

Questions and Answers from Member States

CTD format acceptance

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According to the Directive 2009/9 (Annex I), the chemical, pharmaceutical and biological/microbiological information for the active substance or the finished product may be included in the dossier in CTD format only where the competent authority has publicly announced this possibility.

What is the approach your Agencies will take for this issue?

Authority (MS)	Comments
AUSTRIA	
BELGIUM	We already accept the DMF and the analytical part in CTD format in Belgium as our analyst do both human and vet procedures. I agree with Gabi that such information should preferably be mentioned in Chapter VII.
BULGARIA	
CYPRUS	We can accept DMF and Part II in CTD format.
CZECH REPUBLIC	Currently we accept DMF in CTD format only but we are open for acceptance of the complete analytical Part II in CTD in future. We agree that this information should be mentioned in Chapter 7.
DENMARK	Denmark can accept Part II in CTD format. Part I, III and IV must follow NtA format.
ESTONIA	We accept the DMF and part II in CTD format.
FINLAND	It is accepted that Part II of the dossier as well as the ASMF (DMF) is submitted in CTD format.
FRANCE	Only accept the Drug Master File in CTD format, everything else must follow NtA.
GERMANY Immunologicals	
GERMANY Pharmaceuticals	We already now accept Part II in CTD format. Concerning the public announcement of the possibility to submit the information related to the active substance or finished product in CTD format I suggest asking the NtA group to include this information in Chapter 7 of the NtA. I think NtA Chapter 7 is by far more convenient for applicants to check compared to national homepages or other media where this information could be published.
GREECE	In Greece we accept Part II of the dossier as well as the DMF in CTD format.
HUNGARY	We accept too the DMF and the analytical part in CTD format. Good idea to be mentioned in the NtA in the relevant chapter.
ICELAND	Part II accepted in CTD format. I agree with Gabi that such information should be mentioned in Notice to Applicants.
IRELAND	Ireland presently accepts the DMF in CTD format, however, all other parts of the application dossier must follow the NtA format.

ITALY	In Italy we accept at the moment DMF in NtA format, in future pending agreement between NCA and the applicant the DMF in CTD format could be accepted.
LATVIA	We can accept Part II in CTD format. All other parts of the application dossier must follow NtA format.
LITHUANIA	
LUXEMBOURG	
MALTA	
NETHERLANDS	It's accepted that Part II of the dossier as well as the DMF are submitted in CTD format.
NORWAY	The NoMA would also be able to accept Part II and the DMF in CTD format.
POLAND	Poland can accept Part II in CTD format. All other parts of the application dossier must follow NtA format.
PORTUGAL	We can accept the Drug Master File in CTD format. Everything else must follow NtA
ROMANIA	In Romania we accept the DMF in CTD format. All other parts of the application dossier must follow the NtA format.
SLOVAK REPUBLIC	We accept the DMF and part II in CTD format. All other parts of the application dossier must follow NtA format.
SLOVENIA	DMF is accepted in CTD format, other documents must follow NTA
SPAIN	CTD format is accepted for the DMF and the analytical part. Agree with having this information in NtA.
SWEDEN	It is accepted that Part II of the dossier as well as the ASMF (DMF) is submitted in CTD format.
UK	Only accept the Drug Master File in CTD format, everything else must follow NtA.