

## General FAQ relating to e-Submission for Veterinary Applications

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## Glossary

# 1. GENERAL QUESTIONS

## ***1.1. What is an electronic submission for veterinary medicinal products?***

An electronic submission (or e-submission) for a veterinary medicinal product is a submission of documents in relation to a marketing authorisation (application) to a regulatory agency. The submission should be in compliance with the requirements of the VNeS standard, as detailed in the "Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product", prepared by the Veterinary Harmonisation Group.

## ***1.2. What are the objectives of the Veterinary Harmonisation Group?***

The Veterinary Harmonisation Group, is a key-user group that reports to the eSubmission Expert Group and is made up of representatives from National Competent Authorities, the EMA and Industry. Its objective is to develop and implement standards for the submission of electronic information in the context of European veterinary medicines approval procedures.

## ***1.3. What is planned for the near future?***

The Veterinary Harmonisation Group has finalised the revision of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product and monitors its implementation. It is currently also monitoring the readiness for implementation of the PDF/A format for electronic transfer of documents. It will also be supporting future projects on the development of harmonised approaches in electronic submissions for veterinary applications.

# 2. SCOPE

## ***2.1. Are the e-submission requirements applicable in all Member States and EMA?***

Yes, the requirements outlined in the e-submission guideline are applicable for all dossiers submitted in Member States and EMA.

# 3. TRANSITIONAL PROVISIONS

## ***3.1. Is the electronic submission mandatory for veterinary medicinal products?***

Electronic submission in the VNeS format is mandatory for submissions to EMA as well as for submissions in the Decentralised, Mutual / Subsequent Recognition and National Procedures.

## ***3.2. In which format shall I present my e-submission if a newer version of the e-submission guideline has changed format requirements (transition period)?***

Which transitional period will apply to the newer version of the e-submission guideline is a case-by-case decision, and applicants are advised to follow communication as published by the VHG for the

new releases.

## **4. STRUCTURE AND NAVIGATION OF THE e-DOSSIER**

### **4.1. Are there tools available to create the e-folder structure?**

Yes. The Spanish Agency has developed “templates for folder structure” which can be downloaded [here](#). The templates cover folder structures for

- biologicals (other than immunologicals)
- immunologicals
- pharmaceuticals
- MRLs
- Active Substance Master File (ASMF)
- Vaccine Antigen Master File (VAMF)

### **4.2. Do I have to provide a separate TOC for Part 3E of a dossier for an immunological product containing or consisting of GMOs?**

When providing an assessment required for veterinary medicinal products containing or consisting of GMOs in Part 3E of a dossier for an immunological medicinal product, the presence of a table of contents (TOC) in that section is not a pass/fail criterion. For Part 3E thus the same rules apply as for all other part-specific TOCs.

The current guidance does however strongly encourage the use of part-specific TOCs in the top level folder of a dossier part (e.g. p1, p2, p3 etc.), as this improves the navigation within the dossier, specifically when there are many files are present. This applies likewise for Part 3E.

### **4.3. In case bookmarks are used for dossier navigation are these validated like other types of hyperlinks?**

The VNeS guidance does allow alternative methods like bookmarks in the (G)TOCs to be used if they assure equivalent efficiency of navigation. The guidance also notes that not all such features may be supported by the VNeS checker. Regardless of the specific method used, it is however strongly recommended to follow always the same rules for hyperlinking as stated in the current VNeS validation checklist. Note that the latest version of the VNeS checker does support also validation of bookmarks within (G)TOCs, so not following these rules may lead to invalidation of your submission.

### **4.4. Are there any specific rules for the structure and/or naming of the contents of the “add-info” folder?**

No, just be as clear as possible, as an ambiguous structure and/or naming might result in information being missed by the agencies. Also, do not place documents applicable to **multiple or all** countries in a single country specific folder.

### **4.5. How to build the part 2 (quality) of a submission covering several active substances, pharmaceutical forms or strengths, etc.?**

Data related to quality should be presented in a single Part 2 (i.e. separate VNeS root directories or two or more separate parts 2 would not be acceptable). Instead those sections where differences exist (e.g. data specific for a pharmaceutical form and/or strength) should be repeatedly addressed

in each subfolder in part 2, either as separate files or single files with appropriate bookmarks. For each repeated section the TOC of Part 2 should contain appropriately defined sub-headings as described in the guidance document on (General) Table of Contents: Recommendations for a veterinary electronic dossier.

#### ***4.6. How should a Subsequent Recognition Procedure application be structured?***

The VNeS format applies to Subsequent Recognition Procedure (SRP) applications as well, with some simplification. As SRP applications do not require a new, full assessment, instead relying primarily on the RMS' prior or updated assessment reports, no repetition of any old data is necessary from an assessment perspective. However, as the new CMSs must have access to the full dossier, the old data still needs to be included with the submission. To meet both these requirements, the SRP VNeS should contain the eAF(s) and all Annexes relevant to the SRP placed in the 1a-admin-info folder. Any working documents, documents requested due to national requirements, as well as cover letters should be placed in the add-info folder. All submissions made prior to the SRP should also be placed in the add-info folder and need not be re-structured or re-worked in any way, nor will these be subject to technical validation.

#### ***4.7. Where should literature references be placed in the VNeS folder structure?***

While technically possible to place any literature reference directly below the corresponding Part folder, this complicates dossier navigation for the NCAs and is recommended against. A literature reference should therefore be placed in the subfolder to which its content corresponds the most. The folder granularity covers all topics relevant for the dossier, so finding a suitable destination should normally be easy.

In some cases, the content of a literature reference can cover multiple topics; in these instances, the literature reference should be physically placed only in the subfolder to which it belongs the most. The ToC file should then include multiple entries, for each dossier section the literature reference concerns, each with the same hyperlink.

## **5. FILE / DOCUMENT REQUIREMENTS**

### ***5.1. What file format requirements are applicable for e-submission?***

File format requirements are specified in the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product.

Applicants are also advised to follow the VICH file format criteria (VICH Guideline 53 on Electronic File Format) which came into effect by February 2016. The new VICH guidance improves both harmonisation of format requirements and long-term sustainability of PDF files based on the PDF/A ISO-standard.

Applicants are encouraged to follow the concepts of the VICH guideline 53 for PDF files including the use of PDF/A-compliant files already before the mandatory implementation as VNeS requirement.

### ***5.2. When using a different file system than Microsoft Windows, do I have to observe other rules for file naming concerning upper and***

## ***lower case characters?***

A use of upper-case characters in file names does not lead to invalidation. You should however ensure that filenames are always unique within any folder. So you should not use e.g. A-file.pdf and a-file.pdf in the same folder. The VNeS checker does not use the case of file names during technical validation (neither for the requirement VNeS 015 on prohibited characters used nor when checking hyperlink paths.)

## ***5.3. Where should the Quality Overall Summary and the signature of the quality expert be provided if the quality part of the dossier is in CTD structure?***

In submissions for Human Medicinal Products the CV of the expert which carries a signature is located in Module 1 and the Quality Overall Summary (QOS) is located in Module 2. If QOS are reused for submissions for Veterinary Medicinal Products the QOS file and the signed CV should be allocated either to the folder "p1/1c-cers/1c1-qual" or to the "m2" / "m2/23-qos" folders of the CTD structure.

The signature file and the QOS may remain separate files but should be allocated to the same folder next to each other. Merging the two files is not necessary.

In case the files are allocated to Module 2 folders, in order to avoid validation issues, the applicant should include a statement in "p1/1c-cers/1c1-qual" which is cross-referring to the QOS in the CTD structure. In any case it is highly recommended to point out the use of QOS instead of Critical Expert Reports in the cover letter.

## ***5.4. How can I verify if there are any hidden files in my VNeS e-Dossier on a MS Windows or macOS PC?***

The "Pass/Fail" criterion VNeS\_017 requires the deletion of any hidden files (such as thumbnail cache files) in the VNeS e-Dossier.

On MS Windows, there are different ways to configure the Windows Explorer to display hidden files, depending on the version of Windows, for example:

Windows 11:

- a. Open File Explorer from the taskbar.
- b. Select View > Show > Hidden items.

Windows 10:

- a. Open File Explorer from the taskbar.
- b. Select View > Options > Change folder and search options.
- c. Select the View tab and, in Advanced settings select "Show hidden files, folders, and drives" and select OK.

### MacOS

On macOS 10.12 Sierra to macOS 12 Monterey, you can press the following key combination on your keyboard to make hidden files and folders appear in the finder:

⌘ CMD+⇧ SHIFT+.

Use the same key combination to turn the display of hidden files and folders in the finder off again.

## **6. SIGNATURES**

### ***6.1. Is there an agreed electronic / digital signature?***

There is currently no agreed / harmonised standard for a digital signature available for e-submission for veterinary applications. The use of a digital signature will be explored in future, but currently it is not part of any agreed specification.

*For further input and/or comments on these FAQs, please contact <https://servicedesk.ema.europa.eu> clearly indicating that reference is made to veterinary issues.*

## **Glossary**

CTD	Common Technical Document
GMO	Genetically modified organism
(G)TOC	(General) Table of Contents
ISO	International Organization for Standardization
MRL	Maximum Residue Limit
PDF	Portable Document Format
PDF/A	ISO-standardized PDF version for use in archiving and long-term preservation
QOS	Quality Overall Summary
SRP	Subsequent Recognition Procedure
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products