How to encourage industry to commercialise high quality veterinary medicinal products in the Middle East?

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Overview

• Introduction of IFAH

• Specific challenges of the veterinary medicines market in the Middle East

• Constraints and Incentives to industry

• Potential actions as seen by industry

• Examples for harmonization

• A few words on potential costs of regulation
About IFAH

- IFAH – International Federation for Animal Health
  http://www.ifahsec.org
- Representing the animal health industry around the world
- Members: 11 companies; 26 associations from 5 continents
- Provides the secretariat to the VICH initiative
Market in the Middle East

• Significant species: Mainly dairy, poultry, sheep and goats, but also camels and horses

• Significant variation in standards production
  – Highly sophisticated, integrated, very large farms,
  – Mid-sized dairy farms at varying standard levels
  – Smallholders – one or two cows

• Breeds: local versus high producing introduced breeds

• Large gap in education and animal care

• Significant “live animal for slaughter” sector
Constraints to product development:

- limited budget for research & development (much less than human sector, many more species)
- this lower budget split between vaccines and pharmaceuticals
- challenge to non-mainstream markets
- perceived smaller markets may loose out
Constraints to industry [2]

Constraints to product marketing:

- Distribution: diverse nature of potential customer
  - big establishments – attractive and easy to reach
  - small farmers – large customer base but difficult to reach
- Competition with counterfeit products
- Unclear basis of decisions for access to markets
- Limited availability of supporting veterinary advice / public veterinary services
Incentives to industry [1]

Drivers for company decision to enter a market:

- **Main incentive:**
  - Prospect of properly allocated business

- **Lesser incentives:**
  - Direct monetary or physical support, for example: sponsoring (money) and partnering (research facilities, staff) in public–private partnerships
  - Useful to address specific problems
How to get there?
Potential actions as seen by industry

Governments can do much to influence companies’ actions

• Sensitive regulation of veterinary medicines (registration and import regulations), complemented by

• Quality control of medicines in the market, with pursuit of violations and appropriate fines

• Protection of intellectual property

• Good public veterinary services

• Ensure a climate of good veterinary support
  – good veterinary education,
  – strong associations of practicing veterinarians
Advantages of good regulation

- Acceptance of veterinary medicines by society
  - User confidence – good quality veterinary medicines that work
  - Consumer confidence – medicines for food animals are safe
- Assurance on adequate protection of animal health/welfare
  - Ensured quality
  - Ensured safety
  - Ensured efficacy
- For industry:
  - Strong legal protection for intellectual property provides incentive to innovate and to compete
  - Stimulates competitive success in the animal health industry and new product development
Regulatory Infrastructure – a must!

- Authorisation of veterinary medicines, embedded in veterinary legislation
  - Proof of quality, safety and efficacy
  - Complemented by control of quality, safety and efficacy
  - Vaccines – additional requirements to prevent transmission of infectious agents (underpinned by the OIE Terrestrial Code)

- Practical implementation based on compliance with reasoned, scientifically sound, regulatory guidelines
  - Industry welcomes and supports good regulation of medicines in a framework of scientifically based guidelines
  - Consider creating bigger markets through regional authorization systems; can also help keep costs of
Examples for harmonization of authorizations

1. Regional harmonization of registration of veterinary medicines – the European Union (EU)
   - Dr Mackay will present an overview

2. Local (bilateral or national examples)
   a. UK and Ireland
   b. Switzerland
Joint initiatives – UK and Ireland

- **Harmonisation of Summary of Product Characteristics (SPCs) / Product Literature – national authorisations**
  - A simplified administrative procedure
  - Harmonises texts of SPCs/product literature for products that are identical in formulation, packaging, and manufacture
  - Products can be marketed using same labels and leaflets
  - More efficient and cost effective production of packaging

- **Alignment of immunological products**
  - An initiative to align vaccines licensed in one of the two countries with the other especially in the case of older products
  - Facilitates greater availability of immunologicals

- **Joint UK/IE labelling for mutually recognised / decentrally authorised products**
Unilateral approach (Switzerland)

Facilitated approval if authorized in recognized countries

- **Swiss Medicines Law (Heilmittelgesetz) Article 13**
  Where a medicinal product or procedure has been authorised in a country with comparable control of medicinal products, the results of the completed evaluations will be considered.

- **Implemented by administrative order of 11 November 2008**
  ZL_000_00_001d_VV Anleitung zum Vollzug von Art. 13 HMG @
  applies to human and veterinary medicinal products
Impact of regulatory requirements

**IFAH benchmarking survey 2007 - critical success factors**

- Time to market
- Development Costs

- World-wide market growth in past 15 years: 20%
- Increase in
  - Development costs due to regulatory requirements: 150%
  - Defensive research cost (in some countries): 35%
- Development time increase (on average): 4.5 years
- Varying requirements result in multiple studies to prove the same efficacy and safety endpoints designed to different protocols
  - Very demanding on company financial and manpower
• **Recent initiatives in the EU**
  
  - Review of the EU regulatory system in 2010.
  - Industry (IFAH–Europe) calls for ‘1–1–1’ – 1 dossier – 1 evaluation – 1 decision; more information on the discussion @
    
    http://www.ifaheurope.org/EventDetails.aspx?ID=9&SubMenuId=26&MenuId=4
  
  - Heads of Medicines Authorities reflected on the proposal, see @ www.hma.eu/uploads/media/HMA_TFWG_HMAv_cons_doc.pdf
  
  - Reflects learnings from the experience gained in the EU with
    
    • the harmonization of existing authorization systems in the EU
    
    • different needs and capabilities of different sized countries (small versus large, e.g. Luxembourg versus Germany)

• **Other initiatives in the EU**

  Mutual recognition of GMP inspections and related aspects
Can harmonization work elsewhere?

- Underlying principle: Recognition and Acceptance of one country’s authorization by another

- Benefits of countries working together:
  - facilitated authorisation
  - better availability of authorized veterinary medicines
  - potential to establish centres of excellence in classes of veterinary medicines e.g. antimicrobials or antiparasiticides
  - cost sharing enables stronger emphasis on other areas, e.g. inspection

- Can it work in the Middle East either nationally and/or regionally? The benefits are worthwhile and merit further consideration.
Thank you very much for your attention