Federal agency for medicines and health products

E-submission workshop

22.03.2013

Program

1. General rules for e-submission in Belgium
2. How to use tools and templates to create a dossier
3. Industry example of e-submission
4. Common errors on e-submissions
5. Roadmap for e-submissions
6. quiz

1. General rules on e-submission in Belgium

Submission by E-mail/Eudralink

new applications/line extensions/RU: pre.authorisation.v@fagg-afmps.be

variations, renewals: post.authorisation.v@fagg-afmps.be

Submissions by E-mail ≤ 5 Mb

Eudralink ≤ 80 Mb (file)

Folder-structured submissions: need to be compressed

mail subject :

- type of procedure
- type of documents : initial, ATQ , closing
- the (proposed) name
- dossier ID

1. General rules on e-submission in Belgium

Submission by E-mail/Eudralink

Body of the mail:

- type of procedure (MRP, DCP, NP – grouping, WS (worksharing), MRP-like)
- type of documents : initial, ATQ , closing
- Type of dossier: type IA, IB, II anv, II clv, II phvig, REN, NA, EXT, RUP
- The (proposed) name + pharmaceutical form and target species
- dossier ID
- Pharmacotherapeutic group (IVMP, antibiotic, NSAID, antiparasitic, other)

Cover letter & application form must be foreseen of a signature (scan)

1. General rules on e-submission in Belgium

Submission by CD-ROM/DVD

1. signed cover letter mentioning the number of media components included
2. No password protection (media & files)!
3. Information on label = E-mail/eudralink subject

Do not submit a dossier more than once

Do not send parts of dossiers by email/Eudralink and parts on CD-ROM/DVD

1. General rules on e-submission in Belgium

File format

- Documentation submitted in PDF (PDF in version 1.4 -1.7 - acrobat 5 or higher)
- SPC, label, leaflet to be submitted in PDF (in Part 1) + in word format (under “Add-Info”) + track-changes
- PDF file no larger than 100 MB (no rejection)
- Paper source documents: Resolution for scanned documents = 300 dpi
- Print area for pages to fit on A4 (exception: mock-ups)

1. General rules on e-submission in Belgium

File format

- Pages within a file should be numbered.
- file names should be descriptive and unambiguous (Preferably the file name should include the part of the dossier)
- The length of a path including file name, and extension should not exceed 180 characters.
- use naming conventions in subsequent submissions
- The file name should not contain any 'special' characters for ex: . , : , / , \ , *, ? , ”, < , > , | , & or ‘ ‘ (space)

1. General rules on e-submission in Belgium

Structure of the submission

"add-info"

- Located in the root folder
- dedicated for :
  - word versions of SPC, labelling, package leaflet
  - VneeS Checker validation reports

=> Files and sub-folders in the folder "add-info" are not subject to technical validation

Cave: correct name of the "add-info" folder!

1. General rules on e-submission in Belgium

Structure of the submission

Applications for a new MA

- Folder structure based on NTA Vol. 6B
- Hierarchical structure of folders **within a root folder** => up to 3 level of granularity
- When only little information for a number of folders at the same level, it is acceptable to include all the information in a single PDF at the higher level of the granularity
- Tool to generate empty folder structure available on Spanisch agency website (Template for: MAA immunologicals, pharmaceuticals & MRLs)

1. General rules on e-submission in Belgium

Structure of the submission

Applications for a new MA

- No additional folders permitted(exception "add-info" folder)

- “Empty” folders can be omitted

- root folder (= top level folder) name must start with the letters “root” followed by a specific identification of the submission (the product name, procedure number, submission date - hyphen "-" as separator)

  For example: root-wonderpil-be-v-0123-001-22feb2013

1. General rules on e-submission in Belgium

Structure of the submission

variations / extensions / renewals:

- Submissions with a small number of documents (e.g. type IA variations): may be submitted as a single, bookmarked PDF file
- In case of submissions containing more than one single PDF file: files should be assigned the relevant folder within the VNeeS structure.

Grouped variations or worksharing procedures:

- preferably be submitted on the same media component
- A single file or a single submission structure (i.e. one root folder) may be used in case the documentation is completely identical for all products.
- If these submissions are product specific, one file per product or one submission structure per product should be provided.

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1. General rules on e-submission in Belgium

Structure of the submission

Responses to questions

- more than one single PDF file: the main response document(s) should be located in the folder "responses" in Part 1. Any additional documents submitted with the responses should be assigned to the relevant folders.
- it is not required to send an update of the initial VNeeS submission

Update of the dossier after invalidation

- a **corrected version of the complete application has to be re-submitted**; unless indicated otherwise by the projectmanager.

1. General rules on e-submission in Belgium

Structure of the submission

ASMF-dossiers

For an initial ASMF (containing Applicant's Part and Restricted Part) the relevant VNeeS folders are:

- 1a-admin-info: Letter of access or other administrative documents as applicable
- 1c1-qual: Detailed and critical summary document
- 2c1-act-sub
- 2f1-act-sub (if applicable)

CTD format is acceptable for the ASMF dossier however a **correlation table**

must be provided showing which CTD section corresponds to which vet NtA

section

1. General rules on e-submission in Belgium

Structure of the submission

ASMF-dossiers

- Restricted Part to be provided by ASMF holder on the same CD/DVD as the Applicant's Part provided:

  => either as a separate folder

  => or incorporated in the same structure (using suffix "rp" and "ap" in each file name for clarification)
- In corresponding marketing authorisation application dossier, the documents in the Applicant's Part of the ASMF(s) should be:

  => assigned to the relevant folders and subfolders

  => clearly named for identification, in particular if more than one ASMF is used
- Name of root folder = preferably name of active substance and name of the ASMF holder

- Applicant and ASMF holder have to submit the same version of the ASMF!

1. General rules on e-submission in Belgium

Indexing of the submission

- GTOC => complete index to the whole dossier (referring directly to content documents or via the part-specific TOCs)
- TOC for each part of the dossier => complete index for that part of the dossier
- Files being present in the folder "add-info" need not be included in GTOC
- All documents in the submission to be referenced in a GTOC or TOC using a hyperlink
- GTOC always to be hyperlinked to any part-specific TOCs

1. General rules on e-submission in Belgium

Indexing of the submission

- Hyperlinks should only be made to documents within the same VNeeS submission and not to external sources
- The GTOC should be named "*gtoc.pdf*"
- The files containing the part-specific TOCs should be named "*p1-toc.pdf*", "*p2-toc.pdf*", "*p3-toc.pdf*" and "*p4-toc.pdf*"
- Empty folders should be deleted+ corresponding positions in the TOC
- Very small submissions = only a single PDF file
  => no separate GTOC or TOC files need to be created
  => bookmarks included for efficient navigation

1. General rules on e-submission in Belgium

Validation

TIGES Vet subgroup technical validation checklist

http://esubmission.ema.europa.eu/tiges/vetesub.htm

Technical check can be done by using the VneeS Checker

Until 30/06/2013: version 2.1

From 01/07/2013 on: version 2.2

Verifies:

- Structure of the folder
- Naming convention for folders and files
- Maximum size of files
- Version of PDF files

1. General rules on e-submission in Belgium

Validation

Full compliance with the VneeS criteria on :

- file format
- structure of the submission
- indexing of the submission

Folder structure : compliance of 75% (for new applications)

From 01/07/2013 on: VneeS checker validation report mandatory!
(should be placed in “add-info”)

Submissions on CD-ROM/DVD: also a validation on the medium

questions ?

.be