



# **EU Module 1**

**V3.0**

**Release Notes**  
**July 2015**

## DOCUMENT CHANGE RECORD

Version	Date	Description	Sections
1.0	17.07.2015	Final version	All

## REVIEW

Version	Date	Person / Group / Company / Agency
1.0	17.07.2015	EMA

## DISTRIBUTION

Version	Date	Person / Group / Company / Agency
1.0	20.07.2015	General Public

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# 1. Introduction

This document describes the major differences between v.3.0 of the EU Module 1 eCTD Specification and the previous version (v2.0) to assist potential users of the system during implementation.

The changes within the EU Module 1 v3.0 Specification are summarised below, sorted per section and indication when the Specifications, DTD or Style-sheets have been amended:

#	Change	Summary	Specifications	DTD / Style-Sheet
1	Updated version number to v3.0	Throughout the document the version number of the EU Module 1 eCTD specification was changed from v2.0 to v3.0.	Title of the EU Module 1 eCTD Specification will be accommodated when final	eu-regional.dtd eu-envelope.mod
2	Update to the Glossary of terms	Term names have been updated. Introduction of new terms Submission Type and Submission Unit	Glossary of Terms in Module 1 Specification	No change
3	References to TIGes Guidances updated	Throughout the document the TIGes guidance documents have been renamed	General application in Module 1 Specification	No change
4	Use of Electronic Signatures	Updating Information provided how to use electronic signatures in submissions.	General application in Module 1 Specification	No change
5	Updating backbone attributes/metadata	Removed reference to use of the submission type	General application in Module 1 Specification	No change
6	Update to Envelope section	Revision of Envelope section	General application in Module 1 Specification	Adding attribute 'identifier', 'submission unit' and adding terms like EDQM, several submission types and terms to define submission unit.,
7	Update of section 'Business Protocol'	Deleted references to submissions on physical media		no change
8	Addition of Universal Unique Identifier	Added new section on UUIDs	Module 1 specification: Appendix 1.1: Envelope Element Description	eu-envelope.mod
9	Submission type list updated	List of regulatory activities updated; new terms added, FUM deleted	Module 1 specification: Appendix 1.1: Envelope Element Description	eu-envelope.mod
10	Submission Unit list added	List of Submission Units added to define in relation to regulatory activity	Module 1 Specification: Appendix 1.1 - Envelope Element Description	eu-envelope.mod
11	Examples on how to use submission type and submission unit	Information on the use of submission unit and consequential changes relating to submission type	Module 1 Specification: Appendix 1.1 - Envelope Element Description	no change
12	Destination codes updated	EDQM added	Module 1 Specification: Directory / File Structure (p11) , Appendix 2.1: Destination Codes	eu-regional.dtd
13	Agency name updated	National Competent Authority name for Austria updated	Module 1 Specification: Appendix 2.4: Agency Codes and Names	eu-envelope.mod
14	Agency name updated	National Competent Authority name for Denmark updated	No change	eu-envelope.mod
15	Agency name updated	EU-EDQM added as National Authority name	Module 1 Specification: Appendix 2.4: Agency Codes and Names	eu-envelope.mod
16	Agency name updated	National Competent Authority name for Ireland updated	Module 1 Specification: Appendix 2.4: Agency Codes and Names	eu-envelope.mod

## 2. List of EU Module 1 Changes

Implementing accepted change requests:

- 2.1 Update of agencies names
- 2.2 additional submission types
- 2.3 adding submission unit and related term list
- 2.4 alignment of term lists with respective EUTCT CTL
- 2.5 additional samples and adjusting examples according to the above mentioned changes, adding EDQM to the list of receivers.
- 2.6 Modifications to improve consistency and English wording.
- 2.7 Incorporating comments from eSub CMB, TEAB, HHMG in regard to additional explanations of technical aspects of the UUID, additional submission types, clarifications how to use new submission types and submission unit.