

General FAQ relating to e-Submission for Veterinary Applications

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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 TIGes vet subgroup.

2. 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. 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 HMA in Lisbon in July 2007. Most NCAs were able to comply with this deadline. A map describing the current e-readiness for the veterinary agencies in relation to veterinary submissions after 1 January 2010 is available [here](#).

4. Is the electronic submission mandatory for veterinary medicinal products?

The use of electronic submissions is currently optional for any procedure for veterinary applications. Dossiers presented in an electronic format are encouraged but paper submissions are still acceptable in all Member States / EMA.

5. In which regulatory procedures can an e-dossier be used?

An e-dossier can be used for Centralised Procedures, Mutual Recognition Procedures and Decentralised Procedures as well as national procedures and MRL applications.

For procedures such as requests for Scientific Advice or field trial applications, the use of an electronic dossier is feasible in principle, if accepted by the competent authority/ies. The requirements should follow the current guideline, except for the folder structure. For notifications submitted regarding the deliberate release of a GMO, it is advisable to confirm acceptance of an e-submission with the concerned national agency.

6. 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 (please also note Q 16).

7. What is the structure of the veterinary e-dossier?

The e-dossier follows the structure of the Notice to Applicants, volume 6B. Details on the structure are provided in the "Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product". CTD format is generally not appropriate for veterinary dossiers. However, exceptions might be possible for the chemical, pharmaceutical and biological / microbiological information (Part 2), but need to be confirmed by the NCA prior to submission of the dossier.

Additional (sub)folders to the folder structure given in Tables 1-3 of the guideline are not allowed (except in the folder "add info"). If applicants wish to further separate information within a given folder, this should only be done by clearer guidance in the Table of Contents (e.g. adding additional headings), or by using bookmarks within the appropriate documents (e.g. in order to clearer differentiate between target species, pharmaceutical forms, or lower numbered sections e.g. in the quality or safety dossier).

8. Which types of applications are covered by the defined folder structure?

The folder structure defined in the guidance covers a dossier for a marketing authorisation application (MAA) and MRLs. For all other types of applications (PSUR, renewal, referral, etc), this structure may not be relevant and is therefore not mandatory.

9. What are the requirements for file formats in veterinary e-submission?

The recommended file format for the moment is PDF (version 1.4, introduced with Adobe® Acrobat® version 5) which should be acceptable to all parties; newer versions may be used if justified).

In the case that specific documents (e.g. product information documents) are intended for frequent exchange, editable formats like Microsoft WORD should be applied to facilitate the transfer of documents with the ability to track changes.

Full file requirements are detailed in the "Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product", prepared by the TIGes vet subgroup.

10. What is required for the management of Product Information?

As mentioned in the Guideline, Product Information texts are usually exchanged between the applicant and authorities using editable format such as Microsoft Word. Reference can also be made to Notice to Applicants Chapter 7, where information on requirements for individual agencies is given.

11. Which hard media should be used for the submission of electronic documents?

As a general rule, exchange of electronic files can be made on a non-rewritable medium such as CD or DVD. A secure connection between industry and agencies for electronic submission is currently

under development and will allow submission directly to the agencies without need for any physical media.

12. Can secure email (Eudralink) be used?

Submission of individual files like product information (Summary of Product Characteristics, label, leaflet) or submission of smaller applications and responses (up to 80 MB) can be made via secure e-mail (Eudralink) if accepted by authorities (please check prior to submission). Larger submissions should only be submitted via CD or DVD.

13. How can I pre-validate my submission before sending it to the agencies?

A free software ("VNeS checker") has been co-developed by the French and Belgium agencies and is available online for applicants and authorities [here](#). This tool is compliant with the validation criteria of the e-submission guideline.

14. What are the objectives of the TIGes vet subgroup?

The TIGes Veterinary Subgroup was set up in September 2006 with the objective of developing and implementing standards for the submission of electronic information in the context of European veterinary medicines approval procedures. Its creation has been endorsed by the Telematics Steering Committee with endorsement from Notice to Applicants and HMA. The group reports to the TIGes main group.

15. 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

16. What is planned for the near future?

The TIGes veterinary subgroup has finalised the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product and monitors its implementation. Taking into account the experience gathered so far, a revision of the VNeS guidance comes into force in September 2011. It is currently supporting projects on the development of electronic application form standards for veterinary applications, and a secure connection for veterinary submissions.

17. 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.

18. 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. 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 standard.

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.

19. Is there an agreed electronic folder structure for a renewal application?

The VNeS guidance does not provide a folder structure for renewal submissions as such, but all other principles remain applicable. This means that e.g. all documents should follow the same formatting standards as outlined in the e-submission guideline, like PDF version, naming convention etc.

20. 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.

21. What level of detail should be provided within a Table of Contents (TOC)?

TOCs should follow the structure of the Notice to Applicants and the description of each hyperlinked document should easily allow identifying the contents of the file. In case applicants are using an automated TOC builder, the text of the TOC entry might just be the file name of the hyperlinked document. In such case applicants should put more emphasis on using descriptive file names. If the names of the files are not self-explanatory, the TOC needs to be edited manually e.g. by using commercially available pdf-editing software.

For further input and/or comments on these FAQs, please contact [EMA](#) clearly indicating that reference is made to veterinary issues.