Veterinary Harmonisation Group

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General FAQ relating to e-Submission for Veterinary Applications

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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?

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?

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?

The mandatory implementation of electronic submission is following the revised HMA eSubmission roadmap adopted in February 2017. The document states that this roadmap "should lead to improved efficiency, less administrative burden and increased transparency through sustainable, fully end to end, electronic processing of information. It will also lead to an elimination of paper and physical electronic media. "

Electronic submission in the VNeeS format is now mandatory for submissions to EMA as well as for submissions in the Decentralised and Mutual Recognition Procedures. The updated roadmap provides also a plan for mandatory use of VNeeS in purely National Procedures.

3.2. 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.

3.3. 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?

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?

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?

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 the latest version 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.

4.5. 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.

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 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?

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.)

5.3. How should the new requirements for MRL applications, as set out in Commission Implementing Regulation (EU) 2017/12, be incorporated into the electronic dossier?

Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council came into force on 27 January 2017.

This implementing regulation and its annex set out the data requirements for MRL applications and replaces Annex V of Council Regulation (EC) No 2377/90. Implementation of the new regulation raises two issues in relation to the electronic dossier and its validation, as addressed below.

Location of the DACS in the dossier

The VNeeS structure indicates that both the safety and the residues DACS should be included in Part 1 – Administrative data and summary of the dossier. The annex to Commission Implementing Regulation (EU) 2017/12 indicates that the safety DACS shall be included in the Safety file (Part 2) and the residues DACS shall be included in the Residues file (Part 3).

The structure of the electronic dossier will be brought in line with structure described in the Commission Implementing Regulation. However, this will take some time and consequently, in order to avoid difficulties at validation and given that the change relates only to the location of the DACS in the dossier and not to the contents of the DACS, until the structure of the electronic dossier is changed the DACS should continue to be provided in Part 1 of the dossier. Additional copies of the relevant DACS may also be provided in Parts 2 and 3.

Inclusion of Chapter 3 on Risk Management Considerations

The annex to Commission Implementing Regulation (EU) 2017/12 indicates that the dossier should include a section on Risk Management Considerations (Chapter 3). This section should include information on the elaboration of MRLs, possible extrapolation of MRLs, relevant risk management considerations and information on any other relevant factors. Up until now this type of information would usually have been provided in the concluding sections of the residues DACS. The annex to Regulation 2017/12 indicates that the Risk Management Considerations should be addressed in the final part of the dossier. The structure of the electronic dossier will be brought in line with structure described in the Commission Implementing Regulation. However, this will take some time, and consequently, in order to avoid difficulties at validation, and as there is a place where this information can be provided in the interim, until the structure of the electronic dossier is changed, the Risk Management Considerations should be presented at the end of the Residues DACS.

On rare occasions, e.g., where a modification of the ADI is proposed with no new residue data, a dossier may not include a residues DACS. In such cases the Risk Management Considerations should be presented at the end of the safety DACS.

5.4. 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? NEW

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 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-dacs/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-dacs/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 DACS in the cover letter.

For general acceptability of CTD for the quality part and QOS instead of DACS in Decentralised and Mutual Recognition Procedure see CMDv guidance documents Guidance on format and number of copies for new marketing authorisation applications and Guidance on Format and number of copies in post-authorisation procedures under http://www.hma.eu/568.html

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 https://servicedesk.ema.europa.eu 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.