



# WORKSHOP REPORT

## Global Animal Health Workshop 2017

Good Regulatory Practice for the Marketing Authorisation  
of Veterinary Products in an African Context

12-14 June 2017  
Nairobi, Kenya

Organising Committee

BILL & MELINDA  
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Protecting Livestock – Improving Human Lives

Republic of Kenya  
  
Ministry of Agriculture  
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Health for Animals  
global animal medicines association



## WORKSHOP REPORT

### SUMMARY

The Global Animal Health Workshop on good regulatory practice for the marketing authorisation of veterinary products (VPs) in an African context, was organised by HealthforAnimals together with partners from the World Organisation for Animal Health (OIE), GALVmed, the European Medicines Agency (EMA), the US Food and Drug Agency (USFDA) and the Drug Information Association (DIA), with participation from the Kenyan Ministry of Agriculture Livestock and Fisheries, and Japanese Ministry of Agriculture Fisheries and Food.

Forty three Participants from 28 African countries attended this workshop and shared their experiences in open discussions facilitated by a professional moderator. Together they formulated a list of recommendations on best regulatory practice for the market control of veterinary medicines, and how to improve cooperation and promote animal health. The recommendations recorded in this report, which were derived from the workshop discussions, supplement the recommendations already inherent in the presentations given to introduce each topic and published in the Workshop Workbook.

This event was supported by the Bill & Melinda Gates Foundation.

### WORKSHOP AIMS

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.

### WORKSHOP OBJECTIVES

To review and discuss:

- The essential elements of a regulatory system for the marketing authorisation of veterinary products and the opportunities for stimulating the entry of new quality assured, safe and effective products on the market.
- The roles of legislation and guidance documents, and alignment with international standards.
- Good manufacturing practices (GMP), authorisation procedures for veterinary products and pharmacovigilance.
- The benefits and hurdles of mutual recognition of marketing authorisation processes from other regions with internationally recognised regulatory systems, including GMP.
- The benefits and hurdles of the formation of regional organisations to pool resources and the advantages of alignment with international standards.
- The processes necessary for market control of veterinary products. How to tackle falsified products? What are the critical elements and where should resources be focussed?

### THE WORKSHOP TEAM

**Rick Clayton**, HealthforAnimals, Belgium, (chair)

**Talina Sterneberg**, HealthforAnimals, Belgium

**Gilly Cowan**, GALVmed, UK

**Glen Gifford**, OIE, France

**Laura Huffman**, FDA, USA

**Kristen Anderson**, FDA, USA

**Lisbet Vesterager Borge**, European Medicines Agency, EU

**Catherine Lambert**, ANSES, France

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**David Mackay**, European Medicines Agency, EU

**Melanie Leivers**, UK

**Erik de Ridder**, Elanco, Belgium

**Philippe Sabot**, Meril, France now part of Boehringer Ingelheim

**Nao Nakajima**, MAFF, Japan

**Yuko Hosoda**, MAFF, Japan

**Workshop discussions moderated by Claire Davidson (Davidson - Ryan - Dore Partnership, UK), Professional organisational and logistical support from DIA EMEA.**



Global Animal Health Workshop 2017, Nairobi, Kenya  
The Workshop Team

## REPORT AND RECOMMENDATIONS

There were 8 workshops sessions. Each session topic was introduced by a member of the Workshop Team in a short presentation that provided basic information and a recommended approach as a framework for discussion. A short summary of each of the sessions is given below, together with the additional recommendations arising from the workshop delegates during the discussions of the information and recommendations presented to introduce each topic. This report is an adjunct to the introductory presentations, which are publically available in the Workshop Workbook (see HealthforAnimals website).

### SESSION 1: GENERAL OVERVIEW

A short overview of the differences between regulation of veterinary medicinal products (VMPs) and human medicinal products was given. In many countries these two are closely linked, with registrations for both done under the Ministry of Health. The approaches to regulating VMPs differ from country to country, even within a region and the benefits of a robust system where veterinary services, regulators, veterinarians and industry cooperate were explained. Also some of the hurdles, such as capacity problems, and possible solutions, such as collaboration with other authorities and the use of international guidelines, were considered.

#### The recommendations from this session were:

- For countries where the legal framework and agency are not yet established: have a separate legal framework and agency for VMPs. For countries with these already established within one entity: ensure a separate Veterinary Division or Directorate is established and/or strengthened.
- *The advantages and disadvantages of joint or separate agencies are discussed in session 8.*
- Work with international guidelines.

- e.g. VICH GLs, OIE standards, OECD, WHO, Codex (MRLs)
- Regulatory capacity building is needed.
  - To overcome capacity challenges, develop a twinning approach, or mutual recognition procedures, or some form of work sharing to share resources.
- Well-resourced veterinary services are necessary to maximise the impact of regulatory measures.
- Building trust between countries will be very beneficial.
- The use of PANVAC for vaccine quality control as an alternative if there is no access to a national laboratory.
- An African Medicines Agency should be established.



## SESSION 2: LEGISLATION AND GUIDANCE

During this session participants were given examples of how to develop and structure the legislation necessary to create a credible, effective and fair authorisation system and, just as important, how to keep the flexibility to update this system when needed. The differences between regulations and guidelines and how to prepare them were discussed and an overview of available guidelines and international standard setting bodies was given. During a presentation on regulatory convergence the objectives and benefits of this process were explained and one of the examples to work towards convergence was “incorporation by reference”. By using this mechanism a country can include international codes and guidelines in their regulations or guidelines without having to ‘reinvent the wheel’.

### The recommendations from this session were:

- The VICH Steering Committee should provide more communication about the VICH Outreach Forum.
  - Some countries want VICH to approach their government directly to explain the benefits of joining the forum.
- In national guidelines use ‘incorporation by reference’ to refer to international standards and guidelines.
- Use a risk-based approach.
  - An example of low risk would be the acceptance of an assessment or inspection from a well-trusted agency, also called ‘mature regulatory authorities’ (e.g. VICH members).
  - Focus limited resources by considering risk-based options, such as:
    - Fully accept a marketing authorisation decision or inspection from another jurisdiction
    - Do an abridged review of a product registered in another country
    - Do a full review or manufacturing site inspection.

### Recommendations to address the question: How can we work together?

- Avoiding duplication:
  - Consider accepting a scientific assessment from another country (mutual recognition)
  - Work together on the dossier; share the work, each working on a separate part (collaborative assessment).
- Request additional information when necessary for specific circumstances, such as additional local clinical studies after considering national realities and conditions.
- The national authority retains responsibility for granting a national marketing authorisation at the conclusion of these collaborative procedures.
- This way **build trust** between countries.



Gilly Cowan, GALVmed, UK



Glen Gifford, OIE, France



## SESSION 3: MANUFACTURING OF VMP's

This session focused on manufacturing site inspections and distinguished between the control of the final product and control of the manufacturing process and site. Inspections may be done by the regulatory agencies but in-house controls by qualified persons are equally important. A system should be in place to ensure quality is built into a VMP as this cannot be tested only at the end. Clear documentation of this system/process is key.

Inspection programmes by regulatory authorities were discussed and examples of the risk based approach were given. An important aspect of inspections is the training and impartiality of inspectors. Capacity issues occur where some authorities do not have sufficient numbers of adequately trained inspectors. Collaboration with other agencies or acceptance of inspections done by other agencies may overcome these issues.

**Question:** How are we going to recognise the inspections of other jurisdictions?  
We can do this for VICH countries, but how can we establish wider agreements?

### **Recommendations from this session were:**

- Use GMP inspection guidelines based on the international guidelines (WHO, EU, OIE).
- Use a risk-based approach to inspections (which manufacturing sites, and frequency of inspection).
- Use a risk-based approach to sampling and testing from the marketplace.
- Have a system in place to recall the product when necessary.
- Use work sharing to avoid duplication, and resource sharing, such as sharing [regional] testing laboratories.

- GMP inspection teams for VMP manufacturers should not be dominated by pharmacists trained in human medicine manufacturing and testing procedures.
  - They may not be familiar with procedures for formulating and administering VMPs.
  - Lack of specific sector knowledge hinders ability to conduct meaningful inspections.
  - To ensure appropriate inspections, the inspection teams should involve veterinarians or other scientists with knowledge of VMP manufacturing and testing procedures, and the requirements for VMP manufacturers.
- GMP Training of inspectors / competencies could be formalised by inclusion in the OIE Terrestrial Animal Health Code (by reference) and the use of checklists.
- Inspector's qualifications: a scientific qualification, training and experience (in industry). It is useful to include veterinarians in the overall program planning.
- Use a flexible approach for import licence requirements; is it necessary to have one or both of these items:
  - A manufacturing site registration and GMP certificate
  - An existing MA from a trusted regulatory authority (not necessarily country where manufactured).

### **Additional information:**

See the EU EudraGMDP database on manufacturing, import and wholesale-distribution authorisations, and GMP and good-distribution-practice (GDP) certificates:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/eudra\\_gmp\\_database.jsp&mid=WC0b01a-c058006e06e](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/eudra_gmp_database.jsp&mid=WC0b01a-c058006e06e)



Group Work



## SESSION 4: AUTHORISATION PROCEDURES

This session gave an overview of the complete procedure from dossier structure to the review process and the possibility of appeal. In some countries clear dossier structure templates are available on-line alongside guidelines on how to use them, but in other countries this is still being developed. Examples of international guidelines that can be used to develop a system were given.

Review timelines were discussed and these are not always predictable, as many countries struggle with backlogs due to capacity problems.

Possible ways of interaction with applicants and the use of experts were discussed.

The last part of this session covered the opportunities and benefits of harmonisation and mutual recognition. Examples of existing mutual recognition procedures were given and the need for a 4 pillar approach was explained. These pillars are:

- A common set of technical requirements
- A defined registration procedure
- Political will and legal framework
- The implementation detail (hands-on guidance).

### The recommendations from this session were:

- Be transparent in your timelines – publish them. Putting timelines in the legislation provides legal certainty to applicants.
- Be transparent with a tracking system whereby the applicant can follow the progress of the dossier would be useful, especially if no fixed timelines are followed.
- Interaction with stakeholders is important; pre-submission meetings with individual applicants can be useful, particularly for new technology products; however full stakeholder meetings are also needed.
- It is important to have a guideline describing the data requirements, including the minimum data requirements for a fast-track procedure for prioritised products.
- Use guidelines harmonised on a regional basis (see example in box below)

### Example of guidelines harmonised on a regional basis - East African Community:

The countries of East African Community have developed harmonised guidelines, including a specific technical guideline for the data requirements for registration of veterinary vaccines. These already incorporate relevant VICH and EMA guidelines. Regulators receive joint training in dossier assessment and GMP inspection. With the SOPs and guidelines on how to run a Mutual Recognition Procedure (MRP) to a predictable time clock now in place this harmonised system will enable MRPs within the region to start in 2017. Other regions are interested in using this approach for approving veterinary medicines.

- Use international guidelines
  - Countries that are missing specific guidelines, which have already been developed in other regions or at an international level (e.g. VICH), should be encouraged to adopt them or cross reference them or modify them for use as their own guidelines (see examples in box below)

### Examples cited of useful existing regional and international guidelines:

- GL on fast track requirements: EMA/CVMP/222624/06 Requirements for an authorisation under exceptional circumstances for vaccines for use in birds against avian influenza.
- VICH bioequivalence guideline for generic products: CVMP/016/2000 (Rev. 2) Conduct of bioequivalence studies for veterinary medicinal products (currently being revised to align with VICH GL 52 on bioequivalence).

### **Mutual Recognition Procedure (MRP)**

- Political commitment and legislation supporting mutual recognition are essential, supported by strong central coordination (e.g. a central review committee).
  - For example, the EU MRP has a legal basis backed up with a coordination committee which serves as a forum to discuss and agree issues enabling the smooth running of the process.
- Do not 'reinvent the wheel' – look at what other regional organisations have done; copy and paste.
- Implementing MRP: have stakeholder meetings early in the process – make all stakeholders aware of the system and make sure that you have the technical support from the Heads of Agencies.
- Start MR with a small group of countries that are aligned and have political commitment; allow other countries to join as confidence builds (see Zazibona example in box below).
- Establish trust: people need to work together to build trust.

### Example: the success of the Zazibona harmonisation is based upon:

- Political commitment and a central review committee;
- Good training of assessors;
- IT platform to share dossiers;
- Sharing the assessment work and all participating in peer review of each product assessment;
- Final decision remains national.



## SESSION 5: LOGISTICS

This session focused on the very practical issues of how to submit a dossier in a secure way and how to maintain archives. Advantages and disadvantages of paper versus electronic submissions and archives were discussed, as well as the hurdles of setting up an electronic system.

Security of the information provided by industry is very important, to encourage applications for new product registrations, and a confidentiality policy should be in place.

As before, capacity problems became apparent and cooperation was suggested to overcome the problem of large IT investments.

All countries charge fees for the evaluation of a dossier. Some agencies completely depend on these fees, while for others this income is supplementary.

### Brainstorming session on dossier submissions

#### Archiving

- Archiving and retrieval department with a good system for storage and retrieval (numbering system)
- A secure environment-controlled room (see 'Security' below)
- Scan hard copies and store backups in the cloud.

#### Security

- Have security conscious staff and office cabinets that can be locked
- Limit access to archive or storage rooms to a few people; a system for controlled access
- Need confidentiality agreements for staff (some require staff to swear an oath not to disclose info)
- Need fire, water and pest proof strong room for paper archive
- Secure and robust IT systems, supported by experienced IT staff, frequent change of password, regular system updates, back-up systems at a different location, and virus firewall
- Security of premises to avoid theft of documents and hardware (security staff and physical security features).

#### Example:

UEMOA has 2 people handling document storage and archiving and has 2 metal containers storing paper and CDs, with controlled access restricted to only the permanent members of the VMP Permanent Secretariat.

#### Fees

- Fees need to be fair but sufficient to ensure the good operation of the regulatory authority
- Cost recovery should be based on the cost of providing the service
- Fees can benefit the applicant by adequate resourcing helping the systems to run smoothly
- Fees can be different for different types of product, as the amount of work can vary
- Regulation of VMPs is a public good, and market value may not justify payment of registration fees; the government should subsidise the competent authority
- For minor species (or minor indications for a major species) you can waive fees.

#### The additional recommendations from this session were:

- Security of the data submitted is important to encourage applicants to submit data
- Collaborate on software: secure exchange of data; sharing data regionally
- Form private/public partnerships with industry to support/fund cost of introducing software
- Pool resources of cooperating countries to cover up-front cost of an electronic submission system
- Scan documents to create an electronic copy and get rid of paper copies to help with storage issues.

#### Example:

WHO Mednet system can be used to share documents (free) and is used by Zazibona.



Group discussion with **Kristen Anderson, FDA, USA**



## SESSION 6: QUALITY CONTROL OF VETERINARY PRODUCTS

Ensuring the quality of VMPs by a system with marketing authorisations, inspections and surveillance in the market is an essential and basic requirement for the good governance of VMPs. These activities help to prevent the presence and growth of an illegal market of counterfeit products and illegal imports.

### Recommendations from this session were:

#### Illegal import, counterfeit products

- Capacity building for Inspectorate body:
  - Exists in several of the countries present at the workshop, but further training is needed to maintain knowledge and adapt knowledge
- Develop strong cooperation between customs officers, regulatory authorities and the police
- Stronger cooperation between countries is also key, to optimise resources, share know-how and 'intelligence'
- Harmonisation efforts should be encouraged as they contribute to fighting counterfeiting.

### Examples of additional measures to fight counterfeiting:

- Also inspect the stores of the importer; are they importing what is stated on their licence?
- Publish a lists of registered products and manufacturers/wholesalers to inform people of the legal market (e.g. useful information for Customs staff)
- Conduct public awareness campaigns about the use of counterfeit medicines
- Inspectors need to be empowered (through the law), to allow enforcement, but also to be protected because this can be dangerous work
- Inspectors need to be 'veterinary sector' trained

### Surveillance

- The outcome of the UEMOA investigation into the needs for laboratory equipment should be shared and the possibility of using these labs for testing pharmaceuticals in the continent should be investigated.
- Organise resources at a regional level (for example PANVAC).



Group discussion with **Catherine Lambert, ANSES, France**





## SESSION 7: PHARMACOVIGILANCE

This session gave a very practical overview of the essential elements of a basic pharmacovigilance system and how to develop this based on the available international guidelines. Everyone agreed that such a system is essential for continued monitoring of the safety and efficacy of VMPs in the marketplace. Currently very few countries have a system in place.

### Recommendations concerning this topic were:

- Work at a regional level and stay aligned with VICH definitions (VICH GL 24 and 29)
- Keep it simple
- Encourage / reward reporting, make it easy
- Availability of reporting forms; paper or on-line; growth of “smart phones” (e.g. App for easy reporting)
- Make sure people know how/where to report
- Publish guidance for reporters
- Develop guidance for regulators.

### Additional information:

- Uganda has a pharmacovigilance system in place and is willing to share information on this with other national regulatory authorities
- Brochure: The Essentials of veterinary pharmacovigilance (HealthforAnimals website, ‘Publications’: <http://www.healthforanimals.org/resources-and-events/resources/publications/154-pharmacovigilance-guide>)
- VICH Outreach Forum – training materials – PowerPoint presentation “**Pharmacovigilance: Development of PhV systems and processes**” (VICH website, ‘Training Material’: <http://www.vichsec.org/outreach-forum/training/module-6.html>)

### More advanced pharmacovigilance ambitions:

- Goal: develop regional pharmacovigilance databases with the long term goal of a global database
  - Keep international alignment from day 1 to simplify harmonisation later on
- Link the pharmacovigilance database with a registered product database
- OIE should consider how it can support countries in implementing pharmacovigilance
  - Focus on antimicrobial resistance?
  - Promote and take advantage of the OIE disease surveillance platform which already collects and shares data on disease to coordinate pharmacovigilance from such an existing platform
  - Role of OIE in training, communication, cooperation.



Group discussion with **Lisbet Vesterager Borge**, EMA, CVMP, EU



## SESSION 8: KEY ENABLING FACTORS

Summarising many things said in the previous sessions, this session gave a good overview of how to work towards a system that **encourages companies to invest**. Both industry and regulators need to be committed to support strategies that engage stakeholders in an open, transparent and collaborative manner to promote regulatory systems strengthening.

Issues discussed included:

- The benefits of regulatory convergence
- Prioritisation for best use of resources
- Clear and structured information to applicants
- Predictability and reliability of the regulatory system
- The need to account for the unique characteristics of the veterinary sector (beware simple adaptation from human medicines system).

### Joint human/veterinary agencies versus separate veterinary agencies

- Both structures have advantages and disadvantages – impossible to generalise (need to see what suits the situation and legal requirements)
- Ideally have trained people with a good knowledge of the veterinary sector
- Take advantages of synergies with human medicines departments (e.g. infrastructure and access to and budgets and funding)
- **Make yourself visible** to your government minister and raise awareness of your importance to human public health and agriculture.

### Further recommendations:

- Benefit-risk assessment is a judgement based on all the available data; risk can be managed by defining the conditions of use of the product, supported by a pharmacovigilance system; additional and indirect benefits can also be taken into account.  
- N.B. the level of risk is determined by the size of the hazard multiplied by the likelihood or possible extent of exposure to the hazard.
- OIE should also invite regulatory contacts to Focal Point training seminars, in addition to the designated OIE Focal Point for Veterinary Products.
- The EU Network Training Centre\* (EU-NTC) should be open to non-EU countries – create an EU-NTC-outreach.

*\*The mission of the EU NTC is to ensure that good scientific and regulatory practices are spread across the network along with harmonised training standards, through the provision of high quality and relevant training materials identified and shared through by the EU-NTC platform (see <http://www.hma.eu/otsg.html>)*



Group discussion with **Melanie Leivers, UK**



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# Presentations

The presentations (Workshop Workbook) and this report are available on the HealthforAnimals website.

<https://healthforanimals.org/our-sector/global-regulatory-framework/98-6th-global-animal-health-conference.html#-content-section>

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