

## **Guideline for the specifications of e-submission of veterinary medicinal products documents:**

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### ***Media used for submission and its identification***

The electronic presentation of an application should be certified as being identical to the one on paper (if also supplied on paper). This does not apply to files that will be filed electronically only subject to prior agreement with the applicant (for example an electronic-only copy of product information).

Appropriate labels/identification should be attached to the hard medium on which the e-submission is presented. This should include at a minimum: Name of the product, type of application, any procedure number, company, target species (if applicable), version (including date) and indication as to whether multiple media components are used (and if so, these should be numbered).

As a general rule, exchange of electronic files can be made on a non-rewritable medium such as:

CD-ROM

DVD

or via e-mail (also Eudralink).

Submission of Product information (*SPC, label, leaflet*) in an editable format as an addition to a read-only file can be made via e-mail.

### ***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.

### ***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).

A common baseline format should be agreed. This baseline format should be PDF 1.4 (introduced with Adobe® Acrobat® version 5), as detailed in ISO 19005-1:2005(E) [1] or any version according to further update of this ISO norm. Applicants may *offer*, and agencies may *request* newer file formats but neither should be constrained to supply or accept other than PDF 1.4 (or as updated by the ISO norm). Once a PDF file has been created it should not be compressed for submission.

All PDF files should be created using software that allows reading and printing using a version that is available to companies and authorities. To ensure that PDF files can be accessed efficiently, PDF files should be no larger than 100 MB. PDF files should be optimized for fast web view (to enable reading the beginning of a file while the rest of the file is still being accessed).

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### **(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.

### **(b) Electronic source documents**

Where practicable, PDF documents should be created (rendered) directly from their electronic source documents. This allows functionality such as text searching, copying and pasting into editable formats.

#### **▪ Fonts for electronic source documents**

All fonts used in the document should be embedded in the (PDF) files to ensure that those fonts will always be available to the reviewer. All classical fonts are acceptable as well as True Type or Adobe Type 1 fonts in the case of PDF. It is recommended to not use proprietary fonts and to avoid customized fonts.

When embedding fonts, all characters for the font should be embedded, not just a subset of the fonts being used in the document. Embedding fonts requires additional computer storage space. To help limit the storage space taken by embedding fonts, applicants are encouraged to limit the number of fonts used in each document.

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. Blue font can be used for hypertext links.

#### **▪ Page Format and Numbering for electronic source documents**

The print area for pages should fit on DIN A4 sheet of paper with sufficient margins. Pages should be properly oriented to reduce the effort of rotating pages. Pages should be numbered using a unique page ID.

### **(c) Documents to be edited**

In the case that specific documents (e.g. product information documents) are intended for frequent exchange, editable formats like Microsoft WORD might be applied to facilitate transfer of documents with the ability to track changes. In the case of submissions of the same document in multiple formats (e.g. PDF and WORD at the same time), it should be clear which format is intended for which purpose.

### ***Signatures***

The applicant has the obligation to ensure a proper certification of the submitted documents. Valid signatures should be available at the applicant and be presented at the request of the authorities.

### ***Number and Name of Files, structure folders***

The number of files should reflect the size of the dossier. Individual files should not be bigger than 100 MB. An e-submission should include a well-structured dynamic table of contents. The name of the files should be descriptive of the section of the dossier, and, if pertinent, to the specific subsection (using the current version of Notice to Applicants, for instance, "PART\_1C\_EXPERT\_REPORTS.PDF" or "PART\_2G\_STABILITY.PDF") Any information that may help identify the contents of the file is encouraged to be included in the file name. File names should not exceed 230 characters.

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When using software that does not allow creation of long file names, the standard 8+3 notation should be used. Files should have the proper extension (e.g. PDF), and file names should not contain spaces or other characters which are known to give problems (instead, use underscore). In the case that filenames use codes to identify the document an index must be supplied in each directory of the folder structure.

The files should be stored within a hierarchical folder structure to allow efficient location, following the same structure as the Notice to Applicants. Depending on the number of documents this structure might have more or fewer levels. In any case the levels should follow the logic of the Notice of Applicants.

### **Security**

The media carrying the files can be protected by the applicant. In that case, the applicant has to provide authorities with the relevant information and means to access to the files.

However, files themselves must not be password protected or include security settings that may interfere with the process of assessment by the reviewers. 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.

### **Glossary**

**CD-ROM:** "Compact Disc read-only memory"; a Compact 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-rom.

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

**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

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

**8+3 notation:** File names are restricted to eight characters with a three-character extension, upper case letters, numbers and underscore; according to the first level of file system for CD-ROM media defined in the ISO 9660 norm.

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