Summary and Conclusions of Global Animal Health Conference

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Enabling the Business of Agriculture (EBA) – Veterinary Medicines for Livestock 2016

- Very new global study – baseline – outcome to be published in 2017
- **Share Best Practices**
- Promote smart regulations / efficient regulatory processes
- Not all countries have a regulatory framework

**Positive:**
- One unit focused on Veterinary Product is important
- Check dossiers for completeness before submission
- More than one entity licensed to import VMPs
Indian perspective

- Livestock creates employment opportunities and livelihood support for women and marginalised groups
  - Improve efficiency of India’s very large livestock sector!

Recommendations for improved market access:

- Specific regulations and guidelines for VMPs
- Veterinarians to be appointed in Regional FDA houses to evaluate VMPs
- Ease the process of approvals for drugs approved in other regions

- VMPs needs to be safe, efficacious, affordable and accessible
Session 1 – Challenges relating to market access

Feedback from GAHC Workshop:

- **Strive for consistency in the implementation of GLs and standards**
  - Join VICH outreach forum

- **Inspections:**
  - Use risk based approach
  - Veterinary specific training is needed

- **Regional collaboration is highly beneficial**
  - Avoid duplication of work
  - More robust and consistent assessments
Session 2 – Improved registration processes to increase access to animal health products

Optimizing the Regulatory Framework:

• **Predictability** and Consistency of
  • registration timelines
  • dossier content requirements
  • outcome of the evaluation on science-based requirements
• This will encourage applicants applying for MA’s and lead to more VMP’s available

▶ Networking / collaboration

▶ Fees
  • Proportionate and transparent

▶ Early pre-submission dialogue is important!
Session 2 – Improved registration processes to increase access to animal health products

Regulatory Convergence

- Builds capacity, enhances uniformity
- Reduces burdens for industry
- Take into account decisions taken by authorities in other countries

The OIE can contribute to global initiatives for convergence

- Standard-setting role
- Free online documents on technical requirements
- Established networks

Session 2 – Improved registration processes to increase access to animal health products

Case Study – Brazil

More than 10,000 VMPs registered

Initiatives:

- Update of legislation
- Adherent to international standards
- Reinforcement of inspections and surveillance
- Electronic submission system
- Interaction with applicants
Session 2 – Improved registration processes to increase access to animal health products

Case Study – CAMEVET

- 29 member countries
- Industry associate members
- Secretariat - OIE Regional Representation for the Americas

Difficulties:

- No Political Agreement
- Guidelines are not mandatory
- Differences in the implementation of guidelines into the local legislation

Achievements:

- More harmonized level of regulatory standards
- 24 Approved guidelines and documents.
- Registration form accepted by most countries
- Guidelines and documents are used as technical reference by most countries.

Control of Manufacturing – Regulatory Perspective:

► Thailand has been the ASEAN listed inspection service and on the Panel of GMP experts of ASEAN since 2014.
► Thai FDA has been PIC/S member since 2016
► Thai GMP VMP standards cover:
  • All veterinary medicinal products manufactured in Thailand
  • All veterinary medicinal products imported into Thailand

► Different requirements for import from:
  • PIC/S member
  • ASEAN listed country
  • Other
Control of Manufacturing – Industry Perspective:

- Challenges, Initiatives and Benefits at the following levels:
  - Personnel
  - Building and Premises
  - Equipment
  - Utilities
  - Manufacturing and Operation function
  - Quality function
  - Aseptic Manufacturing operations
  - Documentation

- The control of Veterinary Medicinal Products is there for very good reason: The protection of animals, businesses and individuals
Control of the Market Place

- The system should be:
  - reliable, robust, predictable and transparent
- Imports aren’t just final marketed products
  - Important to understand the supply chain
- **Consistent training of investigators at ports is crucial for success**
- Counterfeits – very large market
  - Relatively easy tests available to determine if VMP is real or counterfeit
- Pharmacovigilance could contribute to discover counterfeit / other problems
Case Study – India

- Many cooperating partners
  - National and International
  - Long process towards harmonisation
- Private and government work together
  - Coordination is key
- FMD vaccination strategy
  - India must control FMD
- Environment has become a very important factor
Case Study – Experience with Regional Organisations and Mutual Recognition

- A long process to build confidence; what can be done to accelerate this?
  - A step by step process - 4 pillars

- Common set of technical registration requirements and legal framework

- Regulatory convergence, including alignment to international standards and guidelines is key

- Hands on guidance and build trust between regulators
Recommendations

- Continued work is needed for consistent implementation of regulatory systems

To improve the regulation of VMPs:
  - Learn from each other
  - Work together
  - Use existing standards (VICH, OIE)

- The goal is improved health and welfare for animals, consumer protection and economic growth
Thank you!!