

WITHDRAWAL NOTICE: EU M1 SPECIFICATION V1.2

EU M1 specification v1.2, published May 2006, has been withdrawn following notice of an inconsistency between the presentation of submission information detailed in the current CTD Guidance and the eCTD specification itself:

According to Notice to Applicants Volume 2B (April 2006), Section 1.5 has the following sub-sections:

- 1.5.1 Information for Bibliographical Applications
- 1.5.2 Information for Generic, 'Hybrid' or Bio-similar Applications
- 1.5.3 (Extended) Data/Market Exclusivity
- 1.5.4 Exceptional Circumstances
- 1.5.5 Conditional Marketing Authorisation

Module 1 eCTD specification v1.2 and the accompanying DTD file detail the following sub-sections for Module 1:

- 1.5.1 Information for Bibliographical Applications
- 1.5.2 Information for Generic, 'Hybrid' or Bio-similar Applications
- 1.5.3 Informed consent
- 1.5.4 (Extended) Data/Market Exclusivity
- 1.5.5 Exceptional Circumstances
- 1.5.6 Conditional Marketing Authorisation
- 1.5.7 Accelerated Assessment Procedure

The inconsistency has been corrected and specifications v1.2.1 will be reviewed and published shortly after appropriate review and approval.

Prior to the publication of v1.2.1 and its subsequent implementation in authoring tools, applicants wishing to submit an application using the latest guidance from NtA for paper and eCTD and maintaining alignment should contact EMEA for the Centralised Procedure and National Competent Authorities for other procedures.

EMA recommends that applicants follow eCTD specification v1.1 with the use of node extensions to ensure section alignment in paper and electronic submissions, or to submit a simple electronic submission consisting of a set of files and folders aligned to the new CTD structure.