



e-submission

CMD-h meeting with representatives of
Interested Parties

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eCTD Implementation

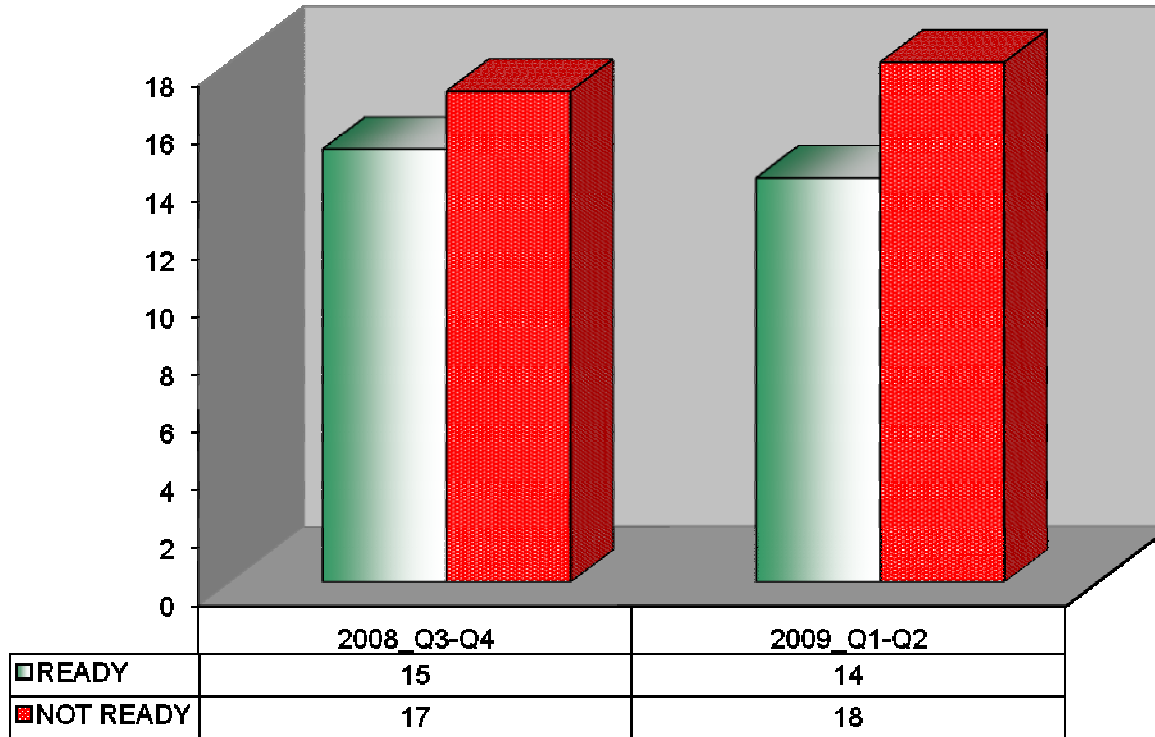


HMA meeting (February 2005) –

- Commitment that at the **end of 2009** the European Medicines Regulatory Network will be ready to accept “paperless applications” for MAs in **eCTD format** by that date.
- Paperless applications mean without paper except for documents where a signature is required.
- NCA would therefore need to have the infrastructure and the processes in place to handle the applications in eCTD format efficiently.

Progress in eCTD implementation has been slow.

Are authorities ready for management and evaluation of MA applications in electronic format only?



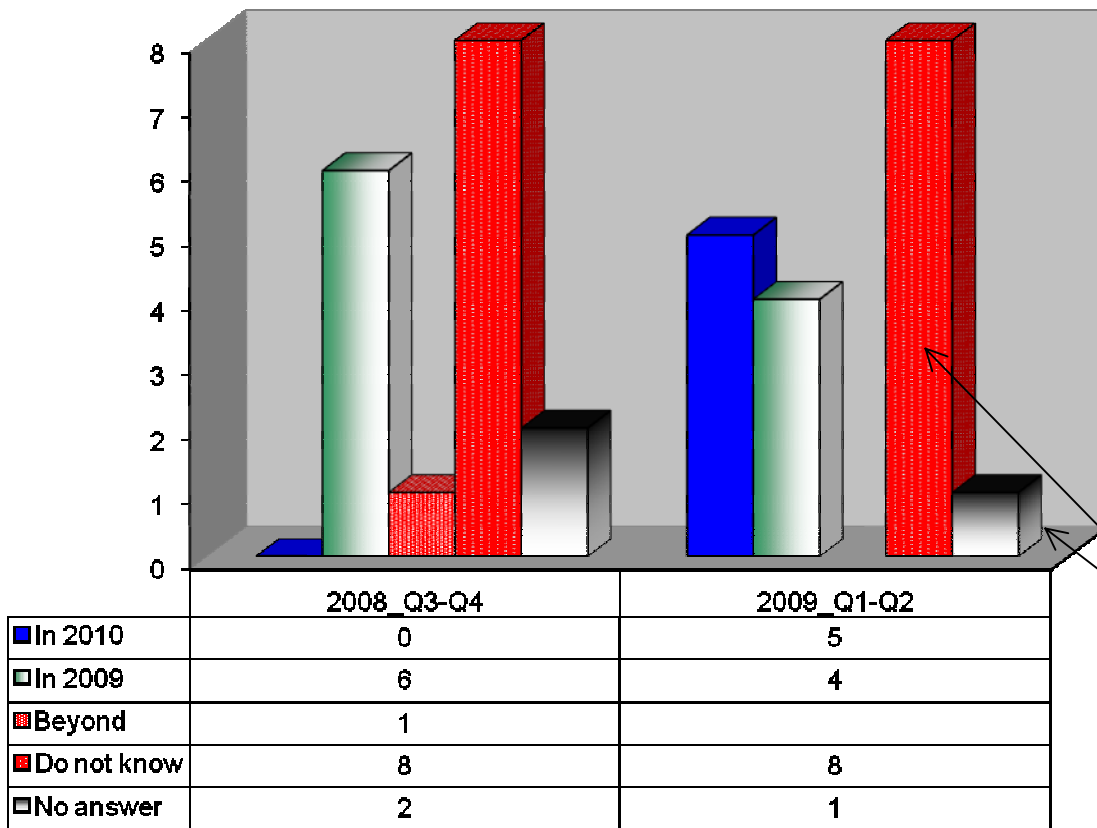
➤ 14 of 32 are ready

➤ 18 of 32 are not yet ready

No progress...

Results from TIGes eSubmissions survey Q1-2 2009

When do the not yet ready authorities plan to be ready for applications in electronic format only?



- Another 4 NCAs plan to be ready in 2009
- Another 5 NCAs plan to be ready in 2010
- still leaves 9 NCAs that don't know yet

Only 18 authorities seem to meet the target of 2009 set at HMA in 2005 !!

To promote eCTD ...



Roadmap, addressing the following points with concrete timelines (*under discussion*):

- that some identified NCAs are accepting eCTDs and NeeS as an electronic form, paperless
- that some identified NCAs are not yet prepared but will meet the target within a concrete timeline
- that all NCAs have an review tool implemented by 1 January 2010.
- that from 1 January 2010, eCTD is highly recommended within MRP/DCP, NeeS is still accepted
- Under discussion: that from a certain timepoint onwards eCTD is mandatory for e-submissions within MRP/DCP for human MPs.

e-submission requirements



The electronic submission should be provided on CD (or preferably on DVD if not fitted into one CD) unless otherwise stated. The application form and cover letter should always be submitted in signed paper original, unless otherwise stated by the Member State.

The Product Information should always be in QRD/CMD(h) template, (see the CMD(h) Annotated QRD template for MR/DC). Response documents submitted during the MR/DC procedure should comply with the CMD(h) recommendations “Application Documents” (http://www.hma.eu/uploads/media/response_ctd.pdf) and for eCTDs also with the EU Module 1 Specification V1.2.1 (see http://www.hma.eu/uploads/media/response_ctd.pdf).

Table 1. Electronic submission strongly recommended instead of paper or with only some modules additionally in paper

Documentation	AT	BE	BG	CY	CZ	DK	DE	EE	EL	ES	FI	FR	HU	IT
Module 1-5 electronic only (No additional paper)	-	1	-	-	-	-	-	-	-	1,7,8,11,13	-	-	-	-
Module 1-5 electronic with additional paper for Module 1 *	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Module 1-5 electronic with additional paper for Module 1-2*	1	-	-	-	-	-	-	-	-	-	-	-	1 ^{7,8}	-
Module 1-5 electronic with additional paper for Module 1-3 *	-	-	-	1	1 ^{6,12}	-	-	-	3	-	-	-	-	-
Response Documents electronic only (No additional paper)	1	1	-	-	-	-	-	1 ⁶	1 ¹	1,7,8,13	-	-	1 ^{7,8}	-

Requirements on eSubmissions for New Applications within MRP, DCP or national procedures

CMDh/083

Hurdles for eCTD in MRP/DCP



eCTD for MRP/DCP should be encouraged, but problems with

- „additional national requirements“
 - o Discussion at the HMA to revisit the national requirements and reduce them as much as possible
- eCTD – currently not mandatory in MRP/DCP
 - o EMEA implementation strategy: eCTD mandatory from 1 Jan. 2010 for all electronic-only submissions for all applications (new and existing) and all submission types.
 - o eCTD mandatory for MRP/DCP????
- National translations?
 - o To be handled outside the eCTD
 - Supported by HMA /CMD-h



Existing guidelines & BPG



Updates of the existing guidance should be pragmatic and simple.

- Clarification on some documents which can be handled outside of the eCTD
 - o This would lead to a tremendous reduction of complexity within the process of managing eCTD sequences
 - o Still all advantages of a dossier lifecycle management by means of eCTD would still be kept.

- Specific validation documents
- Responses
- All e-mails
- National translations



Flexibility is still needed – request from industry!

BPG on the use of eCTD in MRP/DCP



Cooperation between

- eCTD Interlinking group & TIGes
- CMD-h & NTA



Ongoing activity

- Update of the BPG – taking into consideration all comments received
 - Clarification has to be given
 - What can be handled outside the eCTD?
 - Start of MRP rather complex
 - RUP
- Guidance for eCTD in variation procedures – in accordance with the new Variation Reg.

Central repository?



e-submission made to the RMS and all CMS – to be managed as a single, comprehensive eCTD.

- A copy of the eCTD has to be provided to each NCA involved



Wish: central repository!?!

Content provided to each NCA will be identical for all mutual stages

- Activities at pure national level (translations, transfer of ownership, ...) can be provided only to NCA concerned

Structured table – providing a history of the sequences provided to each NCA

Encouraging the use of eCTD means:



- Adapting to an international standard
- Facilitating the management of MA-dossiers
- Facilitating archiving of applications
- Reduce the use of paper
- Streamline the assessment process
- Moving toward a more efficient system.