



4th Global Animal Health Conference 2015

Regulatory Convergence

24-25 June 2015
Dar Es Salaam, Tanzania

BILL & MELINDA
GATES foundation

Health for Animals
global animal medicines association

Organising Committee:

 **WORLD ORGANISATION FOR ANIMAL HEALTH**
Protecting animals, preserving our future


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH




GALVmed
Protecting Livestock – Improving Human Lives


TFDA
Tanzania Food & Drugs Authority


UEMOA


USDA


DIA DEVELOP
INNOVATE
ADVANCE

Conference Report

Executive summary

The Global Animal Health Conference concluded that veterinary medicines are important in developing countries in the interests of food security and human health. Considerable progress has been made in recent years in developing regulatory frameworks that encourage industry to invest in placing products on developing markets. Costs can be reduced and availability increased by regional cooperation to prevent duplication of assessment and make the most efficient use of the limited resources within each country. Countries support the convergence and uptake of harmonised regulatory requirements, such as VICH guidelines, provided that they are relevant to their needs and it is recognised that complete compliance may be the ultimate goal rather than the short term objective. The importance of control of manufacture and control of distribution and use was repeatedly raised during the meeting. GMP inspection, wholesale distribution and sampling and testing were identified as areas where training is needed. Organisers and participants undertook to promote the outcomes from the conference and to foster local leadership through listing specific actions that could be taken at regional level.

The Objectives of the Conference

- Promote market control – including product quality, product testing, and surveillance of products on the market.
- Improve market access – including how to remove obstacles to access and promote a defined registration process with timelines and remove disincentives.
- Promoting mutual recognition and the formation of regional organisations; includes discussions on the advantages of convergence of international standards.
- Implement African regional harmonisation initiatives and discuss local opportunities and challenges towards the implementation of harmonised regulatory systems in compliance with international standards and guidelines.

The Organising Committee

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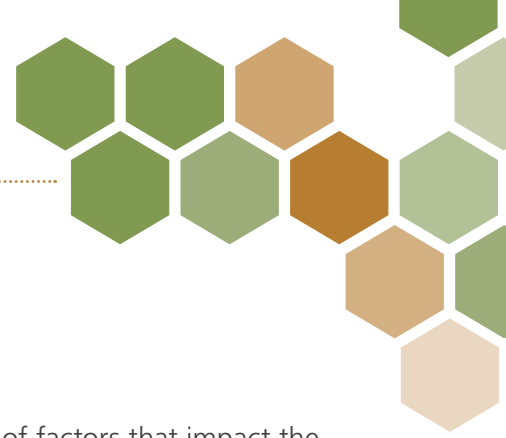
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Opening of the Conference

The conference was opened by keynote speakers from HealthforAnimals and the local host competent authority and Ministry of Livestock Development and Fisheries (Tanzania). These speakers set the scene for the conference by highlighting the following important elements.

Regulatory harmonisation is important for many reasons and is a human health, as well as an animal health, issue. There is a need for safe and effective veterinary medical products (VMPs) of appropriate quality. These VMPs result in reduced animal mortality, disease prevention and treatment. Increased animal health and production leads to more food production. Increased food production is needed to keep pace with a growing population. Harmonisation of standards and regulatory convergence overcomes obstacles to market access for VMPs, makes mutual recognition agreements possible and improves market control.

There are a number of factors that impact the health of animals including increased market access for animal health products, communication and trade. In Africa, many countries are on the verge of rapid economic growth and yet some countries lack legislative frameworks, trained personnel and adequate resources. All countries need a core set of scientific and administrative competencies in place to support and implement a regulatory system.

Regulatory convergence represents a way to expand medicine and vaccine development and marketing by reducing obstacles to trade. Providing greater certainty in the regulatory process can result in improved access to therapies and vaccines for emerging diseases (60% of which are zoonotic). It has the added benefits of reducing duplication, and thus reducing the number animals needed for testing, while also bringing greater legitimacy to regulatory decisions.

Session 1: Regulatory Convergence

There was consensus that regulatory convergence benefits the availability of veterinary medicines by increasing efficiency and reducing duplication of effort by both regulators and industry. Harmonised data requirements allow industry to conduct studies once to meet internally agreed standards that are accepted for submission to multiple regulatory authorities. Likewise, harmonised data requirements allow regulatory authorities to conduct assessments based on internationally agreed datasets, thereby promoting mutual recognition of authorisations.

Regional cooperation has already been shown to be an effective method of promoting regulatory convergence in Africa. Progress has been rapid in the last few years and the prospects remain good to widen and deepen cooperation in all African regions. International organisations, NGOs and Public Private Partnerships all have a

role in assisting national and regional registration authorities in promoting convergence based on intergovernmental standards, trainings, common understanding and sharing of best practice.

However convergence of pre-authorisation activities is only one element of an authorisation and control system for veterinary medicines. Controls on imports, market access and distribution, post-authorisation monitoring and sampling and testing are other important elements. Commitment at political and senior management level, a shared language and the facilities and human resources required for coordination are key elements for successful regulatory convergence and cooperation. It is also important to recognise the work of international bodies such as OIE, Codex, WHO, VICH, and also to take into account established pharmacopoeias.

Session 2: Market Control

Malaysia presented its experience establishing a comprehensive regulatory system that evolved from collaboration through the regional organisation ASEAN. The system is complex, continues to evolve and is kept current by regular discussion in ASEAN. There is a need for benchmarking the competencies of regulatory authorities with the aim of building mutual trust.

The conference delegates also heard about the success of the emergence of the PANVAC initiative.

This arose out of the lessons learned during the Rinderpest outbreak, leading to the eradication of this disease by vaccination. PANVAC established a regional laboratory with testing, market controls and training for other laboratories serving many African countries. It became an OIE Collaborating Center in 2013. PANVAC has been very successful in providing services and controls for the quality control of vaccines in Africa. This case-study demonstrates what is possible through good collaboration and knowledgeable support.

Session 3: Market Access and Mutual Recognition

Africa is having a human population explosion unprecedented in human history. The population is forecast to double in the next 25 years. The livestock population must be increased to meet the demand of this growing human population and the regulatory environment is key in influencing the control of animal diseases that constrain animal production. Animal health companies are ready to support such growth but require a defined regulatory environment in which to operate.

The value of mutual recognition procedures for efficient use of resources was noted and has been realised for veterinary vaccines in East Africa. The tools, such as guidelines, a framework for dossier requirements and other documentation, are now available for other African countries to use. Mutual recognition can bring the following advantages:

- Accelerates the availability of quality vaccines
- Avoids duplication
- Improves predictability
- Builds trust between regulators
- Allows rapid introduction of vaccines against new diseases

Animal health companies need a predictable registration process that is reliable, with consistent criteria, and is aligned with international standards. Simplified processes relying on mutual recognition of the scientific assessments of other regulatory authorities can avoid repetition and redundant administrative burden. A good operating environment also needs effective market control, through appropriate enforcement mechanisms by authorities and regional oversight of manufacturing sites.

From the perspective of manufacturers of veterinary medicines, additional factors that limit market access include:

- Not respecting intergovernmental standards recognised by WTO
- Lack of harmonisation, especially in assessment standards
- Lack of acceptance of new technologies
- Retroactive action on existing products
- Poor control over counterfeit products
- Protection of documentation from uncompetitive use – respect of ownership of data
- Lack of visibility of changes in regulatory environment
- Unreasonable registration costs and delays

Session 4: Regional Organisations

In session 4 the characteristics, benefits and needs of regional organisations were discussed. A fundamental characteristic is the need for technical and regulatory commitment and a legal basis in the cooperating countries for mutual recognition. There is also a need for a suitable structure to bring regulators and industry together on a regular basis. The parties need to devote the necessary time to work together and to build trust. Further essential components are confidentiality and transparency, networking, having an inclusive process and sharing a common language.

To be successful, regional organisations need an appropriate infrastructure, training support for staff and sustainable economically viable systems. This will enable the sharing of resources between countries.

Regional organisations can provide harmonised technical requirements in line with intergovernmental standards, offering organisational and procedural flexibility for the marketing authorisation of veterinary medicinal products. Regional solutions can be adapted to local situations.

Breakout Sessions

The conference delegates discussed the key themes of the conference in a number of breakout groups. The following set of bullet points represents the outcome of this brainstorming.

Regulatory Convergence and Mutual Recognition

- Must have a political will among government departments
 - Capacity building and the need for adequate resources
 - Organisations with common procedures versus those that do not
 - International norms are advantageous with caveats (may not be appropriate for some countries) particularly norms like VICH
 - Communication and capacity building
 - Shared experiences result in improving standards
 - Learn from others' challenges and avoid duplication
- Advantages:
 - Free trade of products
 - Efficient use of resources, increased worksharing
 - Enhancing trust among regulators
 - Regular joint review of guidelines
 - Sharing costs and fair pricing
 - Fixed predictable timelines for evaluation
 - International standards result in increased quality, safe and effective products
 - Increased trade
 - Standardisation of regulatory processes
 - Easy to control and monitor diseases
 - Reduce regulatory and development costs, with possible impact on prices
 - Increased pharmacovigilance
 - Increased monitoring of resistance
 - Increased access to products
 - Simplification and speed; reduce timelines to decision
 - Reduced counterfeit products

- Disadvantages:
 - Take more time to develop processes
 - Capacity building; financial, IT and training resources
 - Loss of flexibility to make local decisions
 - Loss of market to local industry; market disruption
- Challenges:
 - Financial and human resources
 - Access to the necessary expertise
 - Regional systems may not fit national trade streams
 - Unlevel playing field such as inspection findings for GMPs
 - Individual interests can get in the way

How to promote market control

- Political will is necessary
- Collaborate with neighbouring regulatory authorities
- Good governance of veterinary medicinal products
- Identify what exporting countries can provide (certificates)
- Training (lack of specialists in veterinary medicines)
- Ensuring transparency of evaluations
- Harmonising regulatory systems and legislation and base them on global intergovernmental standards
- Capacity building of (a) leaders in the field, (b) end users and (c) professionals
- Strengthening professional organisation and ethical standards
- Improving marketing infrastructure
- Product control and testing:
 - During manufacturing assessment of production through pre-market inspection (GMPs)
 - Post approval – pharmacovigilance (PV) backed by legislative authority to require industry reporting
 - Option to send samples to other country labs





- Have one PV centralised reporting site
- Controlling distributors and retailers – require registration
- Import control at borders – retention fee from registration to pay for control
- Use of bar codes – hard to replicate however; a cost
- Good alerting system – easy to use, easy to report and how to report
- Robust procedures to deal with issues of corruption
- Counterfeiting – information sharing

Improving Market Access

- Obstacles:
 - Registration time, requirements, incomplete dossiers, inconsistent requirement, multiple agencies
 - Lack of resources, admin support, political will, motivation, well-defined policy
 - Misinterpretation of guidelines and cost
- Use of pre-submission advice
- The use of common guidelines, harmonising with other regions
- Impact on the cost of animal health products
- Agency structure – human and veterinary single agency to work together and not compete for resources
- Improvement in information-sharing and problem-solving and transparency

Actions and next steps

The following actions were proposed as a follow-up to the conference:

- Explore further development of regional harmonisation efforts developed by EAC, ECOWAS, UMEOA and others in other regions
- Identify/compile:
 - what are success factors
 - how to overcome barriers to more harmonisation
 - roles and responsibilities
- Provide this knowledge and experience as a shared resource. Where to bring this together?
 - A centre of excellence?
 - One person?
 - A website?
- Organise meetings to promote local (African, Asian, etc.) leadership for better harmonisation
 - List of specific actions – for reaction/action
- Test trial: move a product through in a region (EAC?)

