Antimicrobial resistance: the view of the EGGVP
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 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
<table>
<thead>
<tr>
<th>Antibacterial 1</th>
<th>Antibacterial 2</th>
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<tbody>
<tr>
<td>• Suitable for the control of infections due to susceptible microorganisms in</td>
<td>• <strong>Pigs</strong>: Treatment of respiratory infections caused by <em>Actinobacillus</em></td>
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<tr>
<td>cattle, sheep, pigs, dogs and cats where a single injection giving prolonged</td>
<td><em>pleuropneumoniae</em> susceptible to &lt;API&gt; where the disease has been diagnosed in</td>
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<tr>
<td>activity is required. It may also protect from secondary bacterial invasion</td>
<td>the herd.</td>
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<tr>
<td>due to sensitive organisms in cases where bacteria are not the initial cause of</td>
<td>• <strong>Broilers</strong>: Treatment of respiratory infections caused by <em>Escherichia coli</em></td>
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<tr>
<td>the disease</td>
<td>susceptible to &lt;API&gt; where the disease has been diagnosed in the flock.</td>
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</table>
EGGVP, representing the small and medium sized industry, to contribute **actively and responsively to strive forces** with all stakeholders to fight AMR.