

14 January 2013

eSubmission Gateway release II and eSubmission Web Client now live for all applications for human medicines

The European Medicines Agency's Gateway Release II and the <u>eSubmission web client</u> are now live for all applications for Centralised Procedure marketing authorisations for human medicines.

Gateway Release II is an upgraded version of eSubmission Gateway, the electronic submission channel that the Agency launched in 2012 to allow applicants to submit documents supporting all types of applications for human medicines to the Agency securely over the internet in the <u>Electronic Common Technical Document</u> (eCTD) format. The existing Gateway users will see new features in the system functionality such as an automated confirmation of the technical validation feedback to the applicant and an automated upload to the Agency's eCTD review system.

As part of this project, the eSubmission Web Client, which complements Gateway, is now available as well for applicants with lower transmission volumes. This web-based tool may be more suitable for small and medium-sized companies. Registered applicants can now start submitting all types of Centralised Procedure eCTD human applications through the Web Client.

Applicants who have registered and used the Web Client during the User Acceptance Testing can continue submitting their applications without further registration in the production environment from 15 January 2013.

The Agency strongly recommends using the Gateway or the Web Client for all eCTD submissions. Submissions on physical media (CD or DVD) will continue to be accepted as an alternative method for the time being. It is essential that applicants only use one method of submission as duplicate submissions might lead to negative technical validation and cause a delay in the processing of the application.

The Gateway does not cover applications for veterinary medicines at this stage.

Related information

- eSubmission registration²⁷
- Electronic Common Technical Document (eCTD)[™]
- <u>eSubmission gateway and eSubmission web client</u>[™]
- eSubmission[™]
- Reminder to applicants regarding requirements for future eCTD submissions (07/12/2012)
- Electronic application forms fully available for use (27/07/2012)



 $\underline{\text{eSubmission Gateway now live for all applications for human medicines to the European} } \underline{\text{Medicines Agency}} \; (23/04/2012)$ Contact point: info@ema.europa.eu

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