EGGVP - European Group for Generic Veterinary Products info@eggvp.org www.eggvp.org













# Advice on the impact on the use of antibiotics in animals

Stakeholders meeting London, 28 February 2014



### Q 2 – Advice on classes or groups of antibiotics

WHO and OIE lists:

- Positive from an harmonization standpoint
- Limitations at user level
  - Exceptional use of AMs (human & vet conditions)
  - Species, indications, admin route not considered
- Caution in interpretation, basis for reflexion, updates
- Flexibility for vets
- Suggestion: to emphasize
  - Empirical use (optimization of antibiotic therapy regime)
  - Promote diagnosis and sensitivity testing

Some examples at National level



## Q 3 – Impact of new classes of vet ABs on human health

- Innovation on the vet side yes, but never at expenses of human health
- Considerations:
  - Possible transmission of resistant strains of bacteria (e.g. ESBL strains)
  - Low incidence of transmission of resistance genes, strains in human medicine differ from strains in the veterinary field (e.g. species-specific receptor sites for bacteriophages in Staphylococcus)



#### Q 3.1 – Lack of veterinary medicines

- MRSP pyoderma and ESBL infections (e.g. UTI) in dogs > cats
- Very few authorizations in horses, off-label use (e.g. gentamicin and amikacin)
- In general, less availability for minor species
- No urgent need for developing new antibiotics for FPAs. TT of most important bacterial diseases is covered, and multidrug-resistance is rare in EU.



Q 3.2 – Off-label use

**DIRECTIVE 2001/82/EC:** "The use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics, including the misuse and serious abuse of the product"

EGGVP promotes **responsible use of antimicrobials according to the SPC** approved by responsible national and European authorities.



### Q 3.3 – Use of human ABs in animals

#### Aware for companion animals and horses

Antibiotic	Condition	Species
ciprofloxacin	pyoderma/UTI	dogs > cats
metronidazole	chronic diarrhoea	dogs > cats
cefazolin	Respiratory, joint, bone infection	dogs > cats
aminoglycosides	Gram (-) pathogens	horses
rifampicin	Rhodococcus equi	horses
azythromycin and clarithromycin	respiratory infections	pets and horses

Not aware for FPAs (expensive, no MRLs)



Q 3.4 - Q 3.5 - Q 3.6

Q 3.4: Aware of MAs refused or withdrawn solely or partly due to public health risks of AMR? *Not aware* 

Q 3.5: Impact of requirements in VICH GL27 and 36 on the development of new VMPs? *Positive in terms of transparency and predictability. High level of data required might negatively impact investments for the development of new VMPs.* 

Q 3.6: Aware of product modifications with the goal to reduce the risk for emergence of AMR? *Da Volterra (human, private funded), TRAIN-ASAP (human and vet, FP7 funded)* 



#### Q4 – Risk Mitigation

There is a need to treat animals.

#### "Hygia pecoris, salus populi"

EU animal health sector as reference worldwide

Other sectors / regions to follow to obtain successful results

Continuous and updated information is essential to guide risk management and to determine the effect of possible interventions



#### Q 4.1 – Animal diseases for which use of CIAs is essential

Disease	Specie
MRSP deep pyoderma	dogs
Osteomielytis	dogs
ESBL complicated UTI	dogs
ESBL peritonitis	horses



# Q 4. 2 and 4.3– Impact risk mitigation measures in animals

Antimicrobial	Risk mitigation measures	Outcome	
Cephalosporins	Self-ban of third generation cephalosporins in Danish pig production	Reduction of ESBLs in slaughter pigs	
		Increase meat inspection lesions	



#### Q 4.4– Intervention measures to reduce use of CIAs in animals

Core part of AMR control: Responsible use.

EPRUMA motto:

"as little as possible, as much as necessary"

- Education and communication
- Monitoring use and resistance
- Optimization of therapy regimes
- Guidelines, formularies
- Good farming practices



#### Q 4.4– Intervention measures to reduce use of CIAs in animals (II)

- 1. Innovation on the vet side yes, but never at expenses of human health
- 2. To use existing classes of antimicrobials strategically, supported by sensitivity testing
  - rotation of old molecules
  - substances with no more value at human/vet side to be used reciprocally
- 3. Pragmatic solution for old molecules



#### Q 4.5– Impact of MA exclusivity expiry on sales and use

- Price erosion should not influence vet prescription patterns.
- Quality, safety and effectiveness are the same at generic and originator
- Competitive environment provided by generics can positively influence development of new drugs/formulations with improved pharmacokinetic properties.
- Affordability facilitates appropriate use