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IMPLEMENTATION STATUS OF CTD, eCTD, AND PAPER-FREE SUBMISSIONS: A GLOBAL OVERVIEW

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OBJECTIVE

Follow up the implementation of CTD, eCTD, and paper-free submissions for 58 worldwide regulatory agencies.

METHOD

The CTD/eCTD implementation and paper-free submission requirements were monitored for 58 worldwide regulatory agencies during a 2-year time period (Jan-2010 to Mar-2012).

REGION	AGENCIES MONITORED
North America	Canada, US
Latin America	Argentina, Brazil, Chile, Colombia, Mexico, Peru, Venezuela
European Union	All 27 EU Member States plus the European Medicines Agency (EMA)
Non European Union	Croatia, Iceland, Norway, Russia, Switzerland, Turkey
Asia Pacific	Australia, China, Hong Kong, India, Japan, Malaysia, Singapore, South Korea, Taiwan, Thailand, Vietnam
Middle East and Africa	Egypt, Israel, Saudi Arabia, South Africa

RESULTS

IMPLEMENTATION OF CTD SUBMISSIONS

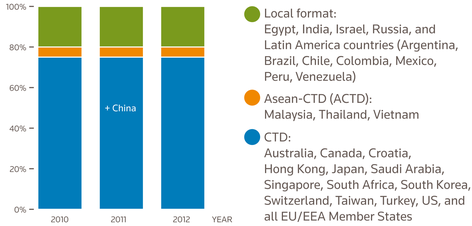

Fig. 1: Implementation of CTD submissions

Of the 58 regulatory agencies considered, only 1 (China) switched to the CTD format during the 2-year time period.

The enforcement of CTD varies across countries/regions:

- Mandatory in EU Member States and Japan since 2003; strongly recommended format in US
- Mandatory for prescription medicines in Australia
- Adopted for New Chemical Entities (NCEs) only in Israel, for biological products only in India (however, agencies are in the process of extending to other types of products)
- Required for new drugs only in South Korea, optional for others

Among the countries that accept the CTD format (Modules 1 to 5), there are a few which continue to accept submissions in the old NTA format (Part I to IV), i.e., Croatia (Standard Technical Document, STD) and Asean Countries, such as Singapore and Taiwan, which also accept the Asean-CTD (ACTD).

eCTD ACCEPTABILITY

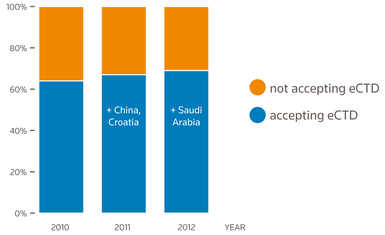

Fig. 2: eCTD acceptability

Of the 58 regulatory agencies considered, 3 announced the acceptability of eCTD submissions during the 2-year time period (China, Croatia, and Saudi Arabia). eCTD acceptability does not mean that the agencies only accept eCTD. For most of them, the Non-eCTD electronic Submissions (NeeS) are also accepted.

IMPLEMENTATION OF ELECTRONIC SUBMISSIONS

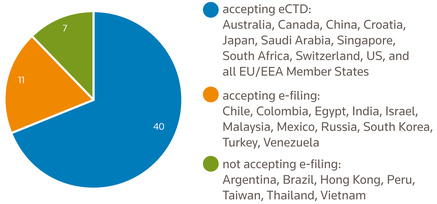

Fig. 3 : Implementation of electronic submissions

Among the agencies not accepting eCTD, more than half still allow the filing of applications in electronic form (scanning of the medicinal product documentation) submitted through CD, DVD, or memory stick (data as of March 2012).

IMPLEMENTATION OF eCTD PAPER-FREE SUBMISSIONS

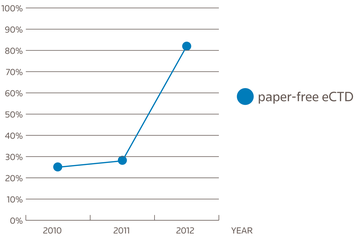

Fig. 4: Implementation of eCTD paper-free submissions*

If in early 2010 almost 75% of agencies accepting eCTD still needed to receive a paper submission, in early 2012 this requirement has been maintained only for 7 agencies (as of March 2012: Australia, Canada, China, Croatia, Saudi Arabia, Singapore, Switzerland).

CONCLUSION

As of March 2012, several countries still require local format dossiers (India, Russia, and all the Latin America countries considered: Argentina, Brazil, Chile, Colombia, Mexico, Peru, Venezuela) while some Asean countries accept both the CTD and the ACTD. Emerging/BRIC countries are still resistant to CTD/eCTD implementation, with only China having adopted CTD/eCTD in 2011.

* When the agency requires the cover letter/application form submitted in paper version, this is still considered a paper-free submission.

AUTHORS DISCLOSURE

Authors: Rosanna Melchior, Senior Manager, Regulatory Intelligence, Thomson Reuters (France) with the collaboration of IDRAC Project Managers and consultants.

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