

Antimicrobial resistance: the view of the EGGVP

London, 15 September 2011

Key actors

Vets

Farmers, animal keepers

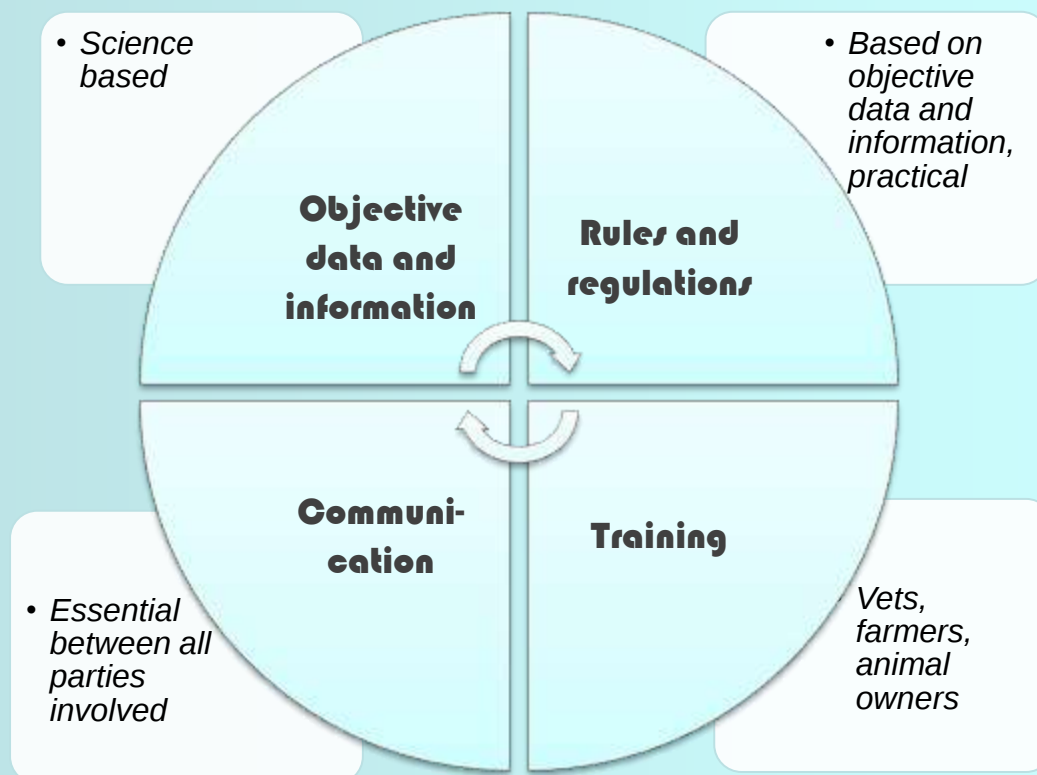
Distributors

Industry

Competent authorities / Regulators

Responsible use is the key step to fight
against resistance

Key actions



EGGVP to **contribute actively and responsively** to fight AMR

Objective data and information

Monitoring. Surveillance. Reporting

- Objective monitoring per **active ingredient**:
 - sales/consumption data
 - resistance
- Approaches harmonized and well coordinated
- Post marketing surveillance of major importance, but also post-authorisation actions
- **Global approach**
 - Covering the whole chain
 - International

Rules and Regulations

- Key for industry

Predictability

Enforcement

Harmonization

- **Control** mechanisms and monitoring tools to prevent abusive use (prescription...)

Increase availability of AB's

- If no risk of AMR: **automatic expand** MA existing products to the rest of MS
- Innovation, development of new antimicrobials or new convenient formulations for existing products.

Motivate industry:

- New legislative proposals – additional data protection (proportionality)
- Practicality
- Not to include restrictions in general
- European Reference product principle

Efficacy

- EMEA/CVMP/627/01 not suitable for control of therapeutic efficacy
- **New GI** has commenced. EGGVP is working on it.

Main concerns:

- distinguish between new API's and well established use compounds.
- PK/PD modelling this is the future.

Training

Training of the vets, farmers, animal owners; **the vets are key** in this process.

- Training of vets (practitioners and students) on responsible use, off-label use / cascade.
- Vets, farmers, animal owners: Establish mechanisms to ensure **antibiotics only on prescription.**
- Record use of drugs.
- Farmers / animal owners respect prescription, follow instructions for correct use.
- Antibacterial formularies per geographic region.

Communication

- Better communication and collaboration between authorities and industry: **improve understanding** from both sides
 - overcome barriers to innovation
 - encourage post authorisation programs.
- Communication to user: **No advertising.**
Advertisement to non-vets to be prohibited.

Conclusion

- New GL urgently needed on Efficacy for AB's
- Discriminate between new API's and WEU compounds
- The prescribing vet's are key in fighting AMR
- Availability of a wide range of antimicrobials is most important

Food4thought



2 different SPC texts for authorised products in the EU

Antibacterial 1

- Suitable for the control of infections due to susceptible microorganisms in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion due to sensitive organisms in cases where bacteria are not the initial cause of the disease

Antibacterial 2

- Pigs: Treatment of respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to <API> where the disease has been diagnosed in the herd.
- Broilers: Treatment of respiratory infections caused by *Escherichia coli* susceptible to <API> where the disease has been diagnosed in the flock.

EGGVP, representing the small and medium sized industry, to contribute **actively and responsively to strive forces** with all stakeholders to fight AMR.

