Veterinary Harmonisation Group

June 2016

General FAQ relating to e-Submission for Veterinary Applications

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 VNeeS 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? - Updated

The Veterinary Harmonisation Group, an evolution of the former TIGes-Veterinary Sub Group, is a subgroup of the eSubmission Change Management Board 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 supporting projects on the development of harmonised approaches in electronic submissions for veterinary applications on European and VICH level, and the secure connection for veterinary submissions.

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.

2.2. Are all regulatory agencies ready to accept an electronic submission for veterinary products? - Updated

In February 2005 a deadline of December 2009 was agreed by Heads of Medicines Agencies, by which the European Regulatory Network will have the infrastructure and processes in place to accept electronic submissions. As it was not clear that this deadline applied to veterinary applications also, the same deadline for veterinary submissions was confirmed by the Heads of Medicines Agencies (HMA) in Lisbon in July 2007. Most NCAs were able to comply with this deadline. Documents describing the e-readiness and related requirements for the veterinary agencies are available on the HMA website as "GUI-22" and "GUI-23".

3. TRANSITIONAL PROVISIONS

3.1. Is the electronic submission mandatory for veterinary medicinal products? - Updated

Electronic submission is strongly encouraged and is the preferred submission format for Member States and EMA. The HMA eSubmission roadmap adopted in October 2014 states that this roadmap "should lead to increased efficiency through sustainable fully end to end electronic processing of information, meaning elimination of paper and physical electronic media, to enable and facilitate electronic collaborative processes and re-use of data as well as increased transparency and sharing of information within the Network".

3.2. Can I go back to paper submissions once I have started submitting electronically?

For logistical reasons after changing to e-submission for a product, the applicant / MAH should make every effort to maintain the electronic format for all subsequent regulatory actions regarding this product. Only in exceptional cases a move back to paper submissions could be acceptable, but should always be discussed with the relevant NCA. An example for such an exception could be e.g. a change in a marketing authorisation holder.

3.3. Can I submit a variation electronically if until now, my existing dossier was submitted in paper?

Yes. For agencies that accept e-dossiers, you can submit any variation electronically.

3.4. Can I change to using electronic format in the middle of an application procedure?

Yes. Even if the initial application was paper-only, applicants can submit later submissions electronically, but only if submissions comply with the VNeeS requirements, outlined in the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product.
Also, a more comprehensive data package may be requested, e.g. for a switch of procedure at the clock re-start when responding to the list of questions, a full electronic Part 1 might also be requested.
However, for other procedures such as procedures with shorter timetables or post-authorisation procedures, a switch should usually not occur during a procedure.

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

A new format may be voluntarily used as soon as it has been published, provided confirmation of acceptability from the receiving agency has been obtained. It will be mandatory for all new e-submissions with a date of receipt by the regulatory agency at or after the date for coming into force of such a new format.

Also, for on-going procedures during which a newer version of the e-submission guideline comes into effect, applicants should switch to the most recently adopted format. However, if there is a need to keep the previous format, this should be discussed with the NCA on a case-by-case basis.

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

Template for immunologicals
Template for pharmaceuticals
Template for MRLs

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? - New

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. How does the VNeeS checker validate multiple hyperlinks which are all directed to the same document? - New

In cases where you use several hyperlinks in the (G)TOCs pointing to the same document please assure that each hyperlink is following the requirements of the VNeeS specification. The validation report will show a technically valid result only when each of these hyperlinks is set correctly.

4.4. In case bookmarks are used for dossier navigation are these validated like other types of hyperlinks? - New

The VNeeS 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 VNeeS 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 VNeeS validation checklist. Note that version 2.4b of the VNeeS checker does support also validation of bookmarks within (G)TOCs, so not following these rules may lead to invalidation of your submission.

5. FILE / DOCUMENT REQUIREMENTS

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

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 formal implementation as VNeeS 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? - New

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 latest release of the VNeeS checker (as of version 2.4b) will not use the case of file names during technical validation (neither for the requirement VNeeS 015 on prohibited characters used nor when checking hyperlink paths.)

6. SIGNATURES

6.1. Is there an agreed electronic / digital signature?

There is currently no agreed / harmonised standard for a digital signature available. 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 EMA clearly indicating that reference is made to veterinary issues.

Glossary

GMO	Genetically modified organism
(G)TOC	(General) Table of Contents
HMA	Heads of Medicines Agencies
ISO	International Organization for Standardization
MRL	Maximum Residue Limit
NCA	National Competent Authorities
PDF	Portable Document Format
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.