21 January 2016
EMA/37970/2016
Procedure Management and Business Support Division

Use of eCTD format for ASMF submissions for human medicines

The EMA's strategy for the electronic submission of applications aims to improve efficiency and streamline processes for all stakeholders.

From 1 July 2016, the use of the eCTD format for all ASMF submissions for human use in the centralised procedure will become mandatory. After this date, it will no longer be possible to submit human ASMF submissions using the NeeS format to EMA.

An eCTD baseline should be provided for ASMFs currently in NeeS format. More information on how to provide an eCTD baseline can be found from the Harmonised Technical Guidance for eCTD submissions.

Background

In January 2010 EMA introduced mandatory use of eCTD for all human centralised procedure submissions. The transitional period to move to mandatory use of eCTD format for all ASMF submissions for centralised procedure human medicines started in September 2013.

Related information

- eASMF
- eSubmission Gateway and Web Client
- Harmonised Technical Guidance for eCTD submissions in the EU

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact