World Organisation for Animal Health

# Substandard and Falsified Veterinary Products Workshop

**4 - 6 March 2025. Dar es Salaam, Tanzania.**

The Fleming Fund

# Substandard and Falsified VMPs- One Health Approach


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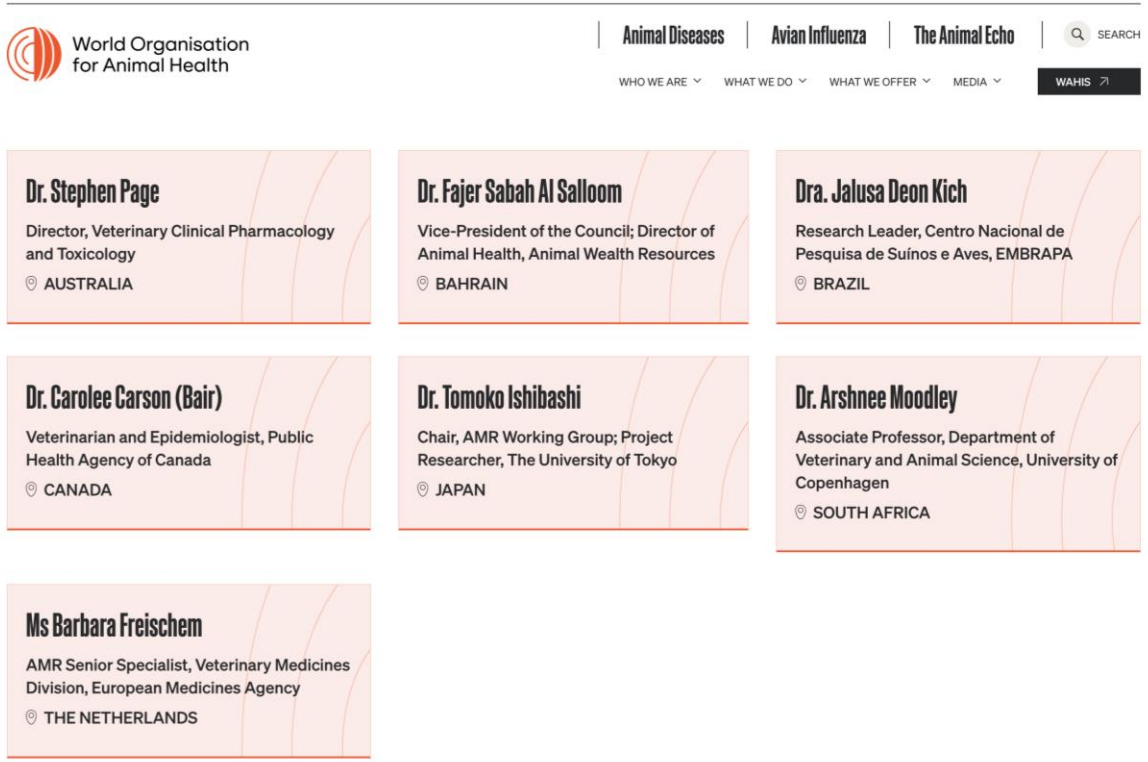
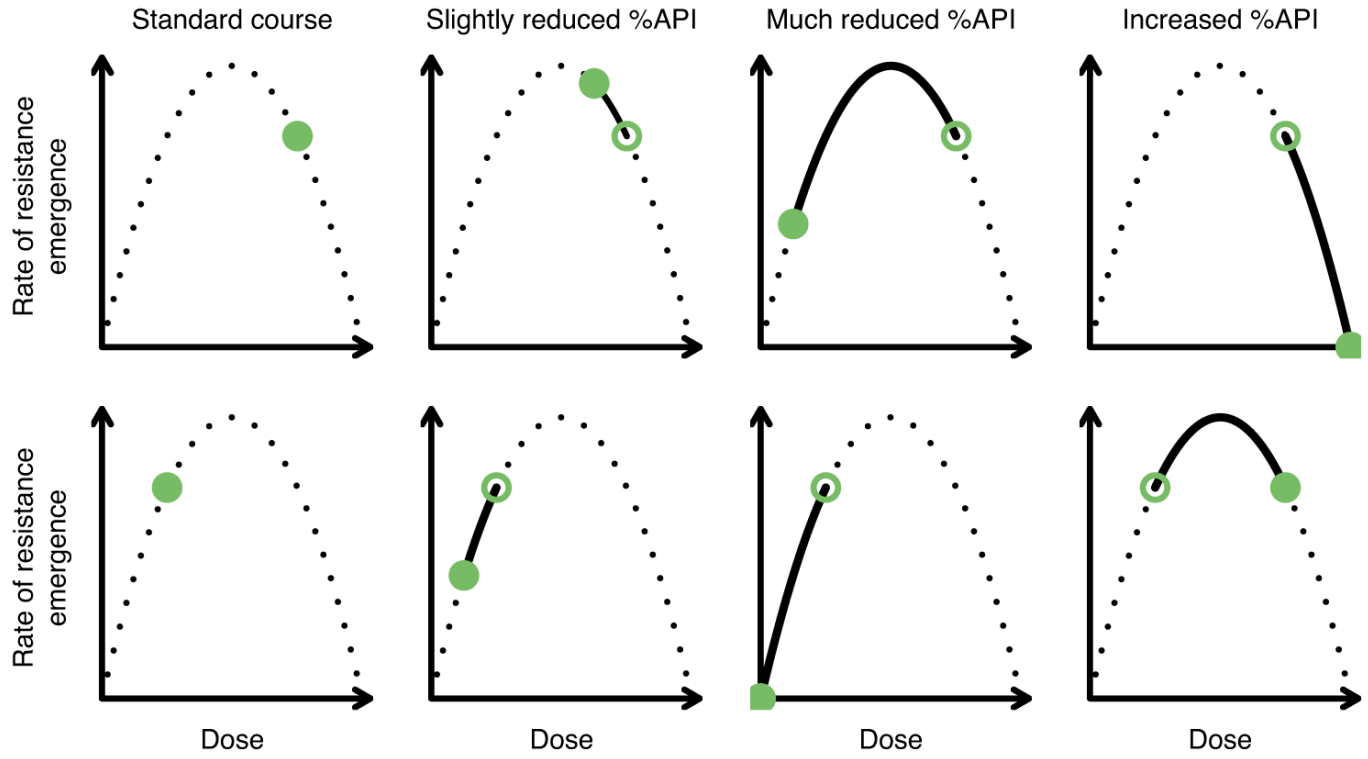
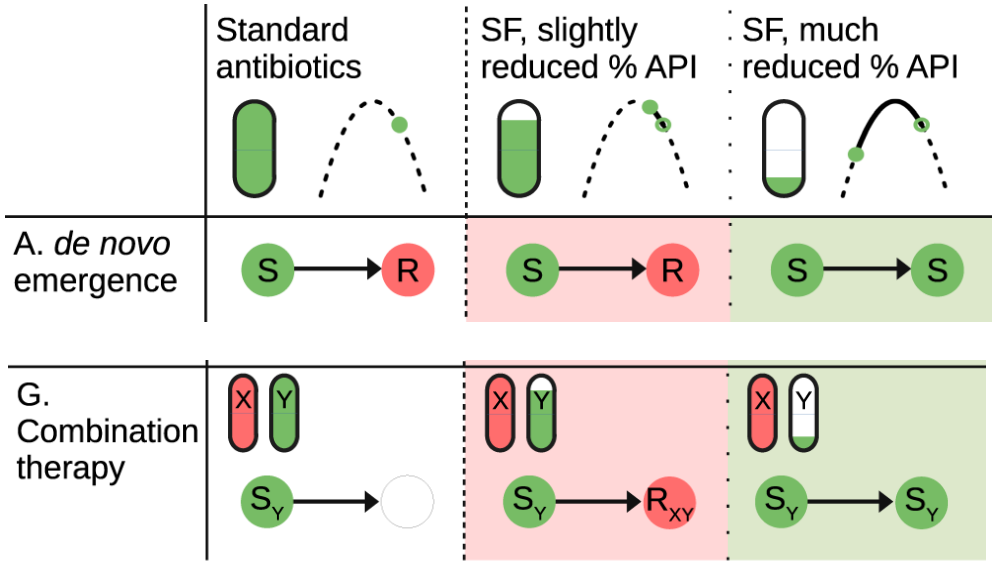



Established in 2019 to support WOAH in implementing its AMR Strategy, enhancing governance, surveillance, and capacity building, advancing international standards, addressing emerging AMR issues, and providing technical advice on veterinary antimicrobial use globally.

# Potential impact of SF antibiotic on the rate of resistance emergence




Cavany et al. 2023

WORLD ECONOMIC FORUM

GEOGRAPHIES IN DEPTH

## How fake animal medicines threaten African livestock

Feb 6, 2015

"International Federation of Animal Health estimates that the **trade in sub-standard and non-registered drugs in Africa is worth US$400m a year** – the same size as the official market."

The true scale of the problem is difficult to pinpoint

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# A narrative review of veterinary pharmacovigilance situations and prospects in East African countries

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**Background:** Veterinary pharmaceuticals must be safe and effective for treating and preventing diseases in animal sectors. Strict adherence to regulations at every stage of production, storage, and administration is necessary as the global sector grows in order to lower the possibility of adverse veterinary drug events. Strong pharmacovigilance regulatory systems are critical in monitoring and managing safety concerns related with veterinary pharmaceuticals.

**Objective:** This review aimed to investigate the implementation of veterinary pharmacovigilance, collaborative initiatives, and reporting practices within the veterinary sector across East African countries.

**Methods:** A thorough search was performed using online platforms such as Google Scholar, PubMed, the Web of Sciences, and regulatory Web sites. The search strategies relied heavily on selecting relevant published findings related to veterinary pharmacovigilance status, veterinary adverse drug event reporting practice, and collaborative efforts in veterinary pharmaceutical sectors within the East African landscape. This article search approach confirmed the inclusion state of veterinary pharmacovigilance and associated collaborative initiatives in the region.

**Results:** In comparison to more developed regions, the review indicated that the veterinary pharmacovigilance system in East African countries was still in its early state. A strong legislative foundation and a large commitment from the veterinary profession are needed to establish a nationwide veterinary pharmacovigilance system. The review reveals a significant lack of consistency in the infrastructure of veterinary pharmacovigilance among the countries of East Africa. Tanzania, Kenya, and Ethiopia have some institutional processes for veterinary pharmaceutical safety, but they lack thorough documentation, which suggests that this systems still require improvement. The analysis emphasizes how inadequate the reporting systems are for adverse veterinary medication events in the majority of East African nations. Given the challenges East Africa faces, customized strategies are required to guarantee the safety and oversight of veterinary medications and improve veterinary pharmacovigilance. For systems to be more effective, veterinary pharmaceutical legal frameworks must be strengthened and stakeholder

- Kenya: Industry estimate that approximately **30% of all drugs in Kenya are substandard**

- Uganda: National Drug Authority received reports of the circulation of **counterfeited and unregistered "Tick Burn Spray," which caused serious adverse effects to both the animals and the human** population exposed to this suspicious product. A particular report from Kyenjojo indicated that **a farmer had lost a milking cow** following the use of the tick burn spray

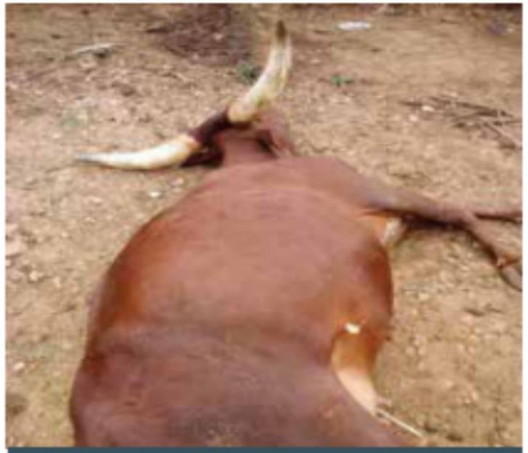

*Photo of a dead milking cow after using Tick Burn Spray in Kyenjojo District*


*Picture of the counterfeit and unregistered Tick Burn Spray used on the farm where the death of the milking cow occurred*

Original research

BMJ Global Health

# The quality of veterinary medicines and their implications for One Health

Vayouly Vidhamaly [1,2,3] Konnie Bellingham [1,2,3] Paul N Newton [1,2,3] Céline Caillet [1,2,3]

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## ABSTRACT

**Objective** Substandard and falsified (SF) veterinary medicines affect animal health, agricultural production and food security and will influence antimicrobial resistance (AMR) in both animals and humans. Yet, our understanding of their extent and impact is poor. We assess the available public domain evidence on the epidemiology of SF veterinary medicines, to better understand their prevalence and distribution and their public health impact on animals and humans.

**Methods** Searches were conducted in Embase, PubMed, MEDLINE, Global Health, Web of Science, CAB Abstracts, Scopus, Google Scholar, Google and websites with interest in veterinary medicines quality up to 28 February 2021. Identified articles in English and French were screened for eligibility. The Medicine Quality Assessment Reporting Guidelines were used to assess the quality of prevalence surveys.

**Results** Three hundred and fourteen publications were included with a failure frequency (the percentage of samples that failed at least one quality test) of 6.5% (2335/35 733). The majority of samples were from post-marketing surveillance by medicines regulatory authorities of the Republic of Korea and China. A small proportion (3.5%) of samples, all anti-infectives, were from 20 prevalence surveys, with more than half (53.1%, 662/1246) collected in low-income and lower middle-income countries in Africa and Asia. The prevalence survey sample size ranged from 4 to 310 samples (median (Q1–Q3): 50 (27–80)); 55.0% of surveys used convenience outlet sampling methods. In 20 prevalence surveys more than half of the samples (52.0%, 648/1246) failed at least one quality test. The most common defects reported were out-of-specification active pharmaceutical ingredient(s) (API) content, failure of uniformity of units and disintegration tests. Almost half of samples (49.7%, 239/481) that failed API content tests contained at least one of the stated APIs below pharmacopoeial limits. Fifty-two samples (4.2% of all samples) contained one or more incorrect API. One hundred and twenty-three publications described incidents (recalls/seizures/case reports) of SF veterinary medicines in 29 countries.

**Conclusion** The data suggest that SF veterinary products are likely to be a serious animal and public health problem that has received limited attention. However, few studies of SF veterinary medicines are available and are geographically restricted. Lower API content and disintegration/dissolution than recommended by pharmacopoeial standards risks treatment failure, animal suffering and contribute to AMR. Our findings highlight the need of more research, with robust methodology, to better inform policy and implement measures to assure the quality of veterinary medicines within supply chains. The mechanism and impact of SF veterinary products on animal and human health, agricultural production, their economy and AMR need more transdisciplinary research.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Substandard and falsified (SF) veterinary medicines logically lead to negative health impacts for animals, farming communities and beyond, but data on SF veterinary medicines are scattered without global understanding of their epidemiology and impact.

### WHAT THIS STUDY ADDS

⇒ In the 20 studies we included aiming to understand their epidemiology, 52% of the 1246 veterinary medicine samples collected in Asia and Africa tested for quality were substandard or falsified.

⇒ The most common reason for sample failure was out-of-specification active ingredient(s) content (46.6%, 481/1032), and 4.2% of all samples contained incorrect active ingredient(s).

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results do not mean that 52% of veterinary medicines are SF globally due to limited data and issues with study methodology; more studies are needed to better inform interventions and policy.

⇒ SF veterinary medicines may be a serious public health problem, impacting One Health, especially in low-income and middle-income countries, with little evidence on their occurrence in high-income countries.

## INTRODUCTION

Humans coexist in complex ecological relationships with other vertebrate animals, whether wild or as companions or livestock, and their environments. Omnivorous humans depend directly on healthy and productive animals for food and economic security, especially in low-income and middle-income countries where for a large proportion of people raising animals provides their





**52%** of veterinary medicine samples collected in Asia and Africa failed at least one quality test

Most frequent issues were **out-of-specification active pharmaceutical ingredient (s)** content, failure of uniformity of units, and disintegration tests

PLOS ONE

RESEARCH ARTICLE

# Substandard and falsified antimicrobials in selected east African countries: A systematic review

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## Abstract

### Background

Globally, millions of people have been affected by fraudulent pharmaceutical products, particularly those in developing countries. Although the problem of falsified and substandard drugs is acknowledged, the extent of the issue is ever-changing, has a dynamic nature, and should be quantified and captured in a recent snapshot.

### Objective

This systematic review seeks to examine the data that can quantify and provide a current snapshot of the prevalence of SF antimicrobials in selected east Africa countries.

### Methods

Scientific studies on antimicrobial quality were searched in PubMed, Embase, Scopus, and Google Scholar from 2017 to February 2023. The search strategy focused on scientific articles published in peer-reviewed scientific journals written in English and the studies exclusively done in any of the selected countries of east Africa. The articles were carefully reviewed by two individuals for inclusion independently, first by title followed by abstract and the full-text retrieval. To minimize bias associated with the methodology used for data collection, the quality of the studies was assessed for quality according to the Medicine Quality Assessment Reporting Guidelines (MEDQUARG). The reporting of this systematic review was done following Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA).

### Results

Fifteen studies that estimated the prevalence of poor-quality antimicrobial medicines in selected four east African countries were included. The overall percentage of samples of



Review of studies from Ethiopia, Kenya, Rwanda and Tanzania, 217-2023

**22.6% failed at least one quality test** but individual studies reported rates ranging from **0% to 80%**

Zabala et al. 2022 found that evidence on **SF antibiotics** is scarce. Estimates that **17.4% of the global antibiotic supply may be SF**

Significant progress has been made in improving the quality and regulation of the human pharmaceutical market

# ILRI Study 1: Mystery shopper

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## Antibiotic quality and use practices amongst dairy farmers and drug retailers in central Kenyan highlands

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**Understanding antibiotic use in dairy systems is critical to guide antimicrobial stewardship programs. We investigated antibiotic use practices in small-holder dairy farms, antibiotic quality, and antimicrobial resistance (AMR) awareness among veterinary drug retailers in a mixed farming community in the central Kenyan highlands. Data were collected from 248 dairy farms and 72 veterinary drug stores between February 2020 and October 2021. A scale was developed to measure knowledge about AMR and antibiotic use using item response theory, and regression models were used to evaluate factors associated with antibiotic use and AMR knowledge. The active pharmaceutical ingredient (API) content of 27 antibiotic samples was determined using high-performance liquid chromatography (HPLC). The presence and levels of 11 antibiotic residues in 108 milk samples collected from the study farms were also investigated using liquid chromatography tandem mass spectrometry (LC–MS/MS). Almost all farms (98.8%, n = 244) reported using antibiotics at least once in the last year, mostly for therapeutic reasons (35.5%). The most used antibiotics were tetracycline (30.6%), penicillin (16.7%), and sulfonamide (9.4%), either individually or in combination, and predominantly in the injectable form. Larger farm size (OR = 1.02, p < 0.001) and history of vaccination use (OR = 1.17, p < 0.001) were significantly associated with a higher frequency of antibiotic use. Drug retailers who advised on animal treatments had a significantly higher mean knowledge scores than those who only sold drugs. We found that 44.4% (12/27) of the tested antibiotics did not meet the United States Pharmacopeial test specifications (percentage of label claim). We detected nine antibiotics in milk, including oxytetracycline, sulfamethoxazole, and trimethoprim. However, only three samples exceeded the maximum residue limits set by the Codex Alimentarius Commission. Our findings indicate that antibiotics of poor quality are accessible and used in small-holder dairy systems, which can be found in milk. These results will aid future investigations on how to promote sustainable antibiotic use practices in dairy systems.**

Animal husbandry currently accounts for approximately two thirds of the global consumption of antibiotics, and this is projected to increase[1]. The widespread use and misuse of antibiotics has raised concerns about potential development and dissemination of antimicrobial resistance (AMR). AMR infections have been estimated to lead to 1.27 million deaths globally in 2019, with most of the burden borne by low- and middle-income countries (LMICs), particularly in sub-Saharan Africa[2]. In these settings, antibiotics serve as 'quick fixes' for hygiene and productivity challenges, acting as substitutes for more costly interventions to improve the conditions within which health workers, farming communities, and animals work and live[3]. In the recent years, there are increasing

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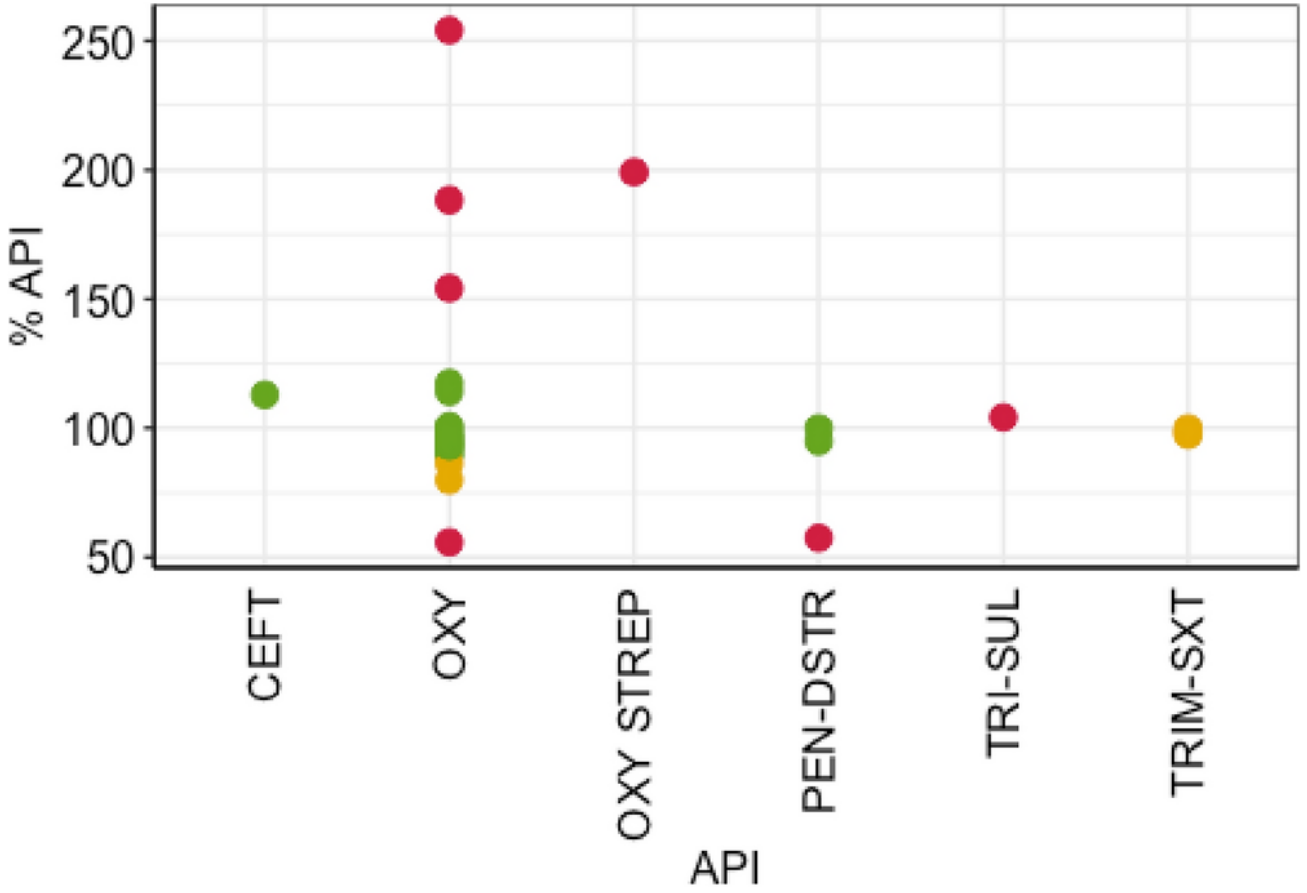
Scientific Reports | (2023) 13:23101 | https://doi.org/10.1038/s41598-023-50325-8 nature portfolio


Scenario 1: dairy cow experiencing respiratory distress symptoms such as nasal discharge, lethargy, labored breathing, and lack of appetite

Scenario 2 broiler flock displaying diarrhoea, weight loss, weakness, lack of appetite, and ruffled feathers.

One of the shoppers, who was a veterinarian, further requested a specific antibiotic brand.

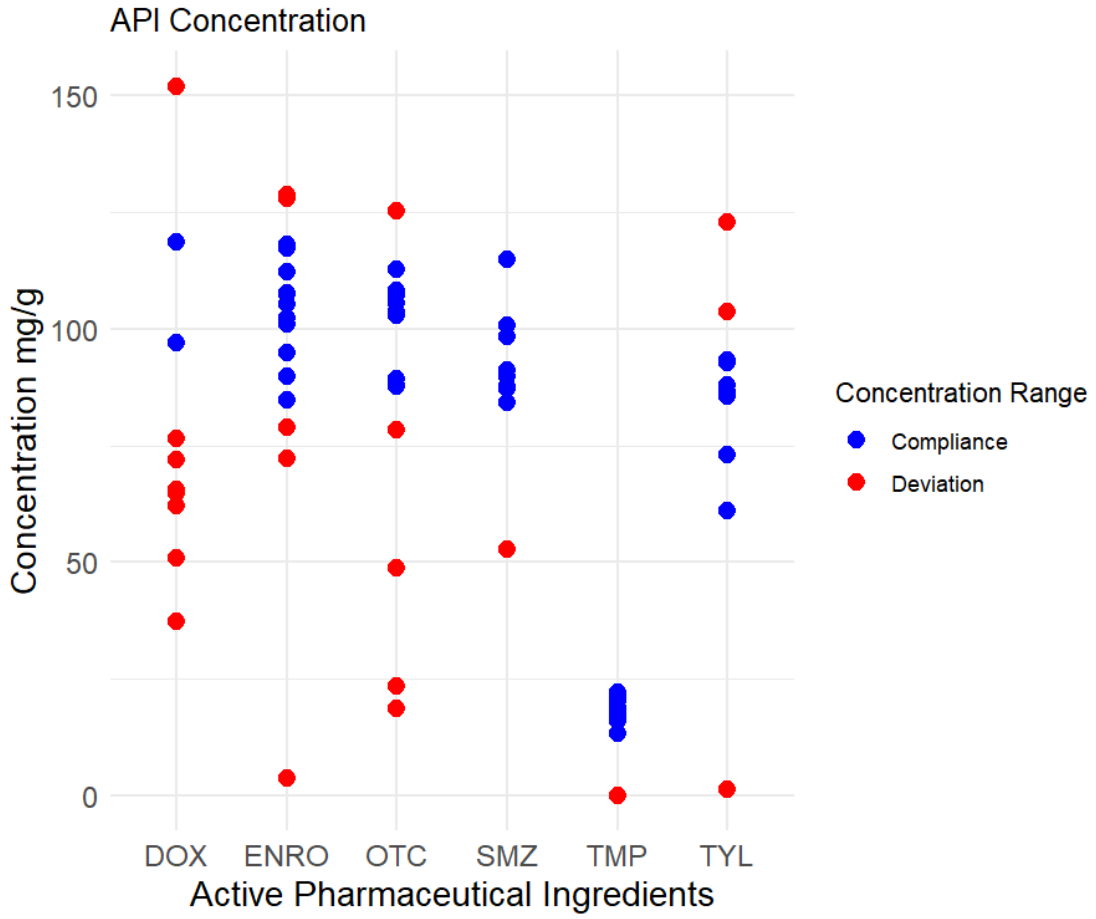
Samples purchased in their original containers.




- 27 antibiotics were purchased
- Able to purchase based on symptoms without a prescription
- 44.4% (12/27) did not meet the USnited States Pharmacopeial test specifications (% of label claim)

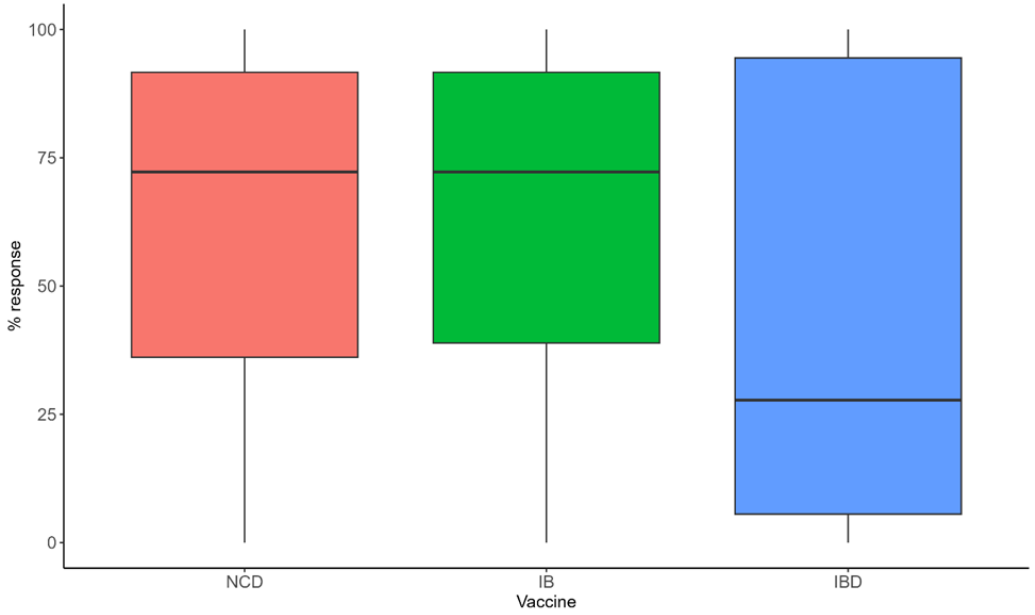
# ILRI Study 2: Antibiotic quality on farm *ongoing*





# ILRI Study 3: Poultry vaccine efficacy *ongoing*

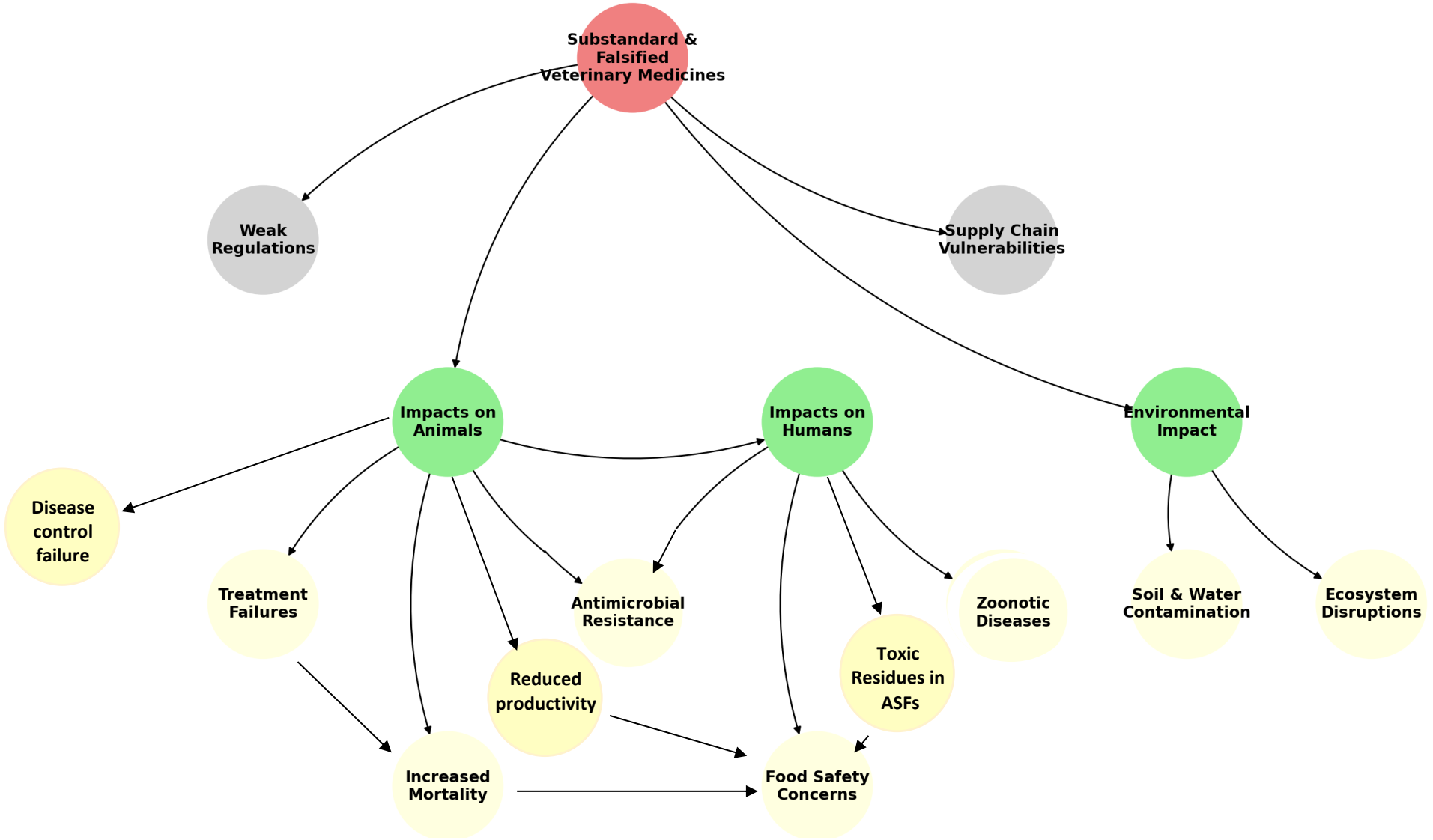
- All farmers said they vaccinated against NCD, IB, IBD
- Serum samples collected at Day 28 from 18 randomly selected birds
- Zoetis ProFLOK ELISA kit against NCDV, IBV, IBDV




antibody response

| Category | NCD | IB | IBD |
|---|---|---|---|
| Good vaccination | 10.5% | 0 | 16% |
| Fair vaccination | 0 | 5% | 0 |
| Poor vaccination | 89.5% | 95% | 84% |

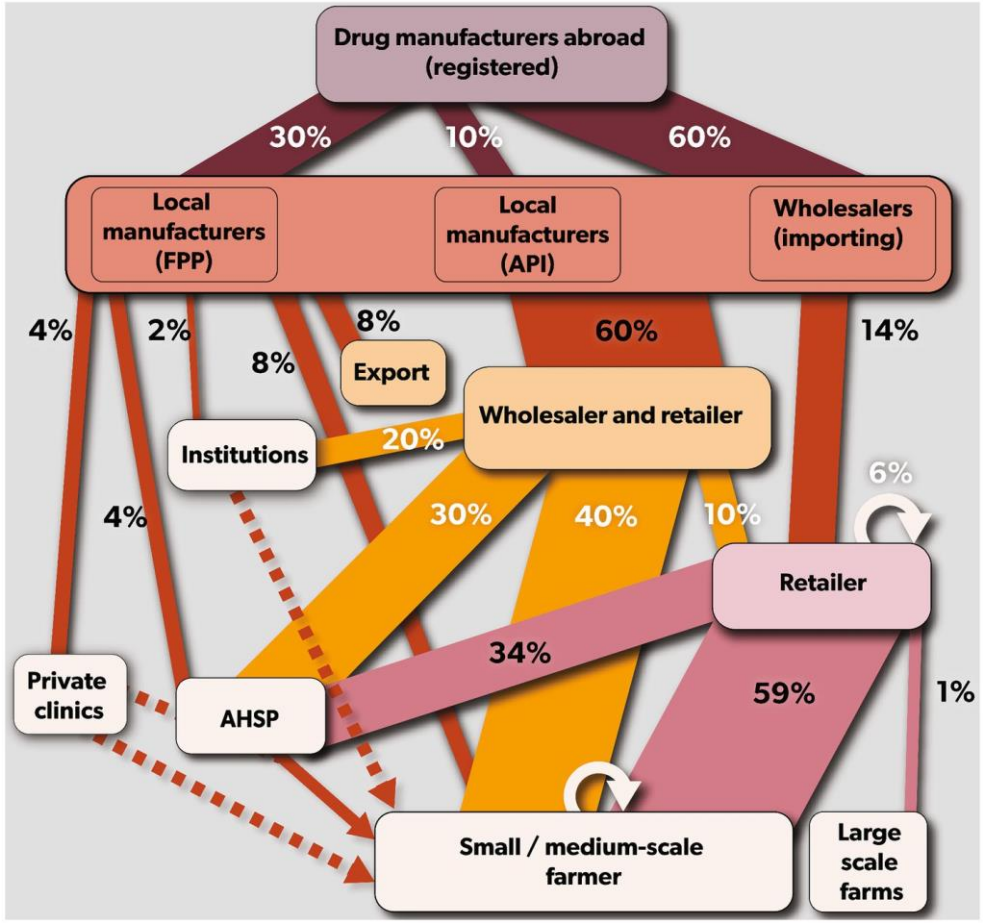
# One Health: interconnectedness and sharing


Substandard & Falsified Veterinary Medicines
Weak Regulations
Supply Chain Vulnerabilities
Impacts on Animals
Impacts on Humans
Environmental Impact
Disease control failure
Treatment Failures
Antimicrobial Resistance
Zoonotic Diseases
Soil & Water Contamination
Ecosystem Disruptions
Reduced productivity
Toxic Residues in ASFs
Increased Mortality
Food Safety Concerns

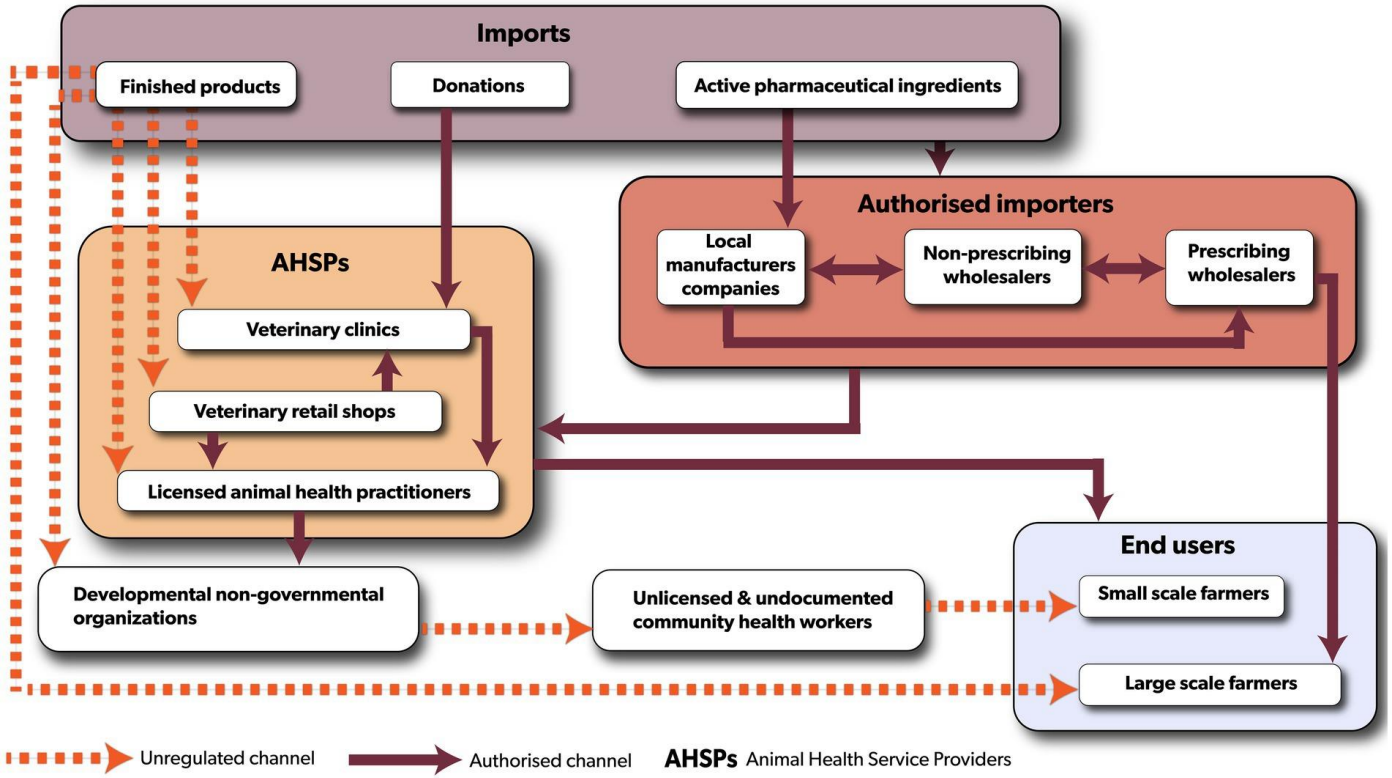
World Organisation for Animal Health

# Complex supply chains

Morang'a et al. 2024




Mhone et al. 2024



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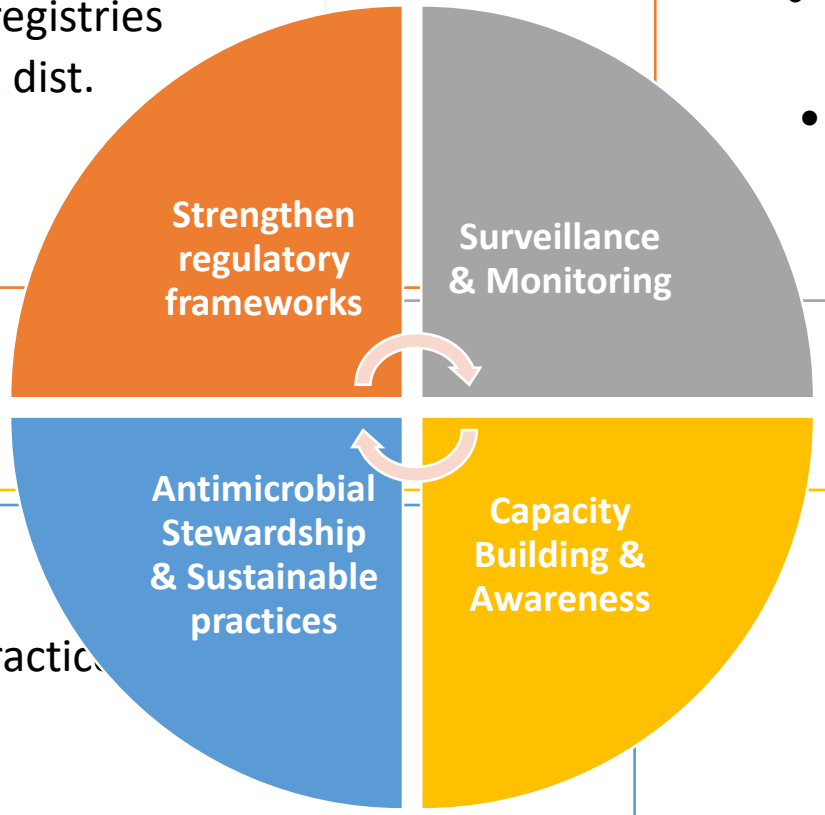
# Addressing SF VMPS

- Harmonize regulations
- Establish centralized veterinary drug registries
- Increase penalties for SF drug prod. & dist.
- Improve post-market surveillance
- Avail pharmacovigilance data

- Routine testing at import & sales hubs
- Tracking systems using barcodes or QR codes
- Encourage whistleblowing and reporting
- Work with regional and global networks e.g. VSAFE




- Encourage good animal husbandry practic
- Scale up vaccination programs
- Support alternatives
- Promote quality-assured products

- Training programs
- Introduce mobile app for instant reporting
- Awareness campaigns
- Integrate into educational curricular



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