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Correction of the new eCTD specification documents Swiss M1 Specification and Swiss eCTD Validation Criteria

12.12.2018

Due to minor errors in the eCTD M1 Specification and the corresponding eCTD Validation Criteria, both of these documents require correction. **For technical reasons, the version number 1.4 will be retained.**

In addition, we are providing more detailed explanations here to clarify a number of points.

The following corrections were made to Version 1.4:

- In the document **eCTD Validation Criteria**:
  - The folder name **151-infoaccordappIVguidelinebioequivalence** is incorrect and should be **151-infoaccordappivguidelinebioequivalence**. IV was wrongly capitalised

- In the document **Swiss M1 Specification**:
  - The notation of the new elements in Section 1.12, Table 4 is incorrect and will be brought into line with the correct notation in the DTD:

81	Number	1.12
	Title	Art 14 Sec 1 Let abis-quater TPA Documents
	Element	m1-12-art14sec1letabisquater
	Directory	m1/ch/*galenic-form*/112-art14
	Comment	General placeholder for information on Art 14 Sec 1 Let abis-quater TPA Documents
82	Number	1.12.1
	Title	Proof of 10 Years EU/EFTA Authorisation
	Element	m1-12-1-eueftaauthorisation
	Directory	m1/ch/*galenic-form*/112-art14/1121-eueftaauthorisation
	File	m1/ch/*galenic-form*/112-art14/1121-eueftaauthorisation/*ch*-eueftaproof-*VAR.EXT*
	Comment	Filename for the 10 years EU EFTA authorisation composed of a fixed component *ch*, a fixed component *eueftaproof* and an optional variable component if required (e.g. ch-eueftaproof-productname.pdf).
83	Number	1.12.2
	Title	10 Years EU/EFTA Authorisation – Documents on the Reference Product

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	Element	m1-12-2-eueftadocreference
	Directory	m1/ch/*galenic-form*/112-art14/1122-eueftadocreference
	File	m1/ch/*galenic-form*/112-art14/1122-eueftadocreference/*ch*-eueftacompar-*VAR.EXT*
	Comment	Filename for the documents on the reference product composed of a fixed component *ch*, a fixed component *eueftacompar* and an optional variable component if required (e.g. ch-eueftacompar-productname.pdf).
84	Number	1.12.3
	Title	Proof of 30 Years Overall Medical Use – 15 Years Medical Use EU/EFTA
	Element	m1-12-3-overallmedicaluse
	Directory	m1/ch/*galenic-form*/112-art14/1123-overallmedicaluse
	File	m1/ch/*galenic-form*/112-art14/1123-overallmedicaluse/*ch*-meduseproof-*VAR.EXT*
	Comment	Filename for 30 years overall medical use - 15 years medical use EU/EFTA composed of a fixed component *ch*, a fixed component *meduseproof* and an optional variable component if required (e.g. ch-meduseproof-productname.pdf).
85	Number	1.12.4
	Title	Proof of 15 Years Cantonal Authorisation
	Element	m1-12-4-cantonalauthorisation
	Directory	m1/ch/*galenic-form*/112-art14/1124-cantonalauthorisation
	File	m1/ch/*galenic-form*/112-art14/1124-cantonalauthorisation/*ch*-cantauthproof-*VAR.EXT*
	Comment	Filename for 15 years cantonal authorisation composed of a fixed component *ch*, a fixed component *cantauthproof* and an optional variable component if required (e.g. ch-cantauthproof-productname.pdf).

- 1.8.2 Risk management system. The hyphen was missing in Table 1 and has been reinserted

1.8.2	Risk-Management System	riskmgtsystem	X	Replace*

- The hyphen in 1.2.1 is different to that in 1.2.2 in Table 4. The notation of the hyphen has been adjusted

6	Number	1.2.1
	Title	Form – Application
	Element	m1-2-1-foapplvar
	Directory	m1/ch/*galenic-form*/12-foapplvar/121-foapplvar
	File	m1/ch/*galenic-form*/12-foapplvar/121-foapplvar/ch-foapplvar-*VAR.EXT*
	Comment	Filename for the Form Application for Authorisation / Variation Human Medicines composed of a fixed component *ch*, a fixed component *foapplvar* and an optional variable component if required (e.g. ch-foapplvar-newdosagestrength.pdf).
7	Number	1.2.2
	Title	Forms - Additional
	Element	m1-2-2-form-add
	Directory	m1/ch/*galenic-form*/12-foapplvar/122-form-add
	Comment	

The following corrections have been noted for the future version 1.5 and will be subsequently corrected in that version. The publication date of version 1.5 is yet to be announced.

- In the document **Swiss M1 Specification**:
  - In Table 1 under 1.2.2, no fixed component of filename and no life cycle operator are necessary

1.2.2	Forms - Additional	~~foadd~~	-	~~New~~

- In line with HMV4, application types **pi** and **eas** are no longer necessary and will be deleted from the table.

In response to questions addressed to Swissmedic, our answers are as follows:

How should a Life Cycle take place in connection with deleted sections (e.g. 1.2.2.4, 1.2.2.5 etc.)? Deleted sections are marked with "this section is no longer applicable..." in the M1 Specification.

Answer:

- Operation **replace/delete** in an existing document in a deleted section -> If there is a Life Cycle, the rule 15.BP3 takes effect and issues a warning. The sequence remains valid.
- Operation **new** in a deleted section -> no Life Cycle should take place any longer. The rule 15.BP3 issues a warning.
- Generally speaking, documents that were previously allocated to these deleted sections are either no longer up to date or have been replaced by new forms in another section.
- Life Cycle in an existing document in the recently deleted section 1.5.3 -> a Life Cycle is not anticipated here.

Are the following notations in document Swiss M1 Spec, Table 1 and Table 4 correct?

Answer:

- 1.2.2.16 **PSUR/PBRER** form for Human Medicines = notation without spaces is deliberate
- 1.2.2.23 Application for **Recognition** of Orphan Drug Status form = capitalisation of Recognition is deliberate
- 1.7.4 FDA **Decision** = use of singular is deliberate
- 1.4.1 Quality (Leaf) = omission of details regarding **Expert** is deliberate
- 1.4.2 Nonclinical (Leaf) = omission of details regarding **Expert** is deliberate
- 1.4.3 Clinical (Leaf) = omission of details regarding **Expert** is deliberate

Next steps

Both eCTD specification documents are currently being corrected in Version 1.4. These will be published within the next few days and will be available on our website.

If further errors are discovered which entail additional adjustments, this will be communicated here in good time.

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