



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



Member States' resources in the MRP/DCP

London, 16 November 2009

European Generic Medicines Association
(EGA)

Feedback on slot booking situation

■ General comments:

- Not all MS act as RMS and capacity for each MS not clear
- Little transparency in 'cancellation' slots that become available. There are companies with dossiers ready to submit and no RMS who could take advantage of cancellations.
- 'Short notice' i.e. less than 6 months slots not available
- Major issues in starting RUP or MRP even when there has been prior agreement to strategy from RMS

Feedback on slot booking situation

- Countries with 6 month advance booking system
 - Many companies reporting not able to get any slots at all in any of the countries (Dk, NI, Se), criteria for allocation not clear.
 - Last option to bring forward a slot if development runs more smoothly
 - Timings of requests for each country 'not compatible'; harmonised request date would be better.

Feedback on slot booking situation

- Countries with longer slot booking systems
 - Slots more available, but still companies reporting dossiers with no slots



Feedback on slot booking situation

- **Proposed solution to both Industry and MS issues with slot cancellation**
 - Central register of dossiers ready for submission or needing slots by therapeutic class in date order of dossier availability. MS can consult this and take the first dossier available in the therapeutic class when they have a cancellation and approach the applicant.

Feedback on slot booking situation

■ EU booking form

- Feedback is positive although for those countries where we are booking a long time in advance often the requested information is not yet defined.

■ Parallel assessments

- Mixed feedback from industry, situation seems to fluctuate, some companies seeing a small improvement, others not. Overall impression, no change.