



Focus Group Meeting on Fluoroquinolones:

Liisa Kaartinen/Gerard Moulin

EMA, 12 October 2006, London

Conclusions

- This focus group meeting can be considered to be successful
 - Good discussions
 - Common goal is agreed on maintaining the efficacy although some reservation has been raised



Conclusions

- 
- A vertical blue bar with five yellow stars, positioned on the left side of the slide.
- Voluntary actions to include prudent use guidance in SPCs is preferred to referrals
 - This is only one of the actions that is needed
 - Prudent use should be promoted
 - Member States willing to promote prudent use and implement precautionary phrases in product literature → active communication (MSs, professional and other associations, ...)

Conclusions

- 
- A vertical blue bar with five yellow stars, positioned on the left side of the slide.
- Some Member States have already implemented measures.
 - Other areas that need further work:
 - dosage regimens of FQs should be carefully determined on the basis of PK/PD properties

Conclusions – technical aspects

- 
- A vertical blue bar with five yellow stars, positioned to the left of the list.
- Overall well balanced document.
 - Positive to be able to revise and comment on the document
 - Terminology to be addressed; fluoroquinolones vs quinolones and breakpoints.
 - Some technical divergencies:
 - Resistance mechanisms
 - Salmonella infections
 - Campylobacter
 - Animal consequences
 - Literature references

Steps forward

SPC prudent use guidance

- Consultation of all industry
- Consultation of all HMA-V once the wording has been agreed with industry
- Other measures need to be considered if voluntary actions not efficacious; review of progress after one year



Thank you!