Global Surveillance & Monitoring of Substandard & Falsified Veterinary Products (SFVP)

Training Seminar for Focal Points on Veterinary Products for the Africa region

(English-speaking Africa)
7th cycle

23-24 FEBRUARY 2022

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OIE – Paris, France

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AGENDA

- Background & context
- Update on the OIE's work on SFVP
- Update on the pilot of the information & alert system for SFVP

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Context & background for work on the quality of veterinary products

Potential consequences of Substandard & Falsified Veterinary Products (SFVP):

- Untreated illness (or preventable illness)
- Loss of faith in veterinarians when treatments don't work
- Poisonings
- Contribution to development of AMR

A problem that impacts:

Antimicrobials, trypanocides, antiparasitics

Regulated & unregulated markets

Terrestrial and aquatic animals

- **Authorised products that fail to meet quality standards and/or specifications**
- **Unauthorised products that misrepresent their identity, composition or source**

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Historical Background

Global Action Plan on AMR
2015

OBJECTIVE 4

Optimize the use of antimicrobial medicines in human and animal health.
"Related weaknesses that contribute to development of antimicrobial resistance include ... the prevalence of substandard medicines for both human and veterinary use.

5th Cycle
2017-2018

SFVP are an issue
Raised by participants to the 5th cycle Focal Point Training Seminar

2nd OIE Global Conference on AMR and Prudent Use of Antimicrobial Agents
2018

RECOMMENDATION 6:

"Explore the possibility of building an information system of falsified and substandard drugs in the animal sectors illegally circulating within and between countries and building on the experience of the monitoring systems set up by WHO for drugs designated for human use taking a "One Health" approach."

3rd OIE AMU Database Cycle

20 Members reported to have issues with illegal or unofficial vet products

What happened since?
2019-2022

1. SFVP SITUATION ASSESSMENT
2. EVALUATION OF WHO SYSTEM & OIE'S FEASIBILITY FOR IMPLEMENTATION
3. ENGAGEMENT WITH OIE MEMBERS THROUGH 6TH TRAINING CYCLE
4. PROJECT PROPOSAL
5. LAUNCH OF PILOT EXPERIENCE

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Project proposal on quality of veterinary products

- Phase 1 (2019-2022)
  - Engagement with Focal Points for Veterinary Products through Training Seminars
  - Development & pilot testing of an information & alert system for SFVP
- Phase 2 (2022-2024)
  - Development of guidelines on post-market surveillance of vet. product quality
  - Explore of options for testing of vet product quality (regional lab. networks)
- Phase 3 (2024→)
  - Guidelines & tools for field level surveillance of vet. product quality

Pilot experience – how does it work ?

Objective: To pilot an information and alert system for SF veterinary products with OIE Members, to allow the collection of:

- Information on the in-country situation related to veterinary product quality
- OIE Members' feedback on the Excel-based data collection tools for their refinement
- **23 Members contacted → 14 joined → 12 engaged (so far)**

Three components:

1. Baseline Questionnaire (Excel)
2. Immediate Notification Form (Excel)
3. General feedback

- **Africa:** Eswatini, Ethiopia, Ghana, Malawi, Senegal, Tanzania, Zimbabwe.
- **Americas:** Colombia, Costa Rica.
- **Asia Pacific:** Chinese Taipei, Nepal.
- **Europe:** Armenia.
- **Middle East:** Bahrain, UAE.

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Baseline questionnaire

- Information on the current status and management of veterinary product quality in your country
- To inform the OIE's understanding of the in-country situation related to SF veterinary products.
- In the longer term, intended to be sent out annually to all OIE Members

OIE Baseline Reporting Form for Information on Substandard and Falsified Veterinary Products

General instructions for completing this form

Please provide as much detail as you can. If you do not have all the information requested on the form, please fill it in with the information that you do have. Follow up information can be sent through by email to r.hibbard@oie.int.
Questions in **bold** are mandatory. Please provide this information as requested. Questions in *italics* are optional.
Please note that an incident is defined as the discovery of (a) substandard or falsified veterinary product(s) at one time and place. An incident can refer to one dose of one veterinary product, or to a container filled with millions of doses.

A. Reporting Agent		
1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
3	**Role with respect to the OIE**	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other
	If you responded"Other", please specify	*<free text field>*
4	**Organisation**	<free text field>
5	**Organisation's Address**	<free text field>
6	**Country**	<free text field>
7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>

B. Information on incidents of substandard and falsified veterinary products		
9	**Were there any incidents of suspected or confirmed substandard or falsified (SF) veterinary products found in your country this year?**	☐ Yes, and the incident(s) has/have been notified to the OIE ☐ Yes, but the incident(s) has/have not yet been notified to the OIE ☐ No incidents of suspect or confirmed SF veterinary products were found ☐ No information is available on SF veterinary products
10	*If you answered yes to question 9, but have not yet provided these details to the OIE, please explain the reasons for not being able to report this incident to the OIE. Please also complete a notification form for these products.*	*<free text field>*
11	*If you answered "no information is available" to question 9, please indicate why the information is not available in your country.*	*<free text field>*
		☐ Yes ☐ No

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Baseline questionnaire

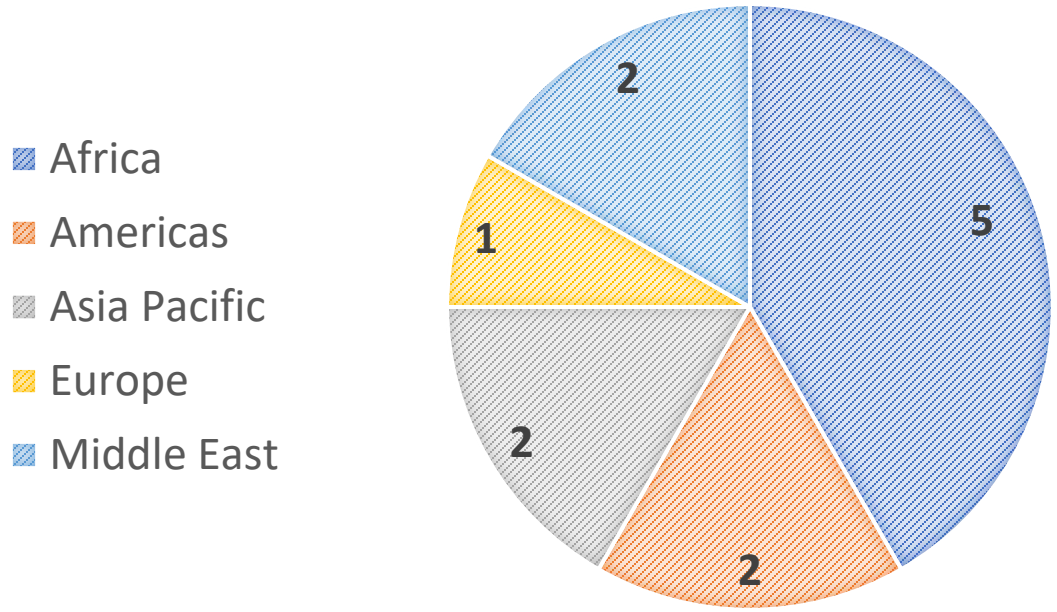

Figure 1: Number of respondents to the Baseline Questionnaire by Region

Baseline questionnaire - Results

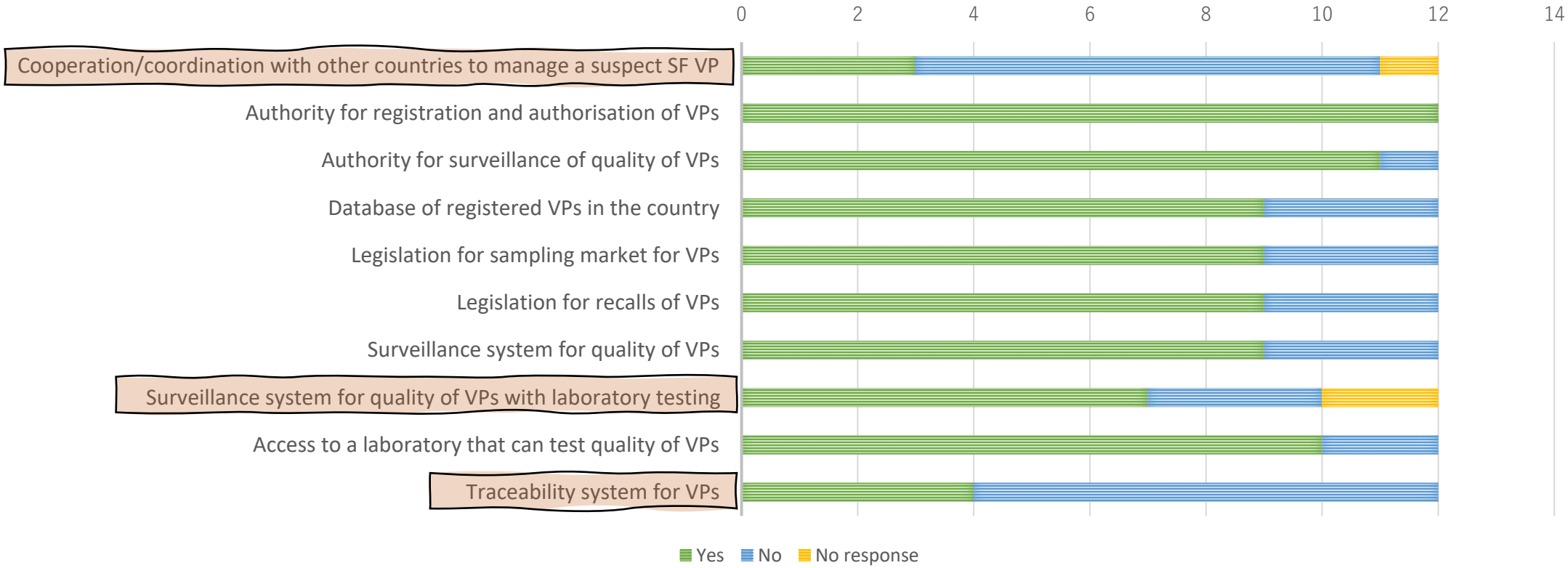

Figure 2: Responses to the OIE SF Baseline Questionnaire as part of the pilot of the Global Information and Alert System for Substandard and Falsified Veterinary Products (of the 12 countries that responded)

Immediate notification form

- To notify the OIE of any suspect SF veterinary products.
- In the longer term, this could be submitted at any point in the year.
- Could, with the agreement of the reporting Focal Point, form the basis of regional alerts.

OIE Immediate Notification Form for Substandard and Falsified Veterinary Products

General instructions for completing this form

Please provide as much detail as you can. If you do not have all the information requested on the form, please fill it in with the information that you do have. Follow up information can be sent through by email to r.hibbard@oie.int and will be added to the incident file.
Questions in **bold** are mandatory. Please provide this information as requested. Questions in *italics* are optional.
Please note that an incident is defined as the discovery of (a) substandard or falsified veterinary product(s) at one time and place. An incident can refer to one dose of one veterinary product, or to a container filled with millions of doses.
If more than one veterinary product is associated with a single incident, please fill in a form for each product.(E.g. if suspect amoxicillin tablets are found with suspect doxycycline tablets, a separate form should be filled out for each - see the sheets). Once you have completed this page, you can use the sheets for Products 2-10 to complete the same details for the next nine products. If you have more than 10 products, please email us.

A. Reporting Agent

1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
3	**Role with respect to the OIE**	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other
	If "Other" , please specify	*<free text field>*
4	**Organisation**	<free text field>
5	**Organisation's Address**	<free text field>
6	**Country**	<free text field>
7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>
9	**Is this report related to an incident you have previously reported to us?**	☐ Yes ☐ No
	If "Yes", please provide more details	*<free text field>*
10	**Do you consent to the OIE sharing the information in this report with other OIE Members in the region?**	☐ Yes ☐ No

B. Details of Suspect Veterinary Product

Questions 11 to 21 relate to the details of the veteirnary medical product which was discovered for this incident. Please enter all details as they are presented on the packaging of the suspect product, even if this is known to be false. If the product was found with no packaging, please respond with "no packaging" for questions 11-18 and move directly to section C.

11	**Name of suspect product (brand name)**	<free text field>	
12	**Active ingredient(s) (generic name) Strength of active ingredient(s)**	Active ingredient 1	Strength of active ingredient 1
		Active ingredient 2 (if applicable)	*Strength of active ingredient 2 (if applicable)*
		Active ingredient 3 (if applicable)	*Strength of active ingredient 3 (if applicable)*
		Active ingredient 4 (if applicable)	*Strength of active ingredient 4 (if applicable)*
		Active ingredient 5 (if applicable) and beyond	*Strength of active ingredient 5 (if applicable) and beyond*
13	*Dosage form (if known)*	*Please select option from dropdown menu*	
		If "Other" , please specify	*<free text field>*
14	*Method of administration (if known)*	*Please select option from dropdown menu*	

Immediate notification form – Results

- Three OIE Members submitted Immediate Notification Forms to the OIE during the pilot

- 18 incidents reported
  - "Incident" = The discovery of (a) SF veterinary product(s) at one time and place. Can include multiple veterinary products.

- Incidents classed as substandard (5), falsified (2), and unknown (5)

- Sites of discovery included:
  - Retail store (unauthorised to sell veterinary products), pharmacy, marketing authorisation holder or manufacturer, distributor.

- Reasons for suspicion included:
  - Recall by manufacturer or veterinary product authority, routine inspection or surveillance, unusual packaging appearance.

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Conclusions & Next Steps

- Refinement of the baseline questionnaire and immediate notification form in response to **feedback from Focal Points**
- Explore **engagement with existing regional and subregional systems** for surveillance of veterinary product quality (search for complementarities & avoid duplication)
- **Engage with phase 2 & 3 of the project**
  - Post-Market Surveillance Guidelines
  - Pilot on Regional Lab. Networks
  - Guidelines a tools for field level surveillance & alert
- Overall, **provision of greater support for OIE Members** in collecting and reporting data on SF veterinary products

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