

8 November 2024
EMA/511024/2024
Human Medicines Division

Notification on arrangements for requesting EMA certificates through urgent and standard procedure for December 2024

The European Medicines Agency will be closed from 20 December 2024 to 5 January 2025.

Urgent procedure

The arrangements for issuing certificates of medicinal products submitted through urgent procedure in December 2024 are as follows:

- Requests submitted to EMA by 13 December 2024 will be processed before the end of 2024.
- For requests submitted to EMA on or after 13 December 2024 it cannot be guaranteed they will be processed before the end of 2024. Where a request made using the urgent procedure will not be processed within 2 working days, the fees applicable to the standard procedure shall be payable.

Standard procedure

The arrangements for issuing certificates of medicinal products submitted through standard procedure in December 2024 are as follows:

- Requests submitted to EMA by 3 December 2024 will be processed before the end of 2024.
- Requests submitted to EMA on or after 3 December 2024 may not be processed before the end of 2024 and may be undertaken on or after 6 January 2025.

These target dates are subject to demand which is expected to rise towards the end of the year.

If you have any enquiries, please send those by email to certificate@ema.europa.eu.

ATTENTION: Exceptional suspension of submissions

Due to the introduction of substantial changes to the submission process following the implementation of the new fee regulation and pre-payment system submissions of requests for certificates will not be accepted between 31 December 2024 and 5 January 2025 for both urgent as well as standard procedure. Any requests received during this period will receive an automated reply asking for these to be re-submitted from 6 January. New submissions will be accepted as of 6 January 2025 via the new procedure only, for which Regulation (EU) 2024/568 will apply. For requests received in 2024, current Council Regulation (EC) No 297/95 applies, even if the certificate is issued in 2025. Guidance on how to submit from next year onwards will be published in the EMA website in early December.