European Medicines Agency
Evaluation of Medicines for Human Use

London, December 2008
EMEA/572459/2008

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

EMEA hereby announces plans to mandate the use of the Electronic Common Technical Document (eCTD) format for electronic-only submissions in the centralised procedure. The introduction of mandatory eCTD is an extension to the existing EMEA strategy for implementation of electronic-only submissions and eCTD.

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 new milestone of the EMEA implementation strategy relating to mandatory eCTD is as follows:

- From *1 January 2010*, the EMEA will mandate the use of the eCTD format for all electronic-only submissions for all applications (new and existing) and all submission types. Rapporteurs and CHMP members will not receive paper copies or other electronic formats.

In addition, until 1 January 2010, any non-eCTD electronic submission provided in the context of the Centralised Procedure must also comply with the EMEA's new specific guidelines for non-eCTD electronic submissions. All other current guidance remains in force.

A question-and-answer (Q&A) document regarding this statement of intent is available under EMEA General Regulatory Guidance

A further Q&A document on practical and technical aspects of eCTD implementation is available under EMEA General Regulatory Guidance

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu