

General FAQ relating to eSubmission for Veterinary Applications

1. What are the requirements applicable to e-dossiers for veterinary submission?
2. Are these requirements applicable in all Member States and EMA?
3. What were the major steps for electronic submissions for veterinary products?
4. Is the electronic submission mandatory for veterinary medicinal product?
5. In which regulatory procedures can an e-dossier be used?
6. Can I submit electronically a variation if until now, my existing dossier was submitted in paper?
7. What is the structure of the veterinary e-dossier?
8. Which types of applications are covered by the defined folder structure?
9. What is required for the management of Product Information?
10. Which hard media should be used for the submission of electronic documents?
11. Can secure email (Eudralink) be used?
12. How can I pre-validate my submission before sending it to the agencies?
13. What are the objectives of the TIGes vet group?
14. What is planned for the near future?

1. What are the requirements applicable to e-dossiers for veterinary submission?

The requirements are detailed in the guideline for the specifications of electronic presentations of veterinary medicinal products documents, prepared by the TIGes vet group. The recommended file format is PDF (version 1.4, introduced with Adobe® Acrobat® version 5) which should be acceptable to all parties; newer versions can be used but check with the agency first to get agreement).

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.

2. Are these requirements applicable in all Member States and EMA?

EMA has published the guideline, and requirements are therefore applicable to the Centralised Procedure. The last version of the guideline was released in October 2009. It will be published in the Notice to Applicants as soon as the guidance is endorsed and agreed by all Member States. Heads of Medicines Agencies have been encouraged to make reference to the guideline from national agency websites.

3. What were the major steps for electronic submissions 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. In October 2009, a revised guideline setting up requirements and specifications was released by the TIGes vet. 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 product?

The use of electronic submissions is optional and currently there are no plans to require electronic-only applications in the near future, for any procedure for veterinary applications. Dossiers presented in an electronic format are encouraged but paper submissions are 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.

For procedures such as MRL applications, requests for Scientific Advice, referrals, PSUR submissions and 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 electronically a variation if until now, my existing dossier was submitted in paper?

Yes. The variation itself is independent and does not impact the dossier submitted earlier. However, if the initial dossier has been submitted electronically, it is strongly advised to submit any further application electronically also.

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 some national agencies for the chemical, pharmaceutical and biological / microbiological information for the finished product (Part 2), but need to be confirmed prior to submission of the 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), as well as other types of applications (e.g. answers to questions, variations).

9. 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. PIM is not applicable to veterinary dossiers. Reference can also be made to Notice to Applicants Chapter 7, where information on requirements for individual agencies is given.

10. 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 regulatory agencies is planned to be developed, and will allow submission directly to the agencies without need for any physical media.

11. 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 40 MB) can be made via secure e-mail (Eudralink) if accepted by authorities (please check prior to submission). It is recommended that larger submissions should only be submitted via CD or DVD.

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

A free software has been co-developed by the French and Belgium agencies and is available for applicants and authorities for free download e.g. on the websites of the [French agency ANMV](#) and the [Belgian agency FAGG-AFMPS](#). This tool is compliant with the validation criteria of the e-submission guideline.

13. What are the objectives of the TIGes vet group?

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.

14. 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 (see Q1). Taking into account the experience gathered so far, a revision of the VNeeS guidance is planned for 2011. It is currently supporting projects on the development of electronic application form standards for veterinary applications, and a secure connection for veterinary submissions.

15. Are there tools available to create the e-folder structure?

Yes. The Spanish Agency has developed templates which can be downloaded [here](#)

- Template for immunologicals

- Template for pharmaceuticals

- Template for MRLs

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