OIE National Focal Points for Veterinary Products training
Johannesburg, South Africa, 23-26 November 2010

Private Sector Perspectives IFAH (worldwide)

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Presentation outline

- Introduction to IFAH
- Regulation of veterinary medicines - view of a global industry
  - Constraints and Incentives to industry
  - Costs of regulation
  - 'Good' regulation as seen by industry
  - Examples for regulatory harmonization

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About IFAH

IFAH Representing the Animal Health Industry

- International non-profit organisation registered under Belgian law, based in Brussels, Belgium, established in 2002
- The GLOBAL representative body of companies engaged in:
  - Research
  - Development
  - Manufacturing
  - Commercialization & support

  } Veterinary medicines, vaccines and other animal health products
- Represents:
  - Animal Health companies (12)
  - National/Regional associations (27).
    - Local medium-sized enterprises
    - International companies

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Corporate members

IFAH Representing the Animal Health Industry

ALPHARMA ANIMAL HEALTH

JANSSEN ANIMAL HEALTH

Bayer HealthCare International Animal Health

Lohmann Animal Health

MERIAL

Boehringer Ingelheim

Elanco

NOVARTIS ANIMAL HEALTH

Intervet Schering-Plough Animal Health

Pfizer Pfizer Animal Health

Virbac

Vétoquinol Signe de Passion

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Member associations

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Member associations

EUROPE

• Europe	IFAH-Europe
• Belgium	Pharma.be
• Denmark	VIF
• France	SIMV
• Germany	BfT
• Ireland	APHA
• Italy	AISA
• Netherlands	FIDIN
• Portugal	APIFARMA
• Spain	VETERINDUSTRIA
• Sweden	LIF
• Switzerland	SGCI Chemie Pharma Schweiz
• United Kingdom	NOAH

AFRICA

• South Africa	SAAHA

NORTH AMERICA

• Canada	CAHI
• Mexico	INFARVET -CANIFARMA
• United States	AHI

CENTRAL & SOUTH AMERICA

• Argentina	CAPROVE
• Brazil	SINDAN

ASIA/PACIFIC

• Australia	The Alliance
• Indonesia	ASOHI
• Israel	MAI
• Japan	JVPA
• Korea	KAHPA
• New Zealand	AGCARM
• South-East Asia	AAHA
• Thailand	Thai APHA

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Mission statement

The mission of IFAH is

- to foster a greater understanding of animal health matters and
- to promote a predictable, science-based regulatory environment that facilitates the supply of innovative and quality animal medicines, vaccines and other animal health products into a competitive market place.

These products contribute to the health and welfare of animals and importantly provide a safe food supply for people.

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Relevant IFAH projects

- Contribution to Codex Alimentarius, the global, science-based food safety standard setting body; sets safe limits for residues of veterinary drugs in food
- VICH – the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products – a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

  IFAH hosts the VICH secretariat.
- Cooperation with OIE on matters of mutual interest.

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Regulation of veterinary medicines

Needs of a global industry

- Understanding drivers:
  Balance between constraints and incentives
- Cost factors: the regulatory environment
- Good, equitable regulation

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Constraints

Product development

- limited R&D budget
  much less than human pharma, more species)
- budget divided between vaccines & pharmaceuticals
- challenge to non-mainstream markets
- perceived smaller markets may loose out

Product marketing:

- Distribution: diverse customers
  - big establishments – attractive and easy to reach
  - small farmers – large base, but difficult to reach
- Competition with counterfeits
- Unclear basis of decisions for access to markets
- Limited availability of supporting veterinary advice / veterinary public services

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Incentives to industry

Main incentive:

- Prospect of properly allocated business:
  - Science-based regulation
  - Same rules for all
  - Equitably enforces

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

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Cost of regulation [1]

IFAH benchmarking survey 2006

- Critical success factors
  - Time to market
  - Development Costs
- World-wide market growth in past 15 years: **20%**
- Increase in
  - Development costs due to regulation: **50%**
  - Defensive research cost (in some countries): **30%**
- Development time increase (on average): **4.5 years**
- Varying requirements result in wastage:
  - **multiple studies** to prove **same** efficacy and safety **endpoints** designed to slightly different protocols
  - Drain on company financial and manpower resources
  - Excessive, unacceptable use of large numbers of animals

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Cost of regulation [2]

Research & Development costs background facts (2006):

R&D investment: EU & US: ≈ 10% of annual turnover

Defensive R&D costs: EU: ≈ 35% of annual R & D budget
US: ≈ 15% of annual R & D budget

Impact of regulatory factors on average development cost (changes in real terms over 5 years prior to 2006)

	Europe	USA	Canada	Australia	Japan
Major Livestock Species	+ 25%	+ 32%	+10%	+ 36%	+ 15%
Companion Animal Species	+ 23%	+ 37%	+ 10%	+ 26%	+ 7%
Minor Species	+ 15%	+ 28%	+ 1%	+ 22%	+ 8%

'Good' regulation
as seen by the worldwide industry

Aim: Availability of quality, safe, & effective veterinary medicines

- Sensitive science-based regulation of veterinary medicines (registration, import regulations), complemented by
- Quality control of product on the market, with pursuit of violations and appropriate fines
- Protection of intellectual property
- Good veterinary services
- Ensure a climate of good veterinary support
  - good veterinary education,
  - strong associations of practicing veterinarians
- Create bigger markets through regulatory harmonization

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Advantages of good regulation

- Acceptance of veterinary medicines by society
  - User confidence – good quality medicines that work
  - Consumer confidence - medicines for food animals are safe
- Assurance of 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

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Examples for harmonization of authorizations

1. **Regional harmonization of registration of veterinary medicines**
   - the European Union (EU) system
2. **Local (bilateral or national examples)**
   a. UK and Ireland -
   harmonisation of labelling for national products<
   Alignment of immunological products,
   joint UK/IE labelling for EU decentralised/mutual recognition procedures
   b. Switzerland –
   facilitated approval if approved by recognised agencies
   c. US vaccines in Latin American countries:
   Import based on acceptance of free trade certificates

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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 centres of excellence in classes of veterinary medicines e.g. antimicrobials, antiparasiticides
  - cost sharing enables stronger emphasis on other areas, e.g. inspection
- Can it work elsewhere? The benefits are worthwhile and merit further consideration.

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Thank you very much for your attention

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