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.

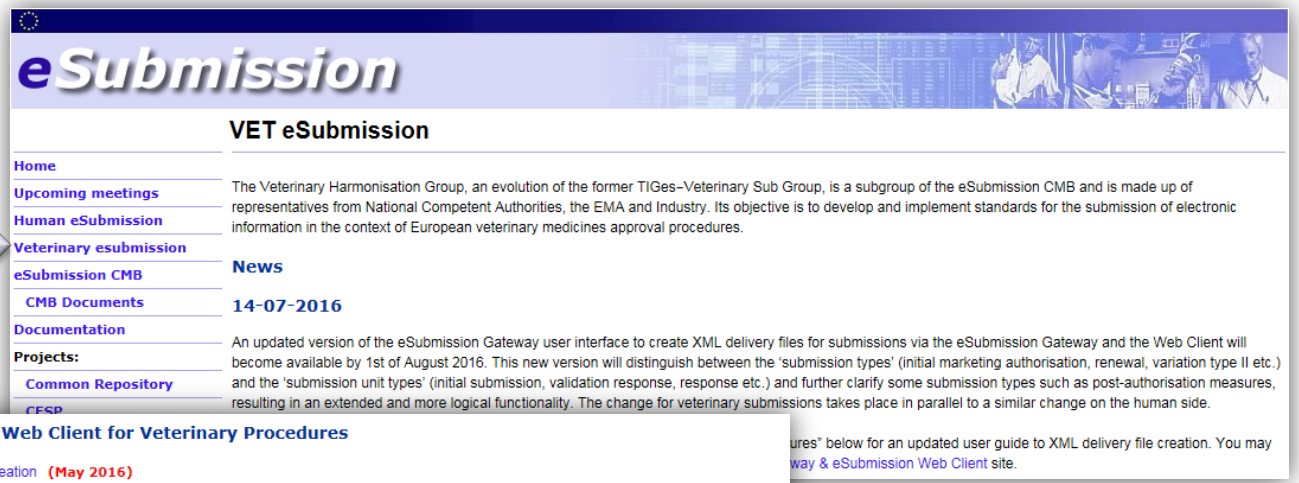
In addition, several ‘submission types’ have been further specified.

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

News announcements

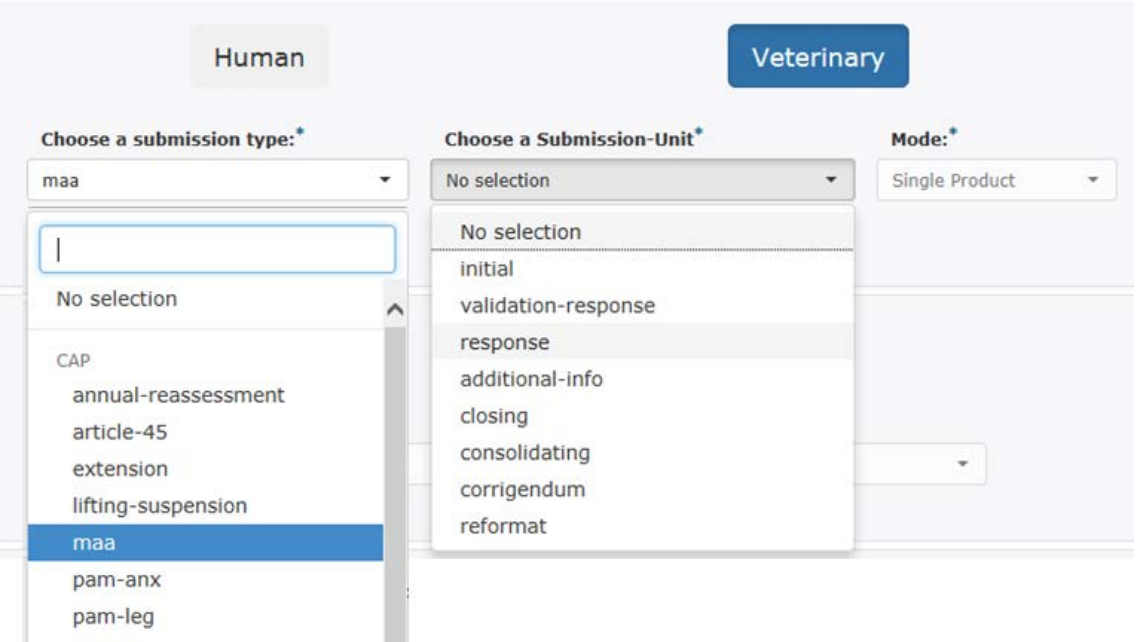


User guide and training materials

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;

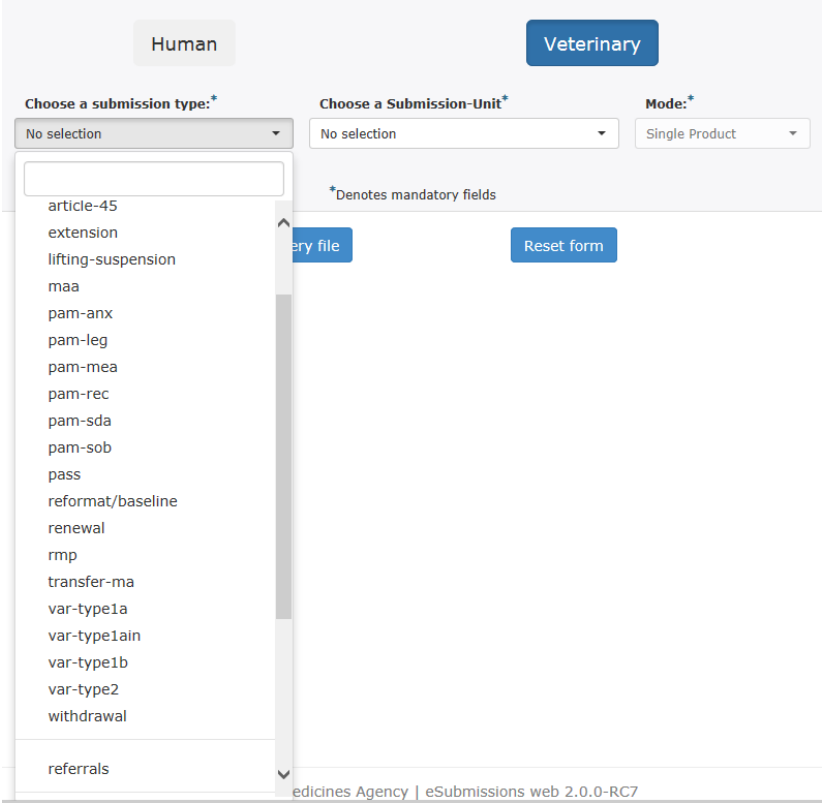


Gateway UI 03.06 – changes to veterinary submissions

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



Further information

Technical support: https://servicedesk.ema.europa.eu
Regulatory support: vet.applications@ema.europa.eu

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