



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Referral Procedures to be sent via eSubmission Gateway / Web Client from 1st of November 2014

From 1 November 2014 all submissions for Referral Procedures for human medicinal products should be sent via the eSubmission Gateway or the Web Client. After 1 November 2014, the EMA is no longer accepting electronic submissions for referrals on CD or DVD.

The European Medicines Agency (EMA) strongly recommends using the electronic submission channels (eSubmission Gateway or Web Client) and the electronic Common Technical Document (eCTD) or NeeS (Non-eCTD electronic Submission) formats for submission of referrals. For Referral submissions related to Centrally Authorised products, it is mandatory to use the eCTD format.

It became mandatory to submit all Centralised Procedure eCTD submissions, including ASMF (Active Substance Master File) via the electronic submission channels on 1 March 2014. The use of eSubmission Gateway / Web Client was extended to Referrals, Paediatric submissions and Veterinary procedures on 1st of April 2014. It is planned that all paediatric submissions are to be sent via the eSubmission Gateway or the Web Client from 1st of April 2015.

The EMA's strategy for the electronic submission of applications aims to improve efficiency and decrease costs for applicants.

The electronic submission channels offer the following benefits:

- easier and quicker way to send eCTD submissions securely over the internet with possibility for sponsors to send updates within very short deadlines;
- feedback to the applicant on the reception of the application, the outcome of the eCTD technical validation and the upload to the EMA's eCTD review system;
- no need to submit physical copy of dossier to the EMA.

All MAH 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](#)

