

Federal agency for medicines and health products

Part 4

Common errors on e-submissions

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5. Common errors

- Subject/body of e-mail/Eudralink is not clear
- Multiple submissions of the same dossier (for ex. CD + Eudralink)
- Absence of the **root folder** (use zip-file for submission by eudralink or e-mail!)
- Inadequate file names – wrong characters
- Absence of (G)TOC



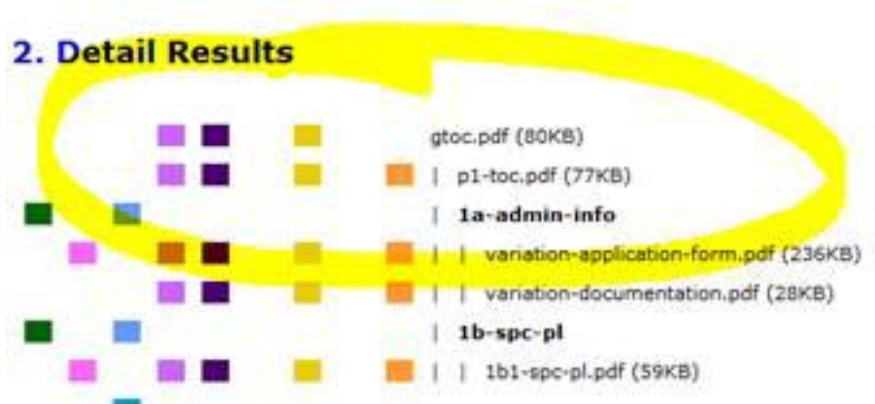
5. Common errors

- No bookmarks in single file submissions
- Selecting the incorrect dossier type
- Issues with CD burning: CD's which are not readable without errors, leads to corrupted PDFs.
- Using outdated (or too new) guideline
- Forgetting to validate



5. Common errors

- Absence of the **root folder**



5. Common errors

"root" followed by a hyphen and a specific identification.

Ex: root-mydrug-be-v-0123-001

- root
- best-reportV.html (18KB)
- general-table-of-contents.pdf (4KB)
- additional information**
- additional-information-toc.pdf (1KB)
- cover-letters.pdf (977KB)
- response-document.pdf (147KB)
- 1b-spc-and-product-literature**
- 1b-spc-and-product-literature-clean.doc (108KB)
- 1b-spc-and-product-literature-tracked.doc (115KB)
- part-1-summary-of-the-dossier**
- part-1-summary-of-the-dossier-toc.pdf (1KB)
- 1a-administrative-information**
- 1a-administrative-information.pdf (5MB)
- 1b-spc-and-product-literature**
- 1b-spc-and-product-literature.pdf (52KB)
- part-2-quality-documentation**
- part-2-quality-documentation-toc.pdf (2KB)
- 2c-control-of-starting-materials**
- 2c4-substances-biological-origin**
- 2c4-substances-biological-origin.pdf (359KB)
- 2e-tests-on-the-finished-product**
- 2e3-identification-and-assay-of-excipient-components**
- 2e3-identification-and-assay-of-excipient.pdf (15KB)
- 2f-stability-tests**
- 2f2-finished-product**
- 2f2-annex-16.pdf (197KB)
- 2f2-finished-product.pdf (450KB)

GTOC file missing
GTOC must be named "gtoc.pdf",

File is not referenced in TOCs

If not named GTOC, the VNeS Checker can't test the hyperlinks



5. Common errors

- Incorrect name of the add-info folder

Validation report: has to be placed in add-info folder

should be named "add-info"

These documents should not be placed in the add-info



5. Common errors

2. Detail Results



UK-V-0300-001-IA-009-G - Belgium

- Part 1
 - CoverLetter.pdf (160KB)
 - Thumbs.db (27KB)
- Part 1A
 - Part1A,Amended,MAA,form.pdf (1MB)
 - Part1A,Application,Form.pdf (982KB)
 - Thumbs.db (74KB)
- Part 2
 - Part 2C
 - Part2C.pdf (16KB)
 - Thumbs.db (8KB)

'root' folder name: root + hyphen + specific identification

No space allowed in file names

Thumbs.db files should be deleted

No GTOC



questions ?

