# eSubmission Web UI (Delivery File UI)
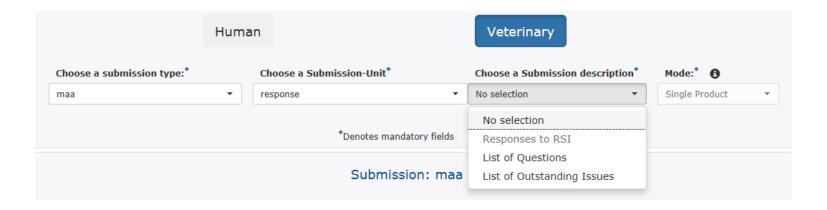
What's new for veterinary applicants

An agency of the European Union

# Submission description - NEW

For veterinary Centralised Procedure submissions, a new field has been added called "Choose a Submission description. When submission unit 'Response' is selected, the attribute **submission description** should be selected to further specify the details of response submitted.

For extension and MAA applications this mandatory field will provide further details on the type of response selected. The user should select List of Questions or List of Outstanding Issues as relevant.



For relevant post-authorisation procedures (eg. variations) the submission description is automatically filled in as Responses to RSI (short for Request for Supplementary Information).
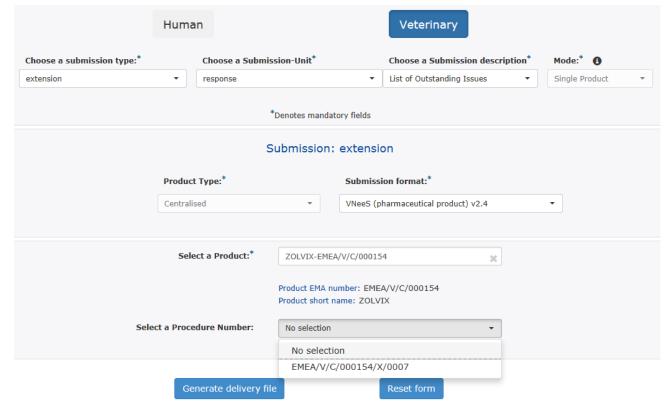
# Procedure number - NEW

For veterinary Centralised Procedure submissions, a new field called "Select a Procedure number" has been added for the relevant post-authorisation submission types. The **Procedure number** should be selected whenever available. Where not available, leave as "No selection" – this field is not mandatory for generating the delivery file.
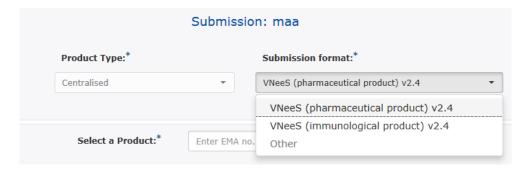
The Procedure number is only requested for annual re-assessments, extensions, variations, renewals, transfers and lifting of suspensions. It does not apply in initial submissions and in WS/IG submissions.

# Submission format - Updated

For Centralised Procedure veterinary submissions, the options given for **Submission format** have been further detailed. Instead of a generic "VNeeS" option, the user must now choose between pharmaceutical/immunological product and the relevant version of the VNeeS guidance used:



For example, "VNeeS (pharmaceutical product v2.4)" means the submission structure follows the *Guideline on eSubmission for Veterinary products - version 2.4*, TABLE 1: Folder structure and Standard files for an electronic application for a <u>pharmaceutical</u> product.

"VNeeS (immunological product v2.4)" means the structure follows the *Guideline on eSubmission for Veterinary products - version 2.4*, TABLE 2: Folder structure and Standard files for an electronic application for an <u>immunological</u> product.
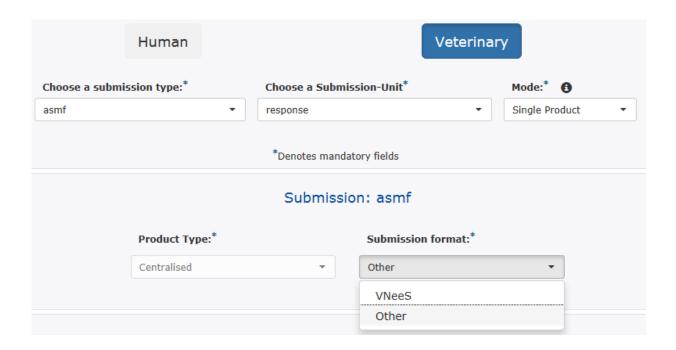
**NOTE:** VNeeS guideline v 2.5 and validation checklist v2.5 entered into force in June 2017. With this new version 2.5, rules for technical validation remain unchanged, therefore the current VNeeS Checker v.2.4b (validation tool) remains valid. Consequently, "VneeS … v2.4" can still be chosen as submission format even if version 2.5 was followed. Consult the Veterinary eSubmissions Website for currently applicable version(s) of VNeeS guidance for your submission type.

# Submission format - Updated

For ASMF submissions, the guidance on what to select as submission format has been updated:

If the submission relates to an ASMF in CTD format (veterinary procedures only), in the Submission format field the user should select "Other", rather than "NeeS". "NeeS" is no longer available as an option.

# Referral - Updated

For veterinary referral submissions, the field called "Referral:" used for entering the referral procedure number has been updated. The previous free text field rule has been replaced by restricted formatting rule, so that it will only be possible to complete the number by entering the last three digits of a procedure. The rest of the number (EMEA-V-A-) is pre-entered by the system.

For example: