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European Medicines Agency

Certificates Processing System: 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:

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1. Procedural questions

1.1. How quickly can the EMA issue a certificate marking a drug as "marketed" after launch? Is any additional documentation required?

Following the initial launch of a drug, the company is required to update the marketing status via EMA's IRIS platform, which can be done on the same day as the launch. On that same day, the company may submit an application for a certificate reflecting the status as "marketed" by specifying this status in the application form. No additional evidence or documentation is required. The process can be completed without delay, provided the company acts promptly.

1.2. Is it possible to request a certificate without affiliation to the marketing authorisation holder (MAH)?

No, only the MAH or an authorised company can request a certificate. Unlike United States (US) certificates, European ones include confidential details, such as the product's composition and manufacturer list, which are not publicly available. These cannot be disclosed without the MAH's authorisation.

1.3. 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.

2. Certificates Processing System (CPS) questions

2.1. Is it possible to save specific details, such as the company name and initial section information, to avoid re-entering them for each request?

Currently, this functionality is not available. However, the suggestion has been noted for potential future improvements.

2.2. As third-party permission letters are no longer required, what is the current process for applying for certificates via the CPS system?

The previous system of Permission Letters has been replaced by a user ID-based authentication process. Authentication is now performed during the login process, making it essential to use the correct user ID and customer number associated with the MAH corresponding to the product(s) for which the application is being

submitted. This serves as proof of affiliation. Detailed instructions as to how to request IDs can be consulted here.

2.3. Is there a possibility to save draft applications?

Currently, this functionality is not available. However, the suggestion has been noted for potential future improvements.

2.4. How can invoices and application status be tracked in the EMA portal? Is this information accessible to both CPS Industry Users and CPS Administrators, or only to CPS Administrators?

Invoice details can be accessed via the EMA invoicing portal. Access is not linked to CPS Industry Users or Administrators. The application status cannot be viewed on CPS but is tracked through emails sent at various stages of the application.

2.5. Is there a dashboard that displays the status of submitted and in-process requests for a specific account number?

No dashboard is currently available. Status updates are provided via confirmation emails at each stage: submission, invoice issuance, payment allocation, and certificate processing.

2.6. If a mistake is identified immediately after submitting a request in CPS (e.g., incorrect contact email or site information), what steps should be taken to correct it?

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 an error is identified immediately after submission, do not pay the issued invoice. Instead, submit a new, corrected application and proceed with payment only for the accurate submission. The invoice must be paid within 30 days; if left unpaid, the incorrect application will not be processed.

2.7. Is there a plan to align site details with substances, products, organisations and referentials (SPOR) data in the CPS portal?

Currently, this functionality is not available, and there is no confirmed timeline for such an enhancement. However, the suggestion has been noted for potential future improvements.

2.8. Can a third-party use the MAH’s customer account number and details to log into the CPS system? If so, should they enter as the "requesting company"?

MAHs can provide their customer number to a third party. As the third-party acts on behalf of the MAH, there is no need to indicate a "requesting company" in the system.

2.9. Is it possible to extract a PDF of the application before submitting the request?

Currently, this functionality is not available. However, the suggestion has been noted for potential future improvements.

2.10. If a variation application affecting the scope of a Certificate is in progress alongside a Certificate request, how does this impact the issuance timeline? Is the Certificate team automatically notified of the variation status?

How soon after positive opinion of a new variation can be implemented in Certificates also depends on which type of variation. Furthermore, it can also be subject to delays due to linguistic reviews to annexes.

3. Payment methods and terms questions

3.1. Which e-mail address should remittance advices be sent to?

Please send your remittance advices to accountsreceivable@ema.europa.eu.

3.2. Are all MAHs of nationally authorised medicines marketed in Europe required to ensure access to the CPS?

The CPS system is only to request Certificates for products authorised via the centralised procedure. For nationally authorised products, national rules should be followed.

3.3. Is EMA intending to implement card payment for certificates?

Currently EMA requires payments to be made by bank transfer in euros, with all bank charges, withholding taxes, and other deductions covered by the payer. However, they may consider implementing alternative methods of payment in the future such as SEPA direct debit and credit card payment. Any changes or developments will be communicated.

3.4. Is the customer ID confidential, or can it be shared with a requesting company?

The customer ID can be shared by MAHs with requesting companies, if they wish to do so.

3.5. Is it possible to request that the invoice be addressed to the requesting company instead of the MAH?

The MAH address is the default billing address for all procedures and fees, and a separate billing address cannot be designated solely for certificate requests. While a different billing address can be specified, it will apply to all procedures requested by the MAH, not just certificate-related requests.

3.6. Does the "invoice paid" email from EMA confirm the start of the request assessment? If so, how long does it typically take to receive this email after the MAH has completed the payment?

The "invoice paid" email confirms that the payment has been successfully allocated, and the request has been released to the certificate team for processing.

Payment completion refers to when the payment is received in EMA’s bank account, not when it is sent. SEPA payments typically take up to 24 hours to process. Once received, payments are usually allocated the following morning, and certificate processing begins according to standard operational timelines.