

Summary and Conclusions of Global Animal Health Conference

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5th Global Animal Health Conference and Workshop 2016

Improved Market Access for Authorised
Veterinary Medicines – The Asian Perspective

Organising Committee:

BILL & MELINDA
GATES foundation


EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH




WORLD ORGANISATION
FOR ANIMAL HEALTH


Protecting Livestock – Improving Human Lives


International Federation of Animal Health


Health for Animals
global animal medicines association


DEVELOP
INNOVATE
ADVANCE



Keynote lecture – World bank program

- ▶ 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



Session 1 – Challenges relating to market access

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.



Session 3 GMP and Market Control

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



Session 3 GMP and Market Control

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**



Session 3 GMP and Market Control

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



Session 4 – Regional Organisations and Mutual Recognition

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



Session 4 – Regional Organisations and Mutual Recognition

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!!



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