The impact of Good Veterinary Services Governance (GVSG) on the control over Veterinary Medicinal Products (VMP’s)

The evaluation of Good Veterinary Governance with the OIE Performance of Veterinary Services Tool (PVS) with specific reference to Veterinary Medicinal Products.

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**Good Veterinary Services Governance**

Recent emergence and re-emergence of transboundary animal diseases,

new risks arising from global warming or globalization

the estimate that 75% of emerging (new) diseases and 80% of pathogenic agents having a potential use in bioterrorist activities are zoonotic

demonstrate the need for Good Veterinary Services Governance (GVSG) on a global, regional and national scale
Global Public Good

The role of Veterinary Services in animal health, specifically in the prevention, control and eradication of animal diseases, as well as having a crucial function in public health and zoonoses control, Veterinary Services (VS) clearly constitute a global public good.
Global Public Good

A global public good is

• **non-rivalous**. Consumption of this good by anyone does not reduce the quantity available to other agents.

• **non-excludable**. It is impossible to prevent anyone from consuming that good.

• **available** worldwide.
One World – One Health

The strategy of “One World – One Health”, relating to the prevention and control of emerging infectious diseases at the animal/human interface such as those with the potential to cause epidemics and pandemics, but also those animal diseases having an impact on food security and poverty, depends on GVSG on all respective levels of activity and service delivery.
GVSG and VMP´s

An essential cornerstone and tool in addressing and sustaining GVSG are veterinary medicinal products (VMP´s), such as veterinary drugs (medicines) and biologicals.

A consolidated legislative framework, establishing mandate and responsibilities of the VS, supported by adequate human, physical and financial resources, are integral and essential components for the control of VMP´s, executed in a public-private partnership with all stakeholders such as the pharmaceutical industry, private veterinary sector and animal (livestock) owners.
The Quality of Veterinary Services (VS) depend on OIE International Standards which are Official references of the WTO SPS Agreement Adopted by consensus of OIE Members and are available as the Terrestrial Animal Health Code (TAHC)
The TAHC

Terrestrial Animal Health Code (TAHC) mammals, birds and bees available at
http://www.oie.int/eng/normes/mcode/en_sommaire.htm
Applicable OIE reference quality standards relating to veterinary medicines and chemical residues are described in the following chapters of the Code:

- Chapter 3.1. - Veterinary Services
- Chapter 3.2. - Evaluation of Veterinary Services
Standards on the Quality of Veterinary Services (VS)

Chapter 3.1. - Veterinary Services  Article 3.1.1

include fundamental principles of an
- ethical
- organizational; and
- technical nature

and VS shall conform to these principles regardless of the political, economic or social situation of the respective country.
These OIE standards, contained in **Chapter 3.2 & 6.10** of the 2009 TAHC, relating to VMP’s are:

- **Art. 3.2.7** – Animal and Veterinary Public Health  
  - control over use of VMP’s  
- **Art. 3.2.9** – Veterinary Public Health  
  - chemical residue testing  
  - veterinary medicines  
- **Art. 3.2.14** – information requirements  
- **Art. 6.10.6** – responsible & Prudent use of antimicrobial agents in Veterinary Medicine
Chapter 6.7.1 of the 2009 TAHC, relating to controlling antimicrobial resistance

the OIE recognizes that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere

and in Chapter 6.10.6 outlines the responsibilities of veterinarians
Chapter 6.10.6 of the TAHC

The concern of the veterinarian is to promote public health and animal health and welfare. The veterinarian’s responsibilities include preventing, identifying and treating animal diseases. The promotion of sound animal husbandry methods, hygiene procedures and vaccination strategies (good farming practice) can help to minimize the need for antimicrobial use in food-producing animals.

Veterinarians should only prescribe antimicrobials for animals under their care.
Chapter 6.10.6
Responsibilities of Veterinarians

1. Use of antimicrobial agents
2. Choosing an antimicrobial agent
3. Appropriate use of the antimicrobial agent
4. Recording
5. Labelling
6. Training.
The OIEPVVS Evaluation Tool and its application to GVSG regarding VMP’s

Any improvement of national veterinary services has to be based on a systematic evaluation of their current performance, and therefore to use set of standard evaluations through the OIE.

In order to evaluate national Veterinary Services’ compliance with these OIE TAHC Standards, as well as to assist in putting into place GVSG, the OIE has established procedures for the evaluation of the VS, based on the provisions in Chapter 3.2. of the Code
Any such EVALUATION of a VS should use the OIE Tool for the Evaluation of the Performance of VS (OIE-PVS Tool)
Based on provisions of the TAHC Chapter 3.2
Articles 3.2.3 to 3.2.13
evaluation criteria
Article 3.2.14
detailed information
The OIEPVS Tool is

✓ not static
✓ updated/amended
✓ at regular intervals based on need and field experiences
The use of the OIE-PVS Tool

1. **Self evaluation** performed by internal and/or OIE experts for the purpose of assessing the performance of VS process reviewed on a regular basis to monitor improvements

2. An evaluation for the purpose of **risk analysis in the international trade in animals and/or animal derived products** to which official sanitary and/or zoosanitary controls apply
The use of the OIE-PVS Tool

3. An independent **evaluation** that provides a strong legitimization of a **request for national and /or International financing**. Major donors have accepted the use of the OIE PVS Tool and the criteria in the *Code* in the evaluation of performance and priorities of VS, as a prerequisite in helping countries make requests for investment.
The OIEPVS Evaluation Tool

Access to markets

Interactions with stakeholders

Technical authority and capability

Human, physical and financial resources

4 Fundamental components
The OIEPVS Evaluation Tool

4 Fundamental components

PVS
For each of the 4 fundamental components, 6 to 12 critical competencies

I. Technical authority and capability
   - Veterinary laboratory diagnosis
   - Laboratory quality assurance
   - Risk analysis
   - Quarantine and border security
   - Epidemiological surveillance
   - Early detection and emergency response
   - Disease prevention, control and eradication
   - Veterinary public health & food safety
   - Veterinary medicines & veterinary biologicals
   - Residue testing
   - Emerging issues
   - Technical innovation
4 Fundamental components

Critical competencies (6 to 12)
The OIEPVS Evaluation Tool

- 5 Levels of advancement
- A higher level assumes compliance with all preceding levels

Level 1
no compliance

Level 5
full compliance with OIE standards
4 Fundamental components

Critical competencies (6 to 12)

5 levels of advancement
Within the 4 fundamental components of the OIE PVS Tool, the following competencies address the control of VMP’s directly or indirectly:

II. Technical authority and capability
   - II.2 Laboratory Quality Assurance
   - II.9 Veterinary medicines & veterinary biologicals
   - II.10 Residue testing

III. Interaction with Stakeholders
   - III.2 Consultation with stakeholders

IV. Access to Markets
   - IV.1 Preparation of legislation and regulations, and implementation of regulations
   - IV.2 Stakeholder compliance with legislation and regulations
   - IV.3 International Harmonisation
II. Technical authority and capability

This component of the evaluation appraises the authority and capability of the VS to develop and apply sanitary measures and science based procedures supporting these measures. *It comprises twelve critical competencies.*

Critical competency:

II.9 Veterinary medicines & veterinary biologicals

II.9. Veterinary medicines & veterinary biologicals

The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals.
<table>
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<tr>
<th>Activity per Level</th>
<th>Level</th>
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<tr>
<td>1 The VS cannot regulate the usage of veterinary medicines and veterinary biologicals.</td>
<td>1</td>
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<tr>
<td>2 The VS has only limited capability to exercise administrative control (including registration) over the usage, including import and production, of veterinary medicines and veterinary biologicals.</td>
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<tr>
<td>3 The VS exercise quality control (technical standards) over the import, production and distribution of veterinary medicines and veterinary biologicals.</td>
<td>3</td>
</tr>
<tr>
<td>4 The VS exercise complete control over registration, sale and usage of veterinary medicines and veterinary biologicals.</td>
<td>4</td>
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<tr>
<td>5 The VS implement systems to monitor the use of veterinary medicines, veterinary biologicals and their side effects (pharmacovigilance).</td>
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Evaluation results in numerous completed OIEPVS Reports indicate critical shortcomings in legislation, administration and quality control over veterinary medicinal products.

In this context it must be kept in mind that the credibility of the VS of a country is closely linked to its ability and performance regarding the control and prudent use of antimicrobials.

The control of veterinary medicinal products is thus an important and integral function and primary responsibility of national public VS´s, executed in a public-private partnership with all stakeholders such as the pharmaceutical industry, private veterinary sector and animal (livestock) owners.
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