



EU Module 1

v1.2.1

Release Notes

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1. Introduction

This document intends to highlight the differences between the EU Module 1 v1.2.1 and the EU Module 1 v1.2 to assist potential users of the system.

The changes within the EU Module 1 v1.2.1 are summarised here below, with indication if DTD, Style-sheets or Specifications have been amended:

#	Change	Summary	DTD	Style-sheet	Specification
1	Common folder in DCP	Use of the "common" folder in the case of Decentralised Procedure	-	-	Envelope, p.6 Appendix 2, p.14 Appendix 2.1, p.30 Appendix 3, p.34 Appendix 4, p.36-37
2	Bulgaria and Romania	Already support Bulgaria and Romania in EU Module 1 but forbid usage before formal accession	eu-regional.dtd eu-envelope.mod	-	Appendix 2.1, p.30 Appendix 2.2, p.31
3	Alignment to CTD	Alignment of DTD elements, folder and file names to the CTD	eu-regional.dtd m1-5	All	Appendix 2
4	Paper PI and PIM	Paper PI and PIM cannot be mutual exclusive in order to cope with Life Cycle Management	eu-regional.dtd m1-3-1	-	Appendix 4, p.41
5	Correction of Typos	Correction of typos in the Specifications	-	-	All
6	Correction website Addresses	Correction of the website address of the European Commission and ICH in the Specifications	-	-	Distribution Regional Info Change Control
7	Update of the Name of Elements	Update of the name of the elements to be closer to the sections of CTD	eu-regional.dtd	-	Appendix 2
8	Removal of Authorship in DTDs	Removal of details on authors and contributors	eu-regional.dtd eu-envelope.mod eu-leaf.mod	-	Appendix 5, p.42
9	Util Folder in eCTD	Move EU Module 1 DTD and style-sheet from the util folder of EUM1 to the util folder at the root level of the eCTD	-	All	Appendix 3
10	CP Scenarios with and without PIM	Scenarios on how to create submissions for Centralised Procedure with and without PIM	-	-	Appendix 3
11	Correction of Examples	Examples have been corrected to match current practice for the related procedure	-	All	Appendix 3
12	Removal of Generic Info for 1.4, 1.5, 1.6	Removal of information attached at the root level of sections 1.4, 1.5 and 1.6	eu-regional.dtd	-	Appendix 2 Appendix 5

2. List of EU Module 1 Changes

2.1 Use of "common" folder in DCP

Addition of the support of the DCP:

- in section "Envelope", page 6
- in appendix 2, row 8, page 14
- in appendix 2.1, page 30
- in appendix 4, pages 36, 37

In appendix 3, a section dedicated to DCP has been added in page 34. When using the DCP, information should be submitted using the "common" folder.

2.2 Bulgaria and Romania

Given the planned accession date of 1st Jan 2007 for Bulgaria and Romania, these two countries and their languages (Bulgarian and Romanian) have already been added into the EU Module 1.

However, these countries and languages cannot be used before the formal accession date of Bulgaria and Romania to the EU.

2.3 Alignment to CTD

Discrepancies between the EU Module 1 and the CTD have been resolved, especially regarding section 1.5 "Specific Requirements for Different Types of Applications".

The EU Module 1 style-sheet has been amended to display the CTD section names instead of the element names. The style-sheet has also been updated to render meta-data like language, country, document type... where applicable.

2.4 Support Paper PI and PIM

In order to support migration of PI from paper to PIM, elements that contain PI in paper (m1-3-1-spc-label-pl) and in PIM (m1-3-1-pim) cannot be mutual exclusive. During the migration, all elements must be submitted, the ones for PI in paper to delete previous files (in PDF and MS Word formats) and the one for PI in PIM for the new file.

Also, as the element "m1-3-1-spc-label-pl" is optional, once it is used, it must contain at least one document; in consequence the child element "pi-doc" has been updated from optional repeatable (*) to mandatory repeatable (+).

2.5 Correction of Typos in Specifications

In section "Regional Formats", page 5, correction of sentence to read "XML, image and archive formats are also accepted on an ad hoc basis."

In Appendix 1, the description of the "submission-description" field becomes "This optional element can be used to describe the submission".

Correction of the references to appendices

- Table 1, page 6, removal of sections that do not belong to product information
- In section "Directory / File Structure", page 7
- In section "File Naming Convention", page 7
- In Appendix 1, description of the element "submission-description" has been corrected
- In Appendix 2, pages 12, 16
- In Appendix 2, filenames for sections 1.8.1 and 1.8.2 have been corrected.

2.6 Correction of EC Website

Correction of the website address of the European Commission in the Specifications:

<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>

Correction of the website address of ICH in the Specifications:

<http://estri.ich.org/ectd>

2.7 Update of Element Names

Some of the sections as displayed in the style-sheet have been renamed to be more descriptive and to differentiate more clearly between different sections.

Changes apply to

- m1-5-2-generic-hybrid-bio-similar
- m1-5-3-data-market-exclusivity
- m1-5-5-conditional-ma
- m1-7-2-market-exclusivity
- m1-9-clinical-trials
- m1-additional-data

2.8 Removal of Authorship in DTDs

Details about authors and contributors have been removed from the DTD files. Only names have been kept under "Contributors". For the mod files, there has been no other change of content but the version number, to keep in synch with the Specifications.

2.9 Use "util" folder at the root level of the eCTD

The DTD and style-sheet of the EU Module 1 should be placed in the "util" folder at the root level of the eCTD.. This is to be inline with the eCTD Specifications.

2.10 CP Scenarios With and Without PIM

The Specifications have been enhanced to describe the Central Procedure submissions with and without PIM, with a zoom on the content of section 1.3.

2.11 Correction of Examples

The EU Module 1 examples for Centralised, Decentralised, National and Mutual Recognition Procedures have been updated to match current practice.

2.12 Removal of Generic Information (1.4, 1.5, 1.6)

The placeholder to attach information at the root level of 1.4 (Information about the Experts), 1.5 (Specific Requirements for Different Types of Applications) and 1.6 (Environmental Risk Assessment) has been removed. Information can be attached only at the sublevels of these sections.