OIE Conference on Veterinary Medicinal Products in the Middle East

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

Barbara Freischem, IFAH

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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 industry [1]

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 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 regulation in check
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

Clarification papers available on the VMD website @ http://www.vmd.gov.uk/General/AppsPage/guidance.htm
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 @ http://www.swissmedic.ch/rechtstexte/00626/index.html?lang=de
  applies to human and veterinary medicinal products

• Establishes equivalent countries:
  Australia, EFTA countries, EU, Japan, Canada, Singapore, USA
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 resources
  - Excessive and unacceptable use of large numbers of animals
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 see EMEA website @ http://www.emea.europa.eu/Inspections/MRA.html
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