



World Organisation  
for Animal Health



# Training Seminar for National Veterinary Products Focal Points

**Veterinary Products: A Vital Tool for Improving Animal Health and Welfare**

05 – 07 September 2023 Lilongwe, Malawi



The  
Fleming  
Fund



Funded by  
UK Government

# WOAH reporting system on substandard & falsified veterinary products (SFVPs)

Ana Mateus

Scientific Coordinator

AMR & VP Department, WOAH



# Background

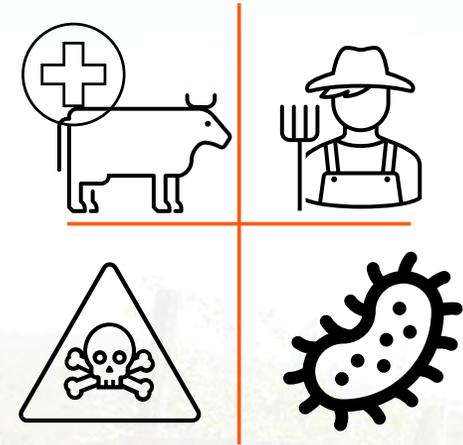
Worldwide, 1.3 billion people raise livestock  
Global trade of VMPs estimated at US\$30 billion/ year

52 % of 1246 VMPs tested in Africa & Asia were SFVPs



## Consequences

- Negative impact on animal health & farming communities
- Risk of AMR
- Hinders achieving SDGs



(Source: [Vidhamaly V, Bellingham K, Newton PN, et al. The quality of veterinary medicines and their implications for One Health. BMJ Global Health 2022](#))



# Historical Background

## 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."

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

2018



3rd OIE AMU Database Cycle

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

5th Cycle

2017-2018

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



OBJECTIVE 4

Global Action  
Plan on AMR

2015

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."

What happened since?

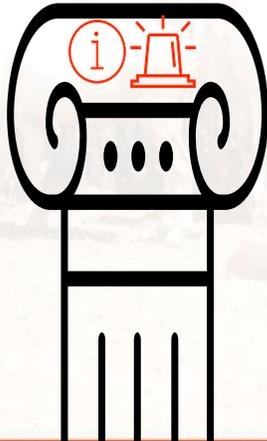
2019-2022

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**

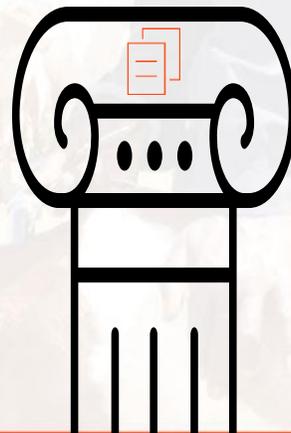
# WOAH project on SFVFPs



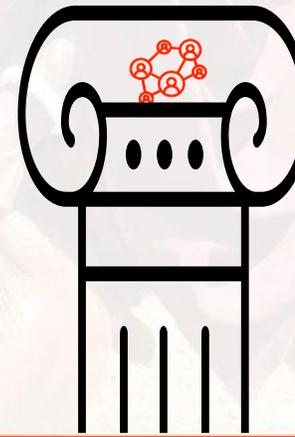
Development an  
information & alert  
system for SFVP



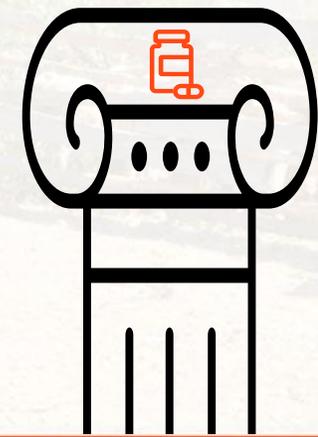
Development of  
Guidelines on post-  
marketing surveillance



Development  
Regional Laboratory  
networks



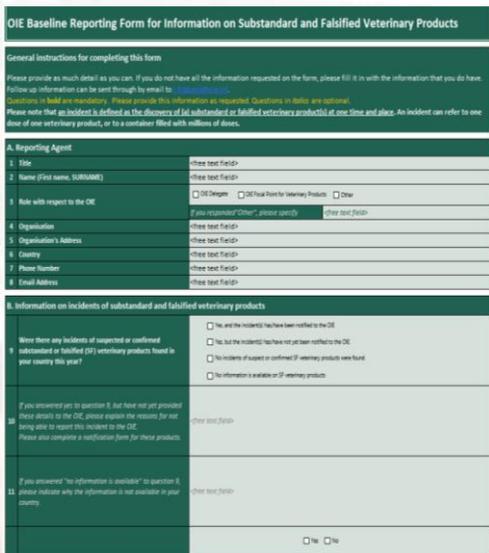
Guidelines &  
tools for field  
level surveillance



# WOAH Project on SFVPs - Pilot Phase 1



**i** Baseline Reporting Form

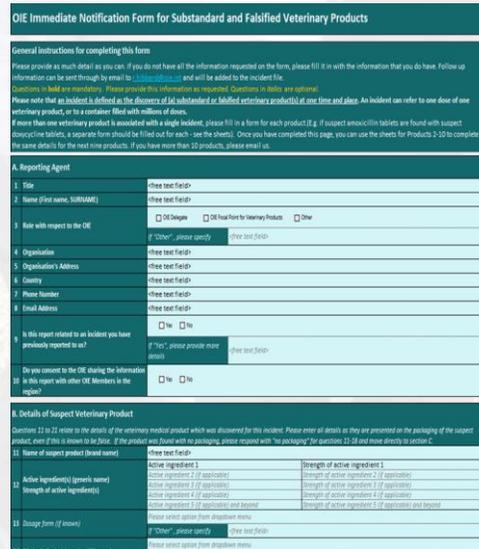


Information on in-country current status and management of veterinary product quality in the country

Sent out **annually** for updates



Immediate Notification Form



Basis of regional alerts  
To notify WOAH of any suspect and/or confirmed cases of SFVP

Submitted **at any time**

Feedback

Understand members' needs and acceptability

Basis to refine and improve system



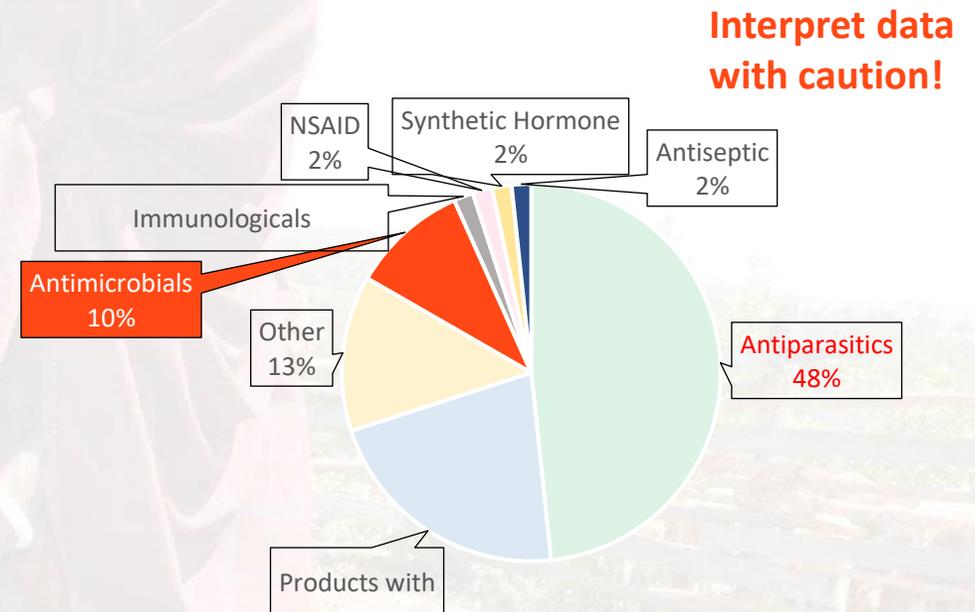
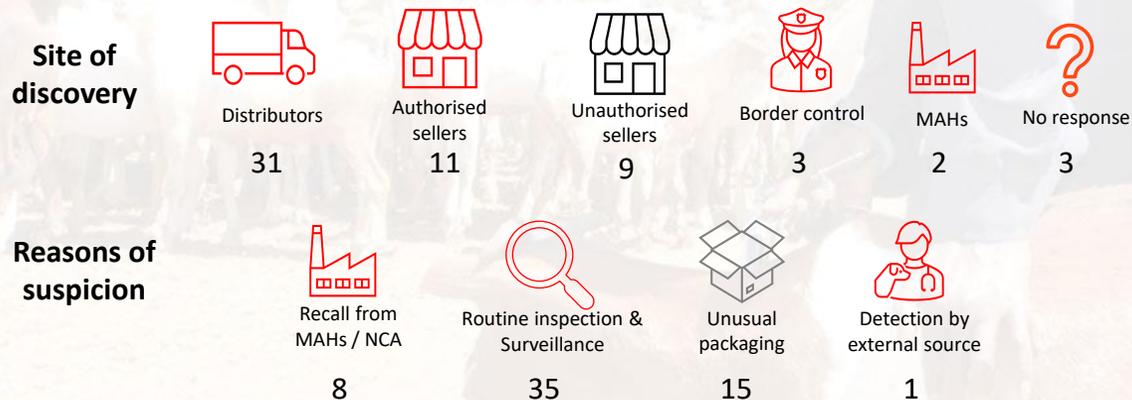
Submitted **at any time**



# Results Pilot Phase 1 – 2022 (14 countries)

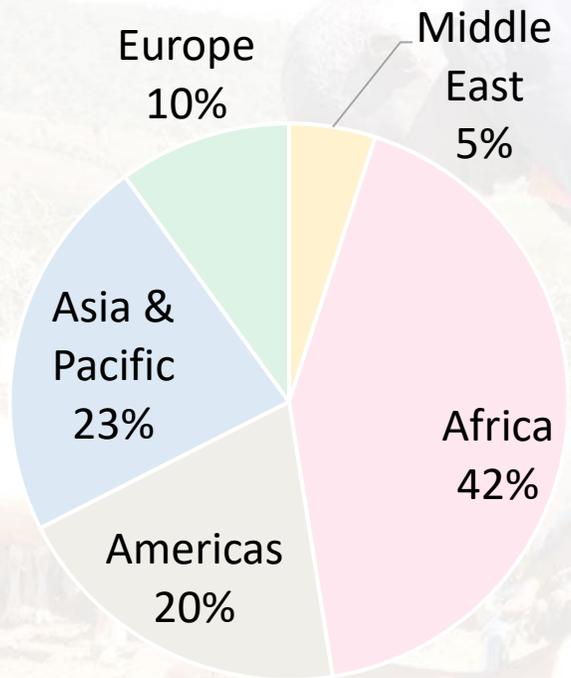


Classification	N incidents	N products		Total N of products
		Suspect	Confirmed	
Substandard	23	19	18	37
Falsified	9	0	11	11
Unregistered	0	0	0	0
Unknown	6	10	1	11
<b>TOTAL</b>	<b>38</b>	<b>29</b>	<b>30</b>	<b>59</b>



# Launch of Pilot Phase 2 – Jan 2023

Open call : 30<sup>th</sup> April 2023

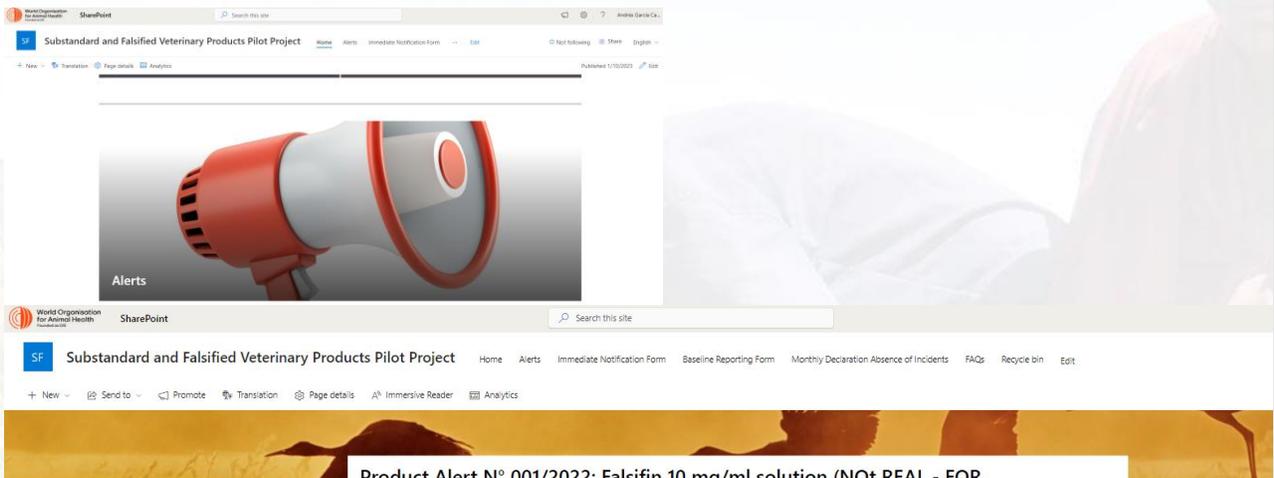


**40** Members from  
**ALL WOA Regions** enrolled





# SPVP- Pilot Phase 2



## Product Alert N° 001/2022: Falsifin 10 mg/ml solution (NOT REAL - FOR DEMONSTRATION PURPOSES ONLY)

Published 1/16/2023

Related

[Medical Product Alert N° 1/2021: Falsified Rabies Vaccines](#)

This Veterinary Product Alert relates to 'Falsifin 10 mg/ml solution for injection' circulating in (Regionland) and reported to WOAAH in November 2022, which has been confirmed to be a falsified veterinary product.

### Alert Summary

WOAH recently received confirmation that falsified batches of Falsifin 10 mg/ml solution for injection were available at distributor. The products identified in this alert are confirmed as falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition, or source. The composition of the vials is currently unknown and laboratory analyses are to be conducted. The product details are presented in the Table below.

Product Name	Falsifin 10 mg/ml solution for injection
Stated marketing authorisation holder (MAH)	VETJUNTOR
Batch Number/s	ABC12345 ABC67899
Expiry Dates	11/2023 12/2023

## Veterinary Product Alert 001/2022 Falsifin 10 mg/ml solution for injection circulating in Lalaland

This Veterinary Product Alert relates to **Falsifin 10 mg/ml solution for injection** circulating in Lalaland (Regionland) and reported to WOAAH in November 2022, which was confirmed to be falsified veterinary products.

WOAH recently received confirmation that **falsified** batches of **Falsifin 10 mg/ml solution for injection** were available at **distributor level**. The products identified in this alert are confirmed as falsified on the basis that they deliberately / fraudulently misrepresent their identity, composition, or source. The composition of the vials is currently unknown and laboratory analyses are to be conducted. The product details are presented in the Table below:

<b>Product Name</b>	Falsifin 10 mg/ml solution for injection
<b>Stated marketing authorisation holder</b>	VETJUNTOR
<b>Batch numbers</b>	ABC12345 ABC67899
<b>Expiry dates</b>	11/2023 12/2023

VETJUNTOR, the genuine **marketing authorization holder** of **Falsifin 10 mg/ml solution for injection** stated:

- The **did not** manufacture the above listed product
- The above listed product referenced in this Alert is falsified on the basis that they deliberately/fraudulently misrepresent their identity and source.

The variable data (batch numbers and manufacturing-expiry dates) are falsified, there are discrepancies in the packaging languages, printing errors on the cartons, and discrepancies in vial types.

Photographs of **Falsifin 10 mg/ml solution for injection** can be found in this [below](#).

WOAH requests increased vigilance within the supply chains of countries likely to be affected by this falsified product. Increased vigilance should include veterinary clinics, pharmacies, wholesalers, distributors, and any other suppliers of veterinary products.

**If you are in possession of the above product, please do not use.** If you have used this falsified product, or if you are aware of an adverse event in a human or animal associated with the use of these products, please seek immediate advice from a qualified veterinary professional, and ensure they report the incident to your National Regulatory Authority for Veterinary Products.

National veterinary authorities are asked to immediately notify WOAAH if this falsified product is discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact [stvp@woah.org](mailto:stvp@woah.org)

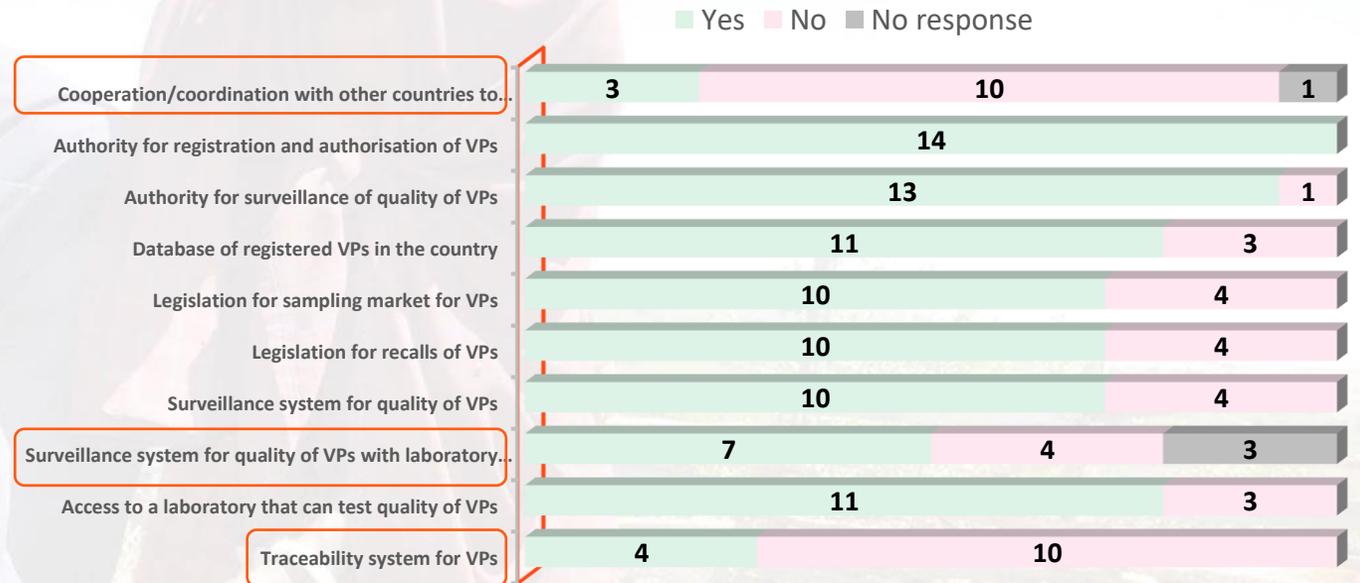
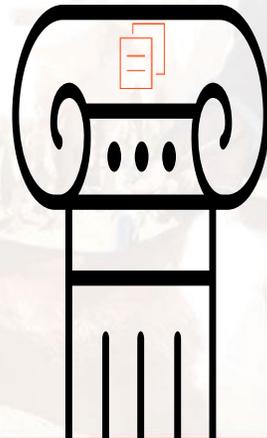




# Next priority



Development of guidelines  
on post-marketing  
surveillance





# Final goal: Integrated final global information and alert system of SFVPs



## Collection of specifications for developing a fit-for-purpose platform

### Experience Pilot Phase 2

- From participants
- From WOAH staff

### Communication with stakeholders

### Satellite projects related to SFVPs



# Actions and take-home messages

- The success of the project depends on creating a **Platform for YOU**
- WOAAH would like to understand our **Members' needs** to create a **platform fit-for-purpose**
- **Participation** is very simple
  - **WOAH Baseline Reporting Form** once a year
  - **WOAH Immediate Notification Form** as early as possible, even if information is incomplete
  - **WOAH Monthly Declaration Form ONLY** if no incidents were found the month before
- **Consent sharing data, totally or partially, is strongly encouraged** but not mandatory
- **Contact [sfvp@woah.org](mailto:sfvp@woah.org)** by email or SharePoint for any questions/ issues

# Thank you !

Ana Mateus  
[a.mateus@woah.org](mailto:a.mateus@woah.org)

12, rue de Prony, 75017 Paris,  
France

T. +33 (0)1 44 15 19 49  
F. +33 (0)1 42 67 09 87

[woah@woah.int](mailto:woah@woah.int)  
[www.woah.org](http://www.woah.org)

