Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product

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1 Introduction

This Guidance Document is intended to assist applicants and regulators with submissions of dossiers in electronic format. It specifies the basic parameters required for an acceptable electronic submission to be known as Veterinary NeeS (VNeeS), the name being inspired by the established NeeS standard for Human medicinal products. The document has been created by the TIGes-Vet Sub Group which is made up of representatives from National Competent Authorities, the EMA and industry. All National Competent Authorities and EMA should adopt this guidance as the basis for their acceptance of electronic submissions for marketing authorisations from applicants.

At a meeting in July 2007 the HMA recorded the following decision, "In response to a direct request from industry, HMA confirmed that the requirement for agencies to be in a position to accept electronic only submissions by 2009 applied to veterinary as well as to human applications. It should be understood that the investment of resources by the Industry will also depend on progress made by the agencies." This decision meant that agencies had to be able to accept electronic submissions from 1 January 2010 as well as continuing to deal with submissions based on paper. The work will continue to achieve a harmonised way of electronic working by all NCAs.

2 Scope

This guidance covers all types of initial applications for marketing authorisation made in the Centralised, Mutual Recognition, Decentralised and National procedures including updates provided during the assessment phase (validation updates and responses to questions).
It applies also to active substance master files (ASMF), MRL applications, and post-authorisation submissions (i.e. variations and extensions, PSUR submissions, renewal applications and dossiers for referral procedures).

3 Media used for submission and its identification

As a general rule, exchange of electronic files can be made on finalised optical media such as CD or DVD. Each hard medium on which the e-submission is presented should include at a minimum the following label information:

- Name of the product,
- type of application,
- procedure number (if known in advance by the applicant),
- name of company,
- target species (if necessary to avoid confusion of products),
- version (including date),
- indication as to whether multiple media components are used (and if so, these should be numbered, e.g. 1/2, 2/2),

This information should preferably be printed directly onto the hard media as hand-written or self adhesive labels may compromise the disc or peel-off in time.

Eudralink has a 40 MB limit and as a result it is unlikely that an e-submission of a complete dossier can be made by this means. If accepted by the competent authority Eudralink may be used for email communication with the authorities, for submission of smaller applications and responses and for the exchange of editable versions of the product information (SPC, label, leaflet). Folder-structured submissions via Eudralink have to be submitted as a zip file. Applicants should ensure that the correct e-mail addresses intended for submission via Eudralink are used.

Electronic submissions should be accompanied by a cover letter when submitted via hard media. For authorities requiring an official signature for legal reasons, an originally signed cover letter or application form may accompany or follow the electronic submission.

Applicants should provide the electronic submission on the smallest number of media components possible, e.g. if the VNeeS submission spans several CDs, the provision of a DVD is recommended.
If more than one media component is needed, the dossier should be split at a logical point within the granularity such that the integrity of the granularity is maintained. Where possible, individual dossier parts (Part 1, Part 2 etc.) should be kept together and not be split over multiple media components.

Several VNeeS submissions for the same medicinal product may be provided on a single media component.

Grouped variations or variations submitted in a worksharing procedure should preferably be submitted on the same media component.

4 Language

In order to facilitate the processing of the application and make the assessment more efficient, the scientific and technical documentation should be submitted in English. Both applicants and authorities should refrain from translations to languages other than English as this makes quality control and validation difficult and less reliable.

5 File Format & Source

All documentation should be submitted using file formats that facilitate both reviews on screen and paper while retaining a similar format.

The portable document format (PDF) is a format which supports the described features. PDF has been accepted as a standard for providing documents in electronic format by the International Conference on Harmonisation (ICH) and will be considered by the veterinary equivalent (VICH).

The PDF format used for a submission should be legible with Acrobat Reader, version 5.0 or higher. Files should be compatible with PDF 1.4 (or as updated by the ISO norm). No PDF documents should be in version PDF 1.3 or earlier.

To ensure that PDF files can be accessed efficiently, PDF files should preferably be no larger than 100 MB.

Product information (SPC, label, leaflet) should be submitted in addition to a PDF file in an editable format like Microsoft Word, normally on the same CD/DVD.

6 Requirements for creating PDF files for electronic submission

6.(a) Paper source documents

PDF documents submitted as scans should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed. Normally 300 dpi gives good results without compromising file size for text; higher resolution may be required for graphics. Applicants should ensure that the quality of the renditions is adequate for regulatory review.

6.(b) Electronic source documents

To allow functionality such as text searching, copying and pasting into editable formats, PDF documents should be created (rendered) directly from their electronic source documents, except where the applicant has no access to the electronic source document or where the document requires a signature. Where only signature pages need to be scanned, applicants should consider providing signatures on separate pages not containing other information key to the understanding of the submission.

Fonts for electronic source documents

Font point sizes should ensure on-screen readability, for example 11-12 for normal text, 9-10 for tables and 8-10 for footnotes. The recommended font colour is black. The recommended fonts are Arial (11) and Times New Roman (12). Blue font can be used for hypertext links.

Agencies cannot guarantee the availability of any fonts except Times New Roman, Arial and Courier, and fonts supported in the Acrobat product itself. Therefore, all additional fonts used in the PDF files should be embedded to ensure that those fonts would always be available to the reviewer.

Page format and numbering for electronic source documents

The print area for pages should fit on ISO 216:2007 A4 sheet of paper with sufficient margins with the exception of the mock-ups for packaging components which may require other formats. Pages should be properly oriented to reduce the effort of rotating pages. Pages within a file should be numbered.

7 Signatures

The applicant has the obligation to ensure a proper certification of the submitted documents. Valid signatures should be available from the applicant and be presented at the request of the authorities. National Competent Authorities should, wherever necessary, accept a signed paper cover letter confirming the correctness of the submitted file(s).

8 Structure of the electronic submission

8.(a) General considerations

The folder structure (granularity) for an electronic submission is based on the Notice to Applicants Volume 6B as amended by Directive 2009/9/EC[1] (Annex I to Directive 2001/82/EC as amended). This hierarchical structure of folders within a root folder gives, depending on the type of submission, up to three levels of granularity. The complete VNeeS folder structure is shown in Table 1 for pharmaceutical products and Table 2 for immunological products and should be used where applicable to prepare any electronic submission consisting of more than a single file.

Root folder

The name of the top level folder ("root folder") of each VNeeS folder structure should allow appropriate identification of the submission, especially in cases where more than one VNeeS structure is located on a single hard medium.

[1] The folder structure and naming convention has of necessity been prepared before the publication of the final revised Volume 6B on Presentation and Content of the Dossier based on the new Annex to Directive 2001/82/EC. The folder structure and naming of folders may need revision after publication of Volume 6B.

For reasons of automated identification and technical validation of e-submissions with tools like the VNeeS checker[2] each root folder name must start with the letters "root", followed by a specific identification of the submission which can be defined by the applicant. A hyphen ("-" character) should be used as separator.

It is recommended to use as specific identification

- the product (invented) name and/or
- the procedure number (if known), especially if more than one procedure is included on the same CD, and /or
- the submission date or day of procedure, to allow tracking of updates during the procedure

For example

root-mydrug
root-mydrug-dk-v-0123-001
root-ema-v-c-0123
root-dk-v-0123-002-1a-003
root-mydrug-ema-v-c-0123-2oct11

Folder "add-info" (additional information)

The folder structure includes a folder called "add-info" located in the root folder for working documents such as editable versions of the SPC, labels and package leaflet.
Where the applicant still has to fulfil any specific national requirements, related country-specific documents should be provided in this folder. If so, subfolders should be included named with the country code of the country concerned as per Table 4.

Any files submitted voluntarily for information only, like validation results of tools like the VNeeS checker or user instructions for the reviewer, should also be placed in the folder "add-info".

Files and subfolders in the folder "add-info" are not subject to technical validation.

Adaptation of folder structure

Where the structure defined in Table 1 to Table 3 applies, including additional folders within the structure of the e-submission is not permitted, with the exception of the folder "add-info" where subfolders could be constructed. However, the total number of folder levels of the submission should never exceed three levels.
If there are empty folders in the submission because no data is provided these should be deleted as the folder structure should reflect only what actually is submitted. Corresponding positions in the relevant table of contents (TOC) should also be deleted.
When only little information is presented for a number of folders at the same level of granularity, it is acceptable to include all the information in a single PDF at the higher level of the granularity. This should be indicated in the TOC.

Folder names

Folder names should be in English and where the VNeeS structure defined in this guidance is applicable follow exactly the conventions given in Table 1 for pharmaceutical products, Table 2 for immunological products and Table 3 for MRL applications.

[2] The VNeeS Checker is a standard non-commercial, and publically available tool for technical validation of VNeeS submissions. For further details please refer to section 10 of this guidance.

8.(b) Folder structure for initial Marketing Authorisation Application

The folder structure for an electronic submission of an initial application for marketing authorisation is shown in Table 1 for pharmaceutical products and Table 2 for immunological products.

If publicly announced by the competent authority, the applicant may also optionally submit the chemical, pharmaceutical and biological / microbiological information for the finished product (Part 2) in a CTD structure using the format for Non-eCTD electronic Submissions (NeeS) for human medicinal products for Module 3 of the CTD. In this case, a correlation table should be provided showing which CTD chapter corresponds to which veterinary NtA chapter.

8.(c) Submission structure for updates during assessment phase

The initial submission and subsequent amendments during the assessment phase should use different root folder names to allow efficient tracking of submissions, e.g. by including the submission date or day of procedure.
Though applicants are strongly encouraged to use in subsequent submissions consistent file naming conventions there is no requirement to exactly preserve file names during life cycle changes; in fact, logical differences in file names can be helpful during review when both files are open simultaneously for comparative or other purposes.

Validation updates

As a consequence of the technical or regulatory validation process there may be the need for updates of the VNeeS submission.
Normally, a corrected version of the full application has to be re-submitted if the submission is technically invalid.
If there is a need to update the dossier due to the content validation, the applicant should liaise with the relevant authority whether these documents could be submitted as single documents, or sending an updated VNeeS submission is required. Single files should be properly named so it is easily understood what is submitted.

Responses to Questions

In response to questions on the initial submission the applicant submits document(s) containing the actual text of the responses as well as amendments to the initial dossier.
If the response submission contains more than a single file, the main response document(s) should be located in the folder "responses" in Part 1. Any additional documents submitted with the responses should be assigned to the relevant folders, as specified in Table 1 to Table 3. The response submission is a stand-alone submission; it is thus not required to send an update of the initial VNeeS submission consolidated with the responses.

8.(d) Active Substance Master Files

The VNeeS folder structure applies also to the Active Substance Master File (ASMF) procedure. For an initial ASMF (containing Applicant's Part and Restricted Part) the relevant VNeeS folders are:

- 1a-admin-info: Letter of access or other administrative documents as applicable
- 1c1-qual: Detailed and critical summary document
- 2c1-act-sub
- 2f1-act-sub (if applicable)

If agreed by the competent authority, the master file holder may also optionally submit the ASMF within a CTD folder structure, e.g. using the NeeS or eCTD format. In this case, a correlation table should be provided showing which CTD chapter corresponds to which veterinary NtA chapter.

The name given to the root folder is the decision of the ASMF holder but should uniquely identify the ASMF, preferably by the name of active substance and name of the ASMF holder.

The Restricted Part should be provided by the ASMF holder on the same CD/DVD as the Applicant's Part. It could be provided either as a separate folder, structured in accordance with the example above, or incorporated in the same structure, but then by using the suffix "rp" and "ap" respectively in each file name for clarification.

In the corresponding marketing authorisation application dossier, the documents in the Applicant's Part of the ASMF(s) should be assigned to the relevant folders and subfolders as specified in Table 1 and Table 2 in this guidance, and clearly named for identification, in particular if more than one ASMF is used.

8.(e) Submission structure for post-authorisation submissions

Variations / Extensions

In case of submissions containing more than a single PDF file, all files should be assigned, wherever possible, to the relevant folder as specified in Table 1 and Table 2, e.g. for quality variations primarily the folders within Part 1 (e.g. for application forms, updated product literature) and Part 2 'Quality Documentation'. Empty folders in the submission should be deleted so that the structure reflects only what actually is submitted.
Submissions with a small number of documents, e.g. type IA variations, may usually be submitted as a single, bookmarked PDF file.

For grouped variations or work sharing procedures, a single file or a single submission structure (i.e. one root folder) may be used in case the documentation is completely identical for all products. If these submissions are product specific, one file per product or one submission structure per product should be provided.

Other post authorisation submissions

For other post authorisation submissions such as PSUR submissions, renewal applications or dossiers for referral procedures the folder structure as defined in Table 1 to Table 3 may not be applicable. When consisting of more than a single file, the applicant should use for such submissions any appropriate folder structure that facilitates the review.

8.(f) Indexing

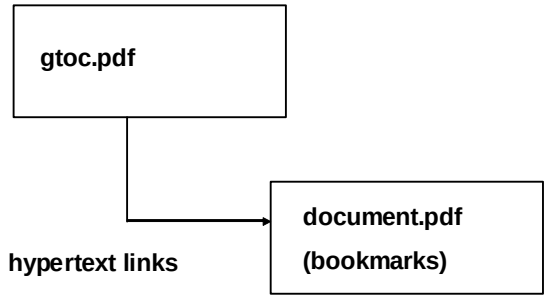
The electronic submission must include a general table of contents (GTOC) in the root directory. A part-specific table of contents (TOC) in the top level folder of each part of the dossier may be added where this improves the navigation within the dossier.
If more than one media component is needed (e.g. several DVDs), TOCs must be provided. In this case, the GTOC should be present only on the first hard medium; part-specific TOCs must be available on the media component where the files covering that part of the dossier are located.

In case of very small submissions consisting of only a single PDF file, no separate GTOC or TOC files need to be created.

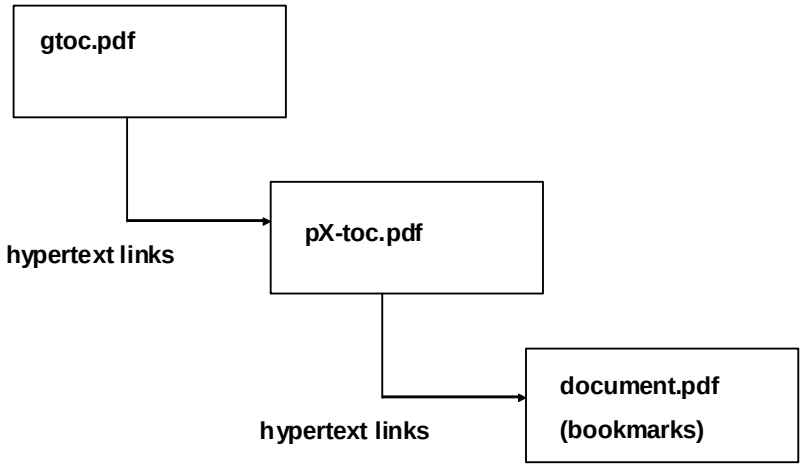
The GTOC should be a complete index to the whole dossier either referring directly to content documents or via the part-specific TOCs, while the TOC for each part of the dossier should be a complete index for that part of the dossier. Files being present in the folder "add-info" need not be included in to the GTOC.
Hypertext links in GTOC or TOCs are essential for efficient navigation through any larger submission. Therefore all documents in the submission should be referenced in a GTOC or TOC using a hyperlink. The general TOC should always be hyperlinked to any part-specific TOCs. Hyperlinks to the documents in each dossier part should be present either in the GTOC or the part-specific TOCs.

The diagrams below illustrate the recommended use of features for navigation. Alternative methods (like use of bookmarks in the (G)TOCs or hyperlinks between specific documents, e.g. from reports to annexes) can be used if they assure equivalent efficiency of navigation, but these features may not be supported by the VNeeS checker.

Navigation via GTOC only:



Navigation via GTOC and part-specific TOCs:



File naming conventions for the table of contents should be followed to allow automated validation tools like the VNeeS checker to easily identify and check GTOC and TOCs, including the functionality of inserted hyperlinks.
The GTOC should be named "*gtoc.pdf*". The files containing the part-specific TOCs should be named "*p1-toc.pdf*", "*p2-toc.pdf*", "*p3-toc.pdf*" and "*p4-toc.pdf*".
In case of immunological products, the contents of Part 3E 'Assessment for products containing or consisting of GMOs' may be covered by a separate TOC for this subpart, named "*p3e-toc.pdf*".

8.(g) Files

Size and number

The number of files should reflect the size of the dossier. Individual files should not be bigger than 100 MB.

If more than one PDF is provided in any section, discrete studies or reports should not be split between PDF files unless necessary. If splitting is necessary it should be done at a sensible point to facilitate the review (i.e. do not split in the middle of a paragraph but rather between the text and the annexes for instance).

Naming

The name of the files should be in English. They should be descriptive and unambiguous especially if more than one PDF is included in a particular section. Any information that may help identify the contents of the file is encouraged to be included in the file name.
Preferably the file name should include the part of the dossier where the document is located. In these cases file names should be based on the naming convention for dossier parts used in the folder structure as defined in Table 1 to Table 3.
However, excessively long file names should be avoided. The length of a path including file name, and extension should not exceed 180 characters.

Examples of valid file names are:

admin-info.pdf
p1c2-dacs-safety.pdf
part-2e3-ident-assay-excip.pdf
p3a2-report-no-12345.pdf
part-3a6-era.pdf

If one document has to be split over more than one PDF because it is larger than 100 MB then the files should be numbered as “1ofx”, “2ofx” for example:

carcinogenicity-rat-1of4.pdf

Where possible, applicants are strongly encouraged to use in subsequent submissions naming conventions consistent with the naming used in the initial submission.

Study reports and/or other literature will usually accompany the information provided in the dossier. These can be provided as individual PDF files or as a single PDF containing a number of studies. In general providing each study as a single PDF file is preferred. PDF files which are required in more than one section of the dossier need not be submitted more than once, although the file(s) can be submitted in each section in which they are required. If a file is only to be submitted once but referenced a number of times then a simple cross–reference or a hyperlink to the section of the dossier where the files can be found is necessary.

Files should have the proper extension (e.g. PDF), and file names should only be made up of characters 'a' to 'z' (preferably lower case only) and '0' to '9' plus '-'. The file name should not contain any 'special' characters in particular the following characters are known to give problems.

' ' SPACE is not allowed (use Hyphen (minus) '-')
'.' FULL STOP is not allowed, except to separate files extension from rest of the file name.

':'	COLON is not allowed
'/', '\'	SLASH, BACKSLASH not allowed
'*'	asterisk not allowed
'? '	QUESTION MARK not allowed
'“' ”"'	QUOTATION MARK not allowed
'<'	LESS THAN not allowed
'>'	GREATER THAN not allowed
'|'	'PIPE' not allowed
'&'	'AMPERSAND' not allowed

Bookmarks and hyperlinks (outside the GTOC or TOC)

Navigation is significantly enhanced by appropriate use of bookmarks and hyperlinks in PDF files. The inclusion of bookmarks / hyperlinks into PDF files aids in the navigation around the document content. Hyperlinks in key documents of the submission (e.g. detailed and critical summaries or written summaries of the applicant) to related files like references, or appendices are helpful and greatly improve navigation efficiency through a VNeeS submission.
Especially in case of submissions consisting of only a single PDF file, without separate GTOC or TOC files, or single PDF files containing several references, bookmarks should be included for efficient navigation.

9 Security

It is not permitted to apply password protection to either the media carrying the files or the files themselves. As with paper dossiers, authorities are obliged to have properly secured systems that guarantee the documentation is accessed only by authorized persons. Applicants have the right to get the assurance that the appropriate level of security is applied.

It has to be recognised that some references taken from journals and other publications may not be able to be stripped of all security settings (e.g. preventing the copying of text from the article) without violating copyright rules. These files must then be exempt from a validation criterion regarding security settings.

10 Technical validation

In order to be accepted as valid, an electronic VNeeS submission has to comply with the common set of technical criteria defined in the 'Technical validation checklist for veterinary electronic submission' as published on the TIGes veterinary eSubmission website.
The criteria listed included in this checklist above should be considered as a maximum set of criteria. Authorities should not enlarge the list as this will result in a non-unified approach to the validation.
Submissions that fail to comply with these technical validation criteria may be rejected and a replacement submission can be requested by the receiving authority (if necessary).
VNeeS submissions can be checked against the technical validation criteria using the VNeeS checker tool. The VNeeS Checker tool can be used as point of reference for technical validity of a submission by both applicants and agencies. It is available for free download e.g. on the websites of the French agency ANMV and the Belgian agency FAGG-AFMPS. The tool will be updated in line with revisions to this guideline.

11 Glossary

CD: "Compact Disc"; an optical disc that contains data accessible by a computer.

dpi: dot per inch; measure of printing resolution (number of individual dots of ink a printer or toner can produce within a linear one-inch (2.54 cm) space).

DVD: "Digital Versatile Disc" or "Digital Video Disc"; optical disc storage media format that can be used for data storage, with a capacity 8 times higher (single layer, single sided) than the CD.

ERA: Environmental risk assessment

EUDRALINK: system designed to enable files to be sent securely over the Internet via a user-friendly Web interface, available to the EMA, Member State Agencies, Industrial Pharmaceutical Companies, Members of Working Parties / Committees and Experts.

GTOC: General Table of Contents. The GTOC should be a complete index to the whole dossier.

Hard medium: Any type of physical media used for storage and transfer of electronic data (e.g. optical media like CDs or DVDs) in contrast to a purely electronic transfer e.g. via Eudralink or any web portal.

ICH: International Conference on Harmonisation

ISO: International Organization for Standardization

MB: Megabyte; unit of information storage or computer storage

PDF: Portable Document Format

SmPC/SPC: Summary of Product Characteristic

TOC: Table of Contents. The TOC should be a complete index for that part of the dossier.

URA: User risk assessment

VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

VNeeS: Veterinary NeeS (the name being inspired by the established NeeS standard for Human medicinal products), an electronic application prepared using standard software and which follows the structure set out in Table 1 to Table 3.

TABLE 1: Folder structure and Standard files for an electronic application for a pharmaceutical product

- **root-<mydrug>** (*submission-specific root folder - see section 8.(a) for naming conventions*)
  - **gtoc.pdf**
  - **add-info**
    - **cc** **(country code as per Table 4)**
  - **p1**
    - **p1-toc.pdf**
    - **1a-admin-info**
    - **1b-spc-pl**
    - **1c-dacs**
      - **1c1-qual**
      - **1c2-saf-resid**
      - **1c3-effic**
    - **1-responses**
  - **p2**
    - **p2-toc.pdf**
    - **2a-qual-quant-partic**
    - **2b-manuf**
    - **2c-contr-start-mat**
      - **2c1-act-sub**
      - **2c2-excip**
      - **2c3-cont-clos-sys**
      - **2c4-bio-origin**
    - **2d-contr-intermed**
    - **2e-tests-fin-prod**
    - **2f-stab**
      - **2f1-act-sub**
      - **2f2-fin-prod**
    - **2g-other-info**
  - **p3**
    - **p3-toc.pdf**
    - **3a-saf**
      - **3a1-ident**
      - **3a2-pharmacol**
      - **3a3-tox**
      - **3a4-other**
      - **3a5-ura**
      - **3a6-era**
    - **3b-resid**
      - **3b1-ident**
      - **3b2-metab-resid**
      - **3b3-resid-analyt-met**
  - **p4**
    - **p4-toc.pdf**
    - **4a-preclin**
      - **4a1-pharmacol**
      - **4a2-resist**
      - **4a3-tas**
    - **4b-clin**

TABLE 2: Folder structure and Standard files for an electronic application for an immunological product

- **root-<mydrug>** (*submission-specific root folder - see section 8.(a) for naming conventions)*
  - **gtoc.pdf**
  - **add-info**
    - **cc (country code as per Table 4)**
  - **p1**
    - **p1-toc.pdf**
    - **1a-admin-info**
    - **1b-spc-pl**
    - **1c-dacs**
      - **1c1-qual**
      - **1c2-saf**
      - **1c3-effic**
    - **1-responses**
  - **p2**
    - **p2-toc.pdf**
    - **2a-qual-quant-partic**
    - **2b-manuf**
    - **2c-prod-contr-start-mat**
      - **2c1-start-mat-in-ph**
      - **2c2-start-mat-not-in-ph**
    - **2d-contr-manuf**
    - **2e-tests-fin-prod**
    - **2f-batch-consist**
    - **2g-stab**
    - **2h-other-info**
  - **p3**
    - **p3-toc.pdf**
    - **3a-gen-requ**
    - **3b-lab-tests**
    - **3c-field-stud**
    - **3d-era**
    - **3e-gmo**
      - **p3e-toc.pdf**
      - **3e-annexes**
  - **p4**
    - **p4-toc.pdf**
    - **4a-gen-requ**
    - **4b-lab-trials**
    - **4c-field-trials**

TABLE 3: Folder structure and Standard files for an electronic MRL application

root-<mydrugsubstance> (*submission-specific root folder - see section 8.(a) for naming conventions*)

- **gtoc.pdf**
- **add-info**
- **p1**
  - **p1-toc.pdf**
  - **1a-admin-info**
  - **1b-sum**
    - **1b1-sum-saf**
    - **1b2-sum-resid**
  - **1-responses**
- **p2**
  - **p2-toc.pdf**
  - **2a-dacs-saf**
  - **2b-ident**
  - **2c-pharmacol**
  - **2d-tox**
  - **2e-other**
  - **2f-adi**
- **p3**
  - **p3-toc.pdf**
  - **3a-dacs-resid**
  - **3b-ident**
  - **3c-metab-resid**
  - **3d-monit-expos**
  - **3e-resid-analyt-met**

TABLE 4: Recommended country codes for country-specific folders when a file is submitted to only one country

at	Austria
be	Belgium
bg	Bulgaria
cy	Cyprus
cz	Czech Republic
de	Germany
dk	Denmark
ee	Estonia
el	Greece
es	Spain
fi	Finland
fr	France
hu	Hungary
ie	Ireland
is	Iceland
it	Italy
li	Liechtenstein
lt	Lithuania
lu	Luxembourg
lv	Latvia
mt	Malta
nl	Netherlands
no	Norway
pl	Poland
pt	Portugal
ro	Romania
se	Sweden
si	Slovenia
sk	Slovakia
uk	United Kingdom