



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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European Medicines Agency

## Contacts at the European Medicines Agency

In this document you can find several ways to contact the European Medicines Agency (EMA) depending on your need for assistance or type of request.

**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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**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](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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# Report an issue with an authorised product

## **Product emergency hotline (outside EMA business hours)**

Outside of [EMA business hours](#) (i.e. Monday to Friday before 08:30 or after 18:00, at weekends or on Agency holidays) you may call the product emergency hotline: +31 (0)88 781 7600.

This is an **emergency number** and should be used only in the event of a **potentially serious problem** with a **centrally authorised product**.

The details of your call may be documented, including personal data if you provide them (such as your name, contact details and nature of the issue raised), in accordance with our [Privacy policy](#).

## **Quality defects and recalls**

Marketing and/or manufacturing authorisation holders are obliged to report to EMA any product quality defect, including a suspected defect, of a centrally authorised medicine which could result in a recall or abnormal restriction on supply, following the [instructions on notifying quality defects](#):

- Complete the [Defective product report template](#)

*Note: This form needs to be opened with a PDF reader. EMA advises to save the document first, and then open with a PDF reader, such as Acrobat Reader.*

- email this to EMA at [gdefect@ema.europa.eu](mailto:gdefect@ema.europa.eu)

You should receive an acknowledgement in four hours during [EMA business hours](#).

If you do not, you can phone EMA on:

- Tel. +31 (0)88 781 6000 (EMA switchboard)
- Tel. +31 (0)88 781 7676 (for use only as stated in the instructions)

Urgent phone number for use outside of EMA business hours:

- Tel. +31 (0)65 008 9457

For full reporting instructions, see [Reporting a quality defect to EMA](#).

For more information, see [Quality defects and recalls](#).

## **Falsified medicines**

Marketing authorisation holders are required to notify EMA of detection of a (suspected) falsified medicine by following the instructions on notifying falsified medicines:

- Complete the [\(Suspected\) falsified medicinal product report template](#)

*Note: This form needs to be opened with a PDF reader. EMA advises to save the document first, and then open with a PDF reader, such as Acrobat Reader.*

- email this to EMA at [gdefect@ema.europa.eu](mailto:gdefect@ema.europa.eu)

You should receive an acknowledgement in four hours during [EMA business hours](#).

If you do not, you can phone EMA on:

- Tel. +31 (0)88 781 6000 (EMA switchboard)
- Tel. +31 (0)88 781 7676 (for use only as stated in the instructions)

Urgent phone number for use outside of EMA business hours:

- Tel. +31 (0)65 008 9457

For full reporting instructions, see [Reporting a falsified product to EMA](#).

For more information, see:

- [Falsified medicines: reporting obligations](#)
- [Falsified medicines: overview](#)

### **Emerging safety issues**

When a marketing authorisation holder becomes aware of an emerging safety issue, they should notify it in writing to:

- EMA by emailing [p-pv-emerging-safety-issue@ema.europa.eu](mailto:p-pv-emerging-safety-issue@ema.europa.eu);
- the relevant competent authority or authorities in the Member State(s) concerned.

To support reporting to Member States, EMA has published a list of national contact points:

- [National contact points for reporting emerging safety issues \(ESIs\)](#)

For guidance on emerging safety issues, see:

- [Good pharmacovigilance practices \(GVP\)](#) Module IX on signal management

### **Withdrawn products**

Marketing authorisation holders should notify a withdrawn product to:

- the Member State(s) concerned;
- EMA by emailing [withdrawnproducts@ema.europa.eu](mailto:withdrawnproducts@ema.europa.eu).

When notifying EMA, please use the [template cover letter](#) and the [notification of withdrawn products](#) report table.

For detailed guidance, see [Notifying a change of marketing status](#).

Marketing authorisation holders have to notify the competent authorities of any of the following actions they intend to take:

- temporary or permanent cessation of marketing of a medicinal product;
- suspension of marketing of a medicinal product;
- withdrawal of a medicinal product from the market;
- request for the withdrawal of a marketing authorisation;
- non-application for the renewal of a marketing authorisation.

Medicinal products affected by any of these actions are considered 'withdrawn products'.

For more information, see [Notifying a change of marketing status](#).

## Compliance issues with pharmacovigilance obligations

Marketing authorisation holders should email [phv-noncompliance@ema.europa.eu](mailto:phv-noncompliance@ema.europa.eu) to notify the European medicines regulatory network about any issues **complying with pharmacovigilance obligations**.

In your notification, please state the actions you are taking to correct the issue and to prevent it happening again, along with timelines.

EMA will deal with the notification in line with its [procedures for pharmacovigilance non-compliance](#).

## Extensions to ICSR submission timeframes

Marketing authorisation holders should email [phv-noncompliance@ema.europa.eu](mailto:phv-noncompliance@ema.europa.eu) to request an exceptional extension to the **submission timeframes for individual case safety reports (ICSRs)**.

This is only for extensions needed for reports from class action lawsuits, in line with section VI.C.2.2.10 of the [guideline on good pharmacovigilance practices \(GVP\) module VI](#).

In your request, please include the:

- reason for requesting the extension;
- planned duration of the extension;
- medicinal products concerned.

## Ask for assistance with an EMA IT system

EMA's **Service Desk** provides technical support for issues related to information technology (IT) systems that are hosted by EMA. This includes creating new accounts, accessing existing accounts, uploading data and using databases.

EMA IT system	Contact details
Clinical Trials Information System (CTIS)	Use the <a href="#">EMA Service Desk for CTIS</a>
IT systems for the Veterinary Medicinal Products Regulation, Union Pharmacovigilance Database (EVVet3) and Union Product Database (UPD)	Use the <a href="#">EMA Service Desk for UPD and EVVet3</a>
All other IT systems, including EudraCT, EudraGMDP, Eudralink, EudraVigilance, IRIS and SPOR services	Use the <a href="#">EMA Service Desk (ServiceNow)</a>

You can log in using your existing EMA username and password.

If you do not have an account or do not know your username and password:

- [Sign up for a new account or reset your login credentials](#)

For urgent technical matters, contact +31 (0)88 781 8520.

## Request access to documents

EMA is committed to ensuring the widest possible access to the documents that it produces, receives and has in its possession.

For **access to documents** that are not already published, use our online form:

- [Send a question to the European Medicines Agency](#)

## Ask a question

For **questions** about EMA and its work, use our online form:

- [Send a question to the European Medicines Agency](#)

You can send your question in any official **EU language**. We will reply in the same language within a reasonable time frame and no later than two months from the date of receipt.

If you need immediate [assistance with an EMA IT system](#), contact the appropriate EMA Service Desk.

## EMA switchboard number

EMA's **switchboard** number is +31 (0)88 781 6000.

The EMA switchboard is open Monday to Friday from 07:30 to 18:30 Amsterdam time, except for [EMA holidays](#).

## Directions to the EMA building

The **EMA building** is located in the Zuidas district in Amsterdam.

For **directions** to the EMA building, see [How to find us](#).

## Other contact details

### *Press office*

#### **EMA press office**

Tel. +31 (0)88 781 8427

Email: [press@ema.europa.eu](mailto:press@ema.europa.eu)

The press office only deals with enquiries from media representatives on matters relating to EMA's work. For further information, see [Media centre](#).

For enquiries from the general public and other parties, use our online form:

- [Send a question to the European Medicines Agency](#)

### *Pharmacovigilance*

#### **For medicinal products for human use:**

Tel. +31 (0)88 781 7599

For general pharmacovigilance queries, use our online form:

- [Send a question to the European Medicines Agency](#)

**For medicinal products for veterinary use:**

Jos Olaerts

Tel. +31 (0)88 781 8624

Email: [vet-phv@ema.europa.eu](mailto:vet-phv@ema.europa.eu)

The constant [safety monitoring of medicines](#) after authorisation ('pharmacovigilance') is an important part of the work of EMA and regulatory authorities in Member States.

***Certificates on medicinal products***

**Julia Lidner**

Tel. +31 (0)88 781 7567

Email: [certificate@ema.europa.eu](mailto:certificate@ema.europa.eu)

EMA issues [certificates of medicinal products](#) in conformity with the arrangements laid down by the [World Health Organization](#). These certify the marketing authorisation and good manufacturing status of medicinal products in the European Union (EU) and are intended for use in support of marketing authorisation applications within and export to non-EU countries.

***Plasma master file and vaccine-antigen master file certificates***

**Plasma master file (PMF) certificates:**

Silvia Domingo

Tel. +31 (0)88 781 8552

Email: [silvia.domingo@ema.europa.eu](mailto:silvia.domingo@ema.europa.eu)

**Vaccine antigen master file (VAMF) certificates:**

Ragini Shivji

Tel. +31 (0)88 781 8698

For all Vaccine antigen master file certificate questions, use our online form:

- [Send a question to the European Medicines Agency](#)

EMA issues [Plasma master files](#) and [Vaccine antigen master files](#) certificates of medicinal products in conformity with the arrangements laid down by European Union (EU) legislation. The certification process is an assessment of the PMF or VAMF application dossier. The certificate of compliance is valid throughout the EU.

***Quality management system***

For all quality management system questions, use our online form:

- [Send a question to the European Medicines Agency](#)

[Quality management practices](#) are an integral part of EMA's governance structure and its business processes. These practices help to ensure that EMA operates to consistently high levels of quality, efficiency and cost-effectiveness.

## ***Meeting and conference management***

### **Meeting and Conference Management**

Tel. +31 (0)88 781 7700

Hotel and travel bookings:

[bookings@ema.europa.eu](mailto:bookings@ema.europa.eu)

This service is responsible for ensuring support to EMA's meetings. It provides an interface between EMA and delegates, assisting them with their travel and hotel bookings and any other query they may have.

### **Financial support services**

Tel. +31 (0)88 781 7105

Financial queries:

[delegatereimbursements@ema.europa.eu](mailto:delegatereimbursements@ema.europa.eu)

This service deals with reimbursement of all expenses related to travel and accommodation of experts attending scientific meetings, inside and outside EMA's premises.

## ***Data submission for authorised medicines***

For support with submitting information on an authorised medicine, you can use the online [EMA Service Desk](#) portal or call +31 (0)88 781 8520 for urgent technical matters.

As per the EU pharmaceutical legislation [Article 57\(2\) of Regulation 726/2004](#), marketing authorisation holders of medicinal products authorised in the European Union and European Economic Area are [required to submit information](#) on these medicines to the European Medicines Agency and must keep this information up to date.

## ***Feedback on this website***

To provide general feedback on EMA's corporate website, [www.ema.europa.eu](http://www.ema.europa.eu), or to make suggestions for future improvement, you can write to [newwebsite@ema.europa.eu](mailto:newwebsite@ema.europa.eu). EMA will take all feedback and suggestions into account, but will not be able to reply to individual email messages.

For questions about EMA and its work, use our online form:

- [Send a question to the European Medicines Agency](#)