Submission of applications and responses[1]

Electronic Submissions

Applications and responses may be submitted electronically ('eSubmission') and in accordance with the TIGesVet Guidelines, which is available on the European Medicines Agency (EMA) website:

- by email using Eudralink[2] to: s.response@vmd.defra.gsi.gov.uk. The maximum capacity is 200 MB. The subject line should identify if the email is a submission of an application, or a response to the VMD.

- using the Common European Submission Platform (CESP)

- on CD or DVD sent to: Information Services, VMD, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS. Only <u>one</u> copy is needed.

We strongly encourage you to submit your application electronically.

Page Numbering
The TIGesVet Guidelines state that each page within a file should be numbered. It does not specifically state whether the numbering should be sequential throughout the whole dossier, so the VMD does not ask for this.

Root Folders
A root folder is part of the TIGesVet structure and should be the first folder you create when preparing your e-submission.

Technical Validation
Following receipt of an application, the e-submission will be subject to technical validation – a check to make sure the technical requirements of the e-submission meet the TIGesVet Guidelines. If the application fails technical validation, you will be informed and told what to do to bring your application up to standard.

Scientific Validation
The validation team will contact you if they need further information from you to bring your application up to standard. When submitting the information, please submit a

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[1] For Marketing Authorisations, Homeopathic Registrations, Animal Test Certificates, Specific Batch Control, Autogenous Vaccines, Non-Food Animal Blood Banks, and Equine Stem Cell Centres

[2] Normal email shouldn't be used.

replacement PDF file rather than just part of a PDF file; this helps maintain the integrity of the application dossier.

Naming Conventions
You should follow the naming conventions for folder and files set out in the TIGesVet Guidelines. For some software programmes using anything other than lower case letters, or numbers 0 to 9, can cause problems and you run the risk of your submission failing technical validation.

National-Only Schemes
Although the application structure for national-only schemes, listed below, do not completely fit within the TIGesVet Guidelines, you may still submit your application electronically using as many of the principles laid out in the guidelines as possible, eg. File size, naming conventions, and indexing.

- Marketing Authorisations for Parallel Import (MAPI)
- Exceptional Marketing Authorisations
- Specific Batch Control
- Animal Test Certificates (ATC)
- Autogenous Vaccine Authorisations (AVA)
- Non-Food Animal Blood Banks (NFABBA)
- Equine Stem Cell Centres (ESCCA)

Active Substance Master Files (ASMF)
ASMFs may be submitted electronically and in CTD or NTA format. CTD format is preferred.

Paper Submissions

Applications and responses may be submitted in paper to: Information Services, VMD, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.

Only one copy is needed.

If using a courier, the VMD can accept deliveries Monday to Friday from 08.30am to 4.30pm.

You can't mix up the format of your submission, so it needs to be either all electronic, or all paper including any subsequent responses.

For further Information, email: s.response@vmd.defra.gsi.gov.uk and state 'Query' in the subject line.