“EU Antibiotic Policy and Strategy: IFAH-Europe point of view”

IFAH-Europe
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Elanco Animal health

CEVC, 5th of April 2016
Outline

• Introduction to IFAH-Europe
• Upcoming legislation : IFAH-Europe
• Innovative solutions : IFAH-Europe
• Commitment to responsible use : EPRUMA
Introduction to IFAH-Europe

300+ companies (originators and generics)
Upcoming legislation: Veterinary Medicines

- Protection of technical documentation is currently insufficient (in particular for antibiotics).

- IFAH Europe calls for:
  - up to 18 years for a new marketing authorisation (with a new active and more than one species)
  - 5 years for significant new data packages for old products (such as extra species, but not additive, granted to whoever submits the data)

  + EU Parliament supports it to mobilise R&D investments for improvement of old VMPs
Upcoming legislation
Veterinary Medicines

Harmonisation of SPCs
What is needed:

• Voluntary harmonisation: should be possible for « same » products originating from the same MAH

• Other harmonisation: Must be limited to « essentially similar » products through referral

• Antibiotics: should not be mandatory to review every AB within 5 years of the new legislation coming into force
Rick,

Is unsure about adding this point.

Up to you as you have a better idea of the audience

David John; 29.3.2016
Upcoming legislation
Veterinary Medicines

- Adaptation and simplification of labelling
- Reduce administrative burden
- Follow scientific advice of EMA on antibiotics according to a harmonised EU approach and at a product/species/indication level for:
  - Reservations (new registrations)
  - Restrictions on cascade-use (existing registrations)
  - Amendments to SPCs for authorised use (by referral)
Article 111 a (new) - Supply and use of antimicrobials

Member States may restrict or prohibit supply/use on their territory if critically important for humans or contradiction to national policy on prudent use.

- Stakeholders to be consulted.
- To be proportionate, Commission to be informed.

Risks:
- Divergent national decisions
- Politically driven decisions
- Blanket bans placing undue pressure on remaining classes
- Lack of suitable range of antibiotics for animals
- Compromise of animal health & welfare

Recommendation to Council/Commission: **REJECT above amendment**
Alternatives to antibiotics
- Need options for zootechnical indications
- Need options for modern vaccines including biotechnology
- Need openness to innovation in general
Upcoming legislation
Medicated Feed

• Medicated feed is a safe and controlled distribution channel

• Need support:
  – ALARA rules on carry over
  – Workable rules on manufacturing
    • Anticipated manufacturing important to plan production
    • Vital for medicated pet feeds
    • But no delivery without prescription
  – Prevention with medicated feed
    • Similar to other VMPs
Innovative solutions

• Imminent treatment gaps:
  – *Brachyspira hyodysenteriae* in swine
  – MRSP in skin infections in dogs

• Emerging Diseases/Pathogens/Strains need consideration
  – *ESBL Escherichia coli* in all species
  – MDR BRD pathogens in the USA

• Increasing restrictions on existing veterinary antibacterial classes increase the pressure on the treatment options left

• ‘Unknown unknowns’ over the next 15-20 years
Innovative solutions

- Vaccines: bacteria are proving hard to target
- Novel alternatives to antibacterials: facing technological challenges

- There will be a continuing need for effective veterinary antibacterials to treat bacterial (including MDR) infections in animals
- EMA answer to EC QU 3:
  ‘The authorisation of completely new classes of antimicrobials for use in animals might decrease animal and public health risk related to antimicrobial resistance provided co-selection by earlier authorised products is not implicated.’
Since the early 2000s, human and veterinary targets have diverged.

This severely limits the ability of animal health the leverage from human health substrate.

Future animal health substrate:
- Existing veterinary classes (unlikely to include human only classes)
- New classes

The previous veterinary antibacterial R&D paradigm is no longer valid.

Human Health Programs: ‘Resistance Management’
- MRSA
- MDR Pneumococci
- MDR Gram -ves
- MDR TB
- Hospital medicine

Animal Health Programs: ‘Improved Solutions’
- Livestock
  - Respiratory Disease
  - Enteric Disease
- Companion Animals
  - SSTI
- Single or 2-dose treatment courses
Innovative solutions

- Financial valuations / analysis during the R&D process (using ROIs, ePNVs or other measures)

- Investment decisions impacting the late 2020s are being made today

- Company valuations / analysis are based on
  - Chance of technical / regulatory success
  - Cost projections
  - Time to approval
  - Revenue projections (incl revenue risks)
Innovative solutions

- Access to substrate [Chance of success]
- All new antibacterials reserved by default for humans - even if no use for humans? [Chance of success]
- Legislation [Chance of success, costs, timelines]
- Guidelines [Chance of success, costs, timelines]
- Formularies and future restrictions [Revenue]
- ...? (further analysis may reveal others)

• Aim is a more predictable R&D and revenue framework
### Innovative solutions

We should ensure to maintain the pipeline continuity in veterinary medicines

<table>
<thead>
<tr>
<th>Human Pre 2000</th>
<th>Human Ca 2015</th>
<th>Vet Med Ca 2015</th>
<th>Vet Med Ca 2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>Few companies active in antibacterial research</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>AMR is an issue (but not recognised as a crisis)</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Investment not supported by commercial models</td>
<td>✔️</td>
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<td>✔️</td>
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<tr>
<td>High level of regulatory uncertainty (humans first)</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>AMR is recognised as a crisis / need for urgent action</td>
<td>✔️</td>
<td></td>
<td>?</td>
</tr>
<tr>
<td>Companies are reinvesting in antibacterial therapeutic area</td>
<td>✔️</td>
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<td>?</td>
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<tr>
<td>Regulatory pathways being made more appropriate</td>
<td>✔️</td>
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<tr>
<td>IMI / ND4BB etc looking at all stages of the development pathway: novel commercial models, access to substrate, development costs etc etc</td>
<td>✔️</td>
<td></td>
<td>?</td>
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</tbody>
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Responsible use of veterinary medicines: Reaching for the next level
A multi-stakeholder platform: best practice + animal health + public health

Since 2005

Goal:
Responsible use prevention & control

Work:
promoting responsible use (EU)
maintaining efficacy + prevent & minimise adverse reactions
Who is EPRUMA?

- **Veterinarians**: FVE & FECAVA
- **Farmers** and agri-cooperatives: Copa-Gogeca
- Manufacturers of **animal medicines and diagnostics** (IFAH-Europe, EMVD & EGGVP)
- **Feed** manufacturers (FEFAC)
- Professionals working in **animal health and sanitary security** (FESASS)
- Professionals working in **sustainable agriculture** (EISA)
- **Pharmacists** (PGEU)
10 partners
4 associate partners

Belgium, the Netherlands, United Kingdom & Spain
Responsible use of veterinary medicines

Holistic approach → minimising disease
Holistic approach
  → minimising disease

- **biosecurity**: preventative measures
  - keep animals healthy
  - limit the spread of diseases
- **housing + ventilation**;
- **hygiene**;
- **nutrition**;
- **regular monitoring**
- Animal health planning
- **Vaccination**
- **Diagnosis + treatment** under veterinary care
- **Use medicines** according to veterinary prescription
- **Pharmacovigilance**
EPRUMA antibiotic framework - 2008

- Responsible Use:
  - a key concept in ensuring appropriate use of antibiotics
  - helps to minimise resistance development
  - helps to maintain the long-term efficacy of antibiotics

A much referenced document in the EU
Available in 12 languages:
CZ, EN, ES, FR, DE, GR, HU, IT, NL, PL, RO & TR
(www.epruma.eu)
New EPRUMA antibiotic framework - 2015

✓ **Builds on the 2008 document** & should be considered in conjunction with it

✓ Combines a holistic & specific approach → facilitate further optimisation of animal health at specific sector level & at individual farm level.

EPRUMA best-practice framework for the use of antibiotics in food-producing animals

REACHING FOR THE NEXT LEVEL

Launched at EPRUMA’s 10th anniversary
December 2015
Download: www.epruma.eu
New EPRUMA antibiotic framework

Aims:

 ✓ Raise awareness of the common goal of protecting animal health, welfare + public health

 ✓ Ensure veterinary medicines are used responsibly → optimise effectiveness now + future in all species for relevant illnesses

 ✓ Provide stakeholders with guidance on how to achieve these objectives, esp. farmers and their consultants
New EPRUMA antibiotic framework

Main objective: highest achievable level of animal health
New EPRUMA antibiotic framework
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