## (General) Table of Contents: Recommendations for a veterinary electronic dossier

The dossier structure in veterinary submissions might vary considerably between applicants and applications, and any veterinary dossier should therefore include clear navigation tools to facilitate the assessment. A clear (General) Table of Contents ((G)TOC) is an essential tool for navigation within an electronic dossier, and examples for TOC entries are provided below. However, the examples are for guidance purposes only; thus, alternative TOCs and file granularity that can ensure a similar and efficient level of navigation are also acceptable.

In case a file granularity is chosen that combines several documents within a single PDF (e.g. for a complete dossier subchapter), further navigation features (e.g. via bookmarks) within the PDF file should be used that follow the same rationale as described for the TOC examples in this guidance.

The TOC examples below provide solutions for

1) simple automated TOC builders, using VNeeS file and folder names only (grey shaded examples), or
2) TOCs that include additional information either through manual creation / editing or by using more complex software solutions to automatically generate TOCs.

Simple TOC builders must only be used where descriptive file names are used throughout the submission, thereby ensuring easy identification of content and efficient navigation.

The TOC should also be in accordance with Annex I to Directive 2001/82/EC as amended by Directive 2009/9/EC[1], which defines the particulars and documents accompanying an application for marketing authorisation pursuant to Article 12 of Directive 2001/82/EC.

The general principles below apply similarly to both pharmaceutical and immunological dossiers.

The blue underlined text illustrates where hyperlinks to individual documents should appear.

### 1. Where applicable, the (G)TOC structure should follow the structure of an application dossier according to Annex I to the Directive

Examples for GTOC level:

| | |
|---|---|
| Part 1 | Summary of the Dossier |
| Part 2 | Quality/Pharmaceutical Documentation |

| |
|---|
| p1-toc.pdf |
| p2-toc.pdf |

Examples for TOC level:

| | |
|---|---|
| **2.F** | **Stability Test** |
| 2.F.1 | Active substances(s) |

| | |
|---|---|
| **2f-stab** | |
| | 2f1-stability-active-subst.pdf |

[1] Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use – *Official Journal L 44 14.02.2009 p. 10-61*

2. **The granularity of the (G)TOC should usually be more detailed than the VNeeS folder structure, and in accordance with the (sub)headings mentioned in Annex I to the Directive, to ensure that documents are easy to find**

Examples:

| **Part 3A** | **Safety tests** |
|---|---|
| … | … |
| 3.A.3 | Toxicology |
| 3.A.3.2 | Repeat-dose toxicity |
| | 28-day oral toxicity study in rats (Report #1234) |

| **3a-saf** | |
|---|---|
| … | |
| 3a3-tox | |
| | p3a32-repeat-dose-28d-oral-rat-id1234.pdf |

3. **Additional sub-structures that are not explicitly mentioned in Annex I to the Directive can also be used in the TOC, to facilitate the identification of documents like published literature or study reports**

Examples:

| **Part 4** | **Efficacy tests** |
|---|---|
| **4 I 1** | **General principles** |
| | Summary of efficacy documentation |
| | Bibliographic references: |
| | Hong-Anh T Tu et al, A review of the literature on the economics of vaccination against TB. Expert Review of Vaccines, March 2012, Vol. 11, No. 3, Pages 303-317. |

| **p4** | |
|---|---|
| | **4a-gen-requ** |
| | p4a-1-summary-efficacy-documentation.pdf |
| | p4a-2-literature-hong-anh-2012-economics-of-tb-vacc.pdf |

4. **For repeated sections (e.g. for applications covering several active substances, pharmaceutical forms or target species etc.), the TOC should contain appropriately defined sub-headings**

Examples:

| **3.A.3.1** | **Single-dose toxicity** |
|---|---|
| | ***Active Substance #1:*** |
| | Acute oral toxicity study in rats (Report #1234) |
| | ***Active Substance #2:*** |
| | Acute oral toxicity study in rats (Report #1236) |

| **3a3-tox** | |
|---|---|
| | p3a31-single-dose-substance1-oral-rats-id1234.pdf |
| | p3a31-single-dose-substance2-oral-rats-id1236.pdf |

| **4.B** | **Clinical studies** | |
|---|---|---|
| | ***Dog / solution for injection / indication #1*** | |
| | Multicentre field study to investigate efficacy and tolerance in dogs (Study 1234-2012) | 4B-1234-2012.pdf |
| | Annex 1: Individual animal reports | 4B-1234-2012-annex1.pdf |
| | ***Cat / tablets / indication #2*** | |
| | Author,C. et al., 2012: Overview of clinical data from chronically ill cats (Vet Record, Vol.x, p 123-126) | 4B-AuthorC.pdf |

| **4b-clin** | |
|---|---|
| | p4b-1-dog-inj-sol-indication1-field-study-id1234-2012.pdf |
| | p4b-1-dog-inj-sol-indication1-annex-individual-reports.pdf |
| | p4b-2-cat-tabl-indication2-lit-author-2012-chronic-disease.pdf |

**5. The format used for bibliographic references should follow where feasible citation principles as commonly used in scientific journals**

Examples:

| Expert JP (1978) Patent parasite B infection in species#1.<br>Vet Parasitol 48, 21-26. |
|---|

| 4b-1-expert-1978-patent-infect-parasiteB-vet-parasitol48-p21.pdf |
|---|

**6. A descriptive file name for each document should be used to allow easy identification of its content where more than one document is listed under the TOC lowest sub-heading.**

Examples:

| **1a-admin-info** | |
|---|---|
| … | |
| | p1a-annex-5-3-proof-of-establishment.pdf |
| | p1a-annex-5-5-cv-qppv.pdf |

| **4b-lab-trials** | |
|---|---|
| | 4b-1-onset-immunity-by-serology.pdf |
| | 4b-2-duration-immunity-by-challenge.pdf |

7. **However where it is not possible to use descriptive file names, e.g. taking into account path length restrictions, the applicant has to add further information to the TOC such as descriptive titles, document reference numbers, authors, etc…**

Examples:

| | |
|---|---|
| Part 1A | Administrative Information |
| … | |
| Annex-5-3.pdf | Proof of establishment of the applicant in the EEA. |
| Annex-5-5.pdf | Curriculum Vitae of the Qualified Person for Pharmacovigilance |

| | |
|---|---|
| 4-b-expertJP-1.pdf | Expert JP (1978) Patent parasite B infection in species#1. Vet Parasitol 48, 21-26. |
| 4-b-expertJP-2.pdf | Expert JP (1982) Patent parasite C infection in species#2. Vet Parasitol 52, 1-20. |

| **4 II b** | **Laboratory trials** |
|---|---|
| Ref-xx1.pdf | Onset of immunity of the vaccine demonstrated by serology |
| Ref-xx2.pdf | Duration of immunity of the vaccine demonstrated by challenge |