

EGA Survey on DCP

London, 21 June 2010

European Generic Medicines Association
(EGA)

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Scope of EGA Survey on DCP

■ Objective:

- To assess implementation of the revised DCP (January 2010)

■ Validation

- Application submitted only in 2010

■ Restarting of clock stop

- Responses to the RMS submitted only in 2010

■ National phase

- Applications finalised in 2009 and 2010

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Validation



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Results on Validation Period (1)

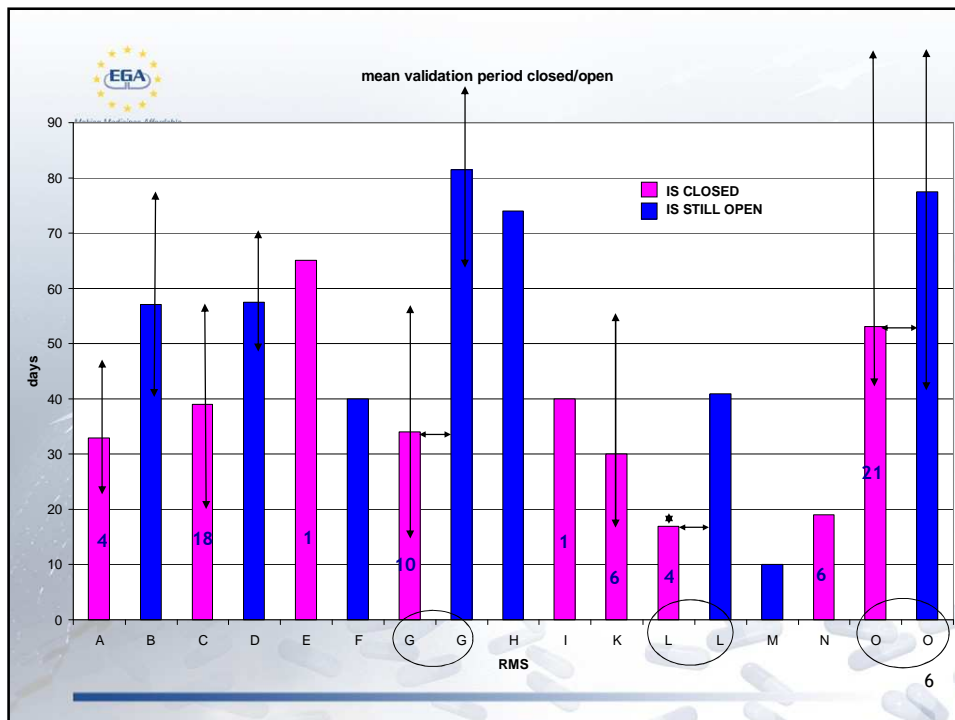
- Validation period is result of performance of both RMS/CMS and applicant
- Revised SOP supposed to reinforce the RMS role/ automatic validation and better respect of timeline
- Overall result not yet satisfactory
 - Takes much longer than in CP (14-30 days)
 - Progress in automatic validation not visible
- Duration of some validation periods relate to a very specific problem (e.g. legal basis, Ref Prod)
 - More optimal way of solving problem?

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Results on Validation Period (2)

- In the case where the RMS immediately issues proposed timetable, validation seems to go quicker
- Where information is received when the procedures are still open, these timelines look less optimal than on already closed ones

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Proposal for Improvement

- Better adherence to the CMD(h) procedural guidance
- Consider no reaction (from CMS) after 7 calendar days to be a positive reaction
- Consider whether some issues can be solved after start of the clock
- Applicants to improve the quality of their submission

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Restart of clock



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Results on Clock Stop (1)

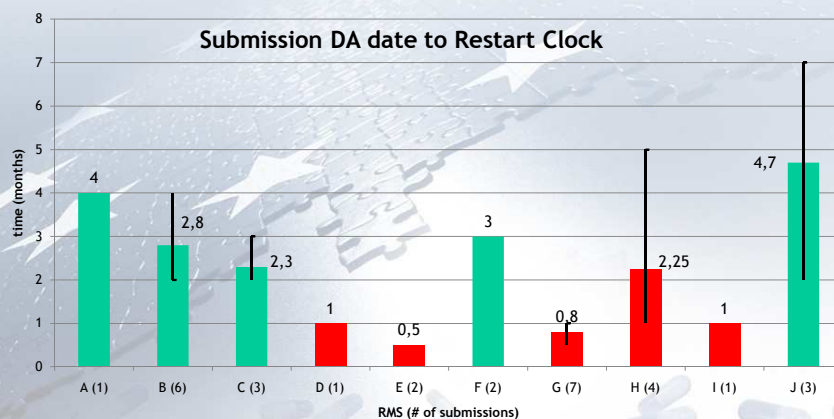
Results on Clock Stop: Feedback within 4 weeks

- Nearly 50% (22/45) of the feedback is not within 4 weeks
- Of the 22 'not within 4 weeks' 50% (11) did not give any feedback yet (2-5 months)
- Of the 10 countries concerned 8 countries do meet (partially) the 4 weeks feedback period

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Time to restart clock



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Results on Clock Stop (2)

- Restart ranges from 1 week after submission of draft answers (DA) to no feedback at all after 5 months
- Some countries do not assess DA unless there are serious risks to public health concerns
 - quick restarts (1 month or less at average).
- Some countries do respond within 4 weeks, but schedule the restart 1-3 months later
- Some cases (4x, different countries) of after giving feedback restart date is still awaited

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Conclusion and Proposal for Improvement

- **Mixed picture after 5 months of experience and room for improvement**
 - Feedback on DA within 4 weeks in combination with quick restart of the clock
- **Point for consideration:**
 - no assessment of DA by RMS unless there are serious risks to public health concerns

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National phase



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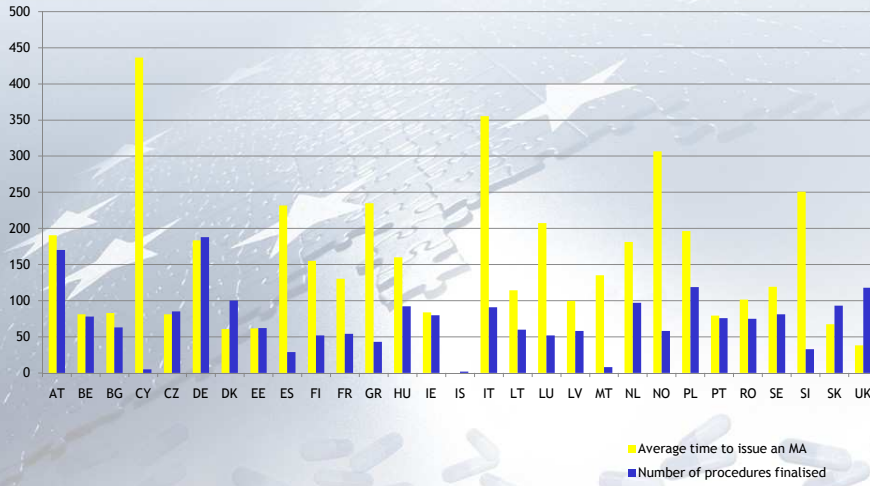
Results on National Phase

- **Results based on 2864 national procedures finalised in 2009 and 2010**
 - Extremely long procedures (going far beyond the average for each MS) not taken into consideration
 - On-going procedures not taken into consideration

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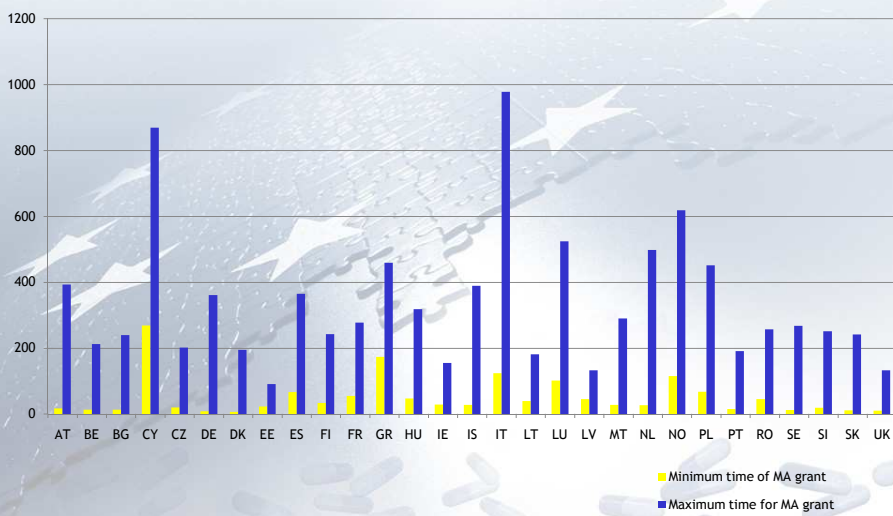
Time between procedure close and MA grant



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Variance by country for MA grant times



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Discussion of data

- 12 MS are showing a tendency or slight tendency to decrease average MA grant times between 2009 and 2010
- For other MSs, there was either no trend to decrease or large variability so no overall conclusion could be drawn

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Submission of translation

- Survey covered a submission of translation within 5 days
 - Replies not fully complete, no statistical analysis presented
 - General feedback- no correlation between timely/late submission and granting of MA
 - Reason for submission longer than 5 days
 - Patent still in place; less time pressure
- Possible agreement?
 - If translation within 5 days- to be treated as priority for granting MA within 30 days



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Conclusions

- **Most countries show a large variability between min and max times for MA grant**
 - Possible reasons to be analysed by both industry and authorities
- **Delay in national phase**
 - Strong disadvantage of the DCP, a weak point which needs improvement
- **Translation versus granting of MA**
 - Good quality translation submitted within 5 days- to be treated by the NAC as priority to grant MA within 30 days
 - EGA to ask applicants to comment on number of questions that are received on translations to validate if the quality of translations is a major issue.