Q&A on how to handle eCTD for ASMF submissions

Q1. Which eCTD sequence(s) do I need to submit for my ASMF in different procedures?

Answer: For ease of lifecycle management of the ASMF in Europe it is advised that for an ASMF there will be only one eCTD lifecycle. This implies that the initial submission of the ASMF submitted in relation to the first marketing authorisation or variation procedure will be sequence 0000. Each subsequent procedure will be the next sequence in this lifecycle.

For example:
When for the first MA procedure sequences 0000, 0001 and 0002 of the ASMF have been submitted to some member states (e.g. MS1, MS2 and MS3), and the ASMF has been approved, then the submission in relation to new countries (e.g. MS4, MS5 and MS6) in support of a next MA procedure will consist of sequences 0000, 0001, 0002 and 0003. The previously submitted sequences 0000, 0001 and 0002 should now also be submitted to MS4, MS5 and MS6. The new sequence 0003 will consist of the cover letter and letters of access for the new MSs and procedure.

In the sequence tracking table should detail to which countries which sequence has been submitted and when.

In case a consolidated 0000 sequence would be submitted in support of the new MA procedure, this would lead to a new eCTD lifecycle for the same ASMF. This would result in the need of maintenance of multiple eCTD lifecycles of the same ASMF which is inconvenient for ASMF holder and competent authorities as this could lead to errors where the same updates are not implemented for all lifecycles and duplicate work.
Therefore, it is strongly recommended to have only one lifecycle for the ASMF in the EU.

Note: ASMFs for veterinary use only can be submitted in eCTD, CTD (NeeS) or VNeeS format. The above applies only to the eCTD format.