European Medicines Agency
Evaluation of Medicines for Human Use

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

EMEA hereby announces plans to implement the electronic-only submission of information in support of marketing authorisation applications in the centralised procedure, and, ultimately, implementation of the Electronic Common Technical Document (eCTD) as the required format for electronic submissions.

The EMEA implementation strategy for eCTD in the centralised procedure falls within the context of a wider EU initiative, as agreed by Heads of Medicines Agencies (HMA) in Reykjavik on 28 February 2005: By an agreed end-2009 deadline, the European Regulatory Network must have the infrastructure and processes in place to handle electronic-only eCTD to successfully support the related decision-making processes for medicinal products within the European Union.

The EMEA's strategy for the centralised procedure is developed in this wider context and in parallel to these activities, but remains distinct.

The major milestones of the EMEA implementation strategy are as follows:

- From *1 July 2008*, the EMEA will accept electronic-only submissions, either in eCTD format or non-eCTD format (eCTD is the recommended electronic format), with no additional requirement for paper copies. This will apply to all applications (new and existing) and all types of submissions to the EMEA in the context of the centralised procedure (e.g. new applications, supplementary information, variations, renewals). Rapporteurs and CHMP members may, however, still have paper-copy requirements at this point.
- From *1 January 2009*, the EMEA will strongly recommend electronic-only submissions, either in eCTD or non-eCTD format (eCTD is the recommended electronic format), and paper will be an exception to the general e-format recommended for any application. This will apply to all applications (new and existing) and all submission types. Rapporteurs and CHMP members will not receive paper copies from this date.
- From *1 July 2009*, the EMEA will strongly recommend eCTD-format electronic-only submissions. Paper and other electronic formats will be an exception to the general e-CTD format recommended for any application. This will apply to all applications (new and existing) and all submission types. Rapporteurs and CHMP members will not receive paper copies or other electronic formats from this date.

Until 1 July 2008, the current guidance remains in force and electronic submissions in eCTD or non-eCTD format will continue to be accepted by the EMEA, Rapporteurs and CHMP members, together with the specified numbers of paper copies.

A question-and-answer (Q&A) document regarding this statement of intent is available here.

A further Q&A document on practical and technical aspects of eCTD implementation in the centralised procedure will follow.

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