16 January 2023
EMA/193330/2014 Rev 15*
Human Medicines Division

EMA certificates of medicinal products - instructions on how to fill the application form

Request for EMA certificates of medicinal products

(1) This form is intended for requesting EMA certificates of medicinal products only. It can be used as of date of publication. Requests cannot be submitted on any other form. A complete request includes Part A and Part(s) B of the form and, if applicable, a statement of composition and permission from the marketing-authorisation holder (MAH) to obtain the certificates on their behalf. Once you have submitted the request, changes or cancellations are not accepted. A flow-chart for requesting certificates is attached at the end of these instructions. Guidance to complete the forms is provided point-by-point in these explanatory notes. You can facilitate certification by avoiding submission of duplicated and other redundant information and documents in your request.

Part A Organisational information

(2) Part A of the request form is for general and organisational information for the request. No other cover is needed for request submission.

A.1 Certifying authority

(3) This section provides contact details for your requests for EMA certificates of medicinal products. *Please submit the completed form to EMA by e-mail in an XML format, by clicking the 'Submit by Email' button in the application form*.

A.2 Marketing-authorisation holder(s) or holder(s) of CHMP Positive Scientific Opinion

(4) Provide the name and full address of the MAH(s) as currently authorised or applied for in the EU.

**Amended and added text in revision 15 (16 January 2023) appears in Italic.*

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

A.2 SME status confirmation attached

(5) Micro, small and medium-sized enterprises (SMEs) are exempted from paying the fees for certificates. In order to obtain such exemption, please obtain from the SME Office at EMA an SME status qualification for the MAH of the product(s) to be certified and for any request of certificates you submit to EMA, attach it to the request and tick the box in section A.2 of the application form.

A.3 Certificate requesting company

(6) The certificate requesting company is the contact towards EMA.

A.3 Contact person

(7) 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. It is essential that the contact person has access to this information. EMA will send the certificates for the attention of the person identified here.

A.3 Fax

(8) If you have a fax, enter the fax number of the contact person. Make sure the number includes the area and country code to be dialled from abroad.

A.3 Telephone

(9) Please enter the contact person telephone number here, including the area and country code to be dialled from abroad. EMA may be able to clarify items over the phone, which may avoid delays or even formal rejection of your request.

A.3 E-mail

(10) Please enter the contact person e-mail address here. EMA will send issued electronic certificates to this e-mail address stated in the application form.

A.3 Company name

(11) EMA can only send the certificates to a different company than the MAH's with the permission of the MAH. Enter the name and address of the receiving company here. *The permission letter needs to be sent to the certificates team.* It will be kept on file and the certificate requesting company will be held responsible to update the permission letter if the name, address or the status of the parties or any conditions defined in this letter change. The requester will be also asked to declare that the last submitted permission letter, if available, remains valid*. Please ensure that box (13) is ticked, if applicable (also see note (13) under A.3).*

A.3 Certify requesting company

(12) Tick in this box, if EMA should certify the name and address of the certificate requesting company. EMA can certify the name and address of the certificate requesting company, only if the MAH has provided a permission letter as outlined in note (11) and (13). If the MAH permission letter was not sent to the EMA, we cannot certify the name and address of the certificate requesting company.

A.3 MAH permission for EMA to send certificates to *a different company*

(13) EMA usually sends certificates only to the MAH (as in A.2). Only the MAH can grant an exception to this rule. If EMA is requested to send certificates to a company other than the MAH, the MAH must provide written permission to EMA to do so. If this is the case, please request the MAH to provide you with the permission (please use the template published on the EMA certificates of medicinal products web page: *https://www.ema.europa.eu/en/human-regulatory/post-authorisation/certifying-medicinal-products/requesting-certificates and* attach a copy of it to your request for certificates. *Tick this box to confirm that the provided permission letter is valid.*

The permission letter should be provided either via regular post or by e-mail electronically signed.

The signature of the digitally signed document must be in compliance with the requirements for electronic signatures, which can be found here: Regulation (EU) No 910/2014 on the electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation).

A.4 Preconditions for acceptance of a request for certificates

(14) EMA can certify medicinal products only if the following preconditions have been met. You must confirm the preconditions for all medicinal products, which you request to be certified, before you submit your request.

A.4 Conditions related to procedure for marketing authorisation

(15) 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). Tick one of the 2 boxes on the right or both, as appropriate, according to the type of product(s) you request to be certified (centralised and/or *EU-M4all* products).

A.4 Conditions for GMP inspections and compliance

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).

A.4 Conditions for the safety and quality of the medicinal product

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. See "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.

A.5 Fees

A.5 Customer number

(16) Please enter your customer number. For queries on customer account numbers, please e-mail: accountsreceivable@ema.europa.eu.

A.5 Application processing

Choose "Standard" for the standard procedure: the current target handling time for standard requests is within 10 working days, starting on the following working day of receipt of request. Selecting this option the application form in XML format will be sent to certificate@ema.europa.eu.

Choose "Urgent" for the voluntary urgent procedure: The current target handling time for urgent requests is within 2 working days, starting on the following working day of receipt of request. Selecting this option the application form in XML format will be sent to certificate_urgent@ema.europa.eu.

Only applications in XML format will be accepted. Scanned applications will not be accepted.

A.5 Number of sets of certificates and the related fees

(17) This field is automatically filled in after you have completed section B.2 of the form.

A.5 Request fee

(18) Every certificate request is subject to a request fee as stated on application form.

A.5 Total

(19) The total fee is the sum of the request fee plus the fee for each set.

A.5 Reference/purchase order to appear in the invoice

(20) Enter here the reference/purchase order that will appear in the invoice you receive for payment of certificates. Enter n/a if not required by your financial procedures.

A.6 Approval of the request

This is the date when the signatory of the request has reviewed and confirmed the correctness and accuracy of all information in the request and its annexes. The date should be close to but is not necessarily the same as the date of submission of the request.

Insert the name of the person, who takes the responsibility for the correctness and accuracy of all information in the request and its annexes. You can also refer to item A.3, if applicable.

Part B Table for requested certificates

(21) The Part B of the request form provides information about the medicinal product (section B.1) and the certificates requested for it (section B.2). EMA certifies all aspects of the medicinal product based on the Commission decision on marketing authorisation, as amended, irrespective of where the medicinal product will be exported. You can adjust the size of cells and number of rows to complete the form *by selecting the button 'Add' under section B.2*. You can also extend the Part B form to several pages *by selecting the button 'New Product' and* submit several Part B forms as an attachment to one Part A.

B.1 Trade name of the medicinal product

(22) The name of the product authorised in the EU, without the strength and pharmaceutical form. If you request certificate for more than one product, please fill in and attach a separate Part B form for each product.

B.1 Pharmaceutical form

(23) Enter the pharmaceutical form you would like to be certified. 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.

B.1 Trade name in the importing country

(24) The EMA can issue certificates including the trade name of the medicinal product in the importing country, which may differ from the name in EU. The certificate will state the trade name, as provided by the requester in addition to the trade name used in 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 is for the applicant to be able to communicate a difference in intended trade name if applicable, e.g. pharmaceutical form nor strength should be included.*

B.1 Medicinal products with an opinion under Article 58 of Regulation (EC) No 726/2004 *(EU-M4all)*

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

B.1 Names, addresses and activities of the sites involved in the manufacturing of the finished product

(26) 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. *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 of the manufacturing sites authorised for manufacturing of the pharmaceutical form or batch release in the EU *that you would like included in the certificate*. Please 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.

B.2. Defining sets of certificates

(27) Please enter the details of the requested certificates in this section. You can adjust the size of the cells and/or the number of rows in order to complete your request. The table in section B.2 can run to a second page, if necessary. Make sure that there is a running page number in the Part A and Parts B of your request.

Importing country

Please enter the importing country to appear on a set of certificates in this section. The country must be outside EU/EEA. Use a separate row per each country. Each row is a new set.

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

EMA can issue certificates either for one presentation only or for all presentations of one pharmaceutical form. You make the choice on this part of the request form. 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 (SP), French (FR) and/or Portuguese (PT), and in any combination thereof*. If you leave the cells blank, EMA will issue the certificates in English by default. *Certificates with annexes for EU-M4all products (previously known as Art. 58) are issued only in English.*

Annexes to certificates

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. *Out of the mentioned parts of the annex that can be chosen,* SPC is the only mandatory annex, with the exception of certificates for products 'under consideration'. 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). Please 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, please include a comment in your request for the latest version to be attached instead of the published one. Please note for the EPAR that it will be attached as published with no possibility of modification.* More information about annexes to certificates is in paragraph 4.5 of the Information package on EMA certificates.

Numbers of certificates in a set

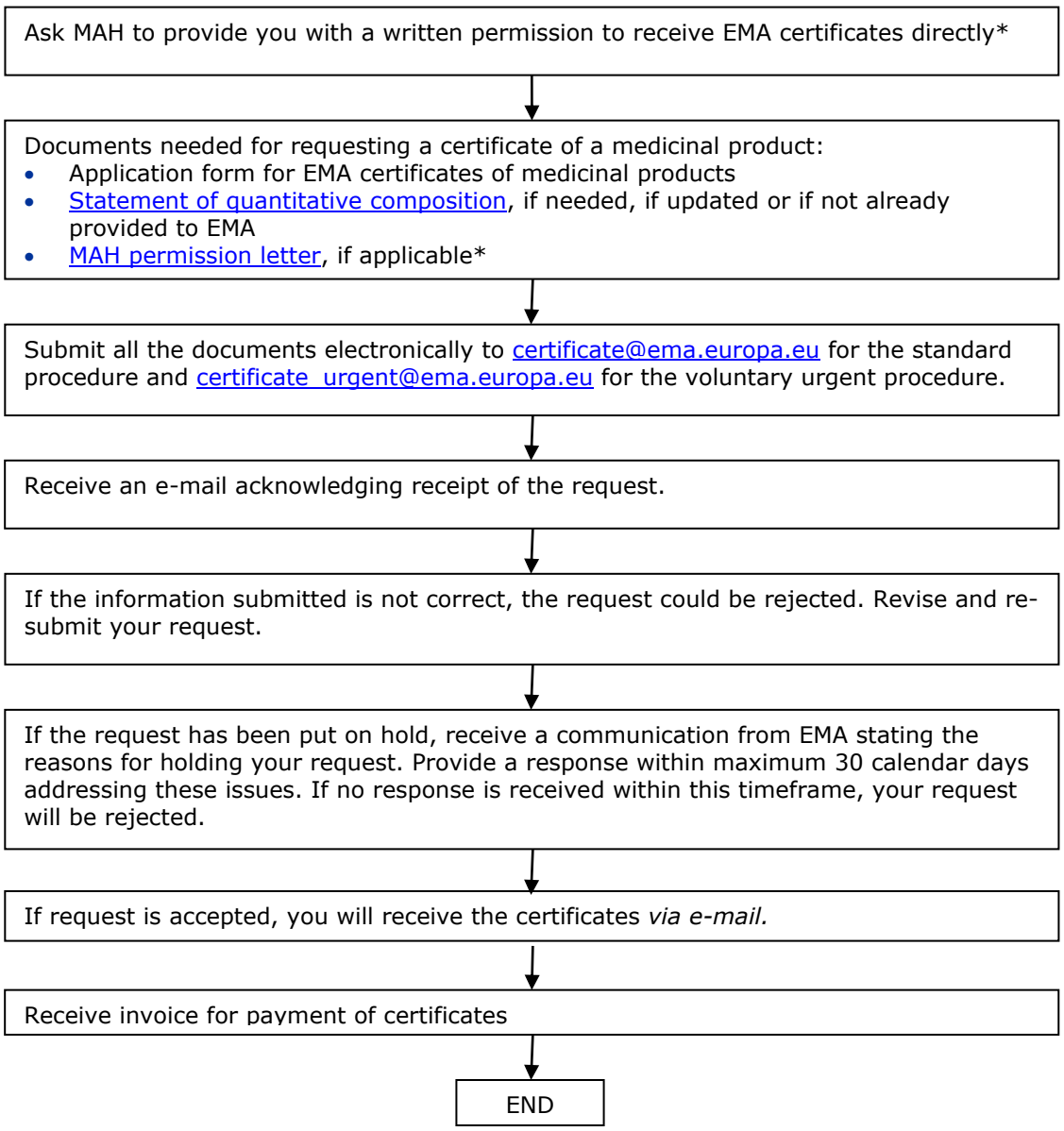
Only one certificate can be requested per set due to the change from printed certificates to the EMA now only issuing electronic certificates. If your request is for more than 50 sets, please inform EMA about the submission in advance by e-mail to certificate@ema.europa.eu.

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

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 requester is different from the MAH)