



Making Medicines Affordable

Optimisation of the MA process- issue of slot booking



EGA commitment regarding slot booking

- The EGA members fully understand the necessity to guarantee the stability of the MA system including financial income for the Competent Authorities (CA)
- The EGA members commit themselves to adhering to an agreed common policy regarding slot booking



Making Medicines Affordable

EGA commitment

- The EGA members will endeavour to avoid any activity which has a negative impact on the resources of the Competent Authorities
- Companies commit to inform the Authorities in advance about changes in their submission plans
 - 3 months in advance gives a chance to use the slot



Support for slot booking fees

- **Partial compensation for blocked but unused resources of the CA**
 - The loss of 'booking fee' if the slot is not used without the Authorities being informed at least three months in advance
 - The booking fees will be credited against the application fee provided the application is received within the agreed time slot.
 - The fees will not be lost in case of agreement with the Authorities in advance to postpone the application.

Constructive solutions proposed by the EGA

- To improve the visibility of available slots by creation of a regularly updated Central Platform
- Allocation of a slot should take place no more than six months in advance
- Faster feedback (2 weeks) on a positive/negative decision to avoid a sequential booking in another MS



Outcome of commitments

Consequences

- More responsibilities and discipline on applicant's side
- CA effort to improve the visibility of slots and faster feedback



Benefit

- Slots available when needed
- More opportunities for last minute submission
- More predictable system
- Less cancelations

