



eCTD in the EU

Current Status & Next Steps

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Open eCTD, March 2006, Brussels

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E&OE



Objectives

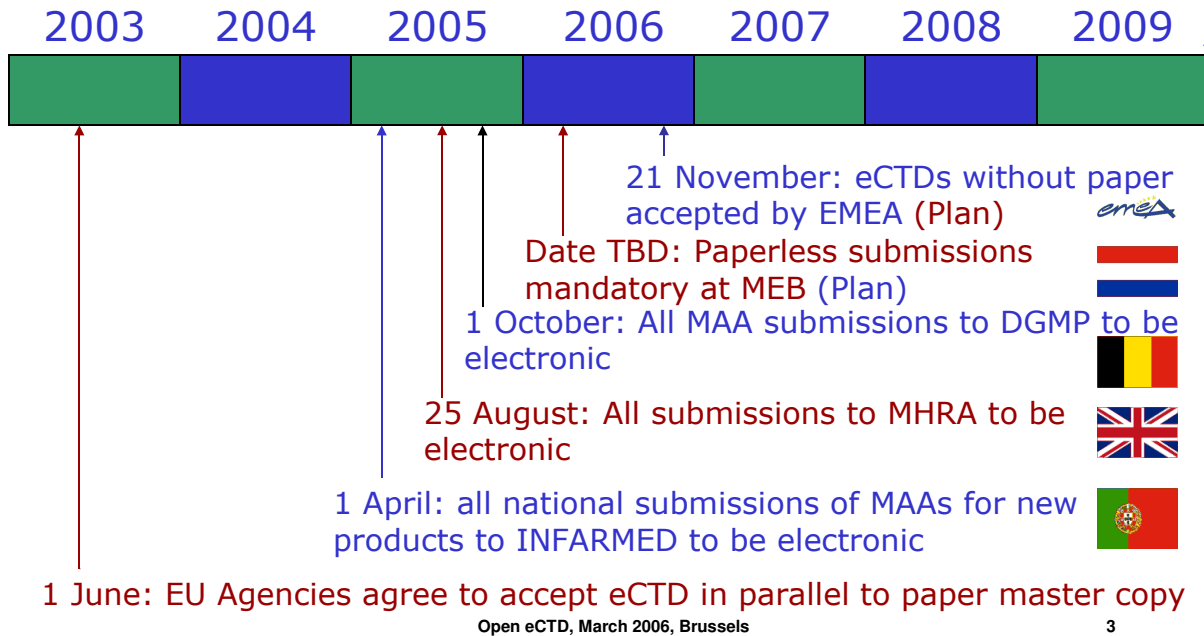
- Status of eCTD implementation
- Factors affecting implementation
- Summary and conclusions

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Implementation status

31 December: Date by which all Agencies will accept electronic-only eCTD submissions



EMA eCTD Statistics

- 28 eCTD submissions received for new applications
- Up to 50 updates to first submission

Implementation (1)

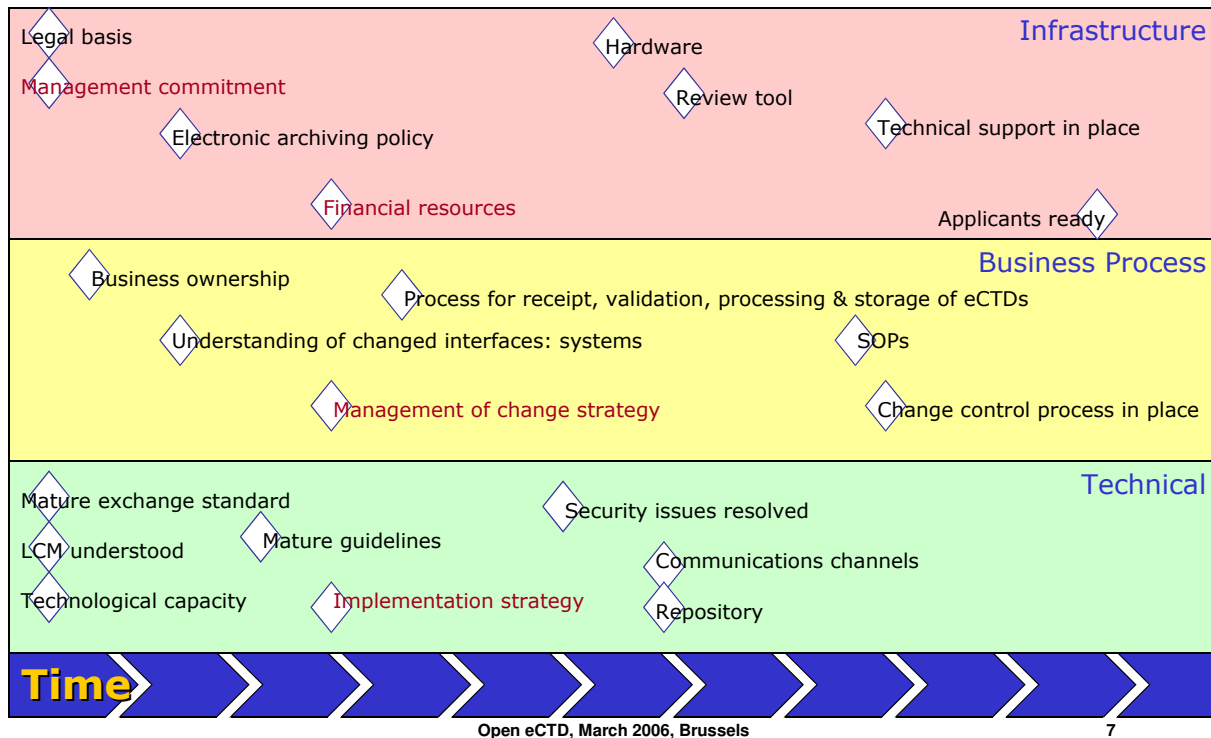
Implementation may be defined as:

- No requirement for any accompanying paper submission or paper archive copies
- Valid for all European procedures (Centralised Procedure, Decentralised / Mutual Recognition Procedure, National Procedures); and,
- Valid for all types of submissions (Marketing Authorisation applications and renewals, Type I and Type II Variations, Responses to the CLOQ, other MA related Follow-Up Measures)

Implementation (2)

- The eCTD is accepted as the 'common currency' for product MAAs.
- Electronic-only submissions are accepted
- The use of eCTD at agencies is supported by appropriate SOPs for receipt, validation, storage etc
- The use of the eCTD at agencies is supported by appropriate business processes
- The use of eCTD at agencies is supported by an appropriate review tool to enable full use of lifecycle management
- This implementation extends as far as possible to MSs implicated in the Centralised Procedure

A Sample Roadmap



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Implementation Strategies (1)

- Pan-European
 - TIGes
 - Adoption of standards
 - eCTD (EU M1)
 - eAF
 - PIM (Centralised; MRP; DCP)
 - Change control
 - EU Review System (EURS)
 - EURS Group
 - Central Repository

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Implementation Strategies (2)

- National
 - National submissions
 - National portals
 - Communication channels
 - National requirements
 - New ways of working

Preliminary experience (1)

- Overall
 - Business case clarifying
 - Process and procedural issues surfacing
- Logistical & process issues
 - Paper & electronic in parallel difficult
 - Validation: Electronic perceived as an extra step
 - CD-ROMs create security issues
 - Still excessively manual
 - Two-way electronic communication

Preliminary experience (2)

- The Review
 - Possible, but room for improvement
 - Everybody still likes paper
 - (eCTD used as search-engine)
 - Life-cycle handling is positive
 - Workplace needs to be adjusted:
 - Double/large screen, high speed, etc.
 - Room for improvement in the Review System

Specifications: Issues

- eCTD; EU Module 1; Application forms
 - Stability
 - eCTD currently under review at M2
 - Module 1 & application forms just issued
 - Uniformity of implementation
 - Clarity
 - Ambiguity
 - What you see is what I see
 - Maturity
 - Including complementary guidelines

Issues (1)

- Lifecycle management
- Review environment
- Archiving
- Communication channel
- Appropriate repository
- Review Tool

Issues (2)

- Clear architectural and operating guidance
- Security
- Semantic interoperability with other EU systems
- Technical support
- Change control processes

Issues (3)

- Management commitment
- Sufficient financial resources
- Business ownership
- An established Business Process for receipt, validation, processing & storage of eCTDs, supported by SOPs.
- Buy-in by all stakeholders
- Pharmaceutical company creation and submission of eCTDs as standard format
- No legal basis to make mandatory

Summary

- The European environment is a complex one in which to introduce new systems and processes
- After a slow start, implementation of electronic submission (and thence, the eCTD) is gaining momentum
- Implementation of the eCTD involves reviewing and (in many cases) re-engineering processes
- Experience is clarifying expected issues and highlighting new ones

Conclusions

- There is a clear commitment to the 31 December 2009 target date
- Other factors (e.g. BPR) mean that this is in fact a backstop date
- Implementation timetables are not uniform
- Implementation of the eCTD is a major challenge
 - Requires all stakeholders to work together
 - Requires harmonisation within the EU

Final slide

Further information:

- <http://www.emea.eu.int>
- <http://www.pim.emea.eu.int>
- <http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm>
- <http://esubmission.emea.eu.int>

Thank you for your attention

Acknowledgements & thanks:

- EU Regulators