



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Web UI (Delivery File UI)

What's new for veterinary applicants

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Veterinary Regulatory and Organisational Support

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.

Human **Veterinary**

Choose a submission type:* maa

Choose a Submission-Unit* response

Choose a Submission description* No selection

Mode:* Single Product

*Denotes mandatory fields

Submission: maa

- No selection
- Responses to RSI
- List of Questions
- List of Outstanding Issues

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

Choose a submission type:* var-type2

Choose a Submission-Unit* response

Choose a Submission description* Responses to RSI

Mode:* Single Product



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 screenshot shows the 'Veterinary' tab selected. The form includes the following fields:

- Choose a submission type:** extension
- Choose a Submission-Unit:** response
- Choose a Submission description:** List of Outstanding Issues
- Mode:** Single Product

*Denotes mandatory fields

Submission: extension

- Product Type:** Centralised
- Submission format:** VNeES (pharmaceutical product) v2.4

Select a Product: ZOLVIX-EMA/V/C/000154

Product EMA number: EMA/V/C/000154
Product short name: ZOLVIX

Select a Procedure Number: No selection

The dropdown menu for 'Select a Procedure Number' is open, showing options: 'No selection' and 'EMA/V/C/000154/X/0007'.

Buttons: Generate delivery file, Reset form

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 "VNeS" option, the user must now choose between pharmaceutical/immunological product and the relevant version of the VNeS guidance used:

Submission: maa

Product Type:*
Centralised

Submission format:*
VNeS (pharmaceutical product) v2.4

Select a Product:*
Enter EMA no.

VNeS (pharmaceutical product) v2.4
VNeS (immunological product) v2.4
Other

For example, "VNeS (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 pharmaceutical product.

"VNeS (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 immunological product.

NOTE: VNeS 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 VNeS Checker v.2.4b (validation tool) remains valid. Consequently, "VneS ... 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 VNeS 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.

Human **Veterinary**

Choose a submission type:* asmf

Choose a Submission-Unit* response

Mode:* ⓘ Single Product

*Denotes mandatory fields

Submission: asmf

Product Type:* Centralised

Submission format:* Other

- VNeedS
- Other



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:

Referral:*

EMA Referral Number: EMEA-V-A-123

Product/referral name:*

MAH Name:*

[Generate delivery file](#) [Reset form](#)