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Use of XML delivery file for submissions via eSubmission Gateway / Web Client – statement of intent on the next step of the phased implementation

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 as the first step of the phased implementation for a XML delivery file system for all types of submissions via the eSubmission Gateway / Web Client.

The XML delivery file replaces filenaming conventions, which are 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 it will guide the applicants and marketing authorisation holders in the preparation of the submission package, hence reducing errors in the submission process and leading to faster availability of submissions by the network.

From 23 May 2016, the use of the XML delivery file will be extended for all procedure types currently sent via the eSubmission Gateway / Web Client, with the exception of Maximum Residue Limit (MRL) and veterinary PSUR submissions.

The new eCTD EU Module 1 specification which enters into force on 1 July 2016 will be supported by a subsequent release, as will all remaining veterinary submissions types. Further details of these future releases will be published in due course.

The use of the XML delivery files will become mandatory from 1 October 2016 to coincide with the mandatory use of the updated eCTD EU Module 1 Specification. Both the filenaming conventions and the XML delivery files can be used for submissions during a transitional period running from 23 May until 1 October 2016. After this date, it will no longer be possible to submit applications using the existing filenaming conventions. The mandatory use of the XML delivery files for all procedure types is introduced to harmonise the submission mechanism for all 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.

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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/NeeS and VNeeS 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/NeeS/VNeeS technical validation and the upload to the EMA's eCTD/VNeeS 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
- PSUR Repository
- Common Repository
- eCTD EU Module 1