

**Questions and Answers from Member States**

**CTD format acceptance**

<b>Adopted</b>	<b>Status</b>
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**ISSUE DESCRIPTION:**

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 of the Member States on this issue?

Authority (MS)	Accept ASMF in CTD-format	Accept Part II in CTD-format
AUSTRIA	Yes	Yes
BELGIUM	Yes	Yes
BULGARIA		
CYPRUS	Yes	Yes
CZECH REPUBLIC	Yes	Yes
DENMARK	Yes	Yes
ESTONIA	Yes	Yes
FINLAND	Yes	Yes
FRANCE	Yes	No
GERMANY Immunologicals		
GERMANY Pharmaceuticals	Yes	Yes
GREECE	Yes	Yes
HUNGARY	Yes	Yes
ICELAND	Yes	Yes
IRELAND	Yes	No
ITALY	In the future, pending agreement between the NCA & applicant, ASMF in CTD-format could be accepted.	No
LATVIA	Yes	Yes
LITHUANIA	Yes	Yes
LUXEMBOURG		
MALTA		
NETHERLANDS	Yes	Yes
NORWAY	Yes	Yes
POLAND	Yes	Yes
PORTUGAL	Yes	No
ROMANIA	Yes	No
SLOVAK REPUBLIC	Yes	Yes
SLOVENIA	Yes	No
SPAIN	Yes	Yes
SWEDEN	Yes	Yes
UK	Yes	No