



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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eSubmission Change Management Board

Electronic Common Technical Document (eCTD) v4.0 draft EU module 1 implementation guide public consultation

Start of public consultation	13 March 2015
End of consultation (deadline for comments)	22 May 2015

Comments should be provided using this [template](#). The completed comments form should be sent to eCTD4consultation@ema.europa.eu



eCTD v.4.0 EU M1 Implementation Guide

This public consultation will concern the EU Module 1 Implementation Guide including eCTD v4.0 Module 1 requirements of the eCTD XML message, the Regional Administrative and Product Information specific for EU purposes and the set of Controlled Vocabularies relevant to EU Module 1 in the format of genericcode files.

The package also includes a comments template.

Access the [eCTD v4.0 webpage](#) or [click here](#) to download the package.

Background

The key documents for the Electronic Common Technical Document (eCTD) v4.0 Modules 2 through 5 have been signed off by the ICH Steering Committee in November 2014 for ICH Step 2. The ICH M8 Working Group on electronic submission has drafted these documents based on the Regulated Product Submission (RPS) standard established by HL7 in September 2014. This standard defines the message for exchanging regulatory submission information electronically between applicants and Regulatory Authorities. The XML message provides the ability to describe the contents of the regulatory exchange and all information needed to process the exchange between these two parties.

The package of relevant documents is accessible on the [ESTRI web page](#) for public consultation from mid of February to 22 May 2015.

The ICH Implementation Guide and the respective set of controlled vocabularies will need to be used in conjunction with the EU Module 1 Implementation Guide and an additional set of EU relevant controlled vocabularies, as the eCTD v4.0 message will be incomplete without all of the contents.