



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Gateway UI 03.06 – what's new in XML delivery for veterinary submissions

25 July 2016
Veterinary Regulatory and Organisational Support

An agency of the European Union





Gateway UI 03.06 – changes to veterinary submissions

The XML delivery file pilot is currently extended to submissions of all types of supplementary information within regulatory procedures, by introduction of an additional 'submission-unit type' functionality end of July 2016.

In addition, several 'submission types' have been further specified.

An announcement has been communicated via the Veterinary eSubmission website together with updated User guide:

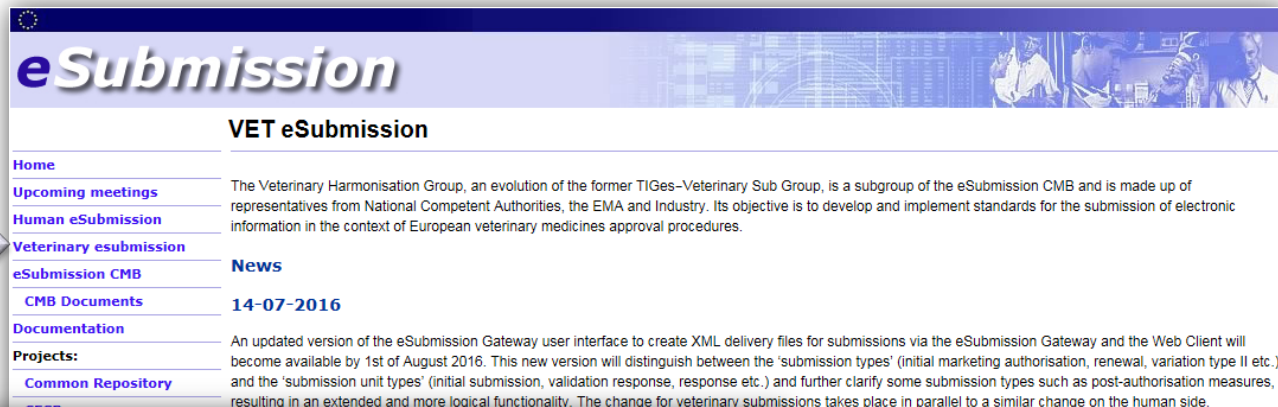
<http://esubmission.ema.europa.eu/tiges/vetesub.htm>

Additional information and training materials will also be available on

<http://esubmission.ema.europa.eu/esubmission.html>

Gateway UI 03.06 – changes to veterinary submissions

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14-07-2016

The Veterinary Harmonisation Group, an evolution of the former TIGes-Veterinary Sub Group, is a subgroup of the eSubmission CMB and is made up of representatives from National Competent Authorities, the EMA and Industry. Its objective is to develop and implement standards for the submission of electronic information in the context of European veterinary medicines approval procedures.

An updated version of the eSubmission Gateway user interface to create XML delivery files for submissions via the eSubmission Gateway and the Web Client will become available by 1st of August 2016. This new version will distinguish between the 'submission types' (initial marketing authorisation, renewal, variation type II etc.) and the 'submission unit types' (initial submission, validation response, response etc.) and further clarify some submission types such as post-authorisation measures, resulting in an extended and more logical functionality. The change for veterinary submissions takes place in parallel to a similar change on the human side.

EMA eSubmission Gateway/ Web Client for Veterinary Procedures

- [User guide to XML delivery file creation \(May 2016\)](#)
- [Presentation from the Training on the use of the XML delivery files for submissions via eSubmission Gateway / Web Client \(3rd June 2016\) New](#)
- [Recording - Training on the use of XML delivery files for Veterinary submissions New](#)
- [Announcement EMA eSubmission Gateway and Web Client - extended scope](#)
- [Questions and Answers on Veterinary Gateway Applications - eSubmission Gateway and Web Client](#)
- [Error codes](#)
- [Annex 2 - A guide to filenaming convention](#)
- [DTD \(XSD\)](#)
- [eSubmission certificates](#)

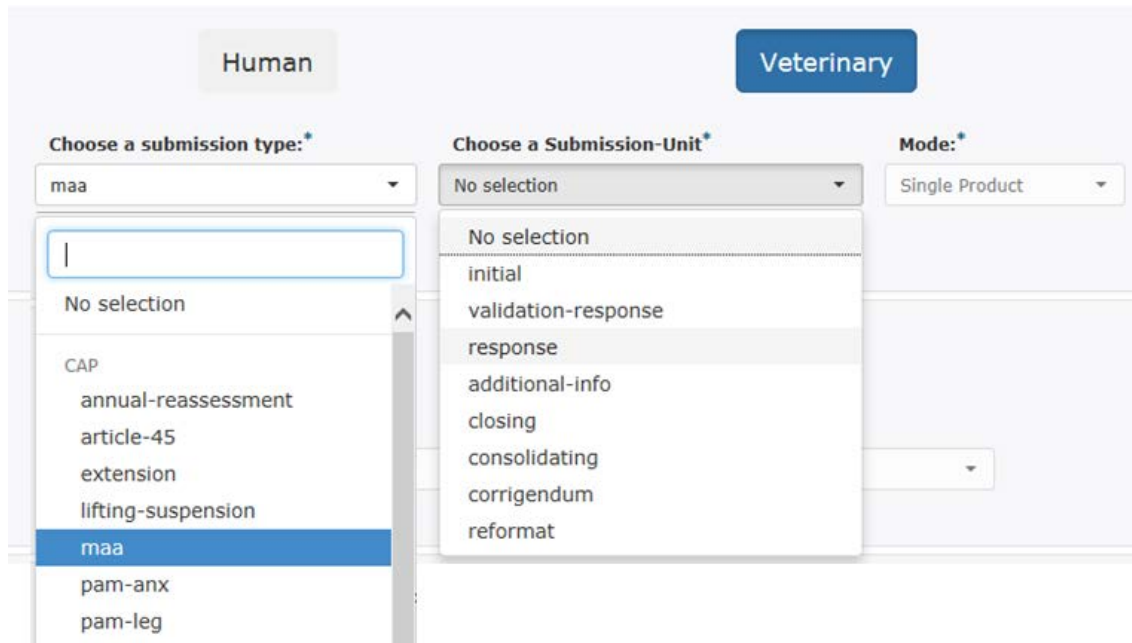
ures" below for an updated user guide to XML delivery file creation. You may
way & eSubmission Web Client site.

User guide and
training materials

Gateway UI 03.06 – changes to veterinary submissions

Change:
 distinguish between **'submission types'** (initial marketing authorisation, renewal, variation type II etc.) and **'submission-unit types'** (initial submission, validation response, response etc.)

Reason:
 Extend the functionality to submission of various types of supplementary information within a given procedure;



The screenshot displays the Gateway UI 03.06 interface for submitting a new submission. The 'Human' tab is selected, and the 'Choose a submission type' dropdown menu is open, showing a list of submission types including 'maa', 'CAP', 'annual-reassessment', 'article-45', 'extension', 'lifting-suspension', 'maa', 'pam-anx', and 'pam-leg'. The 'Choose a Submission-Unit' dropdown menu is also open, showing a list of submission-unit types including 'No selection', 'initial', 'validation-response', 'response', 'additional-info', 'closing', 'consolidating', 'corrigendum', and 'reformat'. The 'Mode' dropdown menu is set to 'Single Product'.



Gateway UI 03.06 – changes to veterinary submissions

Change:

further **specify and add** some 'submission types'

- post-authorisation measures
- variation type IA vs. IAin
- article 45 procedure moved from referrals to CAP procedures
- 'reformat/baseline' option added (optional for vets)

Reason:

- extend functionality; improve submission logic

Definitions for each 'submission type' and 'submission-unit' can now be found in the updated [User guide to XML delivery file creation](#)

Human **Veterinary**

Choose a submission type:* No selection

Choose a Submission-Unit* No selection

Mode:* Single Product

*Denotes mandatory fields

Upload XML delivery file Reset form

article-45
extension
lifting-suspension
maa
pam-anx
pam-leg
pam-mea
pam-rec
pam-sda
pam-sob
pass
reformat/baseline
renewal
rmp
transfer-ma
var-type1a
var-type1ain
var-type1b
var-type2
withdrawal
referrals

Medicines Agency | eSubmissions web 2.0.0-RC7



Further information

Technical support: <https://servicedesk.ema.europa.eu>

Regulatory support: vet.applications@ema.europa.eu

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