6 December 2024
EMA/563623/2024
Human Medicines Division

Notification in preparation for the New Fee Regulation and new prepayment system for certificates of medicinal products, with implementation from January 2025

The legal framework on fees and charges payable to EMA changes from 1 January 2025, when Regulation (EU) 2024/568 (New Fee Regulation | European Medicines Agency (EMA) enters into force.

Information regarding prepayment

A new pre-payment system has been developed for Certificates of medical products that allows applicants to pay any charges upfront.

Should the payment not be received by the deadline specified in the invoice, your intention to submit will be cancelled and the service will not be delivered.

Information on the New Fee Regulation working arrangements is available via the following link new-fee-regulation-working-arrangements_en.pdf

For information on how to pay follow the link How to pay | European Medicines Agency (EMA)

How to submit requests for certificates

From 1 January 2025, EMA certificates of medicinal product should be ordered through the Certificates Processing System (CPS). Submissions received via e-mail will not be considered.

Registration steps required to be able to access CPS

To be able to order certificates you must 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, please follow the guidance Create an EMA Account.

  For further information on how to log into EMA Systems please follow the following link Sign In · EMA Account Management

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

- 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.

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

- You have a valid EMA customer account number.

  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. There are two CPS User role types:

  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.

  CPS Industry User

  To be able to order certificates this role is required.

  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. For information on how to grant access, please follow the instructions on the link Request Access · EMA Account Management

Please note that 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.

Please note that relevant documents on the website will be updated in due course.

For any questions related to the payment of fees, please contact nfr@ema.europa.eu.

For questions related to the creation of an EMA account, please contact EMA Service Desk.

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For any further questions related to the request of certificates please contact certificate@ema.europa.eu

ATTENTION: Exceptional suspension of submissions

From January 2025 the new pre-payment system will be implemented for requesting Certificates of medicinal product and it will no longer be possible to use the mailbox address for new requests. The new pre-payment interface will be deployed between 31 December 2024 and 5 January 2025. During this period, applicants will not have access to the system, therefore submissions requesting certificates will not be possible.

New submissions will be accepted as of 6 January 2025 via the new system only, for which Regulation (EU) 2024/568 will apply.

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