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Veterinary Medicines Division

Electronic submission of veterinary dossiers

Questions and answers

This question and answer document aims to address frequently asked questions and provide guidance to applicants in regard to technical and practical aspects of the Agency's current policy on electronic submissions for veterinary medicinal products.

The basis for any electronic submission for veterinary medicinal products is the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product, as developed and maintained by the Veterinary Harmonisation Group. Any general questions on (the interpretation of) the guideline should now be addressed to esubmissions@ema.europa.eu.

This question and answer document will be regularly updated. New or updated topics are marked 'New' or 'Updated' on publication.

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Questions relating to:

Background **3**

Procedure types **3**

What type of applications can I submit electronically to the Agency? 3

Dossier format **3**

Can I submit a dossier in eCTD or CTD format? 3

Submission media **4**

Can I use the EMA eSubmission Gateway or Web Client to submit dossiers to the Agency? - Updated 4

Do we have to use the EMA eSubmission Gateway or Web Client for all submissions or is it possible to submit some via the EMA Gateway or Web Client and some via physical media (CD/DVD) or Eudralink? - Updated 4

Where can I find more information about the EMA eSubmission Gateway or Web Client? 4

How shall I present the dossier to the CVMP members - Updated 4

What is XML delivery file within the eSubmission Gateway/Web Client and how do I use it? - New 5

Structure of the e-dossier **5**

What naming conventions should I use for folders and files? - Updated 5

How shall I present applications with a number of different presentations? 6

Contact details for submission **6**

When submitting via the EMA eSubmission Gateway or Web Client, how should the dossier containing the veterinary e-submission(s) be sent? 6

In case of submission of responses to list of questions (LoQ) or list of outstanding issues (LoOI), to whom should the submission be addressed? - Updated 7

What do I need to know about the cover letter? - Updated 7

Validation **7**

How are e-submissions processed at the Agency? 7

If the electronic format of my submission is not acceptable by the Agency, can I still amend it during the technical compliance checking period? 7

Submissions during an on-going procedure **8**

Is there a technical compliance check for submissions in an on-going procedure? 8

Background

Submissions of dossiers for veterinary medicinal product or MRL applications in electronic format have been accepted by the Agency since January 2010, and a number of guidance documents on how to create such electronic submissions ("e-submissions") have been provided and published on the Vet eSubmission website: http://esubmission.ema.europa.eu/tiges/vetesub.htm.

The Agency has implemented the guidance provided by the Veterinary Harmonisation Group and this document aims to provide specific information for applicants in regard to dossiers submitted to the Agency.

Procedure types

What type of applications can I submit electronically to the Agency?

You can submit electronically any information made in the context of a **centralised application procedure** or an application for a **maximum residue limit (MRL),** as outlined in the e-submission guideline.

You can also submit data electronically to the Agency in relation to **other procedures** than those stated above; however, please note that these procedures may not be covered by the e-submission guideline, and special data requirements might therefore apply.

For some of these procedures, please consult the guidance for the relevant procedure type:

- Any requests for *pre-submission guidance* – see pre-submission guidance
- Requests for *minor use minor species (MUMS)* classification – see "availability"
- Data in relation to *referral procedures* – see Q&A document on referrals (Q 11)
- Scientific advice applications – see "scientific advice"
- Any submissions in regard to pharmacovigilance (PSUR or renewal) see the post-authorisation Q&A document or for adverse event reporting see Eudravigilance Veterinary. Specific queries regarding pharmacovigilance submissions should be addressed to vetphv@ema.europa.eu.

If you have questions on any other type of submission not listed here, please contact the Agency directly at vet.applications@ema.europa.eu.

Dossier format

Can I submit a dossier in eCTD or CTD format?

Submissions for veterinary dossiers in eCTD format cannot be accepted by the Agency. However, in certain specific cases, (parts of) the quality dossier could be accepted by the Agency in CTD format (Note: not eCTD) provided that a correlation table between the CTD format sections used and the appropriate sections in the Annex I/NtA format is provided. An example for such a correlation table can be found here.

For further details on the specific cases where the use of the CTD format is acceptable, please see the document Exceptions to the VNeeS format.

Submission media

Can I use the EMA eSubmission Gateway or Web Client to submit dossiers to the Agency? - Updated

From 1 January 2017, the use of the EMA eSubmission Gateway or Web Client is mandatory for all veterinary medicines submissions to the Agency, including Active Substance Master Files (ASMFs), veterinary referrals, Maximum Residue Limits (MRLs) applications and Public Safety Update Reports (PSURs) for veterinary Centrally Authorised Products (CAPs).

Applicants need to register to use the EMA eSubmission Gateway or Web Client and can find more information on the use of these submission tools on the Vet eSubmission website. Applicants who have already registered and used the EMA eSubmission Gateway or Web Client for electronic submissions for the centralised procedure or PSUR submissions do not need to register again.

For dossier submission via Gateway or Web Client, no hard-copy cover letter is required.

Do we have to use the EMA eSubmission Gateway or Web Client for all submissions or is it possible to submit some via the EMA Gateway or Web Client and some via physical media (CD/DVD) or Eudralink? - Updated

From 1 January 2017, the use of the EMA eSubmission Gateway or Web Client is mandatory for all veterinary medicines submissions, including Active Substance Master Files (ASMFs), veterinary referrals, Maximum Residue Limit (MRL) applications and Public Safety Update Reports (PSURs) for veterinary Centrally Authorised Products (CAPs). All other submission media would not be accepted.

Where can I find more information about the EMA eSubmission Gateway or Web Client?

A dedicated eSubmission website has been established for all information relating to this system: http://esubmission.ema.europa.eu/esubmission.html

Please bear in mind that many materials listed on this site concern submissions for human medicines. The Agency endeavours to publish all eSubmission Gateway/Web Client information applicable to the veterinary domain in a dedicated section of the Veterinary eSubmissions page: http://esubmission.ema.europa.eu/tiges/vetesub.htm

The Vet eSubmission webpage has considerable information available from how to register, to detailed filename conventions, recording of Webinars and Q&A documents. Applicants are encouraged to review the information on the EMA and Vet eSubmission websites regularly.

How shall I present the dossier to the CVMP members - Updated

Electronic dossiers for veterinary product or MRL applications are accepted by all the CVMP members. Dossier requirements and specific contact details for e-submissions (if needed) for the CVMP members are published on the Agency website (Dossiers requirements of the members of the Committee for

Medicinal Products for Veterinary Use). Submission via CESP is possible and preferable for those member states accepting this submission channel.

For CAP-related submissions of Public Safety Update Reports (PSURs), a separate guidance document is available, namely the Annex to SOP on management of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products (SOP/V/4023) (available here).

What is XML delivery file within the eSubmission Gateway/Web Client and how do I use it? - New

The XML delivery file is a new technology or method of submitting applications via the eSubmission Gateway/Web Client. It replaces the previous filenaming convention method and will become the mandatory method for veterinary submissions from 1 April 2017.

It is based on generation of a delivery file which is included in your submission package. A User Guide on how to generate and use this file is available here.

If you are new to the Gateway, you do not need to learn about the filenaming convention. XML delivery file can already be used for all relevant submission types which removes the need to apply strict rules to the name of your overall submission package (however conventions still apply to your VNeeS root-folder – see below). In the rare event of the technology not being available for your particular submission due to a technical issue, the filenaming convention can be used. In this case, please contact the EMA Service Desk portal: https://servicedesk.ema.europa.eu for further advice.

Structure of the e-dossier

Details for the electronic dossier structure (folder structure, naming of files, navigation, file formats, etc.) are provided in the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product (including MRL application), and should be applied to any submission of data for MRLs or centralised procedures. For submissions to the Agency, please also note the following:

What naming conventions should I use for folders and files? - Updated

Folder name

The highest level ("root level") should include the following information:

- The product invented name, or INN (e.g. for MRLs)
- The EMA procedure number
- In case of different submission steps in the same procedure, further submissions should be labelled in a logic order, e.g. by adding the words "responses-loq"
- The date of submission is not mandatory to be added (as it is obvious from the cover letter); however, if the submission is to fully replace a previously submitted technically invalid application, or is an updated version of a technically valid application, this should be clearly stated in the cover letter.

Example of folder name: "root-Vetpill-v-c-0000" or "root-Vetpill-v-c-0000-II-0000-responses-loq"

Product information files

These are submitted to the Agency in Word format under "add info", and should be named according to the following convention: ProductName-V-ProcedureNumber-pi-language code. Applicants are reminded to use the current QRD form for the submission of the product literature and NOT to split the product literature up into separate sections (SPC, labelling, package leaflet).
For example: "Vetpill-V-0000-II-000-pi-en"

English product information files that are common to all agencies should not be given names that can be misunderstood as being files specific to just one agency / country (e.g. "UK" or NCA names) and should also not be provided in country-specific folders in the "add-info" folder, which are restricted for national requirements only.

How shall I present applications with a number of different presentations?

For centralised procedures, only one submission should be provided, even if the product contains different strengths, pharmaceutical forms or target species which could eventually result in a large number of different presentations. Dossier parts do not need to be duplicated, and appropriate subfolders/headings in the appropriate table of content (TOC) should be used for information specific to individual presentations, clearly indicating, for example, the strength, pharmaceutical form and/or target species concerned.

For example, if a dossier is to be submitted for different pharmaceutical forms and strengths (e.g. 30 mg and 50 mg tablets, 100 mg/ml solution for injection) and for different target species (e.g. cats, dogs):

- The TOC for part 2 (quality) should be structured in such a way that only those sections where differences exist (e.g. data specific for a pharmaceutical form and/or strength) will be repeatedly addressed, but general information that applies to all the pharmaceutical forms/strengths (e.g. on the active substance) would be addressed only once, in a single location.
- Likewise, the part 3 (safety) of such a dossier would mostly contain information relevant for all the presentations, and only limited information specific for a particular target species.
- For the part 4 (efficacy), the TOC could differentiate between trials undertaken for different target species or indications. As there are numerous options possible for different presentations for veterinary medicines, no general rule can be provided here, and applicants are reminded to use their common sense to find a clear and unambiguous way to address the appropriate sections. The overall aim should be to provide assessors with a clear overview that facilitates quick and easy access to the relevant data.

Contact details for submission

When submitting via the EMA eSubmission Gateway or Web Client, how should the dossier containing the veterinary e-submission(s) be sent?

When using the EMA eSubmission Gateway or Web Client, applicants need to register on the EMA's eSubmission website.

In case of submission of responses to list of questions (LoQ) or list of outstanding issues (LoOI), to whom should the submission be addressed? - Updated

Any submissions of responses to LoQ or LoOI should be addressed to Vet applications and sent via the EMA eSubmission Gateway or Web Client.

What do I need to know about the cover letter? - Updated

The cover letter is required to be included in the electronic submission's dossier.

When submitting via the Gateway/Web Client no hard copy of the cover letter is required.

If the submission is to fully replace a technically invalid application, or is an updated version of a technically valid application, this should be clearly highlighted in the cover letter. In case of an update of a valid application the amendments should be clearly identified.

Validation

How are e-submissions processed at the Agency?

It is important that there is a clear understanding of the distinction between "technical compliance" and "validation".

"*Technical* compliance":
This is the check of the technical components of an electronic submission, which will be done for e-submissions only, as the first step when an application is received by the Agency. The Agency is using the VNeeS checker provided by the French/Belgian authorities to check the technical compliance of the data submitted with the requirements laid down in the e-submission guideline. Only once a dossier has been confirmed to be "technically valid", can the validation of the content of the submission start. It is recommended as an offer to help applicants during that phase, that electronic dossiers are submitted about 1 week in advance of the recommended submission date, especially for applicants not familiar with e-submission. This is to ensure that only technically compliant dossiers will be available in time for the validation to commence. However, an earlier submission is not necessary in case applicants successfully check the submission with the current VNeeS checker before submission.

Following the technical compliance check, the Agency will only send feedback to the applicant if there are unresolved technical issues with the submission. Similarly, for subsequent submissions (e.g. responses to questions, variations, etc.) feedback will be sent only if a technical error is identified.

"Validation":
Where there is an issue discovered during validation (for example, missing sections or administrative errors), replacement or additional new documents should be submitted by the applicant, as required, clearly indicating the date of submission of the amended document(s).

If the electronic format of my submission is not acceptable by the Agency, can I still amend it during the technical compliance checking period?

Yes.

If a dossier fails the technical compliance check it is still possible for an applicant to provide the Agency during the technical validation period (only) with the correct(ed) electronic format.

Submissions during an on-going procedure

Is there a technical compliance check for submissions in an on-going procedure?

Submission of data for on-going procedures (e.g. responses to LoQ) will be checked by the Agency for technical compliance. It is therefore also recommended, especially for applicants not familiar with e-submission, to submit e.g. responses to questions, a few days in advance of the actual submission date to ensure that only technically compliant dossiers will be available in time for the assessment to continue. Technical compliance check reports for such submissions will only be sent to the applicant if a technical error is identified.