GALVmed workshop – future of vaccine registration
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Private Sector Perspectives IFAH (worldwide)

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Presentation outline

- Background
- Regulation of veterinary medicines - view of the global industry on harmonisation
  - Components of good regulation
  - Examples for harmonisation of regulation
    - Regional systems – EU system
    - Bilateral systems
    - Unilateral systems
- Suggestions

2

Background

IFAH includes the promotion of a predictable, science-based regulatory environment - facilitates the supply of quality animal health products into a competitive market place.

The bigger the market the more attractive it is – regulatory harmonisation in particular mutual recognition systems create bigger markets without loss of sovereignty.

Registration systems around the world are essentially similar – it is the differences that makes Regulatory Affairs in international companies a challenge.

3

Regulation of veterinary medicines

Components of 'Good' Regulation

- Science-based regulation (registration, imports)
- Good protection of intellectual property (data confidentiality, regulatory data protection, patent laws)
- Same rules for all, equitably enforced
- Market control – control quality, pursue & fine violations
- Harmonise regulation with neighbors
  - creates bigger markets – more attractive
  - can saves costs – e.g. pool expertise, no need to repeat inspections

4

Harmonization of regulation - regional approach (1)

Regional harmonization of registration of veterinary medicines – the European Union

- Three tiers: central procedure- decentralised/mutual recognition procedure – national procedure
- Industry view:
  decentralised/mutual recognition = way to go

	2007	2008	2009
MRP	76	82	47
DCP	26	68	64
CP	8	12	12

5

Harmonization of regulation - regional approach (2)

Regional harmonization of registration of veterinary medicines – the European Union

- Industry view: way to go - BUT

  Issues with the current EU system of mutual recognition (MR)

  - Many new questions in MR process
  - Referrals to CVMP
- Industry advocates farther reaching harmonisation – IFAH –Europe
  - 1-1-1 concept
    (1 dossier – 1 assessment – 1 decisions)
  - www.ifaheurope.org

6

Harmonization of regulation - bilateral approach (1)

United Kingdom & 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

7

Harmonization of regulation - bilateral approach (2)

- **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*

8

Harmonization of regulation - unilateral approach (1)

Switzerland: Facilitated approval if authorized in recognized countries

- **Swiss Medicines Law (Heilmittelgesetz) Article 13**

  Where a medicinal product pr 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

9

Harmonization of regulation - unilateral approach (2)

Latin American countries & vaccines approved in the United States of America (USDA-APHIS-CVB = Center for Veterinary Biologics)

Acceptance of a certificate of free trade issues by the USDA with approval of the vaccine

10

Suggestions

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

- Harmonisation/mutual recognition works – make it work for your environment.
  Underlying principle: Recognition and Acceptance of one country's authorization by another
- Do not reinvent the wheel – use what is already available and learn from experiences of others
- 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 saving allows focus on other areas, e.g. inspection

11

Suggestions

- Needs to go hand-in-hand with additional measures
  Setting up rules is not enough, they need to enforced
- Other presenters highlighted the need for additional measures needed to improve animal health
- Do not wait & tackle the elephant in bite-sized pieces

12

Thank you very much for your attention

13