



EU Module 1

v1.4

Release Notes
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DOCUMENT CHANGE RECORD

Version	Date	Description	Sections
0.1	15/07/2009	First version	All
1.0	06/08/2009	Final - Inclusion of comments	All

REVIEW

Version	Date	Person / Group / Company / Agency
0.1	15/07/2009	EU Regulatory Authorities (members TIGes and NtA), EFPIA, EGA, other interested parties

DISTRIBUTION

Version	Date	Person / Group / Company / Agency
0.1	15/07/2009	EU Regulatory Authorities (members TIGes and NtA), EFPIA, EGA, other interested parties
1.0	10/08/2009	http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm http://esubmission.emea.europa.eu/

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1. Introduction

This document intends to highlight the differences between the EU Module 1 v1.4 and the EU Module 1 v1.3 to assist potential users of the system.

The changes within the EU Module 1 v1.4 are summarised here 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	Reference across Sequences CR: A014, 0014	Guidance relating to the ability to reference files across sequences and/or across modules	General Architecture of Module 1	Examples
2	Update of Attributes CR: QA-20070816-01	Guidance on the possible update of attributes in the EU Module 1	Updating backbone attributes	-
3	Display of Sections with no Content CR: CR-20080129-01	Description of the behaviour of the EU Module 1 style-sheet to display all sections, even with no content	Handling of Empty or Missing eCTD Sections	-
4	Guidance on Use of "common" Country CR: CR-20080129-02, CR-20090506, CR-20090506-II	The "common" country cannot be used in the envelope but it can be used to characterise documents applicable to all countries	Envelope Directory / File Structure Appendix 2.1	-
5	Tracking Number CR: CR-20080514, CR-20080514-01, CR-20080514-05	Use of "tracking number" in the envelope as a generalisation of the "procedure number"	Envelope Appendix 1.1 Annex 2	eu-envelope.mod eu-regional.xsl Examples
6	Further Guidance on Product Information CR: CR-20080514-02	Further guidance on the usage of country, type and language for elements specific to product information	Appendix 1.2	-
7	Related Sequence and Tracking Number CR: CR-20080514-04	Further guidance about the use of the related sequence in addition to the tracking number for sequences of the same regulatory activity	Appendix 1.1 Annex 4	-
8	Convention for Tracking Table CR: CR-20080806	Correction of the file naming convention for the MRP/DCP Tracking Table	Appendix 2	Examples
9	Further Guidance on Additional Data CR: CR-20081023	Extension of the guidance on additional data so as to cover renewals	Appendix 2	-
10	Removal of ATC Field from the Envelope CR: CR-20090517	Removal of the field "atc" from the EU Module 1 envelope	Appendix 1 Annex 2	eu-envelope.mod eu-regional.xsl Examples
11	Maximum Path Length CR: CR-20090310	Update of the maximum path length to 180 characters	File Naming Convention	-
12	EU Module 1 Style-sheet CR: CR-20090310-II	Guidance that the most recent EU Module 1 style-sheet should be used	Appendix 2	-
13	New Variations Regulation CR: CR-20090603	Support of submission modes for variations (single, grouping and worksharing), including guidance on use in EU Module 1	Envelope Appendix 1.1 Annex 2 Annex 3	eu-envelope.mod eu-regional.xsl
14	Submission Types CR: CR-20080415	Review of the submission types supported in the EU Module 1	Appendix 1.1	eu-envelope.mod eu-regional.xsl

2. List of EU Module 1 Changes

2.1 Reference across Sequences

Change Requests A014, 0014

The Specification provides guidance and example on the way to reference files across sequences of the EU Module 1 as well as across modules. The reference must be relative from the source of the XML file, and assumes that all sequences folders (e.g. 0000, 0001...) are stored within the same directory.

2.2 Update of Attributes

Change Request QA-20070816-01

The Specification provides guidance on the possibilities to amend the attributes of the EU Module 1. Such attribute update is not recommended in the eCTD, but a similar need is deemed to be very rare in the EU Module 1 according to the nature of the attributes supported.

2.3 Display of Sections with no Content

Change Request CR-20080129-01

The Specification provides clarification about the behaviour of the EU Module 1 style-sheet. All the sections of the EU Module 1 displays even if no file is attached to each section.

2.4 Guidance on the Use of “common” Country

Change Requests CR-20080129-02, CR-20090506, CR-20090506-II

The Specification provides further guidance on the usage of the “common” country. The “common” country cannot be used in the envelope of the EU Module 1. It can be used to characterise files attached to the EU Module 1, in the case of Mutual Recognition Procedure, and if files are applicable to all EU countries, irrespective of whether they are participating in the procedure or not. The “common” country should also be used in the Decentralised Procedure.

2.5 Tracking Number

Change Request CR-20080514, CR-20080514-01, CR-20080514-05

The notion of “procedure number” has been replaced by “tracking number”, so as to generalise the number effectively used by EMEA and NCAs to identify, manage and track the submissions. Depending on the agency and the procedure used, this may be the EMEA procedure number, the EU licence number, the MRP number, the DCP number, or a national procedure/tracking number.

2.6 Further Guidance on Product Information

Change Request CR-20080514-02

The Specification provides further guidance on the use of attributes specific to product information, i.e. country, language and document type.

2.7 Related Sequence and Tracking Number

Change Request CR-20080514-04

The Specification provides further guidance about the concept of “related sequence”. The Related Sequence number is used, together with the Tracking Number, to identify sequences belonging to the same ‘regulatory’ activity’.

2.8 Convention for Tracking Table

Change Request CR-20080806

The Specification has been amended to correct the file naming convention for the MRP/DCP Tracking Table.

2.9 Further Guidance on Additional Data

Change Request CR-20081023

The Specification has extended to provide guidance on additional data so as to cover renewals.

2.10 Removal of ATC Field from the Envelope

Change Request CR-20090517

The Specification and DTD have been amended to remove the field “atc” (ATC Code) from the envelope of the EU Module 1.

2.11 Maximum Path Length

Change Request CR-20090310

The Specification has been amended to update the maximum length for file path. The new maximum length has been set to 180 characters.

2.12 EU Module 1 Style-sheet

Change Request CR-20090310-II

The Specification has been extended to provide guidance on the style-sheet to use with an EU Module 1. The most recent EU Module 1 style-sheet should always be used.

2.13 New Variations Regulation

Change Request CR-20090603

The Specification and DTD have been amended so as to support the New Variations Regulation. The envelope has been reviewed so as to support the different modes of submission for variations: single, grouping and worksharing.

Examples have also been provided to further describe how to use the EU Module 1 under different scenarios. With the extension of examples, the EU Module 1 Specification has been split into two documents, and examples have been moved into an Annex of the Specification.

2.14 Submission Types

Change Request CR-20080415

The Specification and DTD have been extended to support the following submission types: “Plasma Master File”, “National Variation” and “Paediatric Submission, Article 46”.