.

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

Questions about medicines

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

The Agency 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 the Agency's Committees at the end of the evaluation process. Each EPAR includes a summary 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.

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

The medicine you are looking for may be:

- authorised through natural 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, both of which are authorised at national level.

Can the Agency tell me when a medicine will be approved?

The Agency publishes the names of the actives substance of medicines currently under evaluation but cannot say when the medicines will be approved. The Agency takes around a year to evaluate a medicine, at the end of which it issues a recommendation on whether the medicine should be approved. The Agency 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 the Agency, the European Commission takes around two months to approve a medicine. The European Commission follows the opinion of the Agency in almost all cases.

The Agency 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, the Agency publishes information relevant to the evaluation timetable in the agenda and minutes of the meetings of its relevant scientific committees.

How can I keep up to date with the Agency'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 the Agency, you can subscribe to our RSS feeds or follow EMA on Twitter.

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

Questions about the evaluation of other substances

How are medical devices evaluated?

Medical devices are evaluated by the medicines regulatory authorities in each Member State. However, the Agency is involved in the assessment of certain categories of medical devices.

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.

How are cosmetics evaluated?

Cosmetics are evaluated by authorities in each Member State. They are not evaluated by the Agency.

Questions about competing interests and transparency

How are the Agency's committee members selected?

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

How are competing interests monitored?

The members of the Agency'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.

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

The Agency 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.

Questions about the 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 Sates 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. You can also see information on clinical trials ongoing in Europe in the European Union Clinical Trials Register.

My medicine has been evaluated by the Agency 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 Agency has no control over these decisions. This means that medicines that have received a central marketing authorisation via the Agency 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.

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

No. The Agency 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.

Can you help me to get hold of a medicine?

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

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

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

Questions about pricing, sales and patents

Does the Agency 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. The Agency is not involved in these decisions and does not have any information on pricing or reimbursement arrangements in Member States.

Does the Agency 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.

How can I get sales figures for a medicine?

The Agency 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.

Can the Agency provide me with information on patents on medicines?

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

Questions about medical advice

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

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

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.

The Agency 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.

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

Can you recommend a medical specialist for my condition?

The Agency does not maintain a list of medical specialists and is unable to advise individual patients on where to seek treatment.

Questions about clinical trials

How can I get onto a clinical trial?

The Agency 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. You may wish to consult the EU Clinical Trials Register for information on authorised clinical trials that are ongoing.

Questions about fees

How are fees organised at the Agency?

The European Medicines Agency charges pharmaceutical companies fees for the services it provides. The Agency 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.