



# **EU Module 1**

**v1.4**

**Implementation Guidance**  
**August 2009**

**TABLE OF CONTENTS**

1. Introduction ..... 3  
2. Timeline for Implementation..... 3

# 1. Introduction

This document provides guidance to applicants and tool vendors regarding the timeline for implementation of the EU M1 specification v1.4.

## 2. Timeline for Implementation

The Specifications and DTD of the eCTD EU Module 1 v1.4 include several changes to v1.3 based on change requests (see Release Notes for EU M1 v1.4), but the principal change is support for the Commission Regulation (EC) No. 1234/2008 on variations, specifically the support of grouped variations and worksharing.

The timeline for implementation is specified in two parts as follows:

1. Applicants are advised that, **from 1<sup>st</sup> January 2010**, when the new variation regulation comes into force, the EU M1 v1.4 must be used for any eCTD submission for any European procedure that contains grouped variations or is subject to a worksharing agreement. Grouped variation or worksharing eCTD submissions provided from this date using any previous version of the EU M1 specification (v1.0. v1.1, v1.2.1 or v1.3) will not be accepted.

All European Regulatory Authorities must therefore be able to *accept* eCTD submissions built using EU M1 v1.4 from 1<sup>st</sup> January 2010.

2. Applicants are further advised that, from **1<sup>st</sup> July 2010**, the EU M1 v1.4 must be used for all eCTD submissions for all European procedures, and any eCTD submissions provided from this date using any previous version of the EU M1 specification (v1.0. v1.1, v1.2.1 or v1.3) will not be accepted.

These deadlines apply to all relevant lifecycle sequences/submissions for applications ongoing at the time. Please note that, for existing applications, it is *not* expected that all *previous* existing submissions will be updated to EU M1 v1.4 and re-submitted; it *is*, however, expected that authoring and review tools will allow for a change in DTD mid-lifecycle.

3. Note that during the period from 1<sup>st</sup> January to 1<sup>st</sup> July 2010, once an applicant has created and submitted an eCTD using EU M1 v1.4 for a particular product, all subsequent eCTD submissions for this product must be made using EU M1 v1.4. This is the case even if the subsequent submission type is not one that contains a grouped variation or is subject to a worksharing agreement.