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EGA Survey on DCP

London, 20 June 2011

**European Generic Medicines Association
(EGA)**

Scope of EGA Survey on DCP

■ Objective:

- To assess adherence to the SOP for DCP (January 2010)

■ Validation

- Applications submitted first half of 2010 vs second half 2010 up until June 2011

■ Restarting of clock stop

- Responses to the RMS submitted in first half 2010 vs second half 2010 up until June 2011

■ National phase

- Applications finalised in first half 2010 vs second half 2010 up to June 2011



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Validation



Results on Validation Period (1)

- Validation period is result of performance of both RMS/CMS and applicant
- SOP is supposed to intend to reinforce the RMS role/ automatic validation and better respect of timeline
- Results:
 - June 2010: mean validation period 61 days
 - June 2011: mean validation period 58 days
 - Improvement of about 5 %, but more then four times exceeding standard

Results on Validation Period (2)

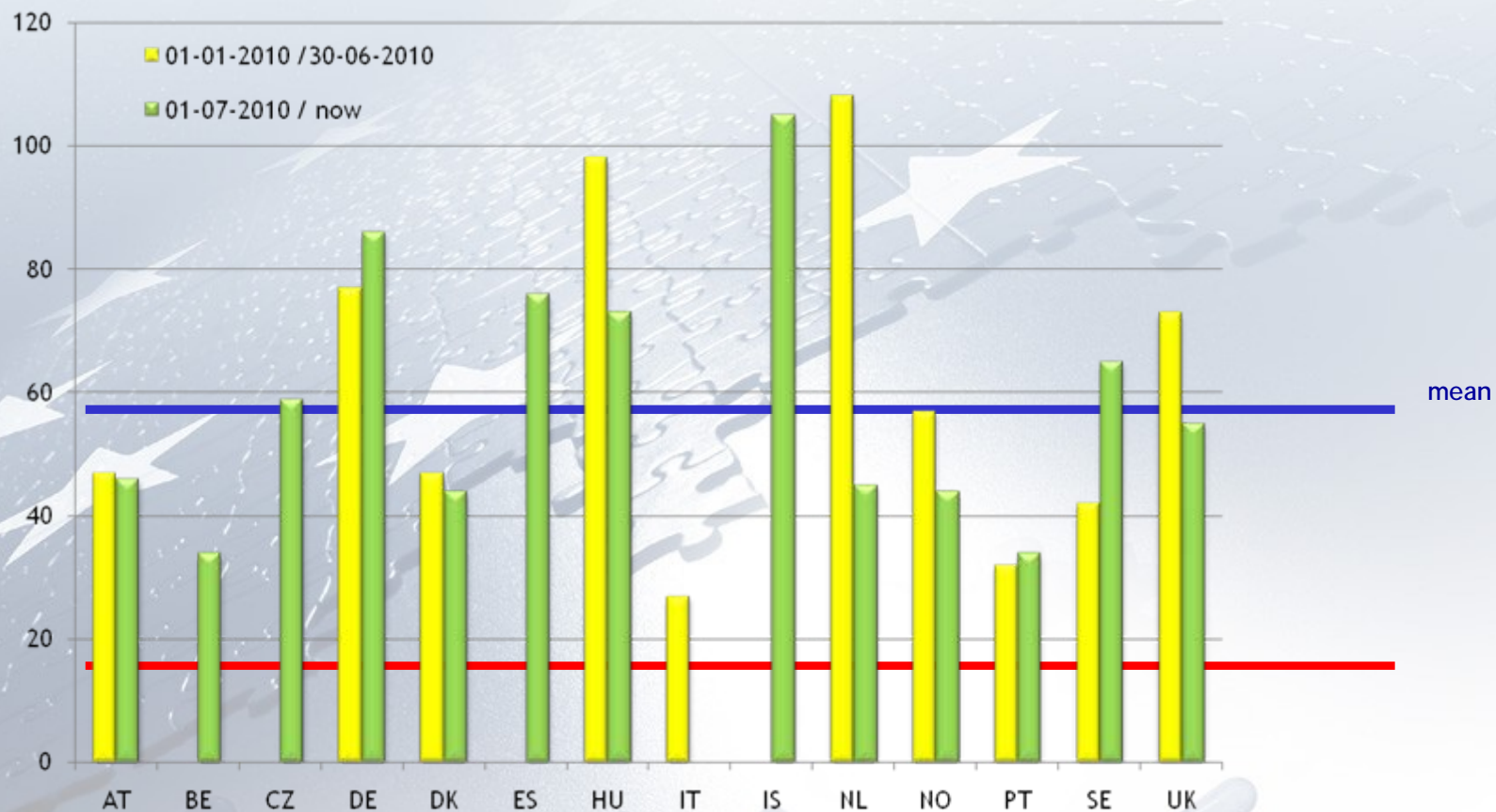
■ Perception of industry

- Upon receipt automatically CTS is turned to invalid, but validation is not immediately started
 - Often first invalidations come in three weeks after submission
- Number of national requirement is still high and changing
- Number of invalidations related to e-topics is increasing



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Mean validation periods in days





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Proposal for Improvement

- Stick to CMD(h) procedural guidance
- Define which invalidations need to be solved before start of procedure and which need to be solved latest in clockstop
- No active invalidation with reasons at day 14 after submission leads to automatic acceptance
- Applicants to improve the quality of their submission



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Restart of clock

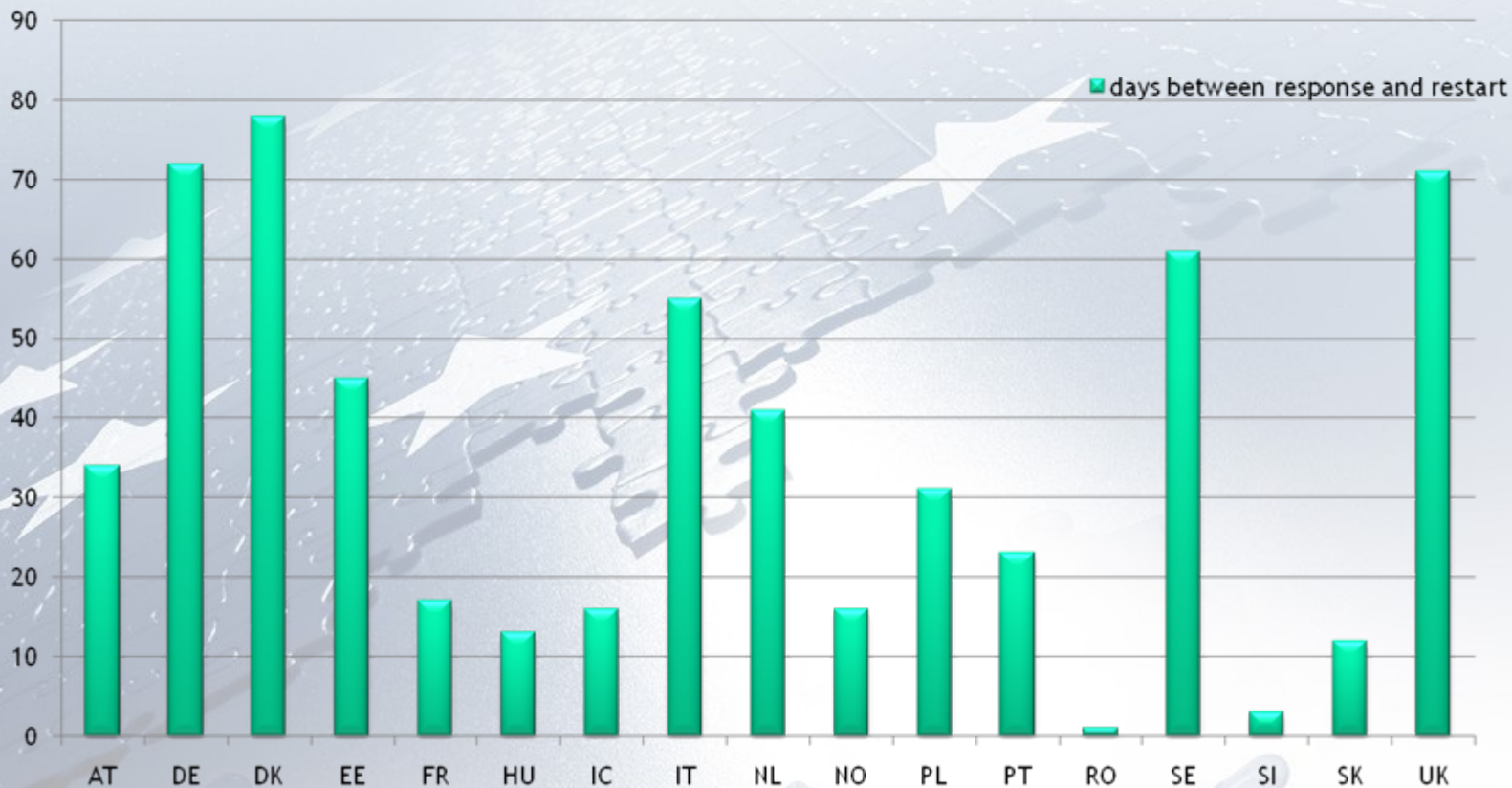




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Results on Clock Stop

days between response and restart





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Results on Clock Stop (1)

■ Results on Clock Stop: Feedback within 4 weeks

- Overall 50 % of the cases the feedback/restart is within 4 weeks
 - Improvement compared to last year (30 %)
- The range from 1 day to 234 days
 - Additionally still many cases without any feedback to date
- It seems that smaller RMS are better able to keep timelines

Suggestions for improvement

- Industry to communicate very clearly when responses will be submitted
- RMS to consider not to assess in the AR the points for consideration as raised by CMS but focus on risks to public health concerns



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National phase





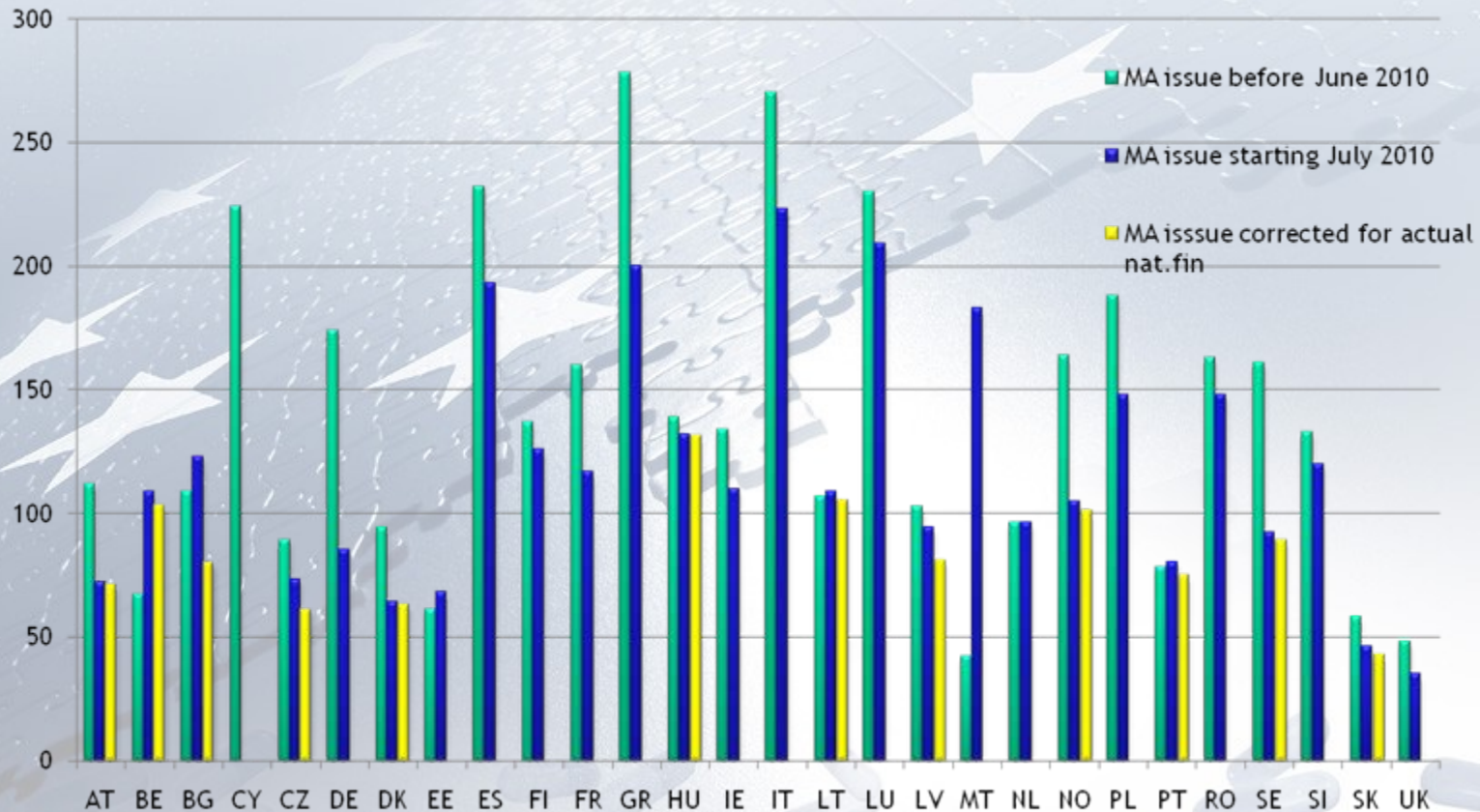
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Results on National Phase

■ Results based on 3693 national procedures for which DCP/MRP closed in 2010 and 2011

- Measured between 01-01-2010 and 30-06-2010 (1939 MA issued)
- Measured between 01-07-2010 and 16-06-2011 (837 MA issued, 917 still open)
- Extremely long procedures (going far beyond the average for each MS) not taken into consideration

Time between procedure close and MA grant





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Observation

- Overall there is an improvement of 15 %, (117 vs 137 days) however this does not take the 917 still open applications into consideration
- Correction of measurement for actual text submission date, if not within 5 days after closure, has in most countries low impact on overall results
- There is still quite some variety within one NCA with respect to MA issue timelines

Suggestions for improvement

- For industry to keep submitting the translations (of good quality) in time
 - Priority treatment for finalisation in case of timely submission
- For authorities to consider the model to issue MA without national translation (especially when no immediate launch is planned)
- For authorities who are making big improvements to share how this was realised

Overall conclusion with focus on timelines only

- If DCP timelines are compared with CP, DCP can improve timelines by
 - Being more flexible in the validation phase
 - Being more strict with restart of the clock
 - Sticking to timelines for national MA issue