

Q1: 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) 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 may be applied to facilitate the transfer of documents with the ability to track changes.

Q2: Are these requirements applicable in all Member States and EMEA?

EMEA has published the guideline and requirements are therefore applicable to Centralised Procedures. The guideline is currently under review within the Member States. It should be published in the Notice to Applicants as soon as common agreement has been received.

In the interim, Heads of Medicines Agencies have been encouraged to make reference to the guideline from national agency websites.

Q3: What is the meaning of the “2009 deadline” for electronic submissions?

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. Although the Member States have agreed to be ready by this date, the use of electronic submissions will remain optional (see below).

Q4: Will the electronic submission be mandatory for veterinary medicinal product?

No. Lots of agencies already accept dossiers presented on CD-Rom (including scans).

Dossiers presented in an electronic format are encouraged but paper submission can still be done in all Member States / EMEA.

There are currently no plans to require electronic-only applications in the near future, also after the 2009 deadline, for any procedure for veterinary applications.

Q5: What is the structure of the veterinary e-dossier?

The dossier follows the structure of the Notice to Applicants. E-CTD format is not appropriate for veterinary dossiers.

Q6: What is required for the management of Product Information?

There are no specific requirements. 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.

Q7: 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-ROM or DVD.

Q8: Can I password-protect the e-submission, or individual files within the submission?

The media carrying the files can be protected by the applicant, but it is advisable to ensure that the means used are accepted by authorities. In that case, the applicant has to provide authorities with the relevant information and means to access to the files.

Files themselves must not be password protected or include any security settings that may interfere with the process of assessment by the reviewers. Applicants should therefore allow printing, annotations to the documents, and selection of text and graphics.

Q9: Can secure email (Eudralink) be used?

Submission of smaller files like Product information (SPC, label, leaflet) can be made via secure e-mail (Eudralink).

It is recommended that larger submissions should only be submitted via CD or DVD.

Q10: 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.

Q11: What is planned for the near future?

The TIGes vet group has finalised eSubmission guideline for veterinary applications for all procedures and monitors its implementation (see Q1). It is currently working on the development of electronic application form standards for veterinary applications.

Filename: Question and Answer Document - TIGes Vet.doc
Directory: C:\Documents and Settings\lnoelj\Local Settings\Temporary
Internet Files\OLK316E
Template: H:\User Templates\Normal.dot
Title: What are the requirements applicable to e dossiers for
veterinary submission
Subject:
Author: CPhilippe-Reversat
Keywords:
Comments:
Creation Date: 21/07/2008 13:32:00
Change Number: 4
Last Saved On: 21/07/2008 13:39:00
Last Saved By: Administrator
Total Editing Time: 7 Minutes
Last Printed On: 22/07/2008 15:05:00
As of Last Complete Printing
Number of Pages: 3
Number of Words: 727 (approx.)
Number of Characters: 4,026 (approx.)