



EU Module 1 Specification

Version 1.4.1

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DOCUMENT CHANGE RECORD

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1.0	30/11/2011	Final version	All

REVIEW

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1. Introduction

This document describes the major differences between v.1.4.1 of the EU Module 1 eCTD specification and the previous version (v1.4) to assist potential users of the system during implementation.

The changes within the EU Module 1 v1.4.1 are summarised below, sorted per change request (CR), and with indication if Specifications, DTD or Style-sheets have been amended:

#	Change	Summary	Specifications	DTD / Style-Sheet
1	Addition of Glossary of Terms CR 20090909-01	Inclusion of a Glossary of Terms to clarify definitions throughout the specification.	Glossary of Terms	No Change
2	Acceptability of "common" CR 20090909-03	Updated to confirm that "common" can be used as a value in Module 1 when the country is specified as "emea" in the Centralised procedure.	General Architecture of Module 1 Directory / File Structure	No Change
3	Clarification re Use of Hyphens CR 20090909-08 CR 20101129	Clarity added re the use of hyphens in filenames with variable components.	General Architecture of Module 1 File Naming Convention	No Change
4	Removal of Reference to DCP CR 20090909-10	Reference to the Decentralised Procedure in Item 8 of the specification removed.	Appendix 2: Directory / File Structure for Module 1	No Change
5	Value for "Applicant" in eCTD Envelope CR 20090922	Note re designating the applicant in the context of a worksharing application removed.	Appendix 1: The EU Module 1 XML Submission	No Change
6	Continued Use of "EMEA" Acronym CR 20091203	Confirmation that the acronym, "EMEA" will continue to be used until the next major version of the EU Module 1 Specification is released.	EU Module 1: Regional Information	No Change
7	Agency Name Updated CR 20091217	National Competent Authority name for Slovenia updated.	Appendix 2.4: Agency Codes and Names	No Change
8	Acceptability of File Formats CR 20101020 CR 20110601	All references to RTF, TGZ and ZIP as an acceptable file format for use in EU Module 1 removed.	EU Module 1: Regional Information Regional File Formats	No Change
9	Supportive Documents CR 20101122	Guidance added re management of supportive documentation.	Appendix 2: Directory / File Structure for Module 1	No Change
10	Release of v.1.4.1 of EU Module 1 Specification CR 20101203	Urgent need for update of EU Module 1 Specification addressed by the release of v.1.4.1.	EU Module 1 Specification	No Change
11	Use of Related Sequence CR 20110309-01 Q&A 25	Clarity added re situations where more than one related sequence value could be utilised and where different categories of activities are referred to.	Appendix 1: The EU Module 1 XML Submission	No Change
12	Use of Node Extensions Q&A 10	Text added to confirm that node extensions should only be used where they are considered to be critical.	General Architecture of Module 1 Node Extensions	No Change
13	Baseline Submissions Q&A 25	Clarity added re the appropriate submission type to be used for amendments to a baseline if it submitted in a modular fashion.	Appendix 1: The EU Module 1 XML Submission	No Change
14	Removal of Reference to PIM	All references to PIM removed based on the closure of the PIM project on 28th March 2011.	EU Module 1 Specification Appendix 1	No Change

2. List of EU Module 1 Changes

2.1 Addition of Glossary of Terms

Change Requests CR 20090909-01

A Glossary of Terms has been added to the Specification in order to improve overall clarity.

2.2 Acceptability of “common”

Change Request CR 20090909-03

The Specification provides confirmation that “common” and / or country folders are acceptable within the “emea” subdirectories of an eCTD submitted in the Centralised procedure.

2.3 Clarification re Use of Hyphens

Change Requests CR 20090909-08, CR 20101129

The Specification confirms that hyphens can be used to separate multiple words which make up the variable component of an eCTD filename.

2.4 Removal of Reference to DCP

Change Request CR 20090909-10

Reference to the Decentralised Procedure is removed from the comment in Item 8 of Appendix 2 of the Specification since it can equally apply to a Mutual Recognition Procedure as both have a national and common phase.

2.5 Value for “Applicant” in eCTD Envelope

Change Request CR 20090922

The following comment has been removed from the description of the “applicant” value in Appendix 1.1: Enevelope Element Description of the Specification:

For ‘worksharing’ procedures, this should correspond to the applicant designated for the worksharing submission (and not all individual marketing authorisation holders for each product concerned).

2.6 Continued Use of “EMEA” Acronym

Change Request CR 20091203

Confirmation is given that the acronym, “EMEA” will continue to be used until the next major version of the Specification is released.

2.7 Agency Name Updated

Change Request CR 20091217

The name of the National Competent Authority for Slovenia has been updated as follows: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

2.8 Acceptability of File Formats

Change Requests CR 20101020, CR 20110601

The Specification has been updated to reflect that RTF, TGZ and ZIP are not acceptable file formats for use in Module 1 of the EU eCTD. Only PDF files should be submitted in Module 1 of the EU eCTD.

2.9 Supportive Documents

Change Request CR-20101122

The Specification has been updated to provide guidance on how to manage supportive documentation not submitted as part of Modules 2-5 of the eCTD. Confirmation is given that such documents should be placed alongside 1.2 Application Form with an appropriate filename / leaf title.

2.10 Release of v.1.4.1 of EU Module 1 Specification

Change Request CR 20101203

Release of v.1.4.1 of the EU Module 1 eCTD Specification closes change request CR 20101203 requesting that this update be expedited.

2.11 Use of Related Sequence

Change Request CR 20110309-01, Q&A 25

The Specification has been amended add more clarity around the use of the Related Sequence attribute. Additional examples are included which reflect common scenarios as is guidance on when not to use Related Sequence.

2.12 Use of Node Extensions

Q&A 10

The Specification confirms that node extensions should only be used in Module 1 of an EU eCTD where the applicant believes that they are critical to the efficient review of the dossier. Warning is also given that inconsistent use of node extensions can have a negative impact on the cumulative view of the submission.

2.13 Baseline Submissions

Q&A 25

The Specification has been updated to add clarity as to what Submission Type should be used when a baseline is submitted in a piecemeal (modular) fashion. A specific example highlighting which Submission Type and the Related Sequence value to be used is provided.