CONFERENCE REPORT

5th Global Animal Health Conference 2016

Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

17 November 2016
New Delhi, India

Organising Committee

BILL & MELINDA GATES foundation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

OIE
WORLD ORGANISATION FOR ANIMAL HEALTH

GALVmed
Protecting Livestock – Improving Human Lives

Indian Federation of Animal Health Companies
INFAH

DIA

Health for Animals
global animal medicines association

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WORKSHOP

A workshop was held immediately prior to the 5th Global Animal Health Conference, on 14 - 16 November, with the support of the Bill and Melinda Gates Foundation and organized by HealthforAnimals together with partners from the European Medicines Agency (EMA), US FDA, The World Organisation for Animal Health (OIE), GALVmed, Drug Information Association (DIA), and the Indian Industry organisation (INFAH). The workshop was dedicated to: Good Regulatory Practice for the Marketing Authorisation of Veterinary Products in an Asian Context. A copy of the workshop report can be requested by contacting the DIA customer service on EMEA@DIAglobal.org or by visiting the HealthforAnimals website.

Rick Clayton, Yoshihiro Shimizu, Vijay Teng, Gilly Cowan, Bettye Walters, Glen Gifford, Melanie Leivers, Anna Elizabeth O'Brien, Talina Sterneberg

CONFERENCE REPORT

EXECUTIVE SUMMARY

The 5th Global Animal Health Conference 2016 focused on improved market access for authorized veterinary medicines in the Asian perspective. Farmers are dependent on the health of their livestock, and access to veterinary medicines is a major factor in keeping and optimizing the health and productivity of the animals. Veterinary medicines should be safe, efficacious and produced to an adequate quality, as well as affordable and accessible. Each country in the world should ensure a specific regulation for the control of veterinary medicines, build regulatory capacity for effective implementation, and strive for consistency in implementation of guidelines and standards. Ensuring control over the products on the market and tackling counterfeit products is important for protection of human and animal health and for consumer confidence. Regional cooperation and mutual recognition of product authorizations and inspections between countries, when based on political will and a legal framework, avoids duplication of work and facilitates access to medicines in the smaller markets. The concentrated effort and the presented initiatives will increase the political awareness and support for the authorization, control, and market access for veterinary medicines.

CONFERENCE OBJECTIVES

- Identify challenges relating to the registration process and improved market access for authorised veterinary medicines and how to promote the implementation of suitable systems.
- Explore the importance and benefits of regulatory convergence, including alignment to international standards and guidelines, and identify the key parameters enabling countries to implement them.
- Identify the needs, responsibilities and challenges relating to control of product quality during manufacture and control of products throughout the distribution chain.
- Through case studies, explore the needs for capacity building, mutual recognition, and regional organisations in the efficient implementation of regulatory systems.

PRE-CONFERENCE PRESENTATION ON SOCIO-ECONOMIC DEVELOPMENT

The 5th Global Animal Health Conference 2016 focused on improved market access for authorized veterinary medicines from an Asian perspective. Introducing an example of successful real-life aid based on small ruminants, Heifer International gave an inspiring presentation of the socio-economic development program in India where poor women in rural areas receive a goat and education in good animal care, breeding, disease control, food production and trade, which increases their living income and reduces hunger and malnutrition. A key principle underpinning the sustainability and impact of the program is the requirement to "pass on the gift" to another person, by passing on some of the off-spring of the livestock. This exponentially scales the effect of Heifer's intervention.

Avni Malhotra, Heifer International, India

CONFERENCE

The conference was opened by HealthforAnimals who thanked the organizers, the Indian government, and the local committee in India for their valuable support. The Bill and Melinda Gates Foundation emphasized it had sponsored the event based on their basic principle that "All lives have equal value", and recognizing that livestock plays a major role in human nutrition and a road out of poverty. Farmers who have livestock can realize a better life, and access to veterinary medicines is a major factor in keeping and optimizing the health and productivity of the animals.

The keynote talk from the World Bank, Enabling the business of agriculture – 2016 survey on veterinary medicines for livestock, presented the project on global data collection and examination of laws, regulations and barriers that influence agricultural business systems. The survey of 62 countries showed that a regulatory framework exists for veterinary medicines in most of these countries. A clear and predictable route to market, and an adequate structure of the governmental institutions are key to companies' willingness to apply for marketing authorizations. Clear requirements, validation of the submitted dossiers prior to the assessment phase and provision of expected timelines reduce the time needed for registration and increase the transparency of the process. Data protection and national disease databases were also identified as important for companies in their plan to bring products to a market. The full survey report will be available in 2017 for countries to investigate and benchmark their own structures.

SESSION 1: CHALLENGES RELATING TO MARKET ACCESS

Session 1 continued to investigate the challenges for market access and the investment strategy in agriculture and livestock. In India, livestock growth is faster than other agricultural sectors, which gives an increase in living income and the empowerment of women. India is the largest producer of milk in the world, but it is "production by masses" (many animals) and not "mass production" (large production per animal), because the livestock sector is not very efficient. Development of the infrastructure, rural communities, biotechnology, and network creation for (online) trading of goods are identified as cornerstones for building future growth.

The ministry of agriculture of India shared its vision on sustainable growth of the livestock sector for nutritional security and economic prosperity. Veterinary medicines are needed to ensure the health and productivity of livestock and should be safe, efficacious and produced to an adequate quality, as well as affordable and accessible. To align with global economies, a dedicated body and legislation for veterinary medicines, in line with international standards and supported with adequate capacity, is necessary to evaluate and control the products and ease the access to markets, both in India and globally.

In a change to the session 1 line-up, the key points from the workshop preceding the conference were presented by HealthforAnimals, resulting from the discussions of the best regulatory practices from an Asian perspective. The workshop recommended that each country in the world should ensure a

specific regulation of veterinary medicines, build regulatory capacity, and strive for consistency in implementation of guidelines and standards, part of which could be through joining the VICH Outreach Forum . It was strongly recommended to use the existing guideline texts and not waste scarce resources on re-inventing the wheel, and to involve stakeholders at an early stage.

On the topic of inspections of manufacture and distribution, it was recommended to use a risk-based approach where the effort is spent on the high-risk products and considering the manufacturer's track-record. Inspectors need legal empowerment, rules and defined duties, and a call for specific training of veterinary GMP inspectors was made. There was consensus that a harmonized dossier structure and regional collaborations are highly beneficial as building blocks towards a global standard. Mutual recognition of product authorizations between countries, when based on political will and a legal framework, avoids duplication of work; and experience shows that it even leads to more robust and consistent assessments. In the review process, predictability, transparency, and security of the submitted data package are important for applicants to stimulate commercial investment. A fee based system will provide resources to support a good regulatory process, facilitated by good cooperation between the ministries of agriculture and health.

Samuel Thevasagayam, Bill & Melinda Gates Foundation, USA

SESSION 2: IMPROVED REGISTRATION PROCESSES

Session 2 focused on improved registration processes to increase access to animal health products. The experience from the EU and its Regulatory Network model with 28 member states shows the importance of early pre-submission dialogue, consistent standards, harmonized guidance, and training of regulators for a smooth operation of the registration processes. Regular benchmarking of all EU agencies ensures consistency and is used as a way for member states to review and optimize their own operative practices.

As the intergovernmental organisation responsible for improving animal health worldwide, the World Organisation for Animal Health (OIE) recognises the importance of the good governance of veterinary medicinal products and the objectives of global convergence and harmonization of regulatory standards. With efficient cooperation, the OIE believes we can minimize the burden for industry, build capacity in authorities, save costs, share the workload, and ultimately take precedence in regulatory decisions from other authorities. It requires a Memorandum of Understanding to enable exchange of regulatory documents between authorities. The OIE codes and manuals for the improvement of animal health and welfare of terrestrial and aquatic animals are freely available online.

From the Brazilian Ministry of agriculture, livestock and food supply, the conference heard about the structure, facilities, and challenges of the Brazilian system for veterinary medicines where more than 10.000 products from 617 companies are registered. Political and regulatory awareness has created ongoing initiatives to improve the system, including updated legislation, adherence to international standards, reinforcement of inspections and surveillance, electronic submission, and better interaction with applicants.

The regional cooperation of the Americas, CAMEVET, was explained as a good example, outside of the Asian region, of a regional organisation working together to deliver coordination and efficiencies. In CAMEVET a board, a secretariat and 14 working groups have managed to stabilize and further harmonize the technical and regulatory requirements. This is based on a wish to foster continuous improvement of veterinary medicines and animal production and welfare. Challenges are the political agreements, resources, and language. Future expectations are improvements within labelling, training, antimicrobial resistance, pharmacovigilance, GMP-status, and aquaculture.

SESSION 3: GOOD MANUFACTURING PRACTICE (GMP) AND MARKET CONTROL

The session started with the presentation of the GMP requirements in Thailand. After several years of preparation and education of manufacturers, Thailand successfully gained membership of the Pharmaceuticals Inspection Cooperation Scheme (PIC/S) in 2016. GMP standards now cover all veterinary medicines manufactured or imported into Thailand, and the GMP standard of an exporting country influences the risk-based process and timelines for import permission.

The Indian Federation of Animal Health Companies (INFAH) expressed the need to cater for the growing animal production with good quality veterinary medicines. Detailed discussion on challenges and benefits of the GMP production was presented, showing the potential for reduction of errors and re-work, as well as improved compliance and quality of products. It is necessary to ensure manufacturing sites are fully capable of producing veterinary medicinal products according to GMP.

The importance of having control over the products on the market and fighting counterfeit products for protection of human and animal health and consumer confidence was the topic of US-FDA's presentation. Import controls, export certificates and understanding the supply chain are key factors. Counterfeit medicine, which is estimated to be a multimillion-dollar business, carries the risk of toxicity for animals and consumers, lack of efficacy in disease control, and undermining of the entire authorization process and public confidence. Political awareness must ensure the tools are in place to limit it as much as possible, including capacity building and the development and use of fast on-site analytical equipment.

Edgar Lucinario Calbitaza FDA, Philippines

Purvi Mehta, Bill & Melinda Gates Foundation, India

SESSION 4: REGIONAL ORGANIZATIONS AND MUTUAL RECOGNITION

Session 4 studied the experience with regional organizations and mutual recognition of product authorizations. Using a case study of Foot-and-Mouth Disease vaccination in India, the challenges were described in relation to regional structures, vaccination strategy compliance, capacity building, vaccine production plants and import licence of such very important veterinary medicines for India to be able to control FMD.

In the final presentation the mutual recognition procedures of four regional organizations were compared, i.e. EU, UEMOA in West Africa, EAC in East Africa and EEC in the Eurasia region. Since animal population growth is a key to support a growing human population, it was emphasized that getting veterinary medicines on the market in small countries would be strongly facilitated by having regional authorization processes, because companies would otherwise focus their products on the larger markets only. Four important pillars were identified for mutual recognition to function well; a common set of requirements, an agreed procedure, a legal framework, and implementing robust step-by-step guidance. Expanding marketing authorizations to many countries by mutual recognition or other cooperation will be beneficial for industry, regulators, customers and animal health and welfare.

The conference was wrapped up by the INFAH president with a summary of the key points and recommendations for next steps and learnings that the participants can take home and implement or consider in their own frameworks. HealthforAnimals closed the conference with their gratefulness for the progress and congratulated the participants, organizers, and sponsors on a very successful and well conducted event. It is the hope that the concentrated effort from the workshop and the many new impressions and initiatives presented during the conference will create the necessary political awareness and support to be carried forward for an improved market access for veterinary medicines.

Marvin B. Vicente, Philippines

Dey Dibyendu Kumar, India

PRESENTATIONS

Presentations, this report and the workshop report are available on www.healthforanimals.org.

ACCESS PICTURES

Pictures taken at the conference are available online:

https://www.flickr.com/photos/gahc2016/albums

If you need further assistance, please contact the DIA customer service on EMEA@DIAglobal.org

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