Guidance document
Guidance eDok

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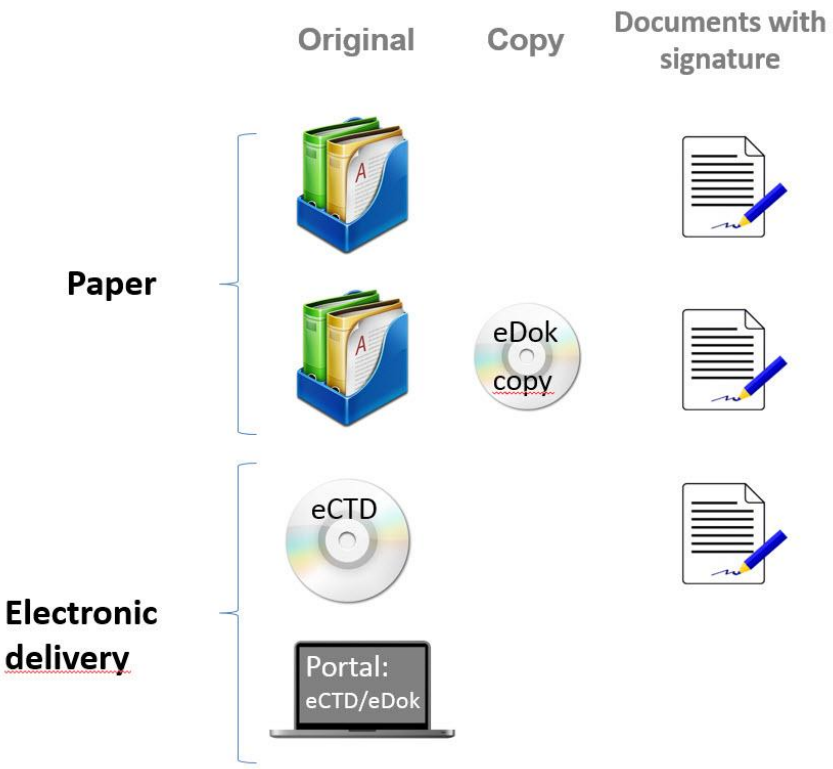
List of contents

1 Principle

eDok is a submission format for authorisation applications. If the eDok application is submitted by post, it is considered to be a paper application and Modules 1 to 5 or Parts 1 to IV respectively must, as a paper original, include an electronic version on a data carrier. The electronic data replaces the paper copies required with a paper submission. Swissmedic carries out its review based on the documentation submitted electronically and archives the paper original as a legally binding document. If the eDok application is submitted via the Swissmedic eGov Portal, the upload completely replaces the submission of paper documents and data carriers. Furthermore, documents with signatures are no longer necessary since authentication takes place via the Portal log-in. Therefore, this type of submission corresponds to a fully electronic application format.



During the life cycle of a medicinal product, the applicant may choose whether applications for authorisations and variations are submitted in paper form or as eDok, i.e. it is possible to alternate between the two formats, even once an application has been started. However, it is not possible to switch from medicinal product applications that have already been submitted in the eCTD format to eDok. “Once eCTD, always eCTD.

This document addresses the processes for postal submission of eDoks. Specific information on submission via the Swissmedic eGov Portal can be found in the information sheet *Swissmedic eGov Portal – Standard functions*.

2 Scope

eDoc submissions are possible for:

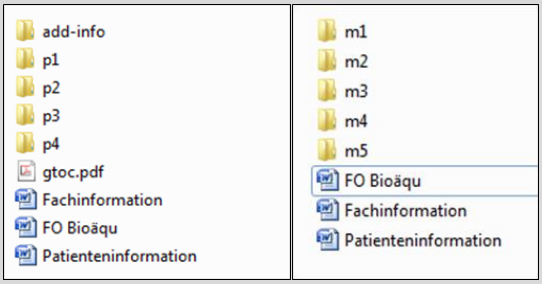
- Authorisation and variation requests regarding
- Human medicinal products (Common Technical Document, CTD)
- Veterinary medicinal products (Notice to Applicants, NTA)
- Homeopathic and anthroposophic medicines, including those for which authorisation is sought via the notification procedure (HOMANT)
- TPP (transplant products)
- Authorisation applications and notifications for clinical trials of medical devices

3 Description of requirements

The requirements are listed in tabular format. They are numbered. Only the table entries defined as requirements are relevant to the formal control. All other text passages are descriptive.
Format of the description of requirements:

No.	Topic	Requirements	M / C	Exceptions
A.1.1.0.1	Description of the topic	Explanation of the requirements	M=must C=can (M will be contested)	This section includes information about special cases and exceptions.
…	…	…	…	…

4 Technical requirements

No.	Topic	Requirements	M / C	Exceptions
E.4.1	Data carrier format	All commonly used DVD, Blu-ray and CD formats are accepted as data carriers. The data carriers must be labelled with the following information: – Name of authorisation holder – Product name(s) – Authorisation number(s) (if known) – Date (dd.mm.yyyy) Format of the submission ("eDok")	M	Excluding RW-Discs (re-writable)
E.4.2	File formats	• In principle, only PDF is accepted as a file format. The eDok submission must not contain any ZIP files. • Documents created digitally are preferred, but scanned documents are also accepted. Scanned documents must nevertheless conform to the OCR standard, i.e. the text must be searchable. • PDF documents must not be password protected..	M	A ZIP file is required for uploading via the Swissmedic eGov Portal. Further details in the *Information sheet on Portal standard-functions.*
E.4.3	Word documents	Swissmedic requires Word documents for the following documents, in addition to the PDF, to facilitate review Please refer to ZL000_00_001e_WL Formal requirements The **additional** Word documents must be submitted on the same data carrier at the top folder level. Although no requirements apply to the file names, names should be self-explanatory. Example:  The Word documents must not be integrated into the eDok structure.	M	Different requirements apply when the Swissmedic eGov Portal is used: No Word files may be present at the top level within the Zip file. Further details in the *Information sheet on Portal standard functions.*
E.4.4	File size	To ensure an effective review, the maximum file size should not exceed 200 MB per PDF file. Larger files must be split.	M	
E.4.5	Maximum length of file and folder names	• The maximum path length is 180 characters. In addition to the specified path, the recommended maximum length for the file names is 60 characters (including file extension).	M	

No.	Topic	Requirements	M / C	Exceptions
		• For submissions in CTD format, the folder names for the trials should not exceed 40 characters. • Path lengths should generally be as short as possible in order avoid technical problems.		
E.4.6	Submission of several eDoks	Several eDoks may be submitted on the same data carrier if this clearly marked as such and the cover letter makes mention of the fact.	C	Different requirements apply when the Swissmedic eGov Portal is used: Here a separate delivery must be made for each eDok. Further details in the *Information sheet on Portal standard functions.*

5 Folder structure

No.	Topic	Requirements	M / C	Exceptions
E.5.0	Structure of the eDok copy	The structure of the eDok copy must correspond to that of the original, i.e. NTA or CTD. **The specified structures are mandatory,** i.e. the documents must be sorted into the corresponding structure. Merging several modular parts in a PDF will not be accepted. Exception: If a NeeS or an eCTD is submitted as an eDok, Modules 2-5 can be accepted without modification, since the structures in this case correspond to those of eDok. Only Module 1 needs to be modified in line with the requirements of the eDok template.	M	
E.5.1	Templates with structural requirements	Swissmedic makes folder templates for the unchangeable parts of the folder structure available in CTD and NTA formats. For the NTA format different templates are available, one for complementary medicines and three for veterinary medicinal products (see Annex).	M	
E.5.2	Fixed / variable names	• The folders in the templates have fixed names that may not be changed. • The names for the folders containing the trials in Module 4 are flexible. They should facilitate the review and therefore be clear and self-explanatory, e.g. Trial_number_product_abbreviation_trial_type. • The naming is NOT case-sensitive.	M	
E.5.3	Parts to be submitted	Only those parts of the folder structure containing data should be submitted. Empty folders must be deleted before submission to Swissmedic.	M	
E.5.4	Subfolders	Subfolders are permitted as follows: **CTD** • M1: Subfolders are generally permitted only at the lowest eDok structural level. • M2: Subfolders are generally permitted only at the lowest eDok structural level.	M	

No.	Topic	Requirements	M / C	Exceptions
		• M3: Subfolders are generally permitted only at the lowest eDok structural level. If several pharmaceutical forms, active substances, drug products etc. are involved, exceptions are possible at the following places: 32a-app → from this level subfolders are permitted 32p-drug-prod → from this level subfolders are permitted 32r-reg-info → from this level subfolders are permitted 32s-drug-sub → from this level subfolders are permitted 33-lit-ref → from this level subfolders are permitted Example for Module 32p and substance1/substance2: *\CTD\m3\32-body-data\32p-drug-prod\stoff1\32p4-contr-exip* *\CTD\m3\32-body-data\32p-drug-prod\stoff2\32p4-contr-exip* • M4: Subfolders are generally permitted only at the lowest eDok structural level. • M5: Subfolders are generally permitted only at the lowest eDok structural level. **NTA, VMP and CHM** • p1-p4: Subfolders are generally permitted only at the lowest eDok structural level.		
E.5.5	Hybrid formats	**NTA for veterinary medicinal products** Sometimes the quality documentation is not available in pure NTA format but in a hybrid format with some sections in CTD format (generally documentation on the active substance). These sections can be inserted into the NTA template p2 at the lowest folder level p2. Example: p2\2f-stab\2f1-act-sub\3.2.p.7	C	

6 File names

No.	Topic	Requirements	M / C	Exceptions
E.6.1	Fixed / variable names	The file names selected must be chosen in such a way that the content can be identified and correctly assigned from them.	M	

7 Contents

No.	Topic	Requirements	M / C	Exceptions
E.7.1	References (TOC)	References are provided in the same way as for a paper submission: via a table of contents and by indicating the Module, page number, etc. References must be designed in a way that permits documents to be easily found electronically, e.g. "*see Module 3.2.P.6, document name, page 25",* or	M	

No.	Topic	Requirements	M / C	Exceptions
		"*see Module 5.3.5.4, Trial 3, 20120831_trial_report, page 87*".		
E.7.2	Hyperlinks	Hyperlinks within documents are appreciated. A table of contents with active links within a document of more than 20 pages is desirable. The entries in the table of contents should be short and meaningful.	C	
E.7.3	Bookmarks (HMP)	Bookmarks within documents are appreciated. Documents with more than 20 pages must contain a document structure using meaningful bookmarks. Alternatively, such documents can be split into individual smaller documents. However, the documents must have meaningful file names.	M	

8 Other requirements regarding the submission

No.	Topic	Requirements	M / C	Exceptions
E.8.2	Parts to be submitted in electronic form only	Case Report Forms (CRFs) must only be submitted in electronic form. Sample CRFs must however also be submitted with an additional, paper version.	C	Not applicable to Portal submissions
E.8.3	Applications for authorisation of medicinal products already authorised abroad (Art. 13 TPA)	• Please note the following when preparing the eDok copy. The reference dossier submitted to Swissmedic must be identical to the documentation (final version), on the basis of which the reference authority approved the medicinal product and/or further variations. • This means that this must also be submitted electronically in exactly this way and must not be consolidated with the Swiss Module 1. • The Swiss Module 1 must therefore be submitted as a separate eDok copy.	M	

9 Annex

All templates referred to below are available to download as ZIP files from the Swissmedic website

9.1 CTD and NTA templates

CTD:
The abbreviations used for the CTD template can be found in the ICH eCTD Specification (for Modules 2-5) and the Swissmedic Guidance for Industry on Providing Regulatory Information in eCTD Format (for Module 1).

NTA TAM (Veterinary medicinal products):

The structure of the template is the same as the VNeeS structure and is based on the currently valid EMA specification documents.

A total of three templates are now available:

- For a pharmaceutical product
- For a biological product other than immunological

- For an immunological product

NTA KPA (Complementary medicines):

The given structure is based on the Complementary and Phytotherapeutic Products Ordinance (KPTPO), Annex 1.

➔ https://www.swissmedic.ch/swissmedic/en/home/services/submissions/paper-submission---edok.html

9.2 Submissions relating to clinical trials

Swissmedic created this structure specifically for this type of submission.
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/klinische-versuche/emessage-ct-md.html

Change history

Version	Change	sig
3.9	Adjustments to chapters E.7.2 and E.7.3	mra
3.8	Chapter 1.1 deleted	mra
3.7	New layout, no content adjustments to the previous version.	dei
3.6	New eDok template VMP, minor changes (password protection)	mra
3.5	Link to new EU Guideline VNeeS v2.7	mra
3.4	New NTA template for veterinary medicinal products	mra
3.3	Adapted to reflect HMV4, editorial changes, submissions relating to clinical trials permitted	mra
3.2	Hybrid submission for veterinary medicinal products; submissions for TPP now permitted	mra
3.1	Correction Spelling error eDok structure 2.7.6	mra
3.0	Changes re HOMANT submission and eDok template extension for VMP	mra
2.0	Modification relating to eGov Portal	mra
1.0	New QM ident (old ident: SU000_00_002e_WL)	wis