



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Certificates Processing System: 2nd Demo & Q&A session for Industry stakeholders (H+V)

Questions and Answers

Official guidance:

- [Certification of medicinal products](#)
- [Requesting certificates](#)

New Fee Regulation: published questions and answers

- New fee regulation: [General questions and answers for all applicants](#)
- [Annex I questions and answers](#) – Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use
- [Annex II questions and answers](#) – Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- [Annex III questions and answers](#) – Annual fees and remuneration
- [Annex IV questions and answers](#) – Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices

Disclaimer:

The information provided in this document is for general informational purposes only and should not be considered legally binding. It is based on the Q&A clinic that was hosted, where answers were provided live. While efforts were made to ensure accuracy, due to the live format, discrepancies may arise. In case of any conflict or inconsistency, the applicable official guidance shall take precedence over the content of this document.



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1. Procedural questions

1.0. What are the processing timelines for urgent and standard requests?

Target handling time for standard requests is 10 working days. For urgent requests the target handling time is 2 working days. Please note that the handling times may at times be subject to delay.

1.1. What is the expected timeline for issuing a certificate of pharmaceutical products (CPP) when delays occur?

The target timeline for issuing a CPP is ten working days. This timeframe starts once the finance department confirms the payment, not from the date of submission. However, during peak periods with high request volumes, processing may take longer. We kindly ask stakeholders to refrain from sending follow-up emails immediately after the tenth day, as responding to enquiries can divert resources from processing certificates.

1.2. Does the EMA issue hard copies of CPPs?

No, EMA has exclusively issued electronic CPPs since 2020. Hard copies are no longer available.

1.3. How long is a CPP held while awaiting confirmation after queries?

There is no formal timeline. Reminders are sent periodically, but if there is no response for several months, the request may be closed. If a request is no longer needed, we encourage stakeholders to inform us to prevent prolonged open cases.

1.4. How are issued certificates delivered?

Certificates are sent via email, as per the existing process.

1.5. What is the process for amending a CPP after submission?

If a correction is needed and EMA initiates the request, we can amend it directly upon receiving confirmation of the correct information. However, applicants cannot amend submissions themselves.

1.6. How can a correction be made after a CPP has been issued?

Once a request is submitted, it cannot be amended as the submission is finalised. It is essential to review all details carefully and deselect any unnecessary options before submission. If the error was made by EMA, corrections can be requested via the certificate's mailbox (certificate@ema.europa.eu). If the mistake was on the applicant's side, a new request must be submitted with the correct details.

2. Payment, refunds and administrative process questions

2.0. Is it possible to cancel CPP requests after payment?

Requests can be withdrawn before payment; however, it is not possible once payment is received. If your request is withdrawn after the Agency has received the payment of the applicable charge, the amount paid will not be returned to the applicant.

2.1. What happens if an invoice remains unpaid for more than 30 days?

Unpaid CPP invoices are automatically cancelled by the EMA system between 30 to 36 days from the date of the invoice. Companies having an unpaid CPP invoice on their account and not receiving an invoice cancellation after 36 days should contact the EMA accounts receivable team at accountsreceivable@ema.europa.eu.

2.2. What is the process for refunding CPPs that are not issued?

All certificates are issued as per the standard process. If an urgent certificate is not issued within target handling time of two days, the charge is aligned with the standard rate, a credit note is issued, and the difference is refunded to the bank account from where the original payment was made.

2.3. Can a refund be issued if the marketing authorisation holder (MAH) has changed but the applicant was unaware

No, the MAH is responsible for informing the requesting company. EMA issues certificates to the MAH, and internal communication between the MAH and intermediaries is outside our scope. As the certificate was correctly issued, no refund can be provided.

3. Future Enhancements and System Improvements

3.0. Will the system be updated to include features such as request tracking, a list of submitted requests, an alphabetically sorted country list, a print PDF option, the ability to save progress, delete attachments, support special characters, or duplicate company addresses automatically?

At present, these functionalities are not available. However, we acknowledge the importance of these enhancements and will take them into consideration for future improvements. No specific timeline is currently available for implementation.