Mandatory use of XML delivery files for submissions of veterinary medicines via the eSubmission Gateway – Statement of Intent

The EMA's strategy for the electronic submission of applications aims to improve efficiency and streamline processes for all stakeholders.

The use of the eSubmission Gateway / Web Client will become mandatory for veterinary submissions on 1 January 2017.

From 1 April 2017, the use of XML delivery files will replace the use of filenaming conventions for all veterinary submissions to the EMA via eSubmission Gateway / Web Client.

Background

The use of eSubmission Gateway / Web Client was introduced for veterinary submissions in April 2014 and in May 2016 EMA introduced the use of XML delivery files for veterinary submissions.

The XML delivery file replaces filenaming conventions, which are currently used to provide additional metadata allowing the EMA to 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 improving the submission process. Filenaming conventions will thereafter no longer be maintained and related guidance will be made obsolete.

Related information

- eSubmission Gateway and Web Client

- Veterinary eSubmission