October 2017

Release Notes for the version 2.0 of the

Harmonised Technical Guidance for ASMF Submissions in eCTD format in the EU

Formerly called PRACTICAL GUIDANCE ON THE USE OF THE eCTD FORMAT FOR ASMFs FOR ACTIVE SUBSTANCE MASTER FILE HOLDERS AND MARKETING AUTHORISATION HOLDERS

The former version of this guidance document, version 1.0, was published in January 2010. The Human Harmonisation Maintenance Group (HHMG) published a new draft revision version (v.1.5) for public consultation in June 2016. The consultation did not raise any major concerns and only minor updates were needed. However, due to different reasons, the final version (v 2.0) was not until now adopted and published.

The changes compared to version 1.0 are quite substantial and will therefore not be described in details in this document. However, the guidance does not require the actual handling of the eCTD for ASMFs to change in relation to the implementation, especially since the use of the use of 'ap' and 'rp' as suffix instead of prefix in the filenames to pass technical validation has already been communicated in the published eCTD validation criteria.

Version 2.0 comes into force immediately and should be followed for all ASMFs in eCTD format submitted to authorities within EU. By following the guidance (together with the eCTD specification and other relevant guidance documents referred to in the guidance), an ASMF should be found valid in a technical validation using the current validation criteria.