



Making Medicines Affordable

Member States' Resources in the MRP/DCP

London, 21 June 2010

European Generic Medicines Association
(EGA)

Feedback on Slot Booking Situation

- **EU booking form**
 - Feedback is positive although often for countries where we book a long time ahead the requested information is not yet defined
 - More slots available, but still companies report dossiers with no slots
 - Data exclusivity 10/6 years still has an impact on choice of RMS



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Reasons for Slot Cancellation

- **Delay/ issue in development**
- **Mergers/ acquisitions**
 - Duplication of projects
- **Market changes**
 - Tendering/ price cut
- **Double booking**
 - Difference in systems/ deadlines for booking in various MS- no feedback from one MS before deadline in a second MS
 - Pressure on RA departments to submit when dossier is ready



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Possible Solutions

- **Compulsory re-confirmation of slot by the applicant 3 months in advance**
 - If no communication, booking fees/ slot lost
- **Some evidence of the project being advanced**
 - but in line with the reality of development
- **Timings of requests for each country 'more compatible' and harmonised**



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Possible Solutions

■ Mixed model

- still booking partially, but moving into free system for upcoming applications

■ More visibility on available slots (including therapeutic class)

- “Eurostar visibility” on available slots
- One database regularly updated by the MSs would help to get an overview
 - Instead of “central booking” as suggested in the past

Possible Solutions

- **More flexible use of resources at NCA**
 - If resources unexpectedly available, re-allocation to some other activities where there is a significant delay
- **Parallel assessments**
 - Still mixed feedback from the industry, situation seems to fluctuate, some companies seeing a small improvement, others not
 - Overall impression, still no significant change