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

Session 1 - General Overview

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Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

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)\(^1\) estimates....

- 60% of human pathogens are of animal origin.
- 5 new human diseases appear each year, 3 are of animal origin.
- 75% of new, emerging human infectious diseases have been zoonotic.
- 20% of animal production losses are caused by diseases globally

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:

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 and multiple husbandry settings (animal)

Regulatory requirements and timelines: multi phase clinical trials (human) versus single clinical trial (animal)

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

Food Safety- don’t eat people; additional layer of safety regulations to ensure food from treated animals is safe for 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.

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....

- 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.
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 discussions:

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

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

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 confidentiality agreements and sharing propriety information.
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:
- 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/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.
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
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.
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?
Thank you!

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Back-up slide Australian initiative

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.
