

18 March 2015
EMA/136579/2015
Procedure Management and Business Support Division

Use of XML delivery file for submissions via eSubmission Gateway / Web Client – phased implementation for all types of centralised submissions

The EMA's strategy for the electronic submission of applications aims to improve efficiency and decrease costs for applicants. In January 2015, the EMA introduced the use of the XML delivery file for PSUR submissions via the eSubmission Gateway and the Web Client as the first step of the phased implementation for a XML delivery file system for all types of submissions via the eSubmission Gateway and /or the Web Client.

This PSUR XML delivery file replaces the existing filenaming convention, which is currently used to provide additional 'metadata' allowing the EMA to automatically validate and process submissions. The [XML delivery file creation screen](#) has built in validation rules and guides the MAH in the preparation of the submission package, hence reducing errors in the submission process and leading to faster availability of submissions by the network. The use of the filenaming conventions for other procedure types will remain for the time being; however it is planned that the use of the XML delivery file will be extended to all types of submissions via the eSubmission Gateway/Web Client in future.

From 1 September 2015, the use of the XML delivery file for all PSUR submissions via the eSubmission Gateway and/or the Web Client will become mandatory. After this date, it will no longer be possible to submit PSUR submissions using the existing filenaming convention. The mandatory use of the PSUR XML delivery file is introduced to harmonise the submission mechanism for all PSURs and it will apply to all types of PSUR and PSUR supplementary information submissions.

Background

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. The use of the eSubmission Gateway and the Web Client became mandatory for all centralised procedure submissions in March 2014 and for Referral submissions in November 2014.

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 and the Common and PSUR Repositories;
- and no need to submit physical copy of dossier to the EMA.

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](#)