



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

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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>



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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 veterinary submissions. It features two tabs: 'Human' and 'Veterinary'. The 'Veterinary' tab is selected. Below the tabs, there are three dropdown menus. The first dropdown, 'Choose a submission type:', is open, showing a search bar and a list of options. The 'maa' option is highlighted. The second dropdown, 'Choose a Submission-Unit:', is also open, showing a list of options. The 'response' option is highlighted. The third dropdown, 'Mode:', is set to 'Single Product'.



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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](#)

The screenshot displays the 'Veterinary' submission type selection interface. At the top, there are two tabs: 'Human' and 'Veterinary'. Below the tabs, there are three dropdown menus: 'Choose a submission type:\*', 'Choose a Submission-Unit\*', and 'Mode:\*'. The 'Choose a submission type:\*' dropdown is open, showing a list of submission types: 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, and referrals. The 'Choose a Submission-Unit\*' dropdown is set to 'No selection'. The 'Mode:\*' dropdown is set to 'Single Product'. Below the dropdowns, there is a blue button labeled 'Upload file' and a blue button labeled 'Reset form'. A small asterisk note indicates that the asterisk denotes mandatory fields. At the bottom right, the text 'edicines Agency | eSubmissions web 2.0.0-RC7' is visible.



## Further information

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

Regulatory support: [vet.applications@ema.europa.eu](mailto:vet.applications@ema.europa.eu)

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