efpia

European Federation of Pharmaceutical Industries and Associations

# e-CTD/NeeS Impact on the Centralised Procedure

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# EFPIA Position on e-Submissions

- EFPIA supports the HMA stated goal from 2005
  - "Submission of eCTD target date – eCTD is the electronic format for the marketing authorization application developed by ICH. The end of 2009 was adopted as the target date."
- Clarified to mean the use of the eCTD:
  - without paper
  - for all procedures
  - for all submission types

  if the applicant chooses to submit electronically

# Use of the eCTD in Europe

- EFPIA's experience clearly shows that the eCTD has been more successfully implemented in the CP than other procedures
- Partly due to the less complicated procedure
  - A single owner of the process
  - A single submission to the EMEA (cf. the more complex MRP/DCP)
- But is this all?

# EFPIA View on the EMEA Activities

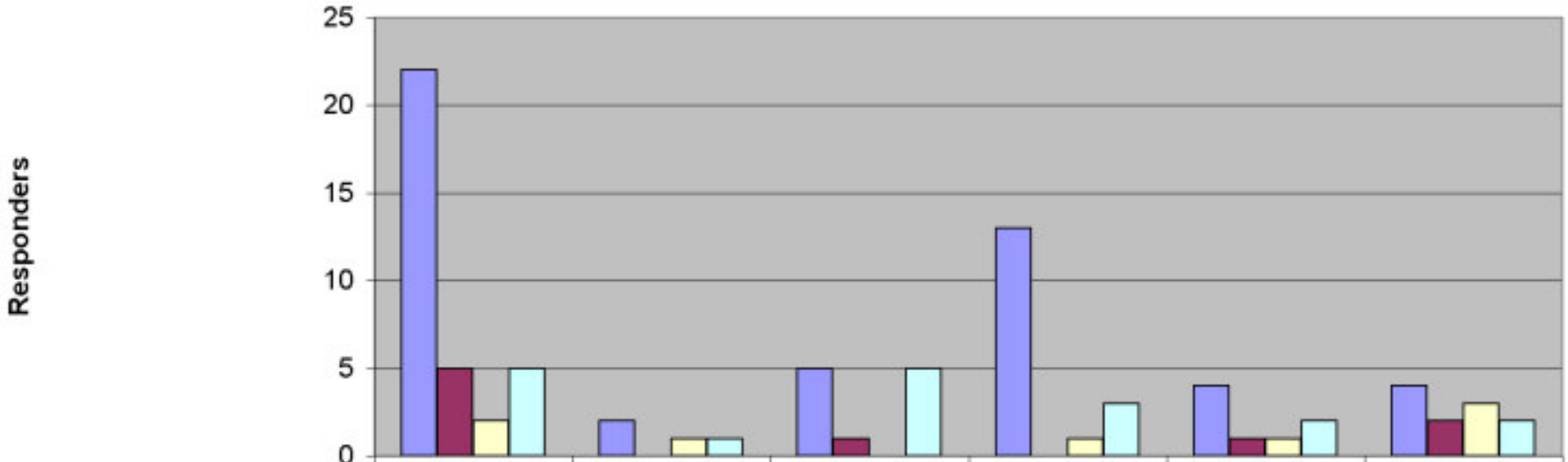
- The feedback from EFPIA companies has been very positive about the steps and actions that the EMEA has taken
- We note that this covers the full range of eCTD topics
  - The technical specification
  - A clear plan of action (the Statement of Intent)
  - Guidance for use of the eCTD, including transition via the NeeS
  - Tools for viewing the eCTD
  - Business process for use of the eCTD
  - Business support for the eCTD

# eCTD Readiness Survey

- In Summer 2008 EFPIA ran a joint survey with other EU Trade Associations (EGA, AESGP, EuropaBio) on eCTD readiness
  - 50 responses from EFPIA affiliated companies
- The EMEA Statement of Intent has clearly had an impact on EFPIA companies
  - Note: the survey was run before the update of the Statement of Intent on the mandatory use of the eCTD from Jan 2010
  - This is only likely to strengthen these findings

# Question 1

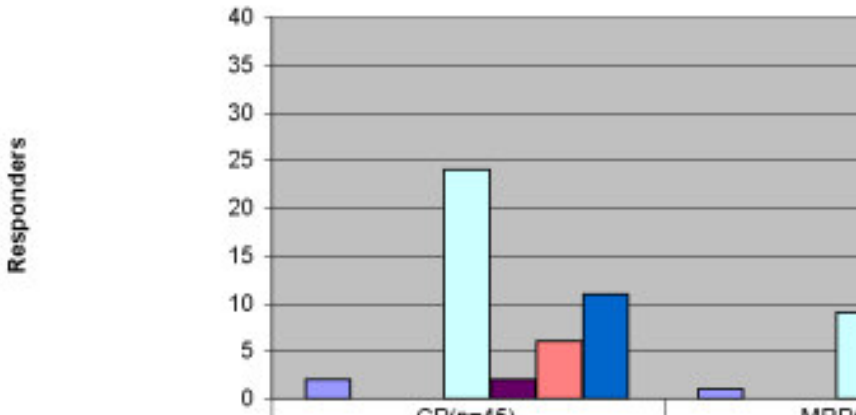
**Question 1:** **Date for company readiness to submit first eCTD in Europe? (tr=85)**




| | Already submitting (t=34) | Mid-2008 (t=4) | End-2008 (t=11) | Mid-2009 (t=17) | End-2009 (t=8) | >2009 (t=11) |
|---|---|---|---|---|---|---|
| EFPIA (n=50) [r=100%] | 22 | 2 | 5 | 13 | 4 | 4 |
| EB (n=9) [r=90%] | 5 | 0 | 1 | 0 | 1 | 2 |
| AESGP (n=8) [r=100%] | 2 | 1 | 0 | 1 | 1 | 3 |
| EGA (n=18) [r=100%] | 5 | 1 | 5 | 3 | 2 | 2 |

# Question 5

**Question 5:** **Planned Date to Switch to eCTD only**
**[Combined Values]** **(tr = 71) (by procedure)**

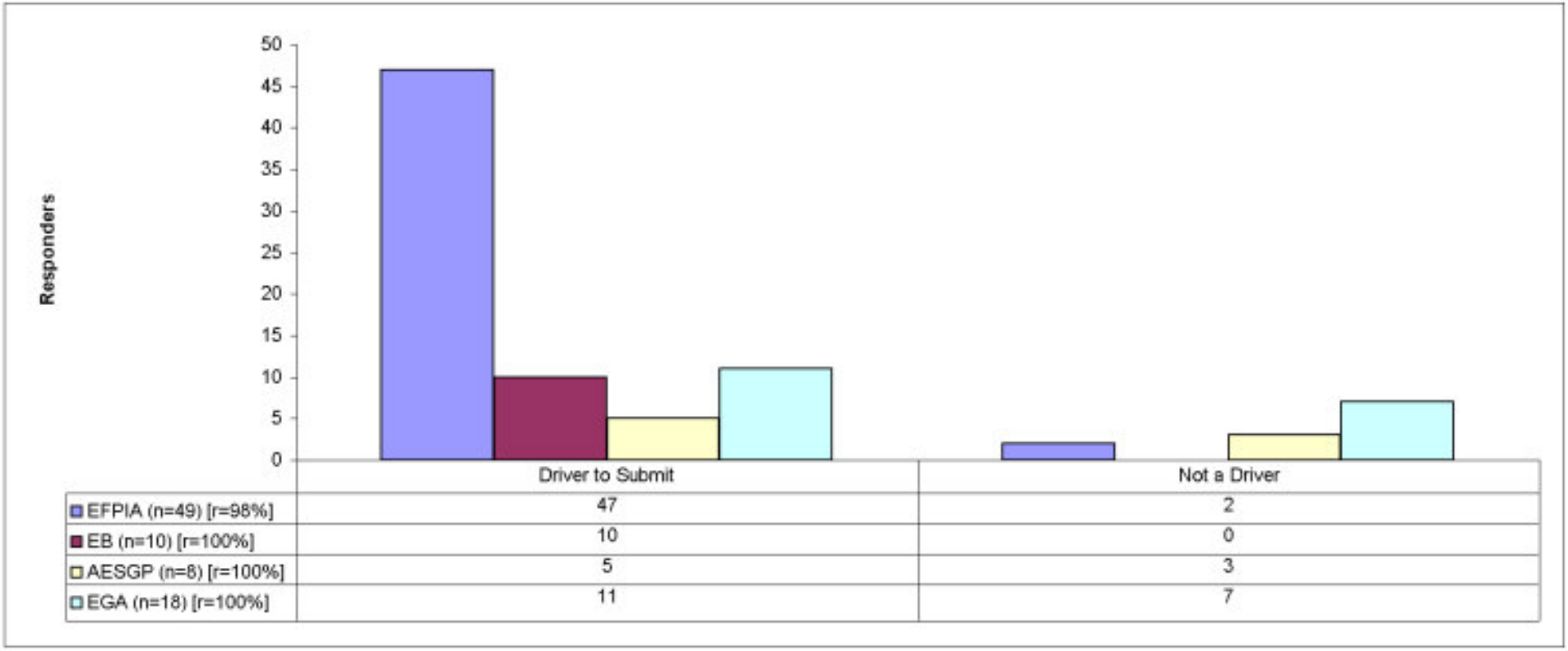



| | CP(n=45) | MRP(n=54) | DCP(n=51) | NP(n=57) |
|---|---|---|---|---|
| Already Submitted | 2 | 1 | 1 | 3 |
| Mid-2008 | 0 | 0 | 0 | 0 |
| End-2008 | 0 | 0 | 0 | 0 |
| Mid-2009 | 24 | 9 | 6 | 4 |
| End-2009 | 2 | 6 | 7 | 5 |
| > 2009 | 6 | 11 | 10 | 11 |
| Unknown | 11 | 27 | 27 | 34 |

Procedure Type

# Question 6

**Question 6:** **Is EMEA Recommendation a Driver to Submit in eCTD format (tr=85)**




| | Driver to Submit | Not a Driver |
|---|---|---|
| EFPIA (n=49) [r=98%] | 47 | 2 |
| EB (n=10) [r=100%] | 10 | 0 |
| AESGP (n=8) [r=100%] | 5 | 3 |
| EGA (n=18) [r=100%] | 11 | 7 |

# EFPIA and EMEA Collaboration

- The positive view from EFPIA is due in large part to the collaboration between EFPIA and EMEA
  - Consultation and feedback on initial Statement of Intent
  - Feedback and commenting on the practical guidance
  - Active membership of the EURS (review tool) group
  - Consultation on use of NeeS in CP
  - (Also inclusion in TIGes, Interlinking, specification development, etc. but these are not solely EMEA activities)

- Is there any more to do??

# The Vision

- The applicant can work without paper or hard media in the CP
- A system that supports
  - A portal that can be used to submit to a central repository
  - Automated submission (technical) validation
  - Distribution to the PTL and Rapp/Co-Rapp
  - A receipt message back to the applicant
  - All responses made electronically back to the applicant
- The whole procedure is tracked and managed electronically

# The Electronic Submissions Gateway (ESG)

- The implementation of an ESG will allow a fully electronic interaction
  - Allowing the elimination of any hard media (CDs, DVDs, etc.)
- EFPIA companies have participated in some of the early proof of concept testing which will help set the direction of this project and we expect to continue to participate as this moves forward
  - Companies are eagerly awaiting progress on the ESG
- When will this “go-live” for routine use?

# The Central Repository (CR)

- The completion of testing and implementation of the CR will allow the submission of a single eCTD to meet the needs of the whole of the EU
- EFPIA is observing the progress on the testing and eagerly anticipating the successful implementation of the CR
- When will this “go-live” for routine use?

# Use of Eudralink

- We need the EMEA/NCAs to consistently use Eudralink when communicating back to the applicant
  - Too many faxes and hard copy
- Really need an improved secure e-mail application (c.f. FDA)
- What plans do EMEA have in this area?

# The Challenges for 2009 and Beyond

- The new Variation regulation
  - We need to ensure that the requirements of the new variation regulation can be fully met within the eCTD
  - May need the eCTD Next Major Version to be able to fully utilise all of the changes proposed
- eCTD Next Major Version
- e-Application Forms
  - Require common forms across procedures
- Digital Signatures

# Summary

- The use of the eCTD in the CP is seen as a successful implementation project
- The success is due in large part to the good collaboration between industry (EFPIA in particular) and the EMEA
- The project has considered and integrated business and technical issues
- Fresh challenges await us so that we can move into a fully electronic Centralised Procedure with more automated processing