European Medicines Agency
Evaluation of Medicines for Human Use

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EMEA IMPLEMENTATION OF ELECTRONIC-ONLY SUBMISSIONS AND MANDATORY eCTD SUBMISSIONS IN THE CENTRALISED PROCEDURE: STATEMENT OF INTENT RELATING TO NON-eCTD SUBMISSIONS

EMEA has announced plans to mandate the use of the Electronic Common Technical Document (eCTD) format for electronic-only submissions in the centralised procedure from 1 January 2010.

From 1st July 2009 until 1 January 2010, EMEA will continue to accept non-eCTD electronic-only submissions (eCTD is, however, the recommended format).

Within this context, EMEA hereby announces the introduction of a set of specific guidelines on submission structure, format and presentation, which non-eCTD submissions should adhere to for the centralised procedure from 1 February 2009 until such time as the eCTD format is mandatory.

The EMEA's non-eCTD electronic submission guidelines will apply for a finite period of time (to 1 January 2010) and are intended to improve the standardisation and quality of all non-eCTD electronic submissions provided in the context of the centralised procedure during this time period. Adherence to the guidelines is further intended to facilitate the transition to the eCTD format for all submissions.

Until 1 January 2010, therefore, any non-eCTD electronic submission provided in the context of the centralised procedure should also comply with these specific guidelines from EMEA for non-eCTD electronic submissions.

All other current guidance remains in force.

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