



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Use of eSubmission Gateway / Web Client extended to new procedure types from 1st of April 2014

The EMA will extend the use of eSubmission Gateway and the Web Client to all Referral procedures, all Veterinary Medicines submissions including Veterinary Referrals, and to Paediatric submissions such as Paediatric investigation plans, waivers and modifications from 1st of April 2014.

The eSubmission Gateway and the Web Client create the possibility to submit applications securely over the Internet to the EMA and aims to improve efficiency and decrease costs for applicants.

The EMA launched the electronic submission channel, eSubmission Gateway, in 2012 to allow secure submission over the internet for all types of eCTD applications for human medicines. The eSubmission Web Client was launched in January 2013 to complement the Gateway and is aimed for applicants with lower transmission volumes. The use of the eSubmission Gateway / Web Client is mandatory for all electronic Common Technical Document (eCTD) submissions through the centralised procedure from 1st of March 2014.

Applicants who wish to use the eSubmission Gateway / the Web Client must complete the necessary registration process as detailed in <http://esubmission.ema.europa.eu/esubmission.html>. The applicants that have registered and used the Gateway / Web Client previously for Centralised Procedure eCTD submissions or PSUR Single Assessment (PSUSA) Procedure submissions can continue submitting their applications without further registration.

Submissions on physical media (CD/DVD) for Referrals, Veterinary submissions and Paediatrics will continue to be accepted as an alternative method for the time being. It is essential that applicants only use one method of submission and do not submit duplicate submissions with a physical media (CD/DVD)/Eudralink as these might lead to negative technical validation and cause a delay in the processing of the application.

Applicants are invited to register to use the eSubmission Gateway or the free web-based Web Client solution as soon as possible.

Related information

- [eSubmission Gateway and Web Client](#)
- [eSubmission Registration](#)
- [eSubmission Web Client](#)
- [Electronic Application Forms](#)

