



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



SOP on Decentralised Procedure

London, 16 November 2009

European Generic Medicines Association
(EGA)

Issues (1):

■ Validation phase:

- Delay's up to 2-3 months
- RMS' allow CMS' validation questions after Day 14

■ Clock stop:

- No clear & fixed time schedule
 - Restart of the Clock is an issue. RMS Assessment Draft Response takes one month or even longer.
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Issues (2):

■ Assessment step II:

- After Day 145 status is clear (minors/majors). However, still procedural steps to take.

■ National phase:

- Even if the MAA submits PIL/SmPC in time (within 5 days) significant delays (up to 12 months) in a number of countries
 - Requirements for national contacts in some countries (e.g. SK, RO)
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EGA proposal to improve the DCP further (1)

- **Validation Phase:**
 - RMS' are requested to safeguard the 14 days validation period.



EGA proposal to improve the DCP further(2)

■ Clock stop & Assessment step II:

- Applicant dispatches responses in parallel to RMS & CMS (in principle within 90 days) > day -7 for Day 106
- Validation period of 7 days
- Day 106 restart clock
- RMS dispatches DAR at Day 150
- CMS final comments Day 175
- Applicant responds latest Day 180
- No consensus at Day 195: communication RMS with applicant
- DCP closes at Day 210



EGA proposal to improve the DCP further(3)



Pro's:

- Structures and simplifies the process (Clock-off, after Day 145, Breakout sessions)
- Covers issues restart Clock
- Respects time needed for assessment by RMS & CMS



EGA proposal to improve the DCP further(4)

■ National Phase:

- MS' are requested to respect the 30 days MA granting period. MAA to submit PIL/SmPC within 5 days!
- MS' are asked to accept EU contacts