Working group breakdown **by country**

Addis Ababa – Debre-Zeit (Ethiopia) 9-11 July 2019

GROUP 1	GROUP 2	GROUP 3
Egypt	Angola	Eritrea
Gambia	Botswana	Ethiopia
Ghana	eSwatini	Kenya
Libya	Lesotho	Malawi
Nigeria	Mauritius	Seychelles
Somalia	Mozambique	South Sudan
Sudan	Namibia	Tanzania
	South Africa	Uganda
	Zimbabwe	

Veterinary Medicines Regulatory Authority

Rapid Alert Notification Reference number: F5-07-2019

Product: Veterinary medicinal product	**Marketing Authorisation Number:** 0000XYZ
Brand name: Amoxilot	**Generic name:** Amoxicillin
Batch number: 047438E	**Expiry date:** 06/2022
Marketing Authorisation Holder: Pharmavet	**Manufacturer(s):** Pharmavet

Details of incident:

On 2nd June, a batch of 'Amoxilot' was reported to the local medicines authority after a number of clients complained to their veterinarians about a lack of efficacy. It was subsequently confirmed by the manufacturer on the 12th June that that this product had a batch number that did not correspond to any existing batch numbers. Upon further testing, five products with this batch number were found to contain no amoxicillin.

Action taken:

A recall to veterinary level is planned. Veterinarians and consumers should be informed of the products in question so that the affected products and batches can be recalled.

Definitions

The following definitions are adapted from the WHO definitions of substandard, falsified, and unregistered/unlicensed medical products to be applicable for veterinary medical products (VMPs). Examples are provided to illustrate the definitions and make them clearer, but these are not the only situations to which these definitions could apply.

- *Substandard veterinary medical products:* Authorised veterinary medical products that fail to meet either their quality standards, or their specifications, or both.
  For example: An antibiotic that was produced by an authorised manufacturer, but for some reason (poor storage conditions, production error) contains only 80% of the active ingredient listed on its label. This could be discovered by a veterinarian or livestock owner through treatment failure, or be picked up by the manufacturer in routine testing of their own products.

- *Falsified veterinary medical products:* Veterinary medical products that deliberately/fraudulently misrepresent their identity, composition, or source.
  For example: A vaccine vial that was intentionally filled with water, or tablets that were intentionally filled with paracetamol (a painkiller) rather than the ingredient listed on the tablet's box. This could be discovered through errors in the packaging (unusually long or short expiry dates, spelling errors, non-existent manufacturers, etc.) by veterinarians or livestock owners, and confirmed with the manufacturers. It could also be discovered through treatment failure, or, in the case of contamination with another product, poisonings or even death.

- *Unregistered/unlicensed medical products:* Veterinary medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
  For example: An antibiotic taken by one individual from a country where it is registered, to be sold or distributed in a neighbouring country where it is not authorised for use. The product is still of good quality, it is just not legally allowed to be used. This could be detected through verification of the product against the list of VMPs authorised for use in the country.

This definition is sourced from the "How to set up a pharmacovigilance system for veterinary medicinal products" (page 3) prepared by HealthforAnimals in support of the OIE 6 th cycle Focal Points Seminar alignment with VICH Guidance and international standards.

- *Pharmacovigilance:* Pharmacovigilance is a process by which information is collected to detect and prevent unexpected or unwanted adverse effects following the use of (veterinary) medicinal products. The scope of veterinary pharmacovigilance is mainly the safety and efficacy in animals and safety in people, and may include other events associated with the use of the product, such as lack of expected efficacy, residues exceeding the established safe limit, environmental issues and suspected transmission of infectious agents (for vaccines).

Name of the country: ....

1) If you were given a report or information of a veterinary product that did not have the expected effect, how would you determine if it was:

- ☐ A substandard veterinary product?
- ☐ A falsified veterinary product?
- ☐ A secondary effect (adverse drug reaction) to a good quality product?

Please use the attached sheet of definitions when composing your response.

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2) What would you do, and who would you contact, if you were given confirmation of:

- ☐ A substandard veterinary product?
- ☐ A falsified veterinary product?
- ☐ A secondary effect (adverse drug reaction) to a good quality product?

Please consider what other individuals might need to be informed (such as veterinarians, livestock owners), and how you would get this information to them.

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3) Is there any surveillance system or reporting system in place in your country to detect and follow up when there is something wrong with a veterinary medicinal product?

☐ Yes ☐ No

Who is or could be the main/first contact person/authority to manage the situation (within a short time frame)?

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Please find attached a notification sheet as an example. Would it be feasible for you to take appropriate action under your responsibility via your network?

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4) Do you have a regularly updated database of veterinary medicinal products (VMPs) used in your country, including imported VMPs with their detailed composition? Is a database of VMPs with a summary of their product characteristics available for public consultation?

5) Is there a national or regional laboratory for controlling and monitoring the quality of VMPs? If yes, for which products? (Drugs/Pharmaceuticals? Vaccines?)

6) Does your country have a surveillance programme for the quality of VMPs? if yes, how many VMPs do you analyse each year? What percentage are found to be compliant versus non-compliant?

7) Do you have a legal basis to take samples on the market?

8) Do you have a legal basis to order recall of a batch of VMPS that is not in compliance with the marketing authorisation?

6 th Cycle Regional training Seminar for OIE focal points for veterinary products (Africa)

Addis Ababa – Debre Zeit, Ethiopia

9-11 July 2019

Working Group Session 2

Global Surveillance and Monitoring System for rapid alert, feasibility for veterinary field

Group 1

Nigeria, Ghana, Libya, Sudan, Somalia

Gambia, Egypt

Control of VMP's

- **Nigeria**

Vaccine : CVO, MoA

Drug : NCA , MoH

- Database: Yes
- Lab. (For Vaccine Only)
- Surv. Pro: No
- Sampling: Drugs Only (NAFDAC)
- Recall: Drugs Only (NAFDAC)

- **Ghana**

Vaccine : CVO, MoA

Drug : NCA , MoH

- Database: Yes
- Lab. (For Vaccine Only)
- Surv. Pro: No
- Sampling: Drugs Only
- Recall: Drugs Only

- **Libya**

Vaccine and Drugs

NCA, High Committee., FDA

- Database: Yes
- Lab. Yes
- Surv. Pro: Yes
- Sampling: Yes
- Recall: Yes

- **Gambia**

Vaccine : CVO, MoA

Drug : NCA , MoH

- Database: Yes
- Lab. No
- Surv. Pro: No
- Sampling: Yes (For Drugs)
- Recall: Yes (For Drugs)

- **Sudan**

Vaccine : CVO, MoA

Drug : NCA , MoH

- Database: Yes
- Lab. Yes
- Surv. Pro: Yes
- Sampling: Yes
- Recall: Yes

- **Somalia**

Vaccine : CVO, Mo Livestock

Drug : CVO, Mo Livestock

- Database: No
- Lab. NO
- Surv. Pro: No
- Sampling: No
- Recall: No

- **Egypt**

Vaccine : GOVS, MoA

Drug : NCA , MoH

- Database: Yes
- Lab. Yes
- Surv. Pro: Yes
- Sampling: Yes
- Recall: Yes

THANK YOU

Group II

Angola; Botswana; eSwatini; Lesotho; Mozambique; Namibia; Zimbabwe

6th cycle regional training seminar for OIE focal points for veterinary products (Africa, English)

Addis Ababa I Debre-Zeit, Ethiopia
9 - 11 July 2019

Q3a Is there any surveillance system or reporting system in place in your country to detect and follow up when there is something wrong with a VMP

Angola - No system yet

Botswana - Recently formed an NMRA (BOMRA), in the process of setting up comprehensive surveillance system

Namibia - Yes Legislation in place (Human and vet officially), Vet Legislation being reviewed

eSwatini –DVS has regulations on Animal Diseases Act to control import and export, inspection (wholesalers and retailers), a comprehensive regulation still to be drafted

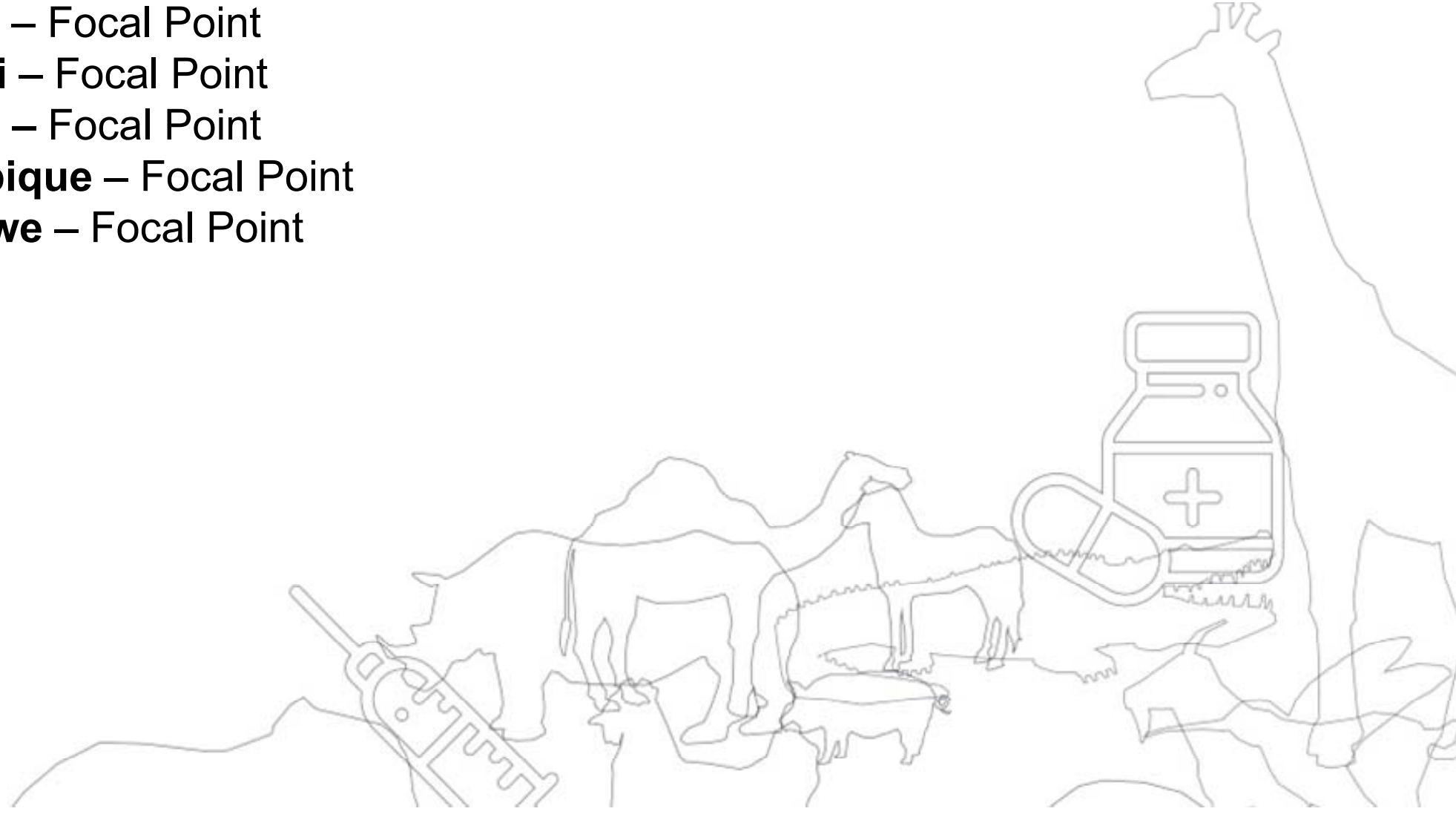
Lesotho – No system exist, Policy is present in draft form

Mozambique – similar to Swaziland, random inspection, legislation being worked on

Zimbabwe – Yes there is a system. Legislation amended to include PVH (draft form). Self Regulation from Industry on their products and report to MCAZ, Police. Liaison meeting between Industry and Regulator on SF 4 times a year

Q3bWho is or could be the main/first contact/authority to mange the situation (within a short time frame)

Angola - Focal Point
Botswana - Focal Point
Namibia – Focal Point
eSwatini – Focal Point
Lesotho – Focal Point
Mozambique – Focal Point
Zimbabwe – Focal Point



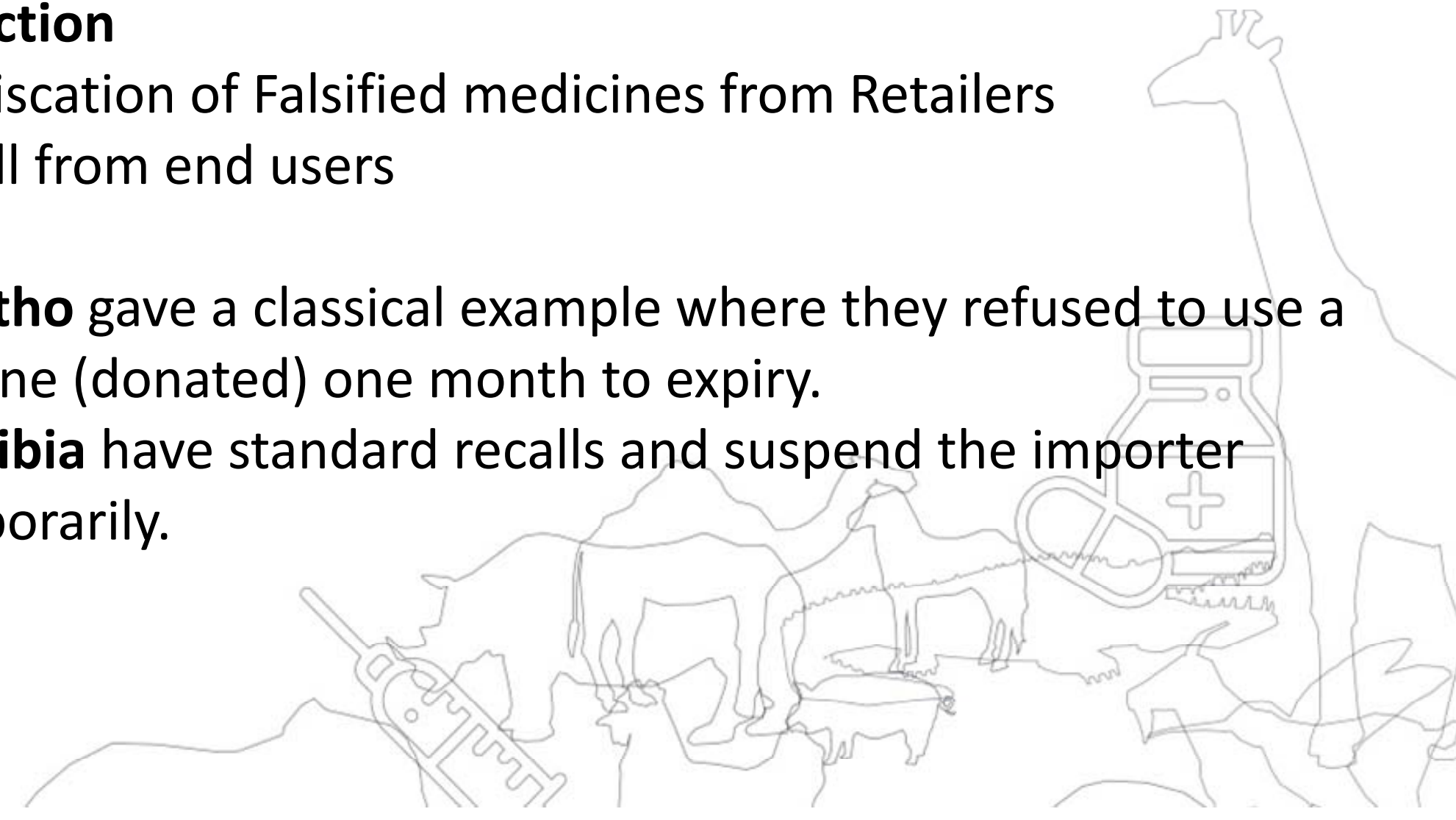
Q3c Case Study SF

- **Falsified medicine**

- **Action**

Confiscation of Falsified medicines from Retailers
Recall from end users

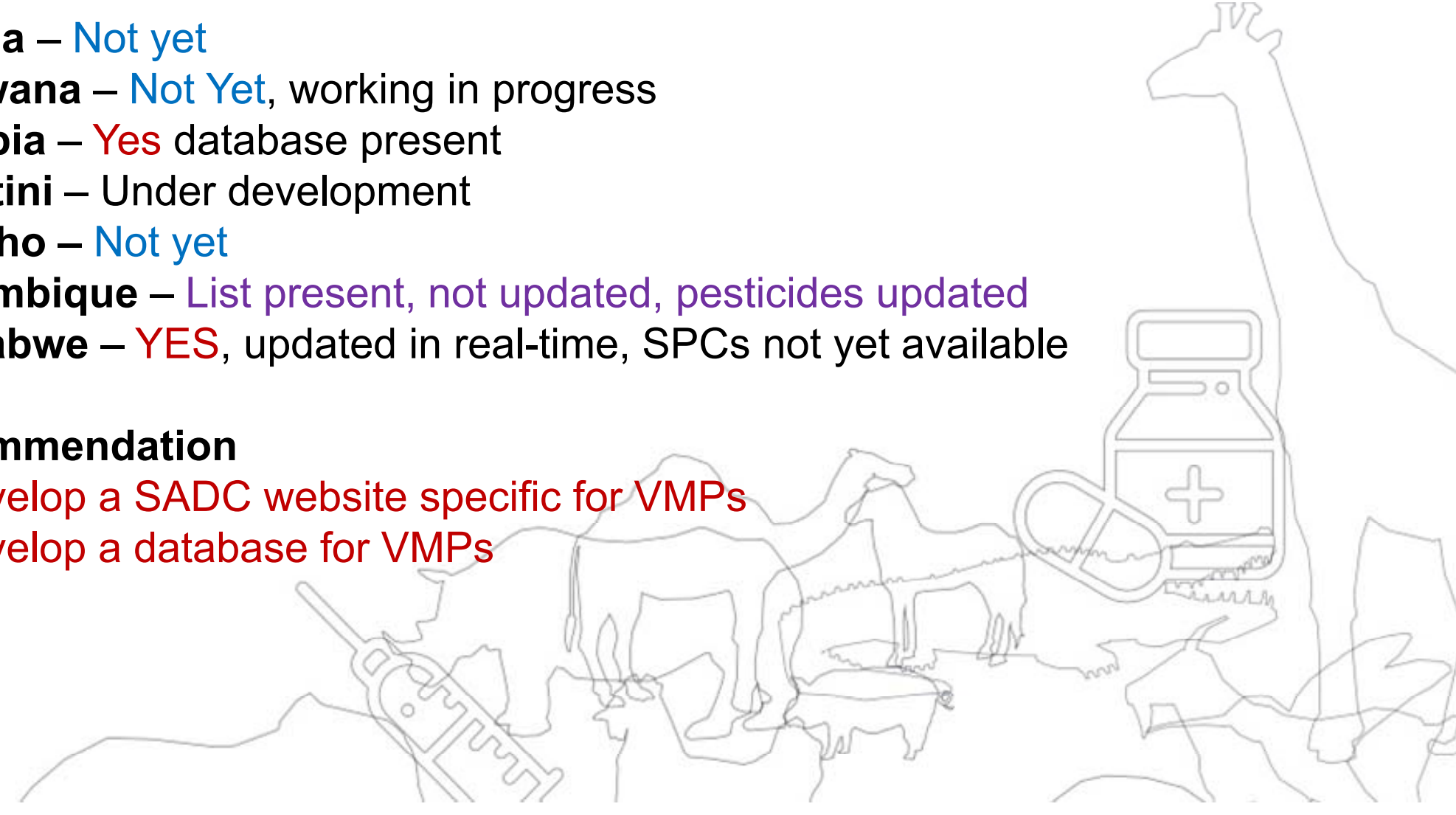
Lesotho gave a classical example where they refused to use a vaccine (donated) one month to expiry.
Namibia have standard recalls and suspend the importer temporarily.



Q4 Do you have a regularly updated database of VMPs used in your country? Is the database with SMPs available for public consumption

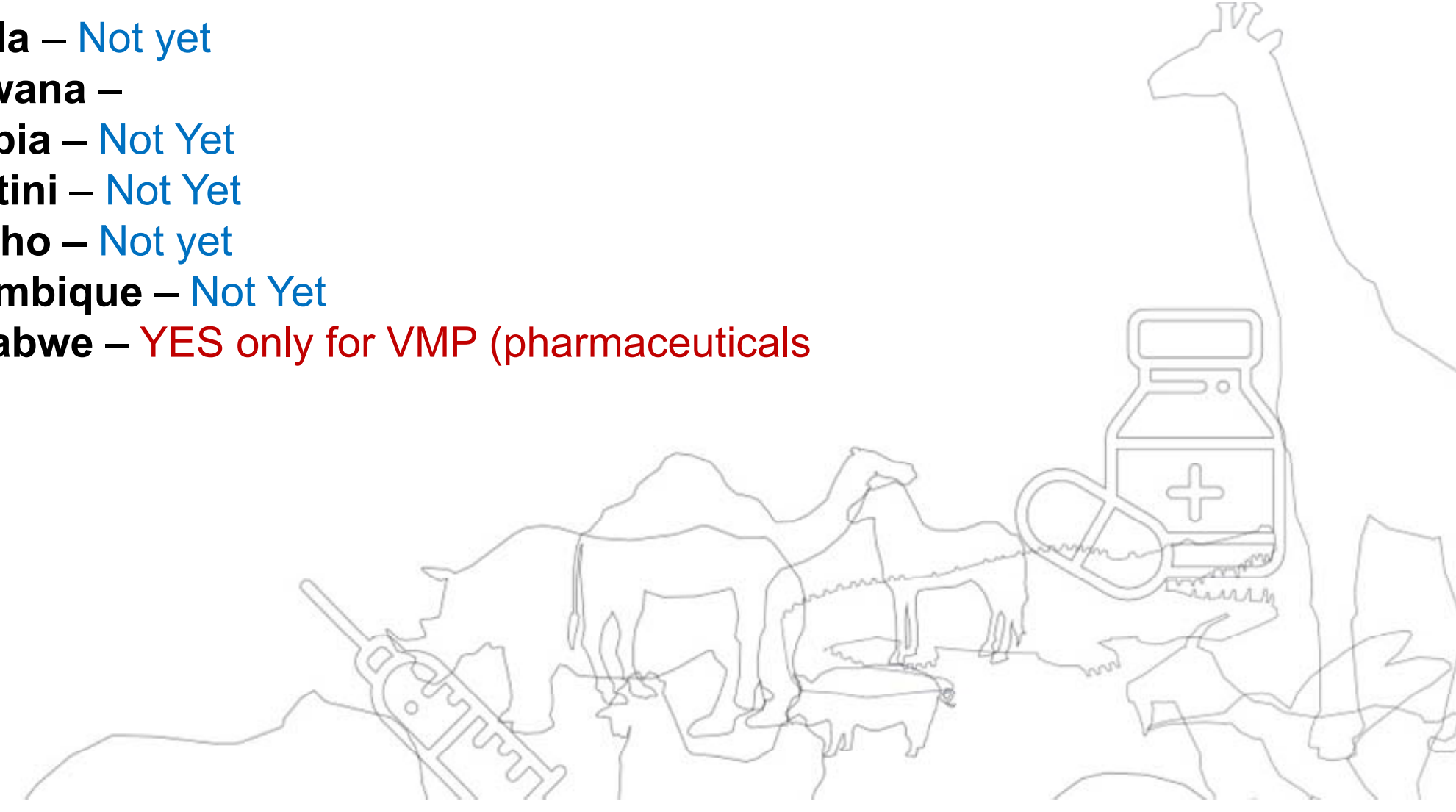
Angola – Not yet
Botswana – Not Yet, working in progress
Namibia – Yes database present
eSwatini – Under development
Lesotho – Not yet
Mozambique – List present, not updated, pesticides updated
Zimbabwe – YES, updated in real-time, SPCs not yet available

Recommendation
To develop a SADC website specific for VMPs
To develop a database for VMPs



Q5 Is there a national or regional laboratory for controlling and monitoring the quality of VMPs?

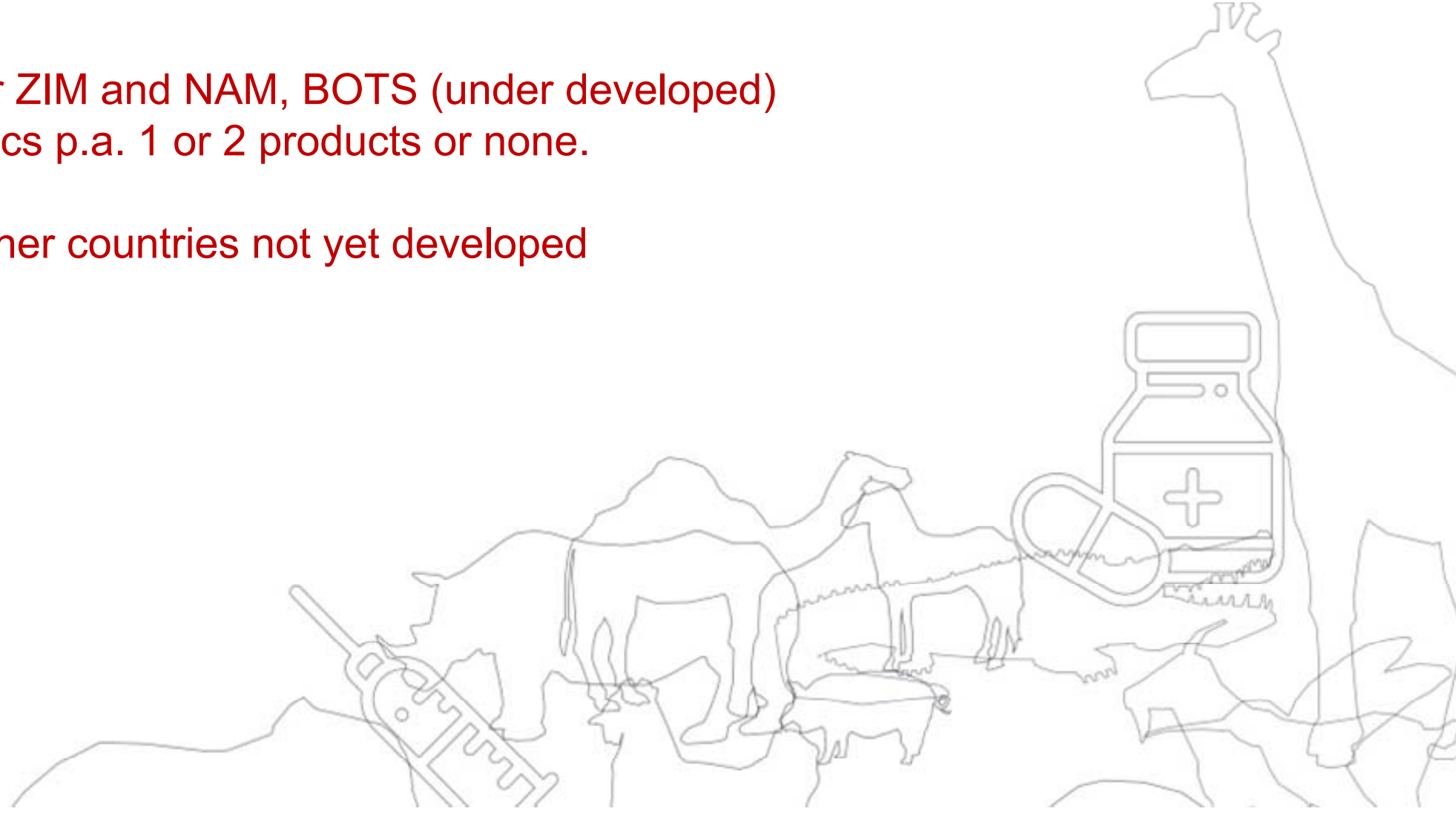
Angola – Not yet
Botswana –
Namibia – Not Yet
eSwatini – Not Yet
Lesotho – Not yet
Mozambique – Not Yet
Zimbabwe – YES only for VMP (pharmaceuticals



Q6 Does your country have a surveillance programme for the Quality of VMPs. If yes what are the statistics like

Yes for ZIM and NAM, BOTS (under developed)
Statistics p.a. 1 or 2 products or none.

The other countries not yet developed



Q7 Do you have legal basis to take samples on the market

Yes for NAM, BOTS, ZIM

Swaziland would find a way

No for the other countries

GROUP 3

Is it is substandard Product?

- Compare with what was registered- NRA records
- Laboratory analysis (quality) - submit sample competent lab- Substandard ? Falsfied?
- Efficacy studies: Conduct study
- Was the product used as recommended by manufacturer?-Investigate
- Determine whether it was a batch problem

A falsified veterinary Product?

- NRA records on market authorization

- Laboratory analysis (quality) - submit sample competent lab

A secondary effect (adverse reaction) to a good quality product

Question 2

- Specific document for reporting
- Investigation of the claim
- Reporting outcome of investigation
- This will determine justification for Withdrawal of product

Question 3

- Yes, the is a surveillance system or reporting system and follow up when there is something wrong with a vet. Med. Product
- First contact person is vet or paraprofessional
- Variable from country to country
- Proposal for sharing between countries
- Harmonization on sharing : Lab results/analysis

Questions 4, 5, 6, 7, 8