Case Study Latin America

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Improved Market Access for Authorised Veterinary Medicines - The Asian Perspective
Brazil – General Characteristics

- The largest country in South America - 8,515,767,049 km²
- Federal Republic composed by twenty-six states and one Federal District.
- The MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY – MAPA and other government Departments are located in Brasilia - Brazil Federal Capital.
Regulatory Framework

Ministry of Agriculture, Livestock and Food Supply - MAPA

Animal and Plant Health and Inspection Secretariat - SDA

Department of Livestock Input Inspection – DFIP

- Special Programs Coordination: Pharmacovigilance and AMR
- Veterinary Products Coordination
- Animal Food Coordination

- Pharmaceutical Products Regulation Division
- Veterinary Products Inspection Division
- Biological Products Regulation Division

Decentralized Unities: Federal Superintendences of Agriculture, Livestock and Food Supply – SFA and Nacional Laboratories - LANAGROS
MARKET CHARACTERISTICS

Decree nº 5.053 of April 22, 2004:

“All establishments that manufacture, handle, pack, label, control the quality, store, sell, distribute, import and export veterinary medicines must be registered in MAPA;”

“All veterinary products must be registered in MAPA;”

- Registered products: more than 10,000.
- Registered firms:
Regulatory Framework difficulties:

- Harmonization among the states – many states with different characteristics;
- Number of auditors in the central Department;
- Bureaucracy;
- Standard procedures;
- Regulatory timeframes;
- Legislation;
- Specialist expertise;
- Transparency;
- Large number of application;
Initiatives adopted

- Updating legislation based on international references like VICH and CAMEVET;
- Eliminating unnecessary administrative burden: not requiring application for all simple changes with no impact on safety and efficacy;
- Increasing the number of auditors available to analyze application: involving auditors of decentralized Unities – Superintendence in the States;
- Creating standard procedures for analysis: guidelines and SOPs based on international references like VICH and CAMEVET;
- Investment in auditors qualification: periodic training with impartial expertise from academia;

Initiatives adopted

- Reinforcement for inspection activities: creating a new Division dedicated to coordinate audits;
- Regulation proposal to prioritize analysis of innovative products;
- Reinforcement surveillance of products: creating a new Coordination Department dedicated to pharmacovigilance;
- Intensive participation in international forum and meetings like VICH and CAMEVET;
- Implementation of Electronic system to analyse register requests: publics reports;
- Interacting with the applicant.
Benefits reached and expected

- Increased regulatory convergence between countries or regions: more access to animal health products;
- Predictable shorter regulatory timeframes;
- Reduction of unnecessary application;
- Efficient regulation for industry and regulators;
- Stimulation of innovative veterinary medicines in the trade;
- Regulators more qualified and supported by impartial expertise from academia;
- Transparency through the public reports from electronic system.

Regulatory harmonization is essential, but to increase the convergence is necessary:

- Take account of particular issues among the countries:
  - Different natural characteristics: climatic zones, microorganisms, parasites and breeds - guidelines needs to have requirements that consider these differences.
  - Different technical and regulatory level.

- Stimulate and intensify the participation of more countries during the elaboration of guides and regulations;

- Political agreements to implement the guides and regulations;
Thank you!!!