



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Instructions on how to submit a request for certificates of medicinal products

Request for EMA certificates of medicinal products

EMA certificates of medicinal products can only be requested through the web interface [Certificates Processing System \(CPS\)](#).

For the submission to be valid all the mandatory fields need to be filled in. If applicable, documents can be added to the submission (i.e. statement of quantitative composition).

Once a request has been submitted and the relevant fees have been paid in full, changes or cancellations are not accepted.

A flow-chart for requesting certificates is attached at the end of these instructions. Guidance on how to submit a request is provided point-by-point in these explanatory notes.

1. How to register to use the Certificates Processing System (CPS)

To be able to access [CPS](#), you will need to complete a few registration steps to ensure that:

- You have an active EMA account in [EMA's Account management Portal](#).

To find out more about how to Create an EMA Account reference the guidance [Create an EMA Account](#).

For further information on how to log into EMA Systems reference the following link [Sign In · EMA Account Management](#)

- You have an affiliation to the organisation holding the marketing authorization of the medicinal product. In order to request access for an organisation, please consult the following guidance [Request Access for Organisations](#).
- You have the appropriate user access role. There are two CPS user role types, CPS Industry User Administrator and CPS Industry User.

*If you are a **Marketing Authorisation Holder (MAH)** you must further ensure that:*

- You have a valid EMA customer account number.

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

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This is a unique reference number assigned to the MAH and should be provided by applicants when submitting a request for certificates. Information on how to set up a customer account and obtain the customer number can be found on the [Agency's 'How to pay' page](#).

For queries regarding customer account number [contact EMA's accounts team](#).

- Your organisation is registered in [EMA's Organisation Management Service \(OMS\)](#).
- You have an appropriate user access role:

CPS Industry User Administrator

Each organisation must first have at least one User Administrator allocated and validated by the EMA. This is done by completing the [affiliation template](#) and signed by an approved signatory (this person should be different from the person submitting the request) from your organisation, then the document can be downloaded or drag and dropped into the allocated box [Request Access · EMA Account Management](#)

A validated CPS Industry User Administrator can approve CPS Industry User roles and will have full control assigning or revoking rights over the CPS Industry Users' access to CPS.

CPS Industry User

To be able to order certificates this role is required.

Please note that being an approved CPS Industry User Administrator does not allow you to request certificates. If you are an approved CPS Industry User Administrator and would like to order certificates, you need to have a CPS Industry User role confirmed as well.

*If you are a **Requesting company** submitting applications on behalf of the Marketing Authorisation Holder (MAH) you must further ensure that you have:*

- A confirmed user access role as a **CPS Industry User**.
- An affiliation with the organisation you are ordering the certificates on behalf of.

A requesting company (different from the MAH) does not need to register as organization. The representative of the Requesting company has to register as CPS Industry User and needs to request CPS rights from the MAH. The MAH's User Administrator needs to provide access to the Requesting Company's representative. The MAH User Administrator will have full control assigning or revoking rights over the Requesting company representative's access for registering new Certificate requests related to the given MAH in CPS.

For information on how to grant access, please follow the instructions on the link [Request Access · EMA Account Management](#)

For technical support liaise directly with [EMA Service desk](#).

2. How to access CPS

To log in use the following link [Certificates | CPS](#)

Log in using your EMA account credentials and confirm your SAP identity entering the SAP ID of the MAH (customer number).

For further information see the instructional video.

3. How to complete a submission in CPS

The system includes step-by-step navigation indicators to show you your progress through the process, along with clearer error messages designed to provide you with more precise guidance during form completion.



3.1 Marketing Authorisation Holder

Marketing Authorisation Holder(s) or Holder(s) of CHMP Positive Scientific Opinion (Art. 58 Regulation (EC) No. 726/2004)

This data is now pre-filled and non-editable, as it is retrieved directly from EMA's Substance, Product, Organisation and Referentials (SPOR), specifically the Organisation Management System (OMS). The customer number you use to log in determines the Marketing Authorisation Holder (MAH) name and address displayed in CPS, and these must correspond exactly to the details included in the Commission Decision. In all cases, the information appearing on the certificate will align with both the Commission Decision and the Summary of Product Characteristics.

Contact person

Enter the name of the person whom EMA can contact regarding your request. Please note that EMA may ask the contact person questions about the marketing authorisation, as amended, and the GMP compliance status of the manufacturing sites. The same information is also needed for filling in this form.

Enter the contact person's telephone number and email address here. EMA will send issued electronic certificate(s) to the attention of the person and to the e-mail address stated in this field.

Title *	First name *	Last name *
<input type="text"/>	<input type="text"/>	<input type="text"/>
Telephone *	Email *	
<input type="text"/>	<input type="text"/>	

Are you a requesting company?

Are you A REQUESTING COMPANY?

If your company details are different in name and/or address to the MAH, tick the box 'Are you A REQUESTING COMPANY?'.

Are you A REQUESTING COMPANY?

Fill in your company's details in the expanded section.

Company name (requesting company)

Certify requesting company

Company address

Company Postcode (Optional)

Country

Certify requesting company

Tick in this box if EMA should certify the name and address of the certificate requesting company in the certificate.

3.2 Precondition for acceptance

Preconditions for acceptance of a request for certificates

EMA can certify medicinal products only if the following preconditions have been met.

Before submitting your request, you must confirm the preconditions for all medicinal products requested to be certified.

Conditions related to procedure for marketing authorisation

EMA can certify medicinal products only if the application for marketing authorisation via the centralised procedure or an application for an opinion under Article 58 of Regulation (EC) No 726/2004 ([EU-M4all](#)), in the context of the cooperation between EU and WHO for the evaluation of certain medicinal products for human use intended exclusively for market outside the community, has been submitted and such an application has passed the validation for assessment (Day 0).

- Application for marketing authorisation has been submitted to the Agency via centralised procedure
- Application under Article 58 of Regulation (EC) no.726/2004 has been submitted to the Agency

Select one of the two statements as appropriate, according to the type of product(s) you request to be certified (centralised or EU-M4all products). If your application contains both types of products, select the first statement and ensure to tick the box for EU-M4all products where applicable in the 'Product Information' section.

Conditions for GMP inspections and compliance

GMP compliance status confirmed and based on recent GMP inspections by an EU/EEA or Mutual Recognition Agreement partner Inspectorate

- Yes Restricted

EMA can certify a medicinal product only if an inspectorate from the EEA or from a country with a valid mutual recognition agreement with the EU has confirmed the GMP compliance status of the relevant manufacturing sites to EMA in writing. The confirmation must be specifically for the site(s) manufacturing pharmaceutical form (bulk finished product) of the medicinal product and must be based on a GMP inspection (the frequency of inspections is determined on a risk-based approach). You should verify this e.g. with your quality assurance department, the supervisory authority or the EMA GMP co-ordinators. If any of the sites is/are not GMP compliant i.e. there are outstanding critical/major observations to be resolved upon the request of the inspectorate, request for certificates will be placed on hold. If any of the sites has not/have not been inspected, the request for certificates will be placed on hold until the inspectors have provided positive conclusion on GMP compliance to EMA. In these

cases, the EMA GMP co-ordinators will contact the supervisory authority for an appropriate action. You should ensure that any GMP compliance matters are resolved to avoid rejection or holding of your request for certificates.

You can choose 'restricted', if any of the involved sites does not comply with the requirements, but there is an alternative authorised site(s) that does. EMA will certify only these alternative site(s).

Conditions for the safety and quality of the medicinal product

Product(s) is free from recently reported, serious hazards

Yes Restricted

You must verify and confirm that there are no recent, serious quality or safety problems with any of the medicinal products before you request EMA to certify them. For the purpose of certification, the defect is considered serious, if it requires provisional revision of the product information (the SPC, labelling, package leaflet and/or EPAR) and/or suspension of the marketing authorisation. If so, the defect is considered recent until EMA has published the outcome of CXMP assessment on it on the EMA website. Before that EMA cannot certify the product and your request will be placed on hold. EMA can resume the certification of the product with a defect once the outcome of CXMP assessment is available. Select 'restricted' if this is the case. You should not request EMA to certify a medicinal product with suspected defects.

Choose 'restricted' in case of any of the authorised products you request to be certified CXMP has adopted provisional product information, but the European Commission has not yet amended the community marketing authorisation accordingly and/or if the marketing authorisation has been suspended, withdrawn or revoked. In these cases, the related EMA public statement and the EPAR and its annexes, as published, will be attached to the certificates. Once the European Commission has endorsed a related amendment to the community marketing authorisation, certification resumes back to normal. For products that have received a positive opinion under Article 58 of Regulation (EC) No 726/2004 (EU-M4all), choose 'restricted' in case of any of the products you request to be certified CXMP has adopted provisional product information, but the annexes (SPC, package leaflet and/or labelling) have not yet been amended by the CXMP.

3.3 Product

Product information

Product information (No. 1)

Trade name of the medicinal product *

Pharmaceutical form *

Trade name in the importing country

Has an opinion under Article 58 of regulation (EC) No. 726/2004 (cooperation with WHO for the evaluation of certain medicinal products for human use intended exclusively for market outside the EU) been issued for the product?

Trade name of the medicinal product

Enter the name of the product as authorised in the EU, without the strength and pharmaceutical form.

Pharmaceutical form

Type the pharmaceutical form that corresponds to the presentation(s) requested. The pharmaceutical form is for example: tablet, capsule, solution for injection, etc. WHO refers to these as dosage forms. EMA certifies only one pharmaceutical form per certificate.

Trade name in the importing country

EMA can issue certificates including the trade name of the medicinal product in the importing country, which may differ from the name in the EU. The certificate will state the trade name, as provided by the requester in addition to the trade name used in the EU. Please note that we will include the trade name in the importing country in the certificate only if different to the centrally authorised name. Since the purpose of the trade name in the importing country is for the applicant to be able to communicate a difference in intended trade name if applicable, e.g. neither pharmaceutical form nor strength should be included.

Medicinal products with an opinion under Article 58 of Regulation (EC) No 726/2004 (EU-M4all)

Select if the product has received a positive opinion under Article 58 of Regulation (EC) No 726/2004 (EU-M4all).

Names, addresses and activities of the sites involved in the manufacturing of the finished product

In accordance with the WHO recommendations, EMA certifies the name(s), address(es) and GMP compliance status for the site(s) authorised to produce the pharmaceutical form.

Site 1: Name(s) address(es) and activity(ies) of the site(s) involved in the manufacturing of the finished products (drug products), to be mentioned in the certificates

Name *

Address *

- Manufacture of the finished product
- Manufacture of the finished product: solvent/diluent
- Batch Release in the EU
- Quality Control of the finished product
- Primary Packaging
- Secondary Packaging

[+ Add a new site](#)

At least one manufacturer of finished product needs to be included in any certificate (if the MAH is a manufacturer of the finished product, this will suffice).

Sites authorised as manufacturer of solvent/diluent, batch release, quality control, primary and secondary packaging in the EU/EEA can be mentioned in the certificates. Identify here the registered name(s) and full address(es) of all the manufacturing sites authorised for the manufacturing of the pharmaceutical form or batch release in the EU that you would like to be included in the certificate.

Tick the requested activity each site is involved in (manufacture of the finished product and/or manufacturer responsible for solvent/diluent and/or batch release and/or quality control of the finished product, etc).

Please note that the activities and sites mentioned in the certificates issued by EMA are for finished product, and do not include active substance manufacturers. If the manufacturer of the biological active substance is mentioned in Annex II, you can choose to have this annex attached to the certificate(s) provided it is requested in the application form.

Trading names of companies cannot be certified without the registered name and only if it corresponds with the approved records.

If more than one site is required to be mentioned in the certificate, click on the '+ Add a new site' button.

Certificates for the product

Enter the details of the requested certificate in this section.

Certificate 1: Certificates for the product. Each certificate is subject to an additional charge

Importing country *

MA Numbers *

EU languages *

Annexes in addition to SPC *

Available on the market in the EU *

+ Add a new certificate

If more than one certificate with the same product information is needed, click on the '+ Add a new certificate' button. Please note that each certificate added is subject to an additional charge.

Importing country

Enter the importing country to appear on the certificate. The country must be outside the EU/EEA.

Number in the community register of medicinal products (MA numbers)

EMA can issue certificates either for one presentation only or for all presentations of one pharmaceutical form.

A presentation is identified with a unique number in the community register of medicinal products, e.g. EU/1/01/001/001. It identifies the smallest entity of the product available on the market e.g. for a patient in a pharmacy.

Alternatively, you can request certificates for all presentations of one pharmaceutical form (tablet, suspension for injection etc.) e.g. EU/1/01/001/001-005.

Ensure that you cover all the presentations e.g. all strengths and pack sizes, including the recently authorised presentations. Failure to comply with this requirement is the most common reason for holding of requests for certificates. Please note that species are taken into consideration when determining full pharmaceutical form for veterinary products.

Languages of certificates

Certificates can be issued in English (EN), Spanish (ES), French (FR) and/or Portuguese (PT), and in any combination thereof.

Certificates with annexes for EU-M4all products (previously known as Art. 58) are issued only in English.

Annexes in addition to SPC

Annexes that can be attached to EMA certificates are: SPC=summary of product characteristics, Q=statement of quantitative composition, L=labelling, P=package leaflet, E=EPAR European public assessment report, AII=Annex II: manufacturer(s) of the biological active substance.

SPC is the only mandatory annex, with the exception of certificates for products 'under consideration'. Additionally, you can ask for Q, L, P, E and/or AII to be attached.

When Q is requested to be attached, it has to be provided by the applicant with the request, unless the one provided to EMA in a previous request is still valid.

SPC, L, P, EPAR and AII will be attached as they are on the EMA website at the time of issuing the certificate(s). Check the published documents before requesting them to be attached to the certificate(s). If a new version affecting annexes is approved and not yet published, include a comment in section 'Additional Documents (OPTIONAL)', field 'Your message', for the latest version to be attached instead of the published one.

Please note that if EPAR is requested, it will be attached as published with no possibility of modification. The EPAR is only available in English (EN). For more information about annexes to certificates see paragraph 4.5 of the Information package on EMA certificates.

Presentation available on the market in the EU

When applying for a certificate for full pharmaceutical form, if at least one presentation is physically available on the market in at least one EU Member State, specify 'yes'.

For single presentations, state 'yes' or 'no' according to its physical availability on the market in at least one EU Member State.

Multiple products

+ Add a new product

If you request certificates for more than one product, click on the '+ Add a new product' button and follow the instructions from section '3.3 Product' above.

3.4 Attach files

Additional Documents (OPTIONAL)

If applicable, attach the statement of quantitative composition (Q) and/or any other documents relevant for the request here.

Upload your documents here (multiple files supported). Accepted formats: .pdf, .docx. Each file must not exceed 20 MB. You can add multiple files by selecting them all in the upload window.

Choose Files No file chosen

The only accepted formats are .pdf & .docx and each file must not exceed 20 MB.

Your message

Enter any comments or specific requirements for the request in this section.

3.5 Fees

Customer number

The customer number you used to log in with will be shown here automatically.

For queries on customer account numbers, please e-mail: accountsreceivable@ema.europa.eu.

Type of procedure requested

Urgent Standard

Choose 'Urgent' for the urgent procedure: The current target handling time for urgent requests is within 2 working days, starting on the following working day after payment of relevant fees has been cleared by the EMA Finance department.

Choose 'Standard' for the standard procedure: the current target handling time for standard requests is within 30 working days, starting on the following working day after payment of relevant fees has been cleared by the EMA Finance department.

Number of certificates and the related fees

This field is automatically filled in after you have completed the 'Product Information' section.

Request fee

The total fee sum will be populated automatically after you have selected the type of procedure.

If the MAH has a valid SME status the relevant incentives will apply, and the displayed fee will not be applicable

If the MAH has a valid SME status the relevant incentives will apply, and the displayed fee will not be applicable.

Reference/purchase order to appear in the invoice

Enter here the reference/purchase order that will appear in the invoice you receive for payment of the fees, if applicable.

Reference/purchase order to appear in the invoice (max 35 characters)

Acknowledgement statement

Select the statement to confirm that you agree with the content and submit your request by clicking on the 'Submit your request' button.

- By clicking on this checkbox, I acknowledge that my application will be considered submitted when the corresponding charge has been paid in full, in compliance with Regulation (EU) 2024/568 of the European Parliament and of the Council and its working arrangements. I acknowledge that my application will be cancelled and the service will not be delivered if the payment is not received by the deadline specified in the invoice. I understand that a fee is payable on submission in accordance with the information submitted and regardless of the outcome of its validation, as per the rules relating to the Agency's fees governed by Regulation (EU) 2024/568 of the European Parliament and of the Council and its working arrangements.

Back

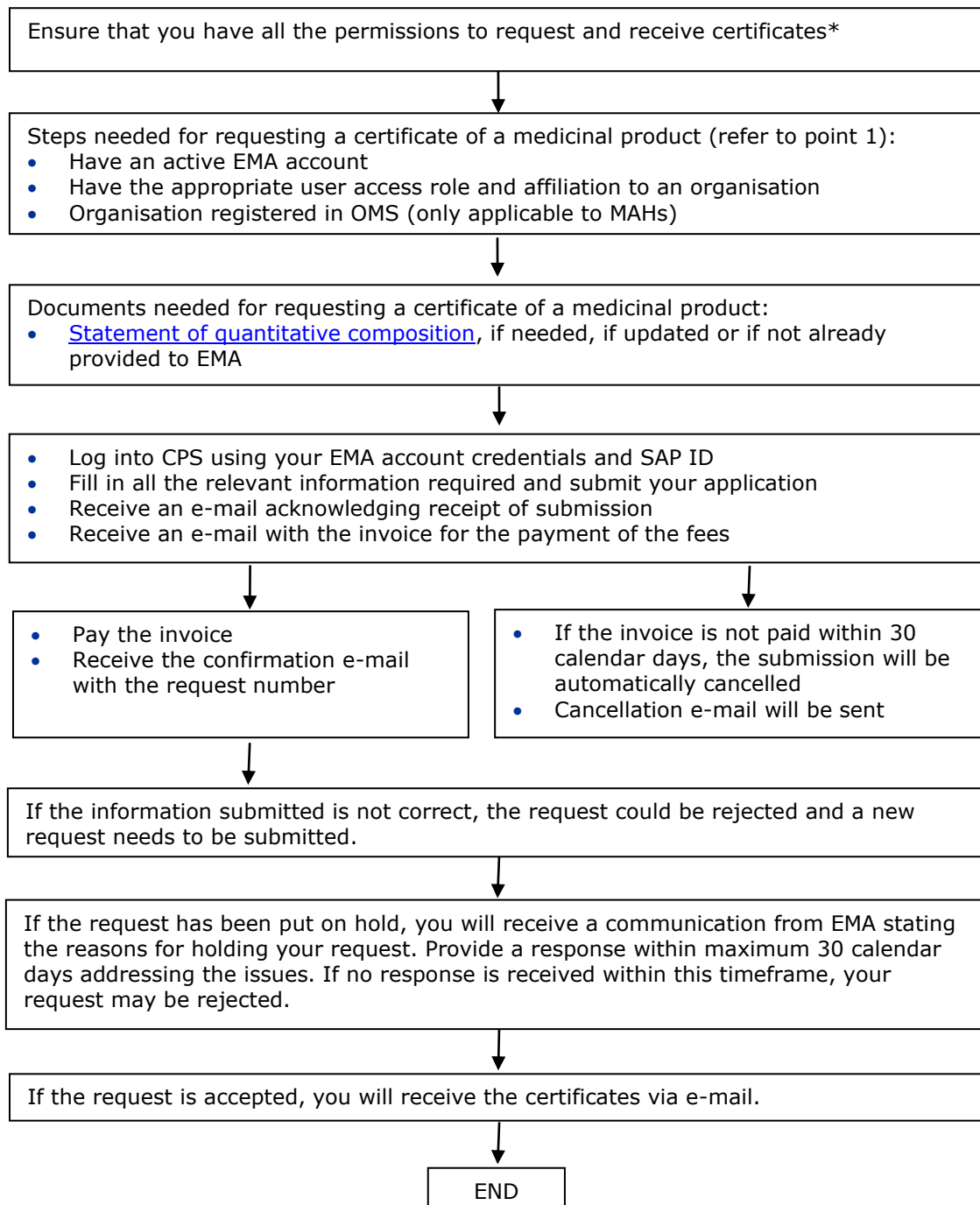
Submit your request

Once the request has been submitted, a success message will be displayed and an e-mail acknowledging the receipt of the submission will be sent to the e-mail address previously provided.

In addition, you will be presented with a pop-up window allowing you to download a PDF copy containing the submitted details. Please note that once the window is closed, you won't have access to the download option again, so make sure the pdf is downloaded for your records, if relevant.

Process for obtaining EMA certificates of a medicinal product

Marketing-authorisation holder (MAH) or any company with different name and/or address from the MAH



(*applicable only if the requester is different from the MAH)