Workshop on good regulatory practice for the registration of VMPs in an African context

Session 1- General Overview

Comments by:
Laura Huffman, M.S.
Regulatory Review Scientist
United States Food and Drug Administration

Philippe Sabot, M.S.
Head, Regulatory Affairs
EMEA Emerging markets - Merial

Global Animal Health Workshop 2017
Good Regulatory Practice for the Marketing Authorisation of Veterinary Products in an African Context

Organising Committee:
Specifically, address these aspects:

• how this can be adapted for local implementation conditions;
• enable continued manufacturing of VMPs
• promote availability and access to authorized products
• encourage market development
• Use of international standards and regulatory convergence
Human health and animal health are interdependent and bound to the health of the ecosystems in which they exist — the ‘one health’ concept.

Domestic animals, wildlife, humans as well as aquatic animals face similar disease threats.

Today the World Organization for Animal Health (the OIE) estimates:
- 60% of human pathogens are of animal origin.
- 5 new human diseases each year (3 are of animal origin).
- 75% of new, human infectious diseases are zoonotic.
- 20% of animal production losses are caused by global diseases.

The World Organization for Food and Agriculture (FAO) estimates the demand for animal-based protein is expected to increase by 50% by 2020, and animal populations are under heightened pressure to survive.....

...thus the need for the approval of safe and effective therapies (including treatment, control and prevention of disease) for animal health could not be greater.

1 http://www.oie.int/en/for-the-media/onehealth/
Similarities and differences of regulating VMPs and human medicinal products:

a) **Market Size** - VMPs are a fraction compared to human products

b) **Number of Species** - one species (human) versus multiple species and multiple husbandry settings (animal)

c) **Regulatory requirements and timelines** - multi phase clinical trials (human) versus single clinical trial (animal)

d) **Costs of medicines** - human medicines often supplemented; animal owners often pay full cost of medicines

e) **Food Safety** - additional layer of safety regulations to ensure food from treated animals is safe for consumption

---

**Global Animal Health Workshop 2017**

---

Similarities and differences of regulating VMPs and human medicinal products:

Market Size - VMPs are a fraction of the total pharmaceutical market when compared to human medicinal products  
Number of Species - human sector = one species; veterinary sector = multiple species

Regulatory requirements - timeline for human drugs to approval much longer than VMPs.  
Example: multi phase robust clinical trials for human products vs single clinical trial to demonstrate safety and effectiveness for a VMP

Costs of medicines - human medicines costs are often supplemented (local country national health services; private insurances etc) however animal owners often pay full cost of medicines  
Food Safety - additional layer of safety regulations to ensure food from treated animals is safe for human consumption;
Many countries have a regulatory approval process for VMP but some may have

- no significant regulatory programs;
- diffuse, non-harmonized controls;
- no defined system.

Global Animal Health Workshop 2017

Many countries have a regulatory approval process for VMP but

- Some countries have no significant regulatory programs;
- Some countries might have diffuse, non-harmonized controls at state or local levels;
- Some countries may even have the need to identify a government focal point and build information-sharing networks.
Benefits of a robust Veterinary Medicinal Product (VMP) authorization system

- Positive impact on local, national, and international economies
- Continued proliferation of global trade agreements
- Importance of alignment with international standards and guidelines
- Quality VMPs lead to healthier animals and, indirectly, humans
- Healthier animals result in greater food production with reduced resource inputs
Good quality and control of Veterinary Medicinal Products (VMPs)

- Veterinarians, regulators, policy makers are key to the success of any such regulated approach.
- VMPs are drugs and vaccines (may include diagnostic test kits and pre-mixes) intended for use in animals (food producing animals intended for human consumption or companion animals)
- VMPs are intended for the diagnosis, cure, mitigation, treatment or prevention of disease in animals
- As with human medicinal products VMPs must also meet a similar requirement for the safe and effective use of these therapies in animals
- Animal and human sectors work together to protect health and ensure food safety and security
A Robust Authorization System for VMPs results in....

Process:
- Transparent and efficient
- Involves a science/evidence/risk based approach

A System:
- Consistent and understandable
- Together with appropriate market control contributes to public protection against counterfeit/illegal marketing
- Supports continued development of VMPs
- Builds trust with all stakeholders: vets, farmers and humans.
- meet standards of safety and effectiveness
  - VMPs are good quality manufactured products;
  - Are properly labelled;
  - And if food from treated animals is intended for human consumption, then shown to be safe

Global Animal Health Workshop 2017

A Robust Authorization System for VMPs results in....

- a transparent, consistent and efficient regulatory process for companies on how to get their products approved to market in the country.
- a transparent process so consumers can understand how VMPs are approved.
- a system that provides a fair market for the approvals and uses of both pioneer and generics drugs and protects against counterfeit and/or illegally marketed products.
- a system which supports the continued development of VMPs.
- a system that enables global cooperation and product development that is more flexible and efficient.

- a system that supports the role of multilateral/multinational organizations, provides transparency; improves trade efficiency.
- a system that builds trust with the stakeholders.
Characteristics of a credible, effective and fair authorization system:

- All regulatory programs need a *core set* of scientific competencies in place, and standards and procedures need to be available and implemented to undertake data assessments and/or understand the assessments conducted by others.

- All authorities should want to know the basis for approvals in their country and or in other countries.

- A system that enables global cooperation and product development that is more flexible and efficient.

- A system that supports the role of multilateral/multinational organizations, provides transparency; improves trade efficiency.

*Global Animal Health Workshop 2017*

All regulatory programs need a *core set* of scientific competencies in place, and standards and procedures need to be available and implemented to undertake data assessments and/or understand the assessments conducted by others.

All authorities should want to know the basis for approvals in their country and or in other countries.

A system that enables global cooperation and product development that is more flexible and efficient.

A system that supports the role of multilateral/multinational organizations, provides transparency; improves trade efficiency.
Questions for discussion:

- Does your region / country have a regulatory framework or system?
  - What are some of the obstacles in establishing this framework?
  - What the benefits of having such a system?

- If you have a framework, what is working, what isn’t working, and what regulatory policies would you like to see implemented?

Global Animal Health Workshop 2017
Addressing capacity problems, expertise...

- International guidelines from Codex, VICH, OIE serve as good resource especially when there is a lack of a regulatory guideline within a country’s regulatory system.
- Partnerships facilitate the exchange of ideas and help address knowledge gaps that arise during the regulatory authorization process.
- Partnerships can be developed within country – especially with other regulatory sectors, other government bodies or with academic institutions.
- Important to have agreements or memorandum of understandings (MOUs) if partnering with international regulatory bodies.
- Agreements with any external regulatory body must have clear understanding of confidentially agreements and sharing propriety information.
- PIC/S: Pharmaceutical Inspection Cooperation Scheme
Addressing capacity problems, lack of expertise...

- Internships within country or with international regulatory agencies - helps to broaden knowledge.
- Meet people and talk - exchange regulatory ideas
- Simultaneous reviews of same product provided drug company is in agreement.
- Reaching out external scientific expertise (Example of Australian initiative)

Global Animal Health Workshop 2017

Addressing capacity problems, lack of expertise...

We have already talked about MOUs and clear understanding of propriety information being key to successful relationship with external organizations. Internships within country or with international regulatory agencies - helps to broaden knowledge. For example, the OIE encourages and supports a scientist exchange program.

Conferences to exchange regulatory ideas - these can be simple as teleconferences or in person meeting between similar regulatory groups. Countries can also work on simultaneous review of same product provided drug company is in agreement. Reaching out external scientific expertise can be an option (Australian initiative)
Benefits of working with other authorities:

- Clear understanding of propriety information and MOUs are key to successful relationship with external organizations. Development of relationships can take time, especially to develop trust and confidence.

- Benefits:
  - increases confidence in decision making process.
  - increases quality of process.
  - builds regional trust/cooperation.
  - opportunity to leverage regulatory resources.
  - reduces in time to market, especially for new, innovative products.
  - Enhances data integrity.
  - Increases knowledge of regulations, regulated products and regulated system performance.

Global Animal Health Workshop 2017

Benefits:
- increases confidence in decision making process.
- increase quality of process by taking best practice of each agency and melding it into one process.
- builds regional trust and cooperation.
- opportunity to leverage regulatory resources.
- potential reduction in time to market for drug product, especially for new, innovative products.
- Enhances data integrity.
- Increases knowledge of regulations, regulated products and regulated system performance.
Risks:

- Local practices/processes could impact final decision outcome and this could be different from other authorities.
- Outside regulatory organization’s process may not be aligned with local country’s process.
- Risk of compromising information (data or review content)
- Loss of transparency
- Logistical issues- IT compatibility, languages and translation of documents

Global Animal Health Workshop 2017
Importance of stakeholder interactions:

- Who are your stakeholders?
  - Public;
  - Industry/trade partners;
  - Government bodies;
  - Non-governmental orgs;
  - Academia, etc.

- Potential benefits: improved review, quality products = to market faster!
- Collaborations are to be well-framed
- Increases public trust - transparency in regulatory decision making

Result: ‘One Health’: approved products leads better animal health and results in a safer food supply

Global Animal Health Workshop 2017

Importance of stakeholder interactions:

Examples of Stakeholders: public; industry; other government bodies; consumers; non-governmental orgs trade partners, academia, etc.
Increased collaboration with industry could result in improved review times allowing for quality products to get to market faster - benefits both consumers and industry. Collaboration are to be well-framed

Increases public trust - transparency in regulatory decision making.
Enables new product development.

Impact on both country’s economy and human and animal health - more approved products leads better animal health and results in a safer food supply, thus promoting One Health
In summary…

The aim of this workshop is to share knowledge and understanding of good regulatory practices and to promote further close cooperation amongst a regional network of regulatory agencies.

This serves the wider aim of promoting animal health and contributes to the One Health approach.

Global Animal Health Workshop 2017
Sample questions for discussions:

- Does your region engage in regulatory collaborations with external organizations, including international agencies?

- If you have a framework or MOU for external collaborations, what is working, what isn’t working, and what regulatory policies would you like to see implemented?

- What are the risks or concerns with collaborating with other authorities? How can these concerns be overcome?

Global Animal Health Workshop 2017
Thank you!

Laura.Huffman@fda.hhs.gov
philippe.sabot@merial.com

Global Animal Health Workshop 2017
The Australian initiative*: allowing for independent - accredited by Authorities - Reviewer to be appointed and directly exchange with the applicant

- APVMA appoints a number of accredited Scientific reviewers.
- Applicant contacts directly with Scientific reviewers. Negotiates fee and timeline for review directly with reviewer.
- Applicant submits Efficacy & Safety data to Reviewer. Output: Reviewer provides an Expert Report is provided directly to the applicant.
- The applicant can use as part of a later full submission.
- With this Expert report included in a submission, APVMA now only requires an ‘internal’ evaluation of the Part 8 (Efficacy & Safety) section.


Global Animal Health Workshop 2017