



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



Making Medicines Affordable

eSubmission

London, 16 November 2009

**European Generic Medicines Association
(EGA)**

eCTD only

■ eCTD only applications by end 2009

- Increase in acceptance of eCTD by NCA's
 - Overview of NCA's accepting "eCTD only" desired
 - Overview NCA's accepting eCTD only?
 - Overview of acceptance per application type (new, variation, renewal, etc)?
 - Overview of requirements for paper documentation -> i.e. original signed cover letter, application forms?
 - By now NCA's had to be ready
Industry should be able submit eCTD only by 2009
-

Implementation of eCTD

■ Actual implementation of eCTD

- Harmonisation across EU on mandatory eCTD
Some MS implemented requirement for eCTD already in local law
- Per procedure discussion (CP/MRP/DCP/nat)
 - CP/MRP/DCP discussion on mandatory eCTD
 - National out of scope (for now)
- Internal check EGA ongoing, issue for SME



Improvements on business requirements eCTD

- National translations
 - For new applications the national translation phase out-of-scope
 - For new variation regulation, translations required with submission?
 - In practise NCA's do not want translations in eCTD format
 - Validation phase
 - National requirements MRP/DCP, variations and renewals
-

Future business model

- **Next Major Version of eCTD**
Clear roadmap of eCTD NMV in EU
 - **Central Repository**
 - Inclusion MRP/DCP
 - Still country specific portals (f.e. variations)
 - **Electronic Application Form**
Clear roadmap for implementation
-