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(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 II to Regulation (EU) 2019/6 as amended by Commission Delegated Regulation (EU) 2021/805[1] , which defines the particulars and documents accompanying an application for marketing authorisation.

The general principles below apply similarly to pharmaceutical, biological 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 II to the Regulation and as detailed in the VNeeS guidance

Examples for GTOC level:

Part 1	Summary of the dossier
Part 2	Quality 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 Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council– Official Journal L 180 21.05.2021 p. 3-77*

2. The granularity of the (G)TOC should usually be more detailed than the VNeeS folder structure, and take into account the order and titles of (sub)headings mentioned in Annex II to the Regulation, 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 II to the Regulation can also be used in the TOC, to facilitate the identification of documents like published literature or study reports

Examples:

Part 3	**Safety tests**
3.A.6	Environmental risk assessment
	Bibliographic references:
	Author B et al. (2021) Comparison of PNEC derivation for different taxonomic levels. Regul. Toxicol. Pharmacol. 123, 45678.

p3	
	3a6-era
	p3a6-1-environmental-risk-assessment.pdf
	p3a6-2-literature-author-et-al-2021-comparison-pnec-derivation.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 trials**	
	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. 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-5-4-loa-communication-applicant.pdf

4b-preclin	
	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-5-4.pdf	Letter of authorisation for communication on behalf of the applicant/MAH

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 b	**Pre-clinical studies**
Ref-xx1.pdf	Onset of immunity of the vaccine demonstrated by serology
Ref-xx2.pdf	Duration of immunity of the vaccine demonstrated by challenge