



EU Module 1 Specification - Annex

Version 1.4.1

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DOCUMENT CHANGE RECORD

Version	Date	Description	Sections
1.0	30/11/2011	Final version	All

REVIEW

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1. Introduction

This document intends to highlight the differences between the EU Module 1 v1.4.1 and the EU Module 1 v1.4 to assist potential users of the system.

#	Change	Summary	Specifications	DTD / Style-Sheet
1	20060627-02	Guidance on the not allowed inclusion of Word format in the eCTD	General Application	-
2	CR-20090615	Guidance on the validity of using replace or delete operation attribute on a document which is no longer in the same location as the document that is being replaced or deleted	General explanation	-
3	CR-20090909-01	Use of the word Application in an unambiguous way	Where applicable	-
4	CR-20090909-02	Clarification on responses as common documents and therefore common folder and variable part should be used. In case of translations of labelling, the country specific folders should be used.	Where applicable	-
5	CR-20090909-03	Guidance on the use of common in the centralised procedure.	Where applicable	-
6	CR-20090909-05	Changing the wording to refer to eCTD submissions per marketing authorisation instead of copying when submitting a grouping or worksharing of variations.	Where applicable	-
7	CR-20090909-08	Clarification in the naming convention to split for those documents pertaining to country-specific items and those not.	Where applicable	-
8	CR-20090909-10	The guidance on the use of the common directory should not include references to specific procedures	Where applicable	-
9	CR-20090922	Removal of a reference to change from marketing authorisation holder to the applicant to prevent a change for every submission in the worksharing procedure	Where applicable	-
10	CR-20091203	New logo and name to be used in the text as a result of changing to the Agency / EMA	Where applicable	-
11	CR-20091210	Guidance on the use of the submission type "Withdrawal" to only be used for the withdrawal of a Marketing Authorisation.	General explanation	-
13	CR-20101022-01	Remove RTF as reference in the whole document	All	
14	EU Change Request A010	Use of node extensions in the eCTD.	General explanation	

2. List of EU Module 1 Changes

All changes do not impact the DTD or the style sheets and are text clarifications and more detailed guidance.