OIE Focal Point Seminar on Veterinary Products
Vienna, Austria, November 20-22 2012

Support for OIE Member Countries
OIE PVS / Gap Analysis, Reference Laboratories and twinning programmes

N. Leboucq
OIE sub-regional Representative in Brussels
CAPACITY BUILDING FOR NATIONAL VETERINARY SERVICES

**Objective:** Strengthen the capacity of Members’ Veterinary Services to achieve the improvement of animal health, veterinary public health and animal welfare, while improving their ability to participate in the development of international standards and guidelines on these matters; and strengthen their ability to apply these standards and guidelines.

=> strengthening the good governance of Members’ Veterinary Services
Support to OIE Members

The OIE’s founding mandate has evolved and has been adapted to Members’ needs, it now includes the following specific missions:

+ To ensure transparency in the global animal disease situation, including zoonoses;

+ To collect, analyse and disseminate relevant scientific information, especially on disease control methods and animal welfare;

+ To provide expertise in the control of animal diseases including zoonoses, as well as at the animal–human–ecosystems interface, while taking into account the “One Health” concept whenever possible;

+ To ensure safety of world trade in animals and animal products by preparing, adopting and promoting the application of relevant health standards for such trade, as foreseen in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”);

+ To improve the safety of food of animal origin from hazards originating in animal production;

+ To establish standards and guidelines for animal welfare through a science-based approach and promote their application;

+ To improve the legal framework, competency and resources of national Veterinary Services, and particularly their global public good components;

+ To address animal health issues related to poverty alleviation and the assurance of food security;
The OIE collaborates with governments, donors and other stakeholders

The OIE PVS Pathway

« Diagnosis »
PVS Evaluation

« Prescription »
PVS Gap Analysis
including Veterinary Services’ Strategic Priorities

« Treatment »
Capacity Building, Specific Activities, Projects and Programs
Veterinary Legislation
Public / Private Partnerships
Veterinary Education
Laboratories
PVS Pathway Follow-Up Missions

The OIE collaborates with governments, donors and other stakeholders
PVS evaluation of Veterinary Services

the diagnosis
The OIE collaborates with governments, donors and other stakeholders.
OIE International Standards

Official WTO SPS reference
Approved standards adopted by consensus of OIE Members, *incl.* on Performance on veterinary services

*Terrestrial Animal Health Code* - *mammals, birds and bees*

- Chapter 3.1. Veterinary Services
- Chapter 3.2. Evaluation of Veterinary Services
OIE International Standards

Quality of veterinary services

✓ Compliance is important to credibility of
  • health status claims
  • international health certification

✓ Quality of vet services depends on set of factors
  • including fundamental principles of an ethical, organizational and technical nature
The OIE PVS Tool

Evaluation of the Performance of Veterinary Services

a tool for Good Governance of Veterinary Services

- applicable to veterinary services in all regions
- vet services comprise public and private sector veterinarians and vet para-professionals

OIE-PVS Tool (public document)
http://www.oie.int/eng/oie/organisation/A_2010_PVSToolexcludingindicators.pdf
Use of the OIE-PVS Tool

- **Self-evaluation** performed by internal and/or OIE experts for the purpose of assessing VS performance.
- An evaluation relevant to **bilateral negotiations** between trading countries, by mutual agreement.
- An **independent evaluation** that provides a strong legitimization of a request for national and/or international financing.
OIE PVS Tool: Structure

4 fundamental components

- Human, Physical, Financial Resources
- Technical Capability and Authority
- Interaction with Stakeholders
- Market Access

6 - 14 Critical competencies

5 levels of advancement

46 Critical competencies
The OIE PVS Tool - structure

46 Critical Competences

CHAPTER I - Human, physical and financial resources

Section I-1 Professional and technical staffing of the Veterinary Services
Section I-2 Competencies of veterinarians and veterinary para-professionals
Section I-3 Continuing education
Section I-4 Technical independence
Section I-5 Stability of structures and sustainability of policies
Section I-6 Coordination capability of the Veterinary Services
Section I-7 Physical resources
Section I-8 Operational funding
Section I-9 Emergency funding
Section I-10 Capital investment
Section I-11 Management of resources and operations
The OIE PVS Tool - structure

46 Critical Competencies
CHAPTER II - Technical authority and capability

<table>
<thead>
<tr>
<th>Section II-n</th>
<th>Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td>II-1</td>
<td>Veterinary laboratory diagnosis</td>
</tr>
<tr>
<td>II-2</td>
<td>Laboratory quality assurance</td>
</tr>
<tr>
<td>II-3</td>
<td>Risk analysis</td>
</tr>
<tr>
<td>II-4</td>
<td>Quarantine and border security</td>
</tr>
<tr>
<td>II-5</td>
<td>Epidemiological surveillance</td>
</tr>
<tr>
<td>II-6</td>
<td>Early detection and emergency response</td>
</tr>
<tr>
<td>II-7</td>
<td>Disease prevention, control and eradication</td>
</tr>
<tr>
<td>II-8</td>
<td>Food safety</td>
</tr>
<tr>
<td><strong>II-9</strong></td>
<td>Veterinary medicines and biologicals</td>
</tr>
<tr>
<td>II-10</td>
<td>Residue testing</td>
</tr>
<tr>
<td>II-11</td>
<td>Emerging issues</td>
</tr>
<tr>
<td>II-12</td>
<td>Technical innovation</td>
</tr>
<tr>
<td>II-13</td>
<td>Identification and traceability</td>
</tr>
<tr>
<td>II-14</td>
<td>Animal welfare</td>
</tr>
</tbody>
</table>
The OIE PVS Tool - structure

46 Critical Competencies

CHAPTER III - Interaction with stakeholders

Section III-1        Communications
Section III-2        Consultation with stakeholders
Section III-3        Official representation
Section III-4        Accreditation / authorisation / delegation
Section III-5        Veterinary Statutory Body
Section III-6        Participation of producers and other stakeholders in joint programmes
The OIE PVS Tool - structure

46 Critical Competencies
CHAPTER IV – Access to Markets

| Section IV-1 | Preparation of legislation and regulations, and implementation of regulations |
| Section IV-2 | Implementation of legislation and regulations and stakeholder compliance |
| Section IV-3 | International harmonisation |
| Section IV-4 | International certification |
| Section IV-5 | Equivalence and other types of sanitary agreements |
| Section IV-6 | Transparency |
| Section IV-7 | Zoning |
| Section IV-8 | Compartmentalisation |
OIE PVS Tool: Levels of Advancement

- 5 levels of advancement (qualitative) for each critical competency

- A higher level assumes compliance with all preceding levels
## II-9 Veterinary medicines and biologicals

### The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorisation, registration, import, production, labelling, distribution, sale and use of these products.

<table>
<thead>
<tr>
<th>Levels of advancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The VS cannot regulate veterinary medicines and veterinary biologicals.</td>
</tr>
<tr>
<td>2. The VS have some capability to exercise administrative control over veterinary medicines and veterinary biologicals.</td>
</tr>
<tr>
<td>3. The VS exercise effective administrative control and implement quality standards for most aspects of the regulation of veterinary medicines and veterinary biologicals.</td>
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<td>4. The VS exercise comprehensive and effective regulatory control of veterinary medicines and veterinary biologicals.</td>
</tr>
<tr>
<td>5. In addition to complete regulatory control, the VS systematically monitor for adverse reactions (pharmacovigilance) and take appropriate corrective steps. The control systems are subjected to periodic audit of effectiveness.</td>
</tr>
</tbody>
</table>

### Terrestrial Code references:

Points 6 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Procedures and standards.

Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.

Sub-point a) ii) of Point 6 of Article 3.2.14. on Animal health and veterinary public health: Assessment of ability of Veterinary Services to enforce legislation.

Chapters 6.6. to 6.10. on Antimicrobial resistance.
OIE PVS Evaluation Teams

- Team Leader + Expert(s) + Observer(s)/Facilitator(s)
- ~ 150 OIE certified PVS experts trained so far (May 06; July 06; Feb. 07; Feb. 08; Dec 11)

- Five operating languages: **English, French, Spanish** + Russian and Arabic
- Geographical balance
- Missions financed through the OIE World Fund
Steps of an OIE-PVS Evaluation

- Official request from the OIE Delegate
- OIE proposes team of experts and dates
- Preparation of the mission
- Evaluation mission (2 – 3 weeks)
- Draft Report
- Peer review by another PVS expert not having participated in the mission
- Country agreement/comments on PVS report
- Final report confidential until this stage

...for release only if agreed by the country
Country PVS Reports

- Country PVS reports are either:
  - Confidential (very few)
  - Available for transmission to Donors and Partners (majority)
  - In the public domain (13% to date): Belize; Bolivia; Brazil; Guinea-Bissau; Namibia; Panama; Paraguay; Uruguay; and Vietnam

  http://www.oie.int/eng/oie/organisation/en_oie_pvs_eval_reports.htm?e1d2
# OIE PVS Evaluation Missions

## State of play (up to 15 October 2012)

<table>
<thead>
<tr>
<th>OIE Members</th>
<th>PVS Evaluation requests received</th>
<th>PVS Evaluation missions implemented</th>
<th>Reports available for (restricted) distribution to Donors and Partners</th>
<th>Publication on the OIE website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>52</td>
<td>51</td>
<td>47</td>
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<tr>
<td>Americas</td>
<td>29</td>
<td>23</td>
<td>21</td>
<td>18</td>
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<tr>
<td>Asia, the Far East and Oceania</td>
<td>32</td>
<td>18</td>
<td>18</td>
<td>11</td>
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<tr>
<td>Europe</td>
<td>53</td>
<td>15</td>
<td>14</td>
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</tr>
<tr>
<td>Middle East</td>
<td>12</td>
<td>12</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>178</strong></td>
<td><strong>119</strong></td>
<td><strong>111</strong></td>
<td><strong>82</strong></td>
</tr>
</tbody>
</table>
Overview of PVS Evaluation missions

Mission requested
Mission completed
Report Available
Specific approach
Evaluation of Aquatic Animal Health Services

‣ Since 2010

‣ as part of a PVS evaluation of Veterinary Services, or as an independent exercise

‣ Reference: Chapter 3.1 of the Aquatic Code on the Quality of AAHS
OIE PVS Evaluation of Aquatic AHS
State of play (up to 15 October 2012)

<table>
<thead>
<tr>
<th>OIE Members</th>
<th>Requests received</th>
<th>Missions implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>52</td>
<td>3</td>
</tr>
<tr>
<td>Americas</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>Asia, the Far East and Oceania</td>
<td>32</td>
<td>3</td>
</tr>
<tr>
<td>Europe</td>
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<td>0</td>
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<tr>
<td>Middle East</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>178</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>
PVS Gap Analysis

the prescription
The OIE collaborates with governments, donors and other stakeholders.
PVS Gap Analysis

- To determine and confirm country priorities (country involvement)
- To identify specific activities, tasks and resources required to address “gaps” identified through the country PVS evaluation
- Estimation of costs (collaboration with Partners and Donors)
- Preparation of an estimated budget
- Support to preparation of investment programmes
PVS Gap Analysis mission

- In practice, this means:
  - Defining the **expected result** (level of advancement defined in the OIE PVS tool) at the end of the five-year period for the priority critical competencies
  - determining the **activities** to be carried out in order to achieve the expected results
  - Determining the **human, physical and financial resources** required to implement these activities to enable the Veterinary Services to function appropriately.
## OIE PVS Tool - Example

<table>
<thead>
<tr>
<th>II-9 Veterinary medicines and biological</th>
<th>Levels of advancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorisation, registration, import, production, labelling, distribution, sale and use of these products.</td>
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Sub-point a) ii) of Point 6 of Article 6.2.14. on Animal health and veterinary public health: Assessment of ability of Veterinary Services to enforce legislation.

Chapters 6.6. to 6.10. on Antimicrobial resistance.
3. Strategy (if relevant)

4. Tasks to implement (chronological)

<table>
<thead>
<tr>
<th>Specific tasks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>III.2 Consultation</td>
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<tr>
<td>IV.1, 2, 3. Legislation</td>
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<tr>
<td>I.3. Continuing Education</td>
<td></td>
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<tr>
<td>III.1 Communication</td>
<td></td>
</tr>
<tr>
<td>I.11. Management of resources and operations</td>
<td></td>
</tr>
<tr>
<td>III.3. Official representation</td>
<td></td>
</tr>
</tbody>
</table>

5. Objectively verifiable indicators (OIE PVS or specific)
The PVS Gap Analysis Tool

PVS Gap Analysis - Budget

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Unit Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Trade</th>
<th>(8 cards)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Health</td>
<td>(5 cards)</td>
</tr>
<tr>
<td>Veterinary Public Health</td>
<td>(4 cards)</td>
</tr>
<tr>
<td>Veterinary Laboratories</td>
<td>(2 cards)</td>
</tr>
<tr>
<td>Management and Regulatory Services</td>
<td>(21 cards)</td>
</tr>
</tbody>
</table>

Cost Estimation Cards

<table>
<thead>
<tr>
<th>Trade1</th>
<th>Trade8</th>
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<tbody>
<tr>
<td>AH1</td>
<td>AH5</td>
</tr>
<tr>
<td>VPH1</td>
<td>VPH4</td>
</tr>
<tr>
<td>Lab1</td>
<td>Lab2</td>
</tr>
<tr>
<td>MVS1</td>
<td>MVS21</td>
</tr>
</tbody>
</table>

Outputs
- Total Budget
- Analysis of the Budget
The PVS Gap Analysis Tool Box

- **Tool 1 - Border posts**
  - Estimation of human and physical resources for Border posts

- **Tool 2 – Animal Health**
  - Field Veterinary Network for Animal Health
  - Estimation of human and physical resources for Animal Health

- **Tool 3 – Veterinary Public Health**
  - Estimation of human and physical resources for Veterinary Public Health

- **Tool 4 – Full time equivalent**
  - Full time equivalent simulation (Human resources)

- **Tool 5 - Management of Veterinary Services**
  - Resources needed for Management and Regulatory Services

- **Tool 6 – Compensation funds**
  - Simulation of Compensation funds
Steps of a PVS Gap Analysis

Two important conditions:

- Country PVS Evaluation completed and Country PVS report finalized
- Official request from the OIE Delegate

- OIE proposes team of experts and dates
- Preparation of the mission / OIE / Team leader / Country contact person(s)
- PVS Gap Analysis mission
- Draft Report / Documents
- Quality check
- Country agreement / comments on the PVS Gap Analysis documents
- Final report confidential until this stage

for release only if agreed
Using the PVS Gap Analysis

- **In country discussions** with the relevant Minister, other Ministries, Ministry of Finance, Prime Minister, Head of State, National Parliament, depending on the context of the country

- **Round tables**, in the country, with Donor Agencies and International Organisations, incl. FAO

- **Preparation of the country Veterinary Services estimated Budget**; and of national or international investments
# PVS Gap Analysis Missions

## State of play (up to 15 October 2012)

<table>
<thead>
<tr>
<th>OIE Members</th>
<th>PVS Gap Analysis requests received</th>
<th>PVS Gap Analysis missions implemented</th>
<th>PVS Gap Analysis missions reports received</th>
<th>Reports available for (restricted) distribution to Donors and Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>52</td>
<td>37</td>
<td>33</td>
<td>32</td>
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<tr>
<td>Americas</td>
<td>29</td>
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<tr>
<td>Asia, the Far East and Oceania</td>
<td>32</td>
<td>12</td>
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<tr>
<td>Europe</td>
<td>53</td>
<td>7</td>
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<td>6</td>
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<td>Middle East</td>
<td>12</td>
<td>8</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
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<td><strong>77</strong></td>
<td><strong>62</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>
Overview of PVS Gap Analysis missions
The PVS Pathway

the treatment
The OIE collaborates with governments, donors and other stakeholders.
OIE PVS missions on Veterinary Legislation
The OIE is aware that in numerous countries veterinary legislation is outdated and inadequate to address the challenges of today and of the future.

At the request of Members, the OIE has developed guidelines on all the essential elements to be covered in veterinary legislation.

Terrestrial Code Chapter 3.4. on veterinary legislation, which replaces the previous guidelines on Veterinary Legislation.

Any Member that has undertaken an OIE PVS Evaluation may request a follow up mission dedicated to advice and assistance in modernizing the national veterinary legislation.
Veterinary Legislation Support Programme

Request for Legislation Support
OIE Conducts a Veterinary Legislation Identification Mission

Country request long term support
OIE propose to enter an Agreement

3 Month Preparatory Phase
OIE Designates an Expert to work with the country to prepare the framework of the agreement
The designated expert advise OIE about the feasibility

Agreement
OIE and the country sign a one-year agreement
OIE Assistance on Veterinary Legislation

- Country PVS report available (important condition)
- Official country request to the OIE
- OIE proposal to the country for an initial mission (identification of needs and context)
- Technical Assistance Convention with the country
- OIE preparatory questionnaire sent to the country
- Creation of a Country Veterinary Legislation Task Force
- Country work linked with OIE experts
Overview of Agreements on Veterinary legislation

<table>
<thead>
<tr>
<th>Region</th>
<th>OIE Members</th>
<th>Legislation Agreement requests received</th>
<th>Legislation Agreement implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>52</td>
<td>2</td>
<td>2</td>
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<td>Americas</td>
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<td>Europe</td>
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<td>0</td>
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<td>Middle East</td>
<td>12</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>178</strong></td>
<td><strong>6</strong></td>
<td><strong>6</strong></td>
</tr>
</tbody>
</table>
Overview of Agreements on Veterinary legislation
OIE Twinning programmes on Veterinary laboratories
Global network of expertise

= OIE RLS + OIE CCs

= OIE Reference Centers

Constitutes the central core of the OIE’s scientific excellence
OIE Reference Laboratories
OIE Collaborating Centres
Laboratory Twinning Program

Each OIE Laboratory Twinning Project...

- Is a link between OIE Reference Laboratory or Collaborating Centre (Parent) and national laboratory (Candidate)

- Aims to improve expertise and diagnostic capacity with eventual aim of reaching OIE standards - Optimal goal is to achieve OIE Reference Laboratory designation

- Should be sustainable once the project is over
Laboratory Twinning

- OIE’s laboratory capacity building programme
- Links an OIE Reference Centre (Parent) with a national institute (Candidate)
- To develop technical capacity and expertise
- Provides opportunities for OIE member countries to improve their veterinary laboratories for early detection and response to TADs
- Inaugural project started in February 2008
- OIE laboratory twinning continue to function well
To provide regional support with better geographical coverage for diseases and topics that are a priority in a given region

Improved access for more countries to high quality diagnostics and expertise

Better scientific expertise allows members to:
- To debate OIE scientific justification for standards on an equal footing with other Members (better representation)
  - To contribute to build a veterinary scientific community worldwide

- Geographical coverage (special effort for developing countries and countries in transition)
OIE Lab Twinning 2012

- 6 projects completed, 33 underway, 5+ on the way
- 42 countries involved
  - Lists on-going projects – to ensure coordination
  - Provides guidance on principles of twinning and application process
  - Promotes outputs of twinning projects and workshops
- Updated Lab Twinning guide - Feb 2012
- Lab Twinning newsletter – June 2012
OIE Laboratory Twinning
Parent and Candidate laboratories
OIE Twinning programmes on Veterinary Statutory Bodies
Veterinary Statutory Bodies Twinning

- OIE Code (Art. 3.2.12)
- PVS Pathway
- PVS Critical Competency (III.5)
- Public-private partnership

- Twinning projects between VSBs
- A Guide to OIE Certified VSB Twinning Projects
OIE Twinning programmes on Veterinary Education
Veterinary Education Establishments Twinning

- The Veterinary Education Twinning Manual has been endorsed by the AHG.
- The Manual will be printed in the three OIE languages and information will be provided on the OIE website.
- Day 1 competencies have been widely distributed
- A Model Core Veterinary Curriculum is currently being developed.
OIE recommendations on the Competencies of graduating veterinarians (“Day 1 graduates”) to assure high-quality of National Veterinary Services
One Health Missions
Activities since last RR/SRR meeting

- Pilot missions
  - Kenya Oct/Nov 2011
  - Philippines Sept 2012
  - Costa Rica received the first pilot mission
- Advancement of methodology
  - Conceptual shift from evaluation → treatment
  - Draft PVS OH mission manual
PVS critical competencies reviewed in PVS One Health

<table>
<thead>
<tr>
<th>I. HUMAN, PHYSICAL AND FINANCIAL RESOURCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-3. Continuing education</td>
</tr>
<tr>
<td>I-6.B. External coordination</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II. TECHNICAL AUTHORITY AND CAPABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>II-1. Veterinary laboratory diagnosis</td>
</tr>
<tr>
<td>II-4. Quarantine and border security</td>
</tr>
<tr>
<td>II-5.A. Passive epidemiological surveillance</td>
</tr>
<tr>
<td>II-5.B. Active epidemiological surveillance</td>
</tr>
<tr>
<td>II-6. Early detection and emergency response</td>
</tr>
<tr>
<td>II-7. Disease prevention, control, and eradication</td>
</tr>
<tr>
<td>II-8.A. Ante and post mortem inspection at abattoirs and associated premises</td>
</tr>
<tr>
<td>II-8.B. Inspection of collection, processing and distribution of products of animal origin</td>
</tr>
<tr>
<td>II-9. Veterinary medicines and biologicals</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>III. INTERACTION WITH STAKEHOLDERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>III-1. Communications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV. ACCESS TO MARKETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV-1. Preparation of legislation and regulations</td>
</tr>
</tbody>
</table>
One Health Missions

Next Steps

• Feedback meeting (20-21 November, OIE HQ)
  • Missions team members and selected others
  • Update on process
  • Input on methodology and “soft training”
• New missions
  • Approach to requesting/accepting requests for missions
  • Challenge - treatment plan vs capacity building
The OIE collaborates with governments, donors and other stakeholders.

The OIE PVS Pathway

« Diagnosis »
- PVS Evaluation
- PVS Gap Analysis
  
including Veterinary Services’ Strategic Priorities

« Prescription »
- Public / Private Partnerships
- Veterinary Education
- Laboratories

« Treatment »
- Veterinary Legislation
- PVS Pathway Follow-Up Missions

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Thank you for your attention