

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



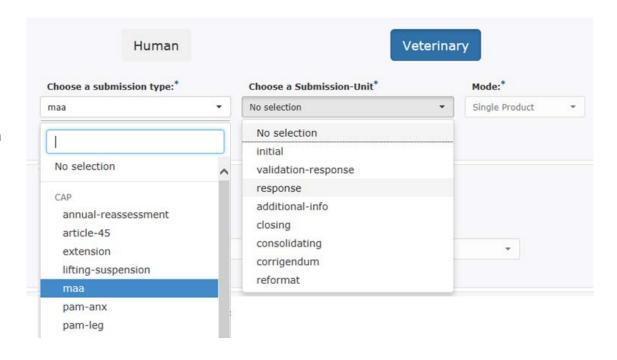


Change:

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;





Change:

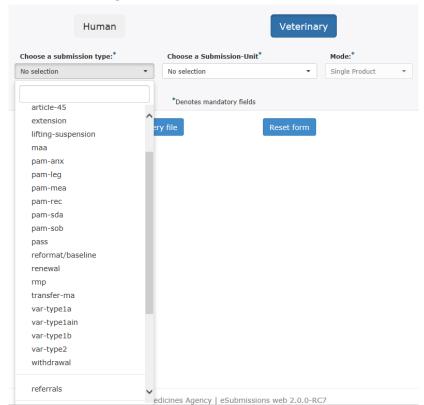
further specify and add some 'submission types'

- 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

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555 Send a question via our website www.ema.europa.eu/contact

Follow us on **9 @EMA_News**