EU Module 1 eCTD Specification

Version 2.0

May 2013

Release Notes

DOCUMENT CHANGE RECORD

Version	Date	Description	Sections
1.0	21/02/2013	Final version	All
1.1	08/05/2013	Final version (Clarification of updates to Agency Codes section 3)	Section 3

REVIEW

Version	Date	Person / Group / Company / Agency
1.0	21/02/2013	Telematics Implementation Group for electronic submission at the Joint Regulators & industry meeting
1.1	15/05/2013	European Medicines Agency

DISTRIBUTION

Version	Date	Person / Group / Company / Agency
1.0	28/02/2013	Publication on the eSubmission website at EMA

Table of Contents

1. Introduction

This document describes the difference between versions v.2.0 and v1.4.1 of the EU Module 1 eCTD Specification to assist users during implementation.

The EU Module 1 v2.0 enables marketing authorisation application in Croatia and can be used from 1 July 2013. A six month period is foreseen from publication of this guidance to upgrade systems that build, validate, and review eCTD. It is anticipated that EU Module 1 v2.0 will be required by EMA and National Competent Authorities from 1 September 2013, but precise guidance on transition will be published in due course. Guidance on how to submit information relevant to Croatia from 1 July using EU Module 1 v1.4.1 will also be published shortly.

The changes within the EU Module 1 v2.0 Specification are summarised below, sorted per change request (CR), where applicable, with an indication when the Specifications, DTD or Style-sheet have been amended:

#	Change/ Change Request (CR)	Summary	Specifications	DTD / Style-Sheet
1	Updated version number to v2.0 No CR	Throughout the documents the version number of the EU Module 1 eCTD specification was changed from v1.4.1 to v2.0.	General application in Module 1 Specification and Annexes	eu-envelope.mod eu-regional.xsl eu-regional.dtd eu-leaf.mod
2	Revision of European Agency acronym CR 20091203	The acronym 'EMEA' was changed to 'EMA' when referring to the Agency and various technical texts, e.g. file and folder names. The CAP procedure numbers will continue to use 'EMEA'.	General application in Module 1 Specification and Annexes	eu-envelope.mod eu-regional.xsl eu-regional.dtd
3	Addition of other PDF versions No CR; Q&A's 32 & 38	In alignment with ICH Q&A, the acceptable PDF versions were revised to 'versions 1.4, 1.5, 1.6 or 1.7'.	Module 1 Specification: Regional File Formats	No change
4	Information to obtain submission number for initial MAA in a CP No CR	Information provided how to obtain a submission number in the case of an initial MAA for the Centralised Procedure (CP).	Module 1 Specification: General Architecture of Module 1 - Envelope and Annexes	No change
5	Removed term "periodic" CR 20091211	Removed term 'periodic' for the 'mode' attribute of the 'submission' element as it may be confused with the annual report.	Module 1 Specification: General Architecture of Module 1 - Envelope; Appendix 1.1: Envelope Element Description	No change
6	Addition of 'rmp' No CR	Addition of new submission type "rmp" [Risk Management Plan (outside any procedure)]	Module 1 Specification: Appendix 1.1 - Envelope Element Description	eu-envelope.mod eu-regional.xsl
7	Change in naming convention for tracking table CR 20130204	The naming convention for the tracking table used for eCTD format MAAs in the MRP/DCP was changed; the location was not.	Module 1 Specification: Appendix 2 - Directory / File Structure for Module 1	No change
8	Agency Name Corrected CR 20101022-01	National Competent Authority name for Czech Republic corrected	No change	eu-regional.xsl
9	Agency Name Updated CR 20101214	National Competent Authority name for Finland updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	eu-envelope.mod eu-regional.xsl
10	Agency Added CR 20110614	National Competent Authority added to components to prepare for the accession of Croatia to the European Union. Croatian language added.	Module 1 Specification: Appendix 2.1: Destination Codes , Appendix 2.2: Language Codes & Appendix 2.4 - Agency Codes and Names	eu-regional.dtd eu-envelope.mod eu-regional.xsl

#	Change/ Change Request (CR)	Summary	Specifications	DTD / Style-Sheet
11	Agency Code Updated CR 20121119	National Competent Authority agency code for Spain updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names Special Annex Example	eu-envelope.mod eu-regional.xsl
12	Agency Name and Code Updated CR 20121126	National Competent Authority name and agency code for France updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names Special Annex Example	eu-envelope.mod eu-regional.xsl
13	Agency Name and Code Updated CR 20121207	National Competent Authority name and agency code for Denmark updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	No Change
14	Agency Name Updated CR 20091217	National Competent Authority name for Slovenia updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	No Change
15	Agency Name Updated No CR	National Competent Authority name for United Kingdom updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	eu-regional.xsl
16	Agency Name and Code Updated No CR	National Competent Authority name and agency code for Cyprus updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	eu-envelope.mod eu-regional.xsl
17	Agency Name and Code Updated No CR	National Competent Authority name and agency code for Romania updated	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	eu-envelope.mod eu-regional.xsl
18	Agencies Names and Codes Removed No CR	Names and codes of National Competent Authorities not responsible for marketing authorisation of medicinal products for human use removed	Module 1 Specification: Appendix 2.4 - Agency Codes and Names	eu-envelope.mod eu-regional.xsl
19	Clarification re values CR 20120209	Clarification added re appropriate values for the country-specific elements and folder structure in the Centralised Procedure	Module 1 Specification: Directory / File Structure , Appendix 2.1: Destination Codes and Annexes	No change
20	Clarification re use of XML CR 20121221	Information when XML can be used to replace PDF format is included	Module 1 Specification: Regional File Formats, Module 1	No change
21	Removed PIM No CR	Removed 'PIM' from Number 1.3.2	Appendix 2: Directory / File Structure for Module 1	eu-regional.dtd eu-regional.xsl
22	Removed attribute 'country' Q&A 24; CR 20090820	In the file eu-envelope.mod, attribute country from related-sequence element has been removed	No change	eu-envelope.mod
23	Provision of track changes in PDF documents (in progress Q&A, not published)	Track changed Product Information provided in Word format is not required to be provided in PDF format within the eCTD except for labelling and rmp documents in the centralised procedure	Regional File Formats	No change
24	m1-Responses – summarised text from Q&A 36 added	Details added to file naming convention for responses to questions	File Naming Convention	No change
25	Business Protocol for Centralised Procedure & acknowledgements (No CR)	Added detail of acknowledgement process incorporated in EMA eSubmission Gateway.	Business Protocol	No change

2. List of EU Module 1 Changes

2.1. Use of the European Agency Acronym

CR 20091203

The Specification and Special Annex have been updated to reflect the use of the acronym "EMA" when referring to the Agency. "EMA" will be used in various technical texts for file and folder names, but "EMEA" will continue to be used for CAP procedure numbers.

2.2. Addition of Other PDF Versions

No CR, Q&As 32 & 38

The ICH Q&A document was updated to include PDF versions 2.4, 1.5, 1.6 & 1.7 as acceptable.

After publication of the M1 revised documents, Q&As 32 & 38 will be retired.

2.3. How to Obtain a Number for an Initial MAA

No CR

Information is provided how applicants can obtain a submission number prior to the submission of an initial MAA for the Centralised Procedure.

2.4. Removal of the Term "Periodic"

CR 20091211

The Specification has removed the term 'periodic' for the 'mode' attribute of the 'submission' element as it may be confused with the Periodic Annual Report.

2.5. Addition of Risk Management Plan as a New Submission Type

No CR

To add clarity for the submission of a Risk Management Plan outside a procedure, a new submission type has been added to Module 1.

2.6. Naming Convention for Tracking Table

CR 20130204

The naming convention for the tracking table provided in sequences for applications in the eCTD format for the MRP & DCP has been changed but the location remains the same.

2.7. Revisions Regarding Agency Names and Agency Codes

Components were updated to correct errors, reflect new names or agency codes for National Competent Authorities as described below:

CR 20101022-01

- The style-sheet has been amended to reflect the correct name of the National Competent Authority for Czech Republic as follows: "State Institute for Drug Control".

CR 20101214

- The name of the National Competent Authority for Finland has been updated as follows: "Finnish Medicines Agency". The new Agency code is "FI-FIMEA".

CR 20110614

- The name of the National Competent Authority for Croatia has been added as follows: "Croatian Agency for Medicinal Products and Medical Devices". The new Agency code is "HR-HALMED".

CR 20121119

- The abbreviation of the National Competent Authority for Spain has been changed to “AEMPS”. The new Agency code is “ES-AEMPS”. The Agency name remains “Agencia Española de Medicamentos y Productos Sanitarios”.

CR 20121126

- The name of the National Competent Authority for France has been changed to: “Agence national de sécurité du médicament et des produits de santé”. The new Agency code is “FR-ANSM”.

No CR

- The style-sheet has been amended to reflect the correct name of the National Competent Authority for the United Kingdom as follows: “Medicines and Healthcare products Regulatory Agency”.

No CR

- The name of the National Competent Authority for Cyprus has been updated as follows: “Pharmaceutical Services, Ministry of Health”. The new Agency code is “CY-PHS”.

No CR

- The name of the National Competent Authority for Romania has been updated as follows: “National Agency for Medicines and Medical Devices”. The new Agency code is “RO-ANMMD”.

No CR

- The names and codes of National Competent Authorities NOT responsible for marketing authorisation of medicinal products for human use have been removed.

2.8. Values for Country-Specific Elements

CR 20120209

The Specification has been updated to reflect appropriate values for the country-specific elements and folder structure in the centralised procedure.

2.9. Clarification on the use of XML format

CR 201212221

The specification now addresses when, and how an XML format can be used to replace a PDF format for regional files.

2.10. Removal of ‘country’ attribute in envelope

Q&A 24 and CR 200090820

The eu-envelope.mod has removed the country attribute from the related-sequence element.

2.11. Provision of Track Changes in PDF Documents

No CR

The description provided regarding tracked changes product Information is in Word format. No PDF formatted document is required, except for the RMP and the labelling.

2.12. File Naming Convention for Responses

Q&A 36

Details provided for file naming convention for response to questions.

2.13. Acknowledgement Process for Submissions

No CR

Details provided about the acknowledgement process when submissions are made through the EMA eSubmission Gateway.

3. Clarification on the use of Agency Codes for Denmark & Slovenia

3.1. *Agency code for Denmark*

CR 20121207

The name of the National Competent Authority for Denmark has been updated in the specification as follows: "Danish Health and Medicines Authority". The new Agency code is "DK-DHMA".

This change has not yet been implemented in the DTD and style sheet of this release. Applicants should continue to use DK-DKMA as the agency code. This change will be incorporated in the next update of Module 1.

3.2. Agency Code for Slovenia

CR 20121217

The name of the National Competent Authority for Slovenia has been updated in the specification as follows: "Javna agencija Republike Slovenije za zdravila in medicinske pripomočke" and Agency code is "SI-JAZMP". This change has not yet been implemented in the DTD and stylesheet of this release. Applicants should continue to use the name: "Javna agencija Republike Slovenije za zdravila in medicinske pripomocke". This change will be incorporated in the next update of Module 1.