THE NEED FOR RESEARCH AND DEVELOPMENT OF VETERINARY ANTI-BACTERIALS

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Some slides of the presentation from Scott A. Brown, Zoetis
What is IFAH?

- Global body representing companies engaged in the research, development, manufacture and commercialization of animal health products in both developed and developing countries across the five continents.

- IFAH’s members include animal health companies and national/regional animal health associations. In turn, these associations represent a broad range of concerns, from small, local businesses to international enterprises. Together, these companies supply approximately 80% of all animal health products used worldwide.

- IFAH is an international non-profit organization, registered under Belgian law, and based in Brussels.

- More information: www.ifahsec.org
IFAH’s Mission

- To foster a greater understanding of animal health, and to promote a predictable, science-based regulatory environment that facilitates the supply of innovative, quality products into a competitive market place. These products contribute to the supply of safe, healthy food, and to high standards of health and welfare for animals and people.
Outline

- Need for Antibiotics
- How Antibiotics are Discovered, Developed, Marketed and Used
- Factors Shaping the Antibiotic Pipeline
- What does the future hold for new veterinary anti-infectives?
Food Economics and Consumer Choice

An overview of the challenge ahead

Key Data

100% more food,¹ and 70% of this food must come from efficiency-improving technology²

In 50 years, the world population will require


TECHNOLOGY’S ROLE IN THE 21ST CENTURY
Factors in Livestock Production Efficiencies

- Genetics
  - Breeding stock
  - Peri- and neo-natal
  - Nursery
  - Growers/finishers
- Animal health
  - Antibiotics
  - Parasiticides
  - Vaccines
  - Probiotics
- Nutrition
  - Reproduction aids
  - Estrus regulators
  - Nutriceuticals
  - Enzymes
- Management
  - Intensive
  - Extensive
- Animal Production
  - Grain yields; Pasture use; Feed costs

↑ Animal Production
Animals Get Sick Like People

- Regardless of the production system
- Regardless of the level of management
- Regardless of the species
- Regardless of the geographical location

Therefore, animals [will always] need infectious disease treatment and prevention
Controlling infectious disease: the toolkit

- Management: housing, nutrition, “all in: all out, all clean in between”
- Biosecurity (shower in/shower out, traffic flow on/off farm, closed herds)
- Vaccines
  - Viral: but viruses mutate and change
  - Bacterial: especially the challenges with bacterial vaccines
    - Efficacy is variable, limited for some infections, injection site reactions, modified live vs. killed vaccines
- Probiotics/direct fed microbials
- Treatment of bacterial infections
- Natural Products (oils, plants, minerals, etc.)
  - Unproven
  - Unintended consequences (eg, environmental, palatability, etc.)
Disease control: The Innovation Paradox

• Animals will continue to get sick, even with optimal use of the tools in the kit
• Antibiotics and vaccines are product categories where constant updates and innovations are indispensable
• Responsibly developing new antibiotics and alternatives to antimicrobials is important to both human and animal health and the regulatory pathway needs to remain predictable, transparent and science based
• Otherwise, industry will invest R&D in other areas with the consequence that veterinarians will have even fewer treatment options available in the future – jeopardizing our one health
Getting Novel Compounds to the Marketplace

Developing Novel Products

• Commercial accessibility of novel compounds depends on
  – Successful new molecule/antigen discovery
  – Advancement of the drug candidate through safety and clinical development
  – Formulation and chemistry
  – Validation of a commercial-scale manufacturing process
  – Efficient regulatory review and final approval by the regulatory agency
  – Timely access to the market to meet the needs
Initiating the Discovery Process – Beginning with the end in mind

**Begins with a Target Profile**

- **Label Claim** (treatment of X disease caused by X organisms)
- **Market differentiators** (single dose, oral, etc.)
  - Requires knowledge of current and future market conditions
- **Market value**

**Key Points**

- **Investment is made at risk**
- **Assumes a defined regulatory process for that class of agent**
- **Timeline for process is 10 – 15 for HH and 8–12 years for AH**
Past and Future Sources of AH AB Substrate

1980s
- Fluoroquinolones
- 3rd Gen Cephs
- Florfenicol

1990s
- 4th Gen Cephs
- Novel Macrolides

2000s – HH and AH targets have diverged

Human Health Programs
- MRSA
- MDR Pneumococci
- MDR Gram-Negatives
- MDR TB

Animal Health Programs
- Livestock
- Respiratory Disease
- Enteric Disease
- Companion Animals
- SSTI
- UTIs

This severely limits the ability of AH to leverage substrate!
The Next Generation of Animal Health Anti-Infectives will need Unique Substrate

- Animal Health Anti-Infective Programs will need to discover novel anti-infectives that meet the veterinarians needs for animal welfare while minimizing impact on human health
  - Not Narrow or broad spectrum but “Veterinary Specific Spectrum”
  - Exploits all available substrate

Traditional Small Molecules
- Novel Classes
  - May exploit an existing target or novel target
  - AH may be able to utilize compounds discarded by HH programs due to delivery or safety issues that are not of concern in AH
- Re-exploration of older generations of existing classes
  - Initiate chemistry program to develop novel analogs within an older class

Non-Traditional Substrate (“Alternatives to Antibiotics”)
- Antimicrobial Peptides
- Bacteriophages (Phage Lysin Constructs)
- Current regulatory position is that these will be regulated using same pathways as traditional agents
  - Time to market is not likely to be shorter than traditional small molecules
  - Regulatory flexibility will be needed.
Getting Novel Compounds to the Marketplace

Intellectual Property Protection

• Patent lifecycle is critical to return on R&D investment

• Recouping investment more difficult for smaller market products of animal health

• Maximization of IP protection hinges on efficient development, predictable regulatory review, and expedient access to the market
What can policymakers do to foster innovation?

Recognize the need for innovation

Inform and educate consumers about value of innovation

Embrace innovation – the status quo will lead to undesirable outcomes

Streamline approval process: predictable, science-based regulation

Extend exclusivity – payback on investment

Think long-term … act with urgency