May 2025
EMA/156481/2025
European Medicines Agency

Certificates Processing System: 3rd 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.

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 gency of the European Union

Table of contents

1. Procedural questions

1.0. 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. However, if more than 30 calendar days have passed since confirmation of payment, you may contact us via the certificate's mailbox (certificate@ema.europa.eu). When doing so, please include your request number to facilitate the investigation.

1.1. Is it helpful to include information that the marketing authorisation holder (MAH) has valid micro, small and medium-sized enterprise (SME) status when submitting a request? In the past, invoices have been received and then followed by cancellation notices after 30 days.

If SME status applies, the system should generate a zero-fee invoice. In some cases, cancellation notices may be triggered automatically if payment is not received within 30 days, even for zero-fee invoices. This could be due to a system-related issue.

Each such case should be examined individually. It is important that SME status is correctly indicated at the time of submission, as this automatically applies the relevant financial conditions, including fee waivers where applicable.

1.2. Regarding feedback received, what should occur if it is unclear in identifying which specific document contains discrepancies, such as in cases involving mismatched manufacturer addresses?

Feedback is based on discrepancies between submitted data and internal records. While efforts are being made to improve the clarity of such queries, there are limitations due to the requirement to issue certificates in strict accordance with the information approved and available on the date of issuance.

For ongoing requests, further clarification can be requested via the certificate's mailbox (certificate@ema.europa.eu).

1.3. What should an MAH do if the wrong or an outdated version of an SmPC is attached to the electronic certificate (eCPP) by EMA?

In such cases, the certificates mailbox (certificate@ema.europa.eu) should be contacted immediately. The issue will be investigated, and corrective action taken where applicable.

1.4. Regarding CPP site addresses being aligned with the Substance, Product, Organisation and Referential (SPOR) database, can EMA issue a declaration letter confirming this alignment and stating that no physical site change has occurred?

Manufacturers' name and address appearing in the certificate are aligned with the registered details for that particular Marketing Authorization. It is the MAH responsibility to align the registered details with the data registered in Organisation Management System (OMS). This process is part of a broader initiative to harmonise EMA-held records with SPOR databases.

EMA does not issue declaration letters confirming address alignment or asserting that no physical change has taken place. This policy has been communicated in multiple public webinars, including sessions attended by third-country authorities. MAHs are advised to provide explanations directly to external stakeholders if discrepancies arise. Any receiving authority can contact us in the certificates mailbox (certificate@ema.europa.eu) if they have any questions on the information included in the certificate.

2. Future Enhancements and System Improvements

2.0. Will the system be updated to include features such as saveable templates by product/country, option to view all open requests in an EMA account, or the ability to reuse past certificate requests?

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.