Ethiopia

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

Veterinary Pharmacovigillance

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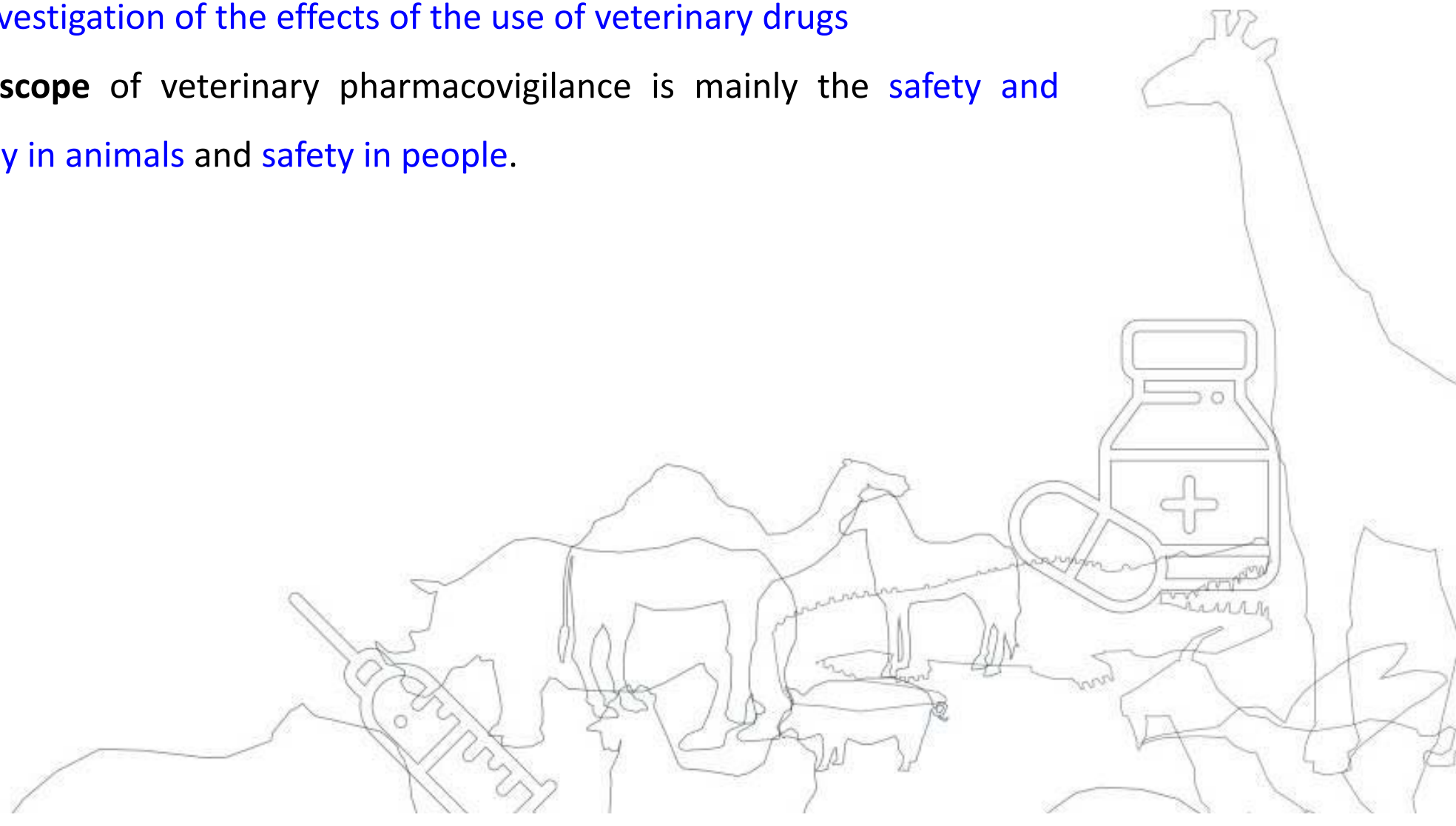
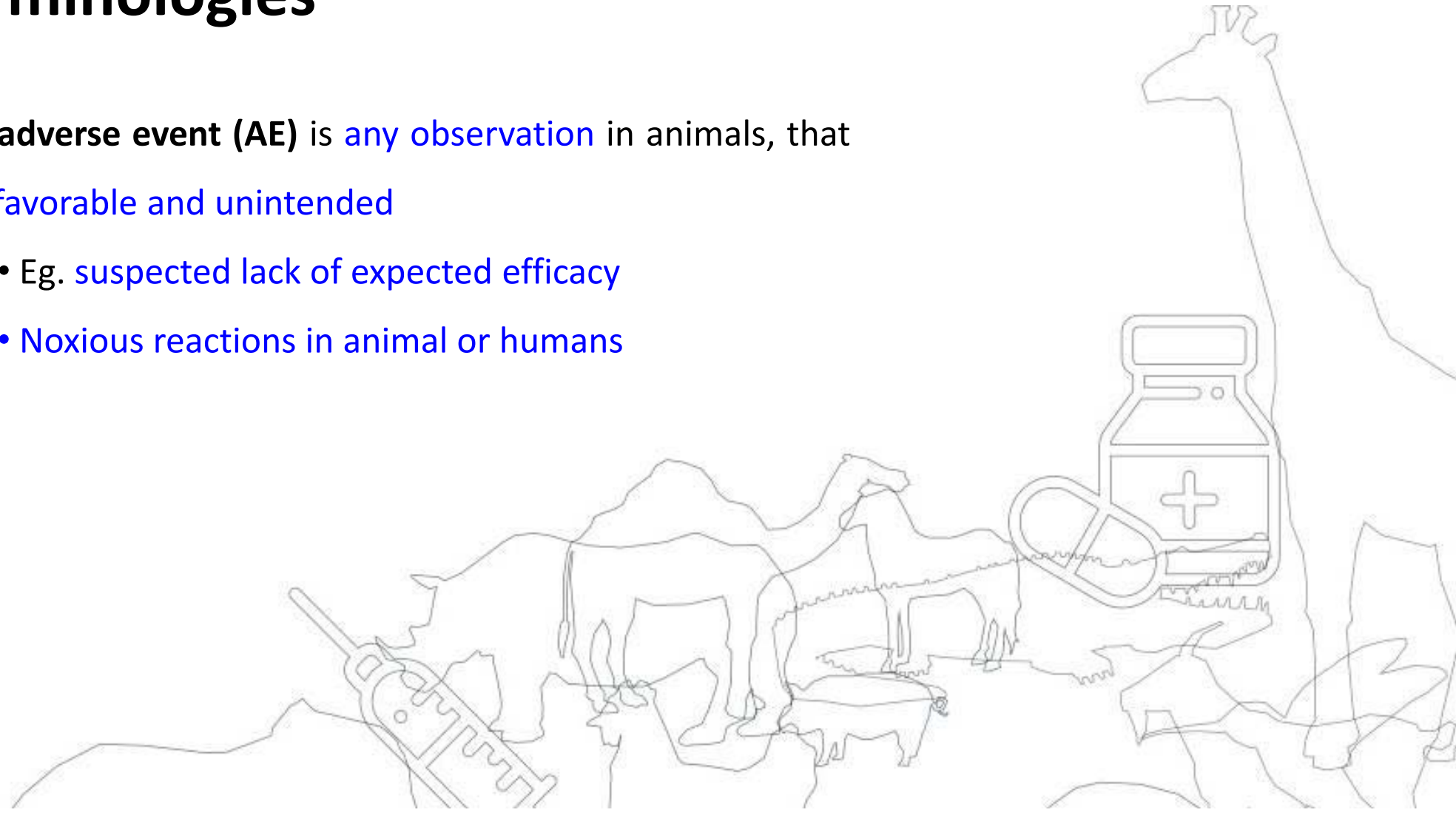
What is Pharmacovigilance?

- Pharmacovigilance of veterinary drugs can be defined as the detection and investigation of the effects of the use of veterinary drugs
- The **scope** of veterinary pharmacovigilance is mainly the safety and efficacy in animals and safety in people.



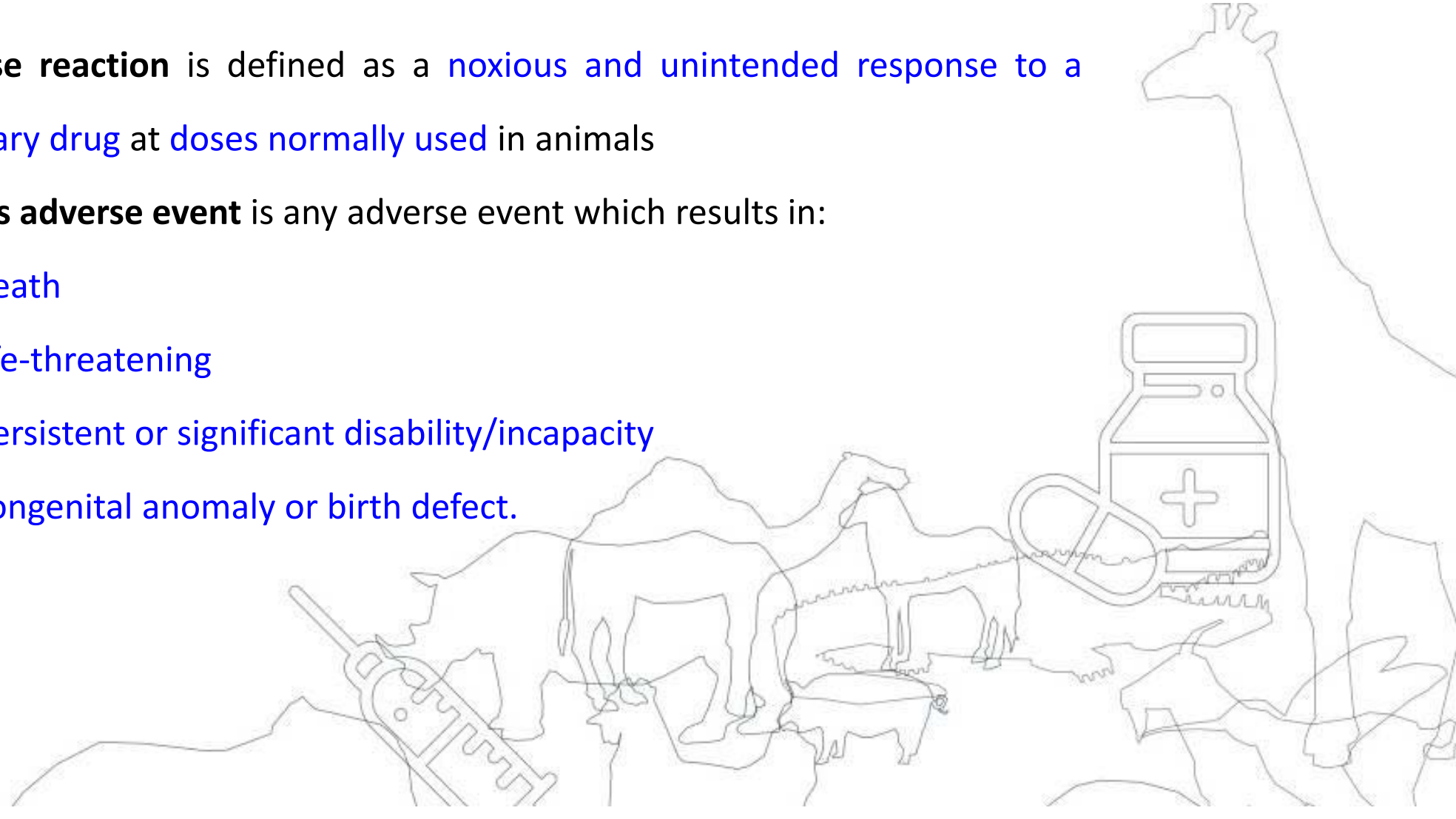
Terminologies

- **An adverse event (AE)** is any observation in animals, that is unfavorable and unintended
  - Eg. suspected lack of expected efficacy
  - Noxious reactions in animal or humans



Terminologies cont.

- **Adverse reaction** is defined as a noxious and unintended response to a veterinary drug at doses normally used in animals
- **Serious adverse event** is any adverse event which results in:
  - death
  - life-threatening
  - persistent or significant disability/incapacity
  - congenital anomaly or birth defect.

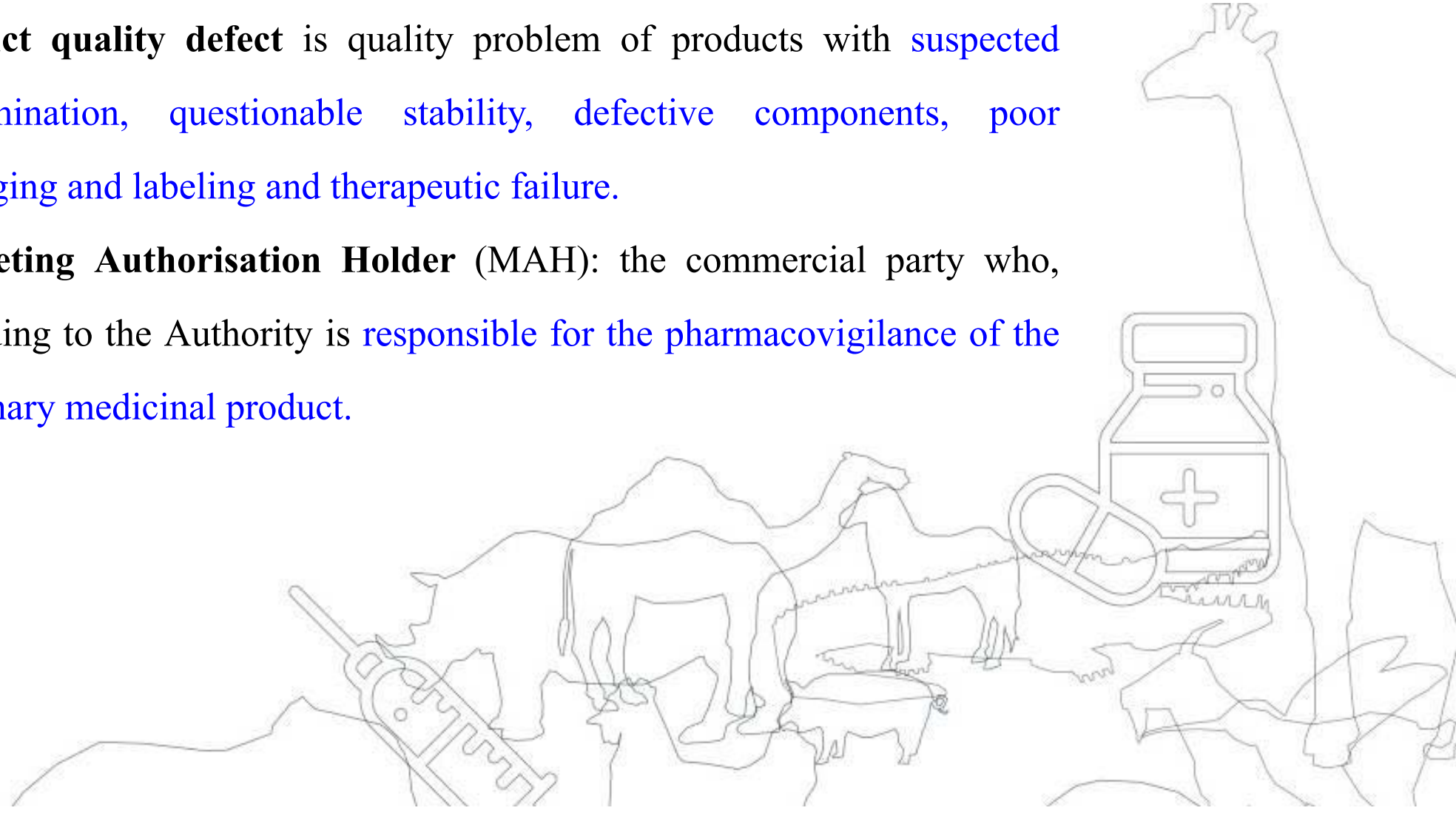


Terminologies cont.

Unexpected adverse event is an adverse event of which the nature, severity or outcome is not consistent with approved labeling

Product quality defect is quality problem of products with suspected contamination, questionable stability, defective components, poor packaging and labeling and therapeutic failure.

Marketing Authorisation Holder (MAH): the commercial party who, according to the Authority is responsible for the pharmacovigilance of the veterinary medicinal product.



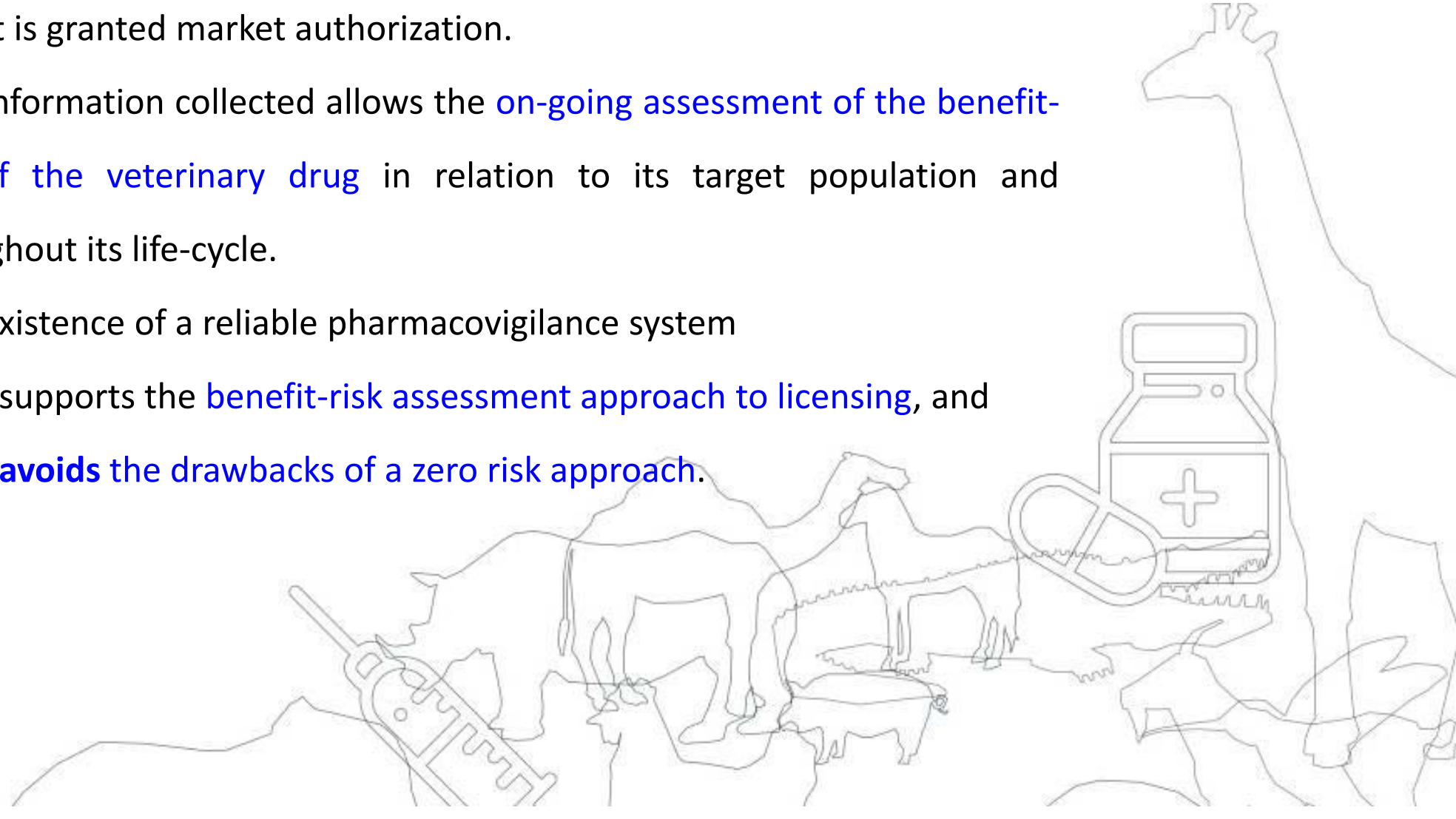
Why is Pharmacovigilance important?

•It is important to continually monitor the safety and efficacy of a drug after it is granted market authorization.

•The information collected allows the on-going assessment of the benefit-risk of the veterinary drug in relation to its target population and throughout its life-cycle.

•The existence of a reliable pharmacovigilance system

- supports the benefit-risk assessment approach to licensing, and
- **avoids** the drawbacks of a zero risk approach.

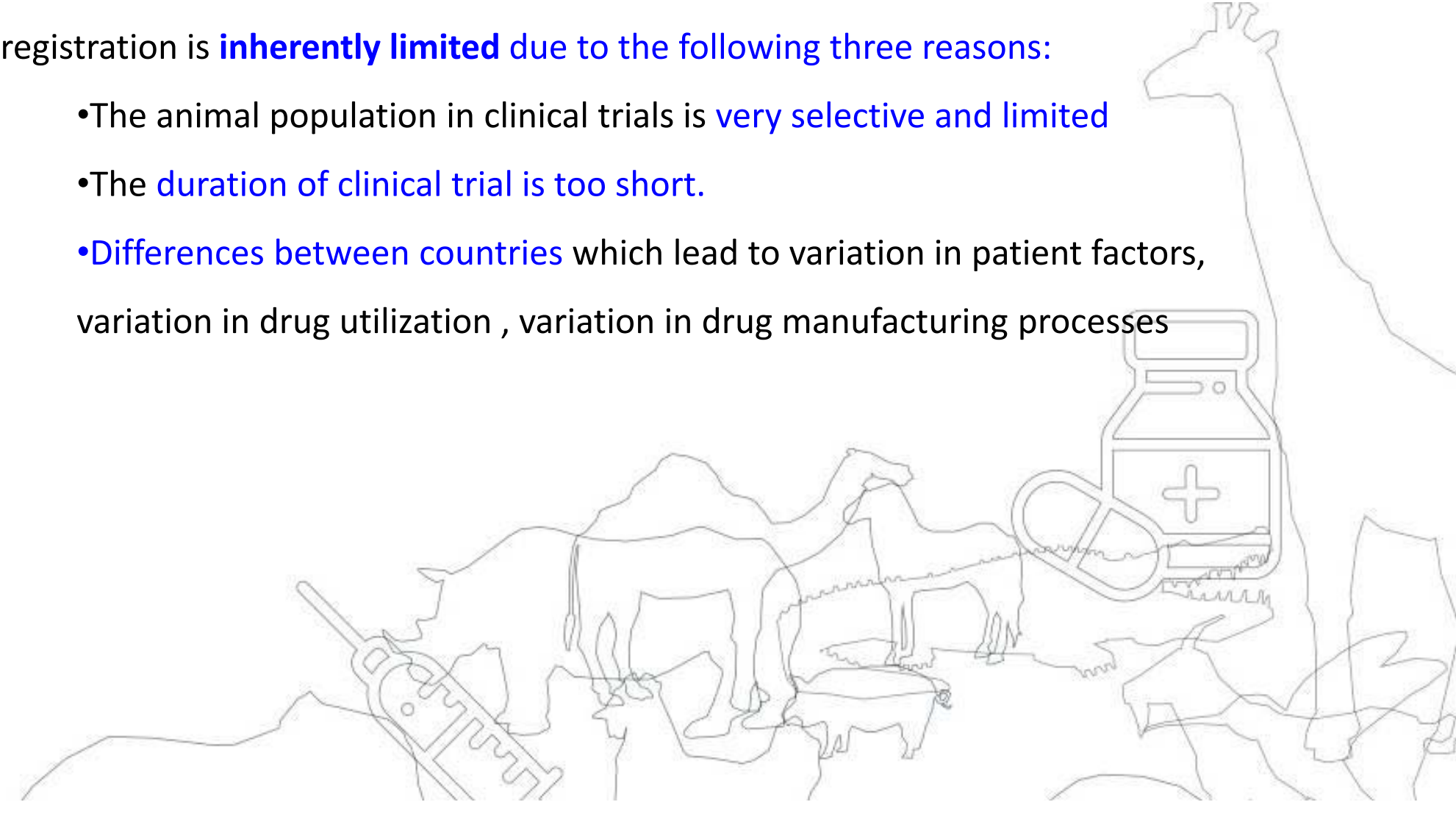


Why is Pharmacovigilance important? Contd

• Information on safety and efficacy of a veterinary drug once it is marketed is limited to premarketing evaluation, clinical trials and other factors

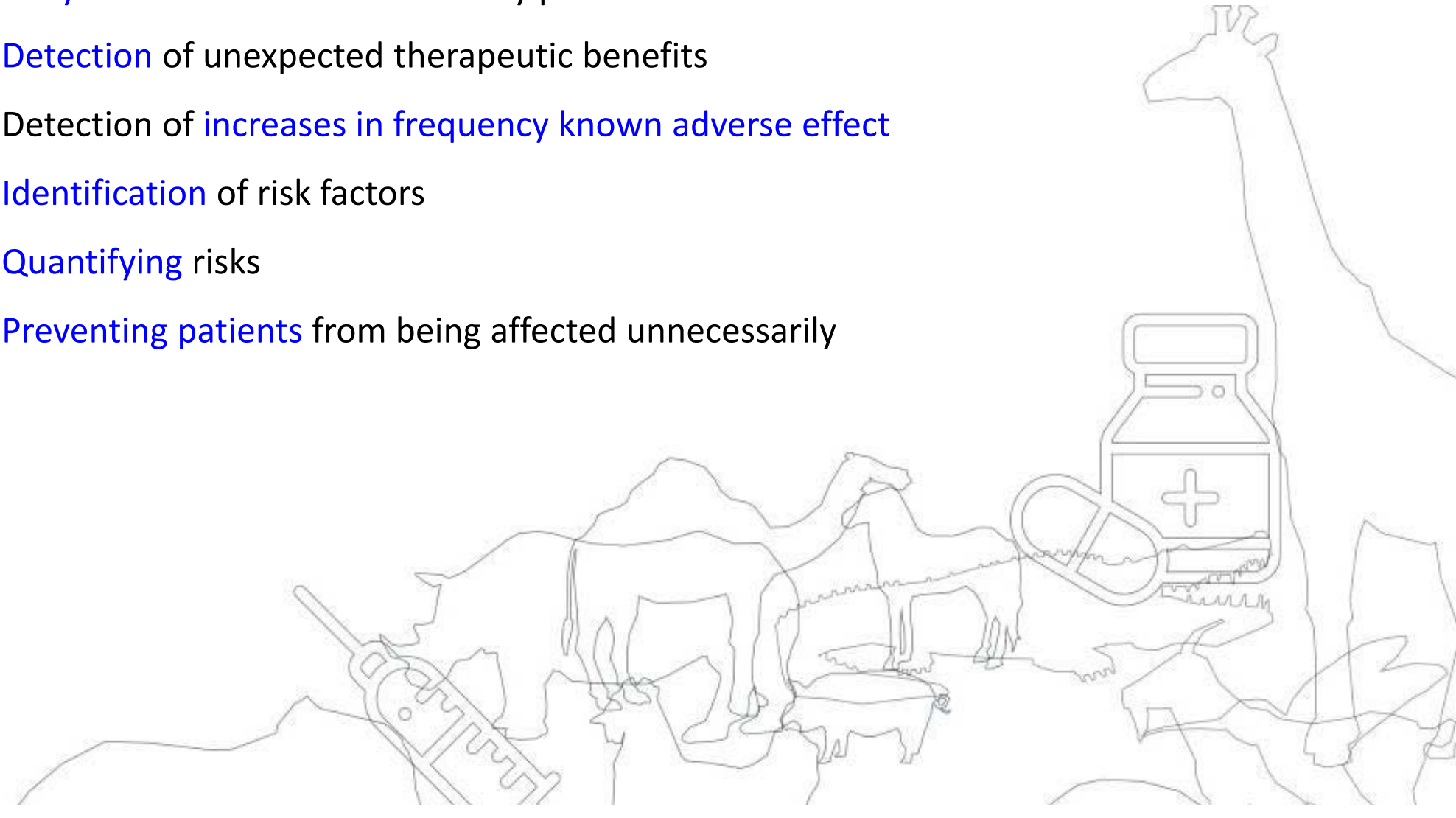
•Therefore, premarketing safety evaluation of veterinary drugs at the time of registration is **inherently limited** due to the following three reasons:

- •The animal population in clinical trials is very selective and limited
- •The duration of clinical trial is too short.
- •Differences between countries which lead to variation in patient factors, variation in drug utilization , variation in drug manufacturing processes



Aims of pharmacovigilance

- Early detection of unknown safety problems
- Detection of unexpected therapeutic benefits
- Detection of increases in frequency known adverse effect
- Identification of risk factors
- Quantifying risks
- Preventing patients from being affected unnecessarily



How do we monitor ADEs ?

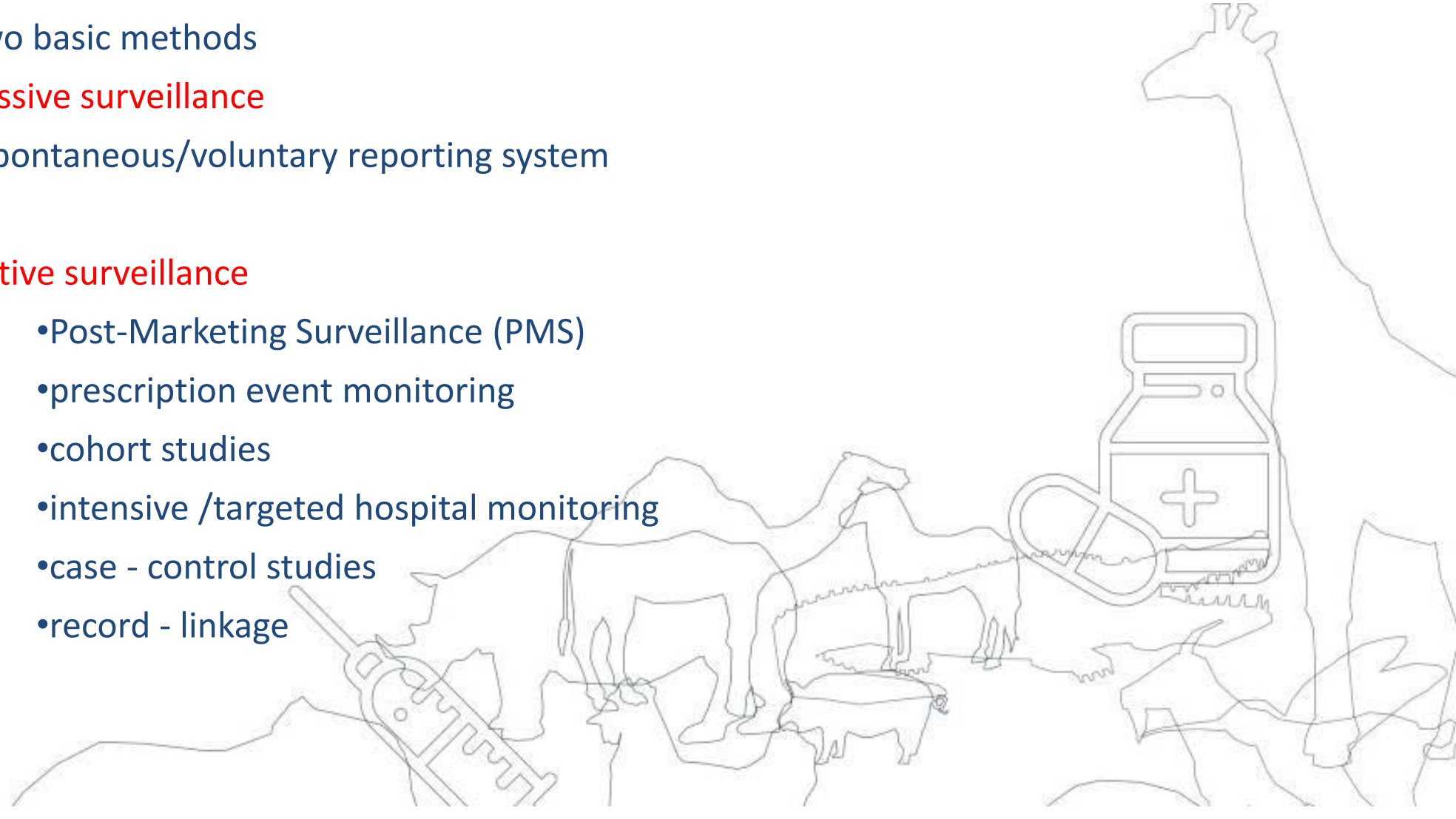
Two basic methods

Passive surveillance

•Spontaneous/voluntary reporting system

Active surveillance

- •Post-Marketing Surveillance (PMS)
- •prescription event monitoring
- •cohort studies
- •intensive /targeted hospital monitoring
- •case - control studies
- •record - linkage



Legal Mandate

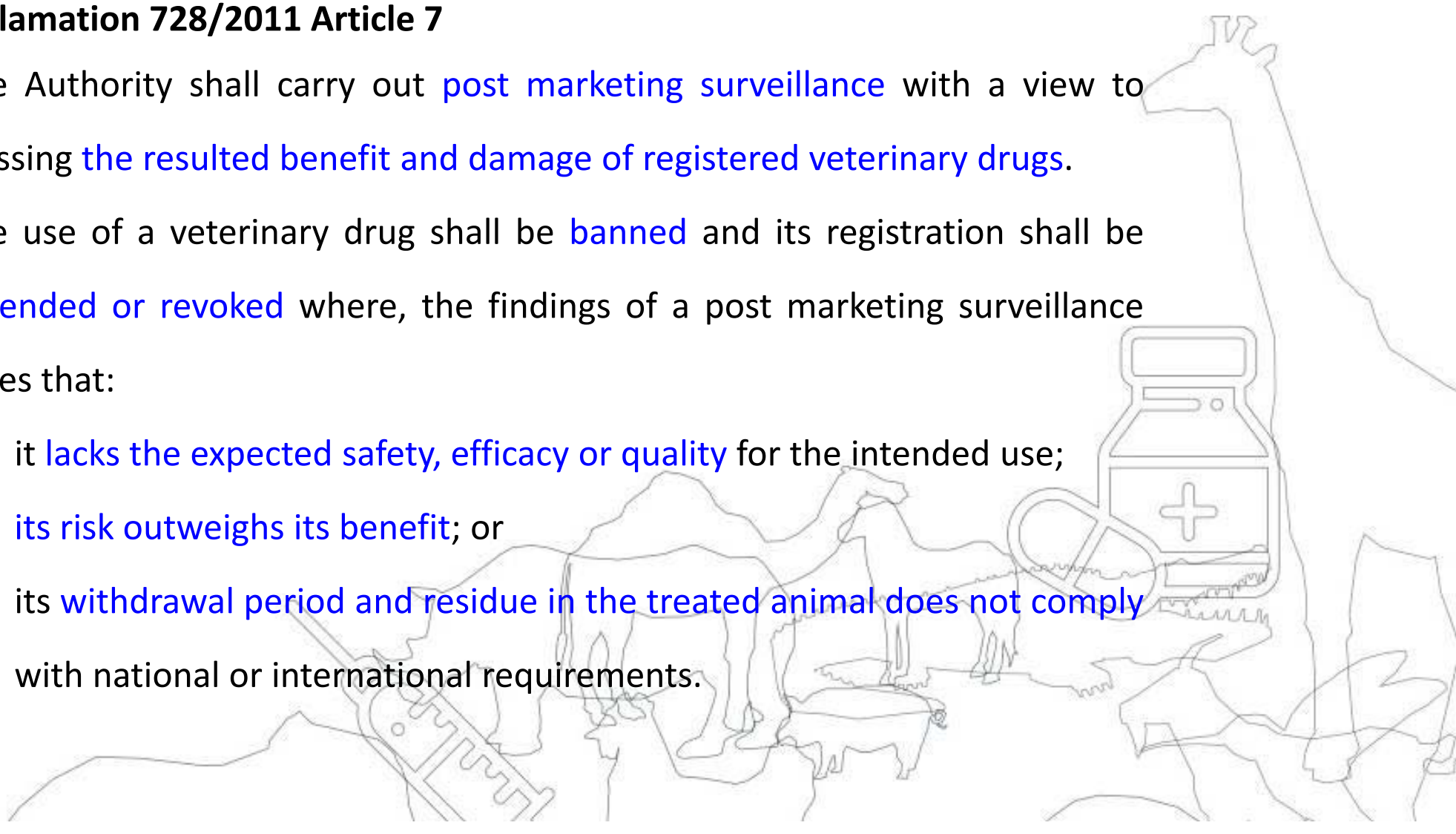
Proclamation 728/2011 Article 7

- The Authority shall carry out post marketing surveillance with a view to assessing the resulted benefit and damage of registered veterinary drugs.
- The use of a veterinary drug shall be banned and its registration shall be suspended or revoked where, the findings of a post marketing surveillance proves that:

a) it lacks the expected safety, efficacy or quality for the intended use;

b) its risk outweighs its benefit; or

c) its withdrawal period and residue in the treated animal does not comply with national or international requirements.



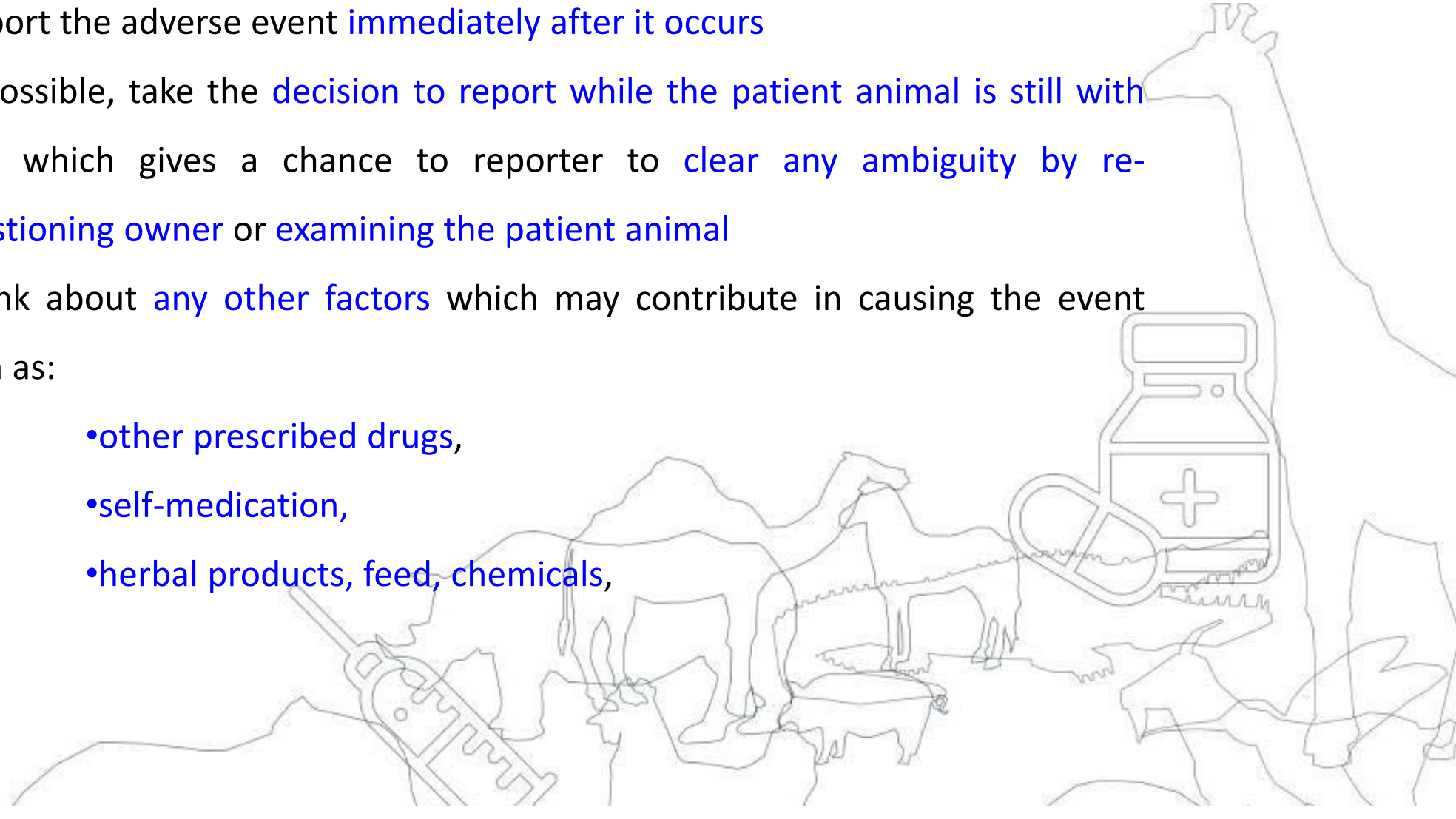
Reporting of ADE
Basic Principles of Efficient ADE Reporting

•Report the adverse event immediately after it occurs

•If possible, take the decision to report while the patient animal is still with you, which gives a chance to reporter to clear any ambiguity by re-questioning owner or examining the patient animal

•Think about any other factors which may contribute in causing the event such as:

- •other prescribed drugs,
- •self-medication,
- •herbal products, feed, chemicals,

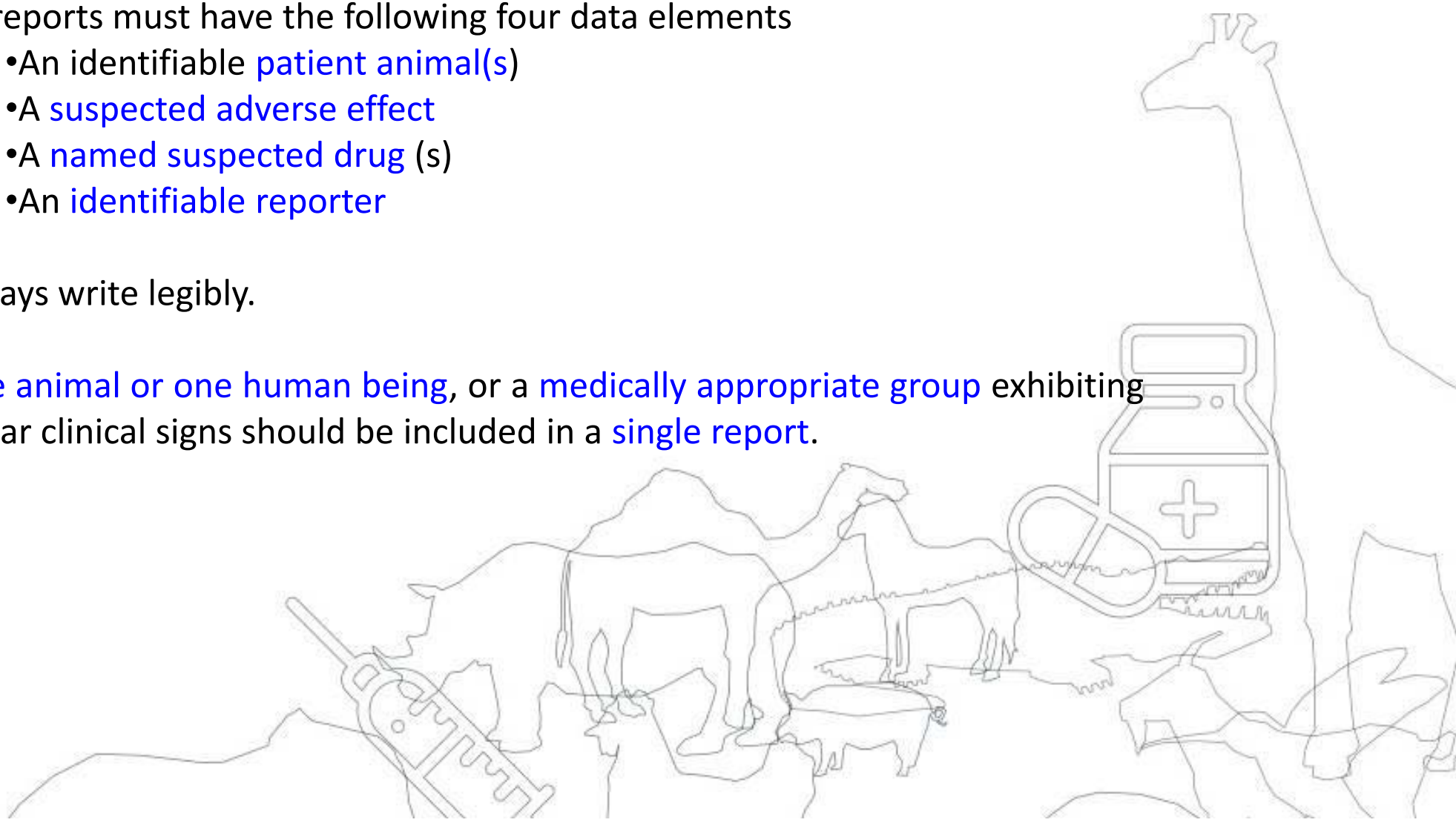


Principles…

- All reports must have the following four data elements
  - An identifiable patient animal(s)
  - A suspected adverse effect
  - A named suspected drug (s)
  - An identifiable reporter

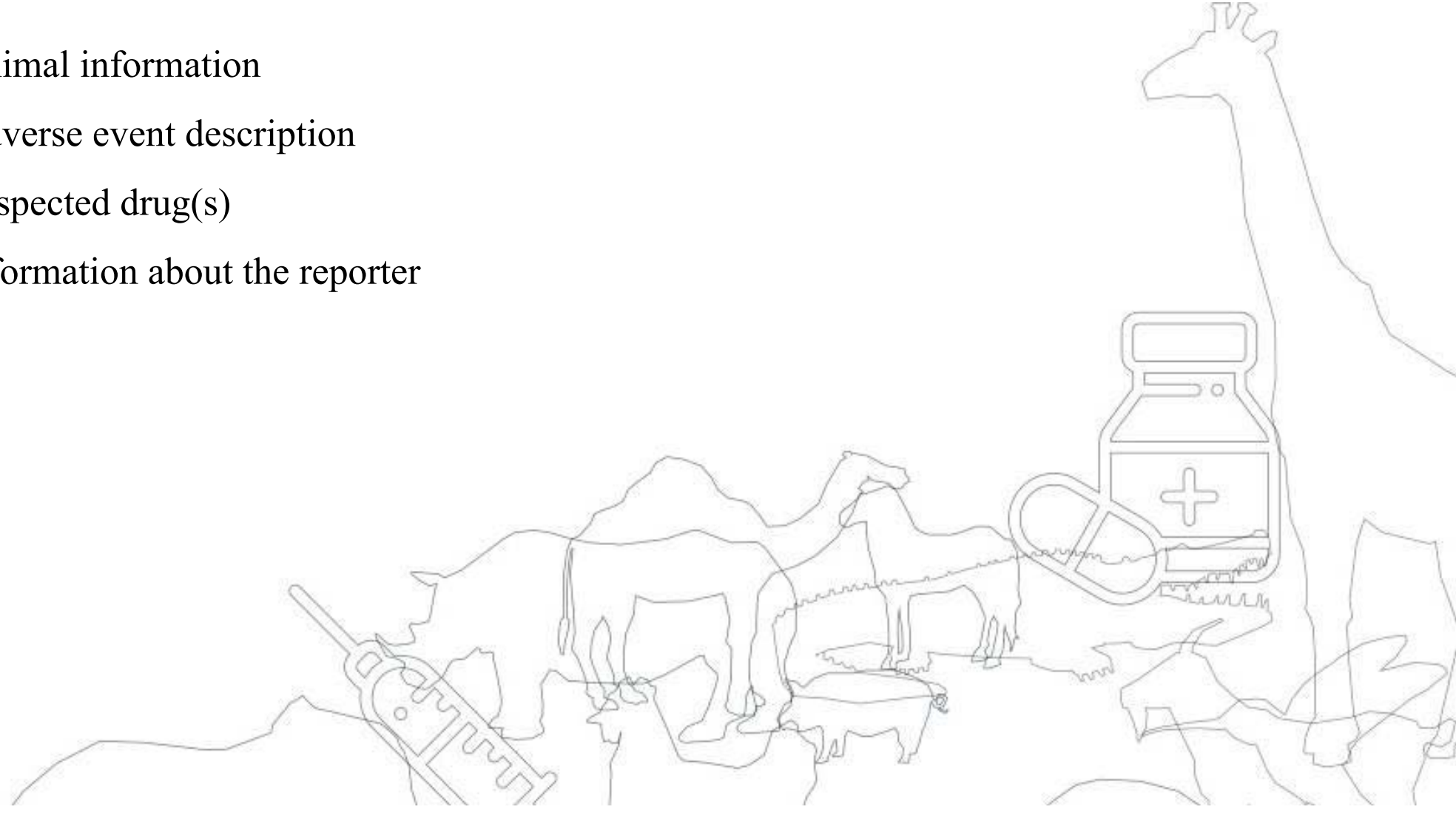
- Always write legibly.

- One animal or one human being, or a medically appropriate group exhibiting similar clinical signs should be included in a single report.



Components of an ADE Report

- Animal information
- Adverse event description
- Suspected drug(s)
- Information about the reporter

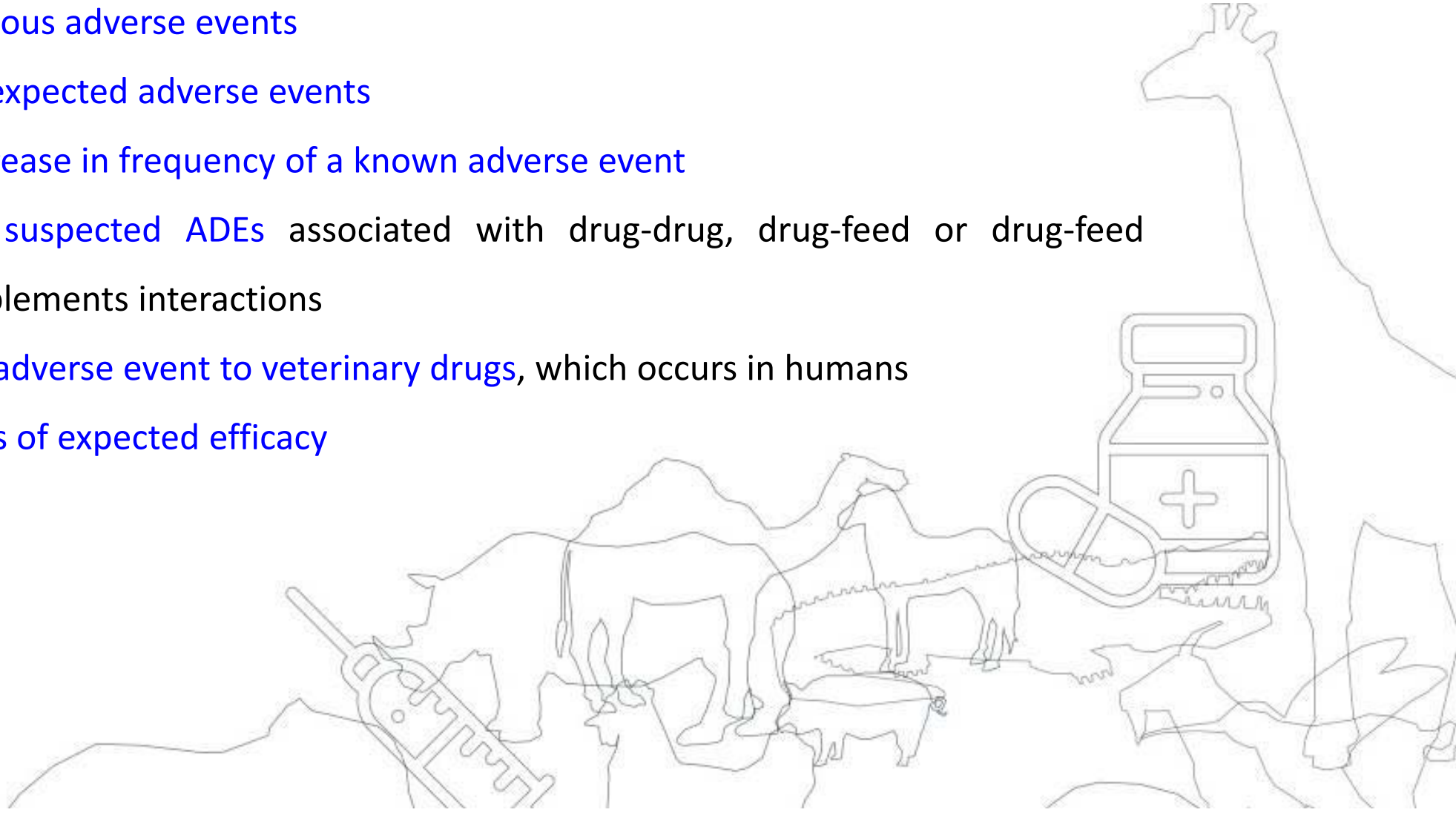


Who Should Report

- All animal health professionals
- Animal health institutions using veterinary drugs (government and private veterinary clinics, veterinary pharmacies, and research and education institutions)
- Marketing Authorization Holders (manufacturers and/or local agents)
- Animal owners

What to Report

- Serious adverse events
- Unexpected adverse events
- Increase in frequency of a known adverse event
- All suspected ADEs associated with drug-drug, drug-feed or drug-feed supplements interactions
- An adverse event to veterinary drugs, which occurs in humans
- Loss of expected efficacy



How to report?

•ADEs can be reported either directly to VDFACA or to the MAH.

•VDFACA is currently using a standardized yellow form to receive reports

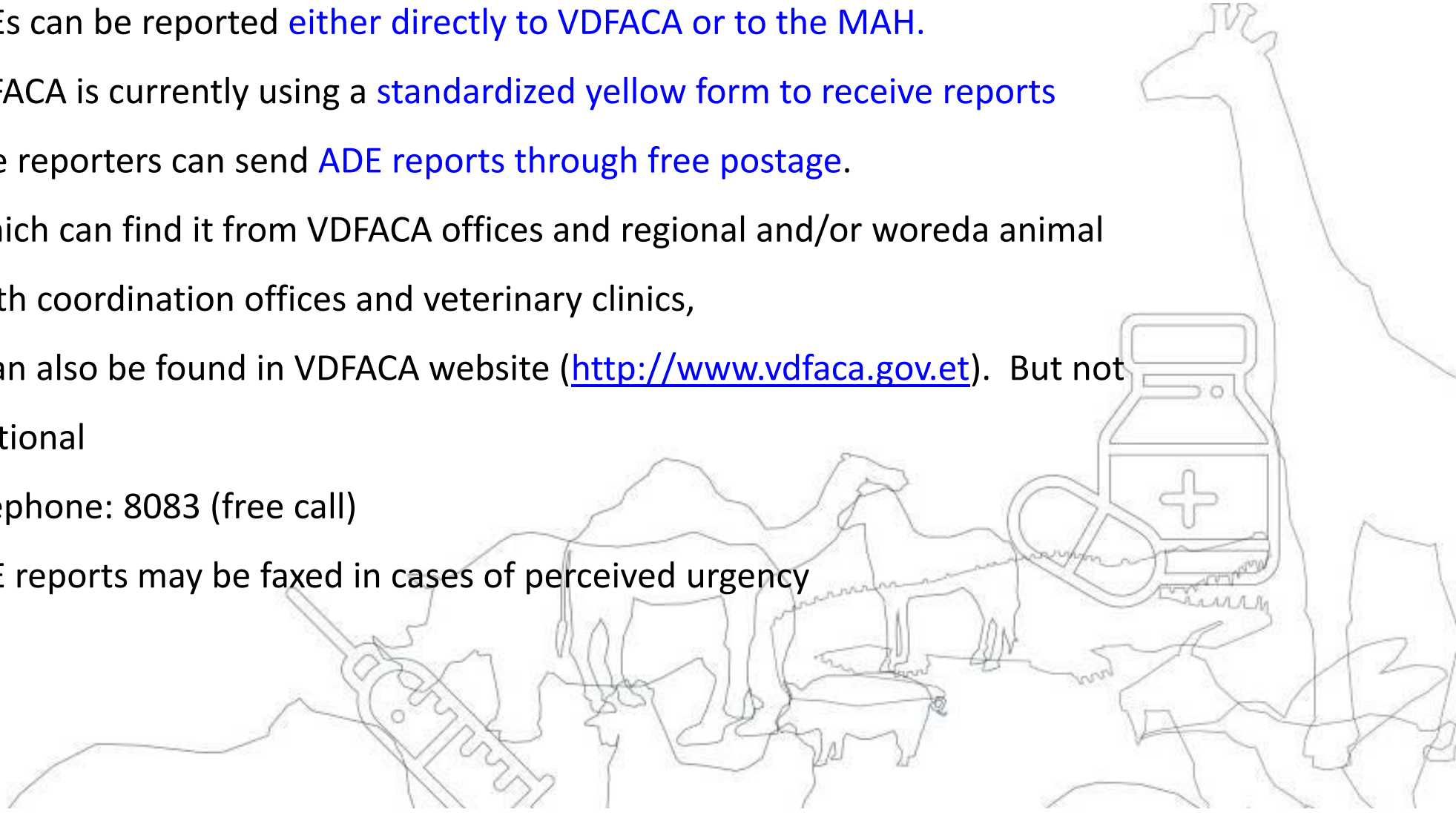
• The reporters can send ADE reports through free postage.

• Which can find it from VDFACA offices and regional and/or woreda animal health coordination offices and veterinary clinics,

•It can also be found in VDFACA website (http://www.vdfaca.gov.et). But not functional

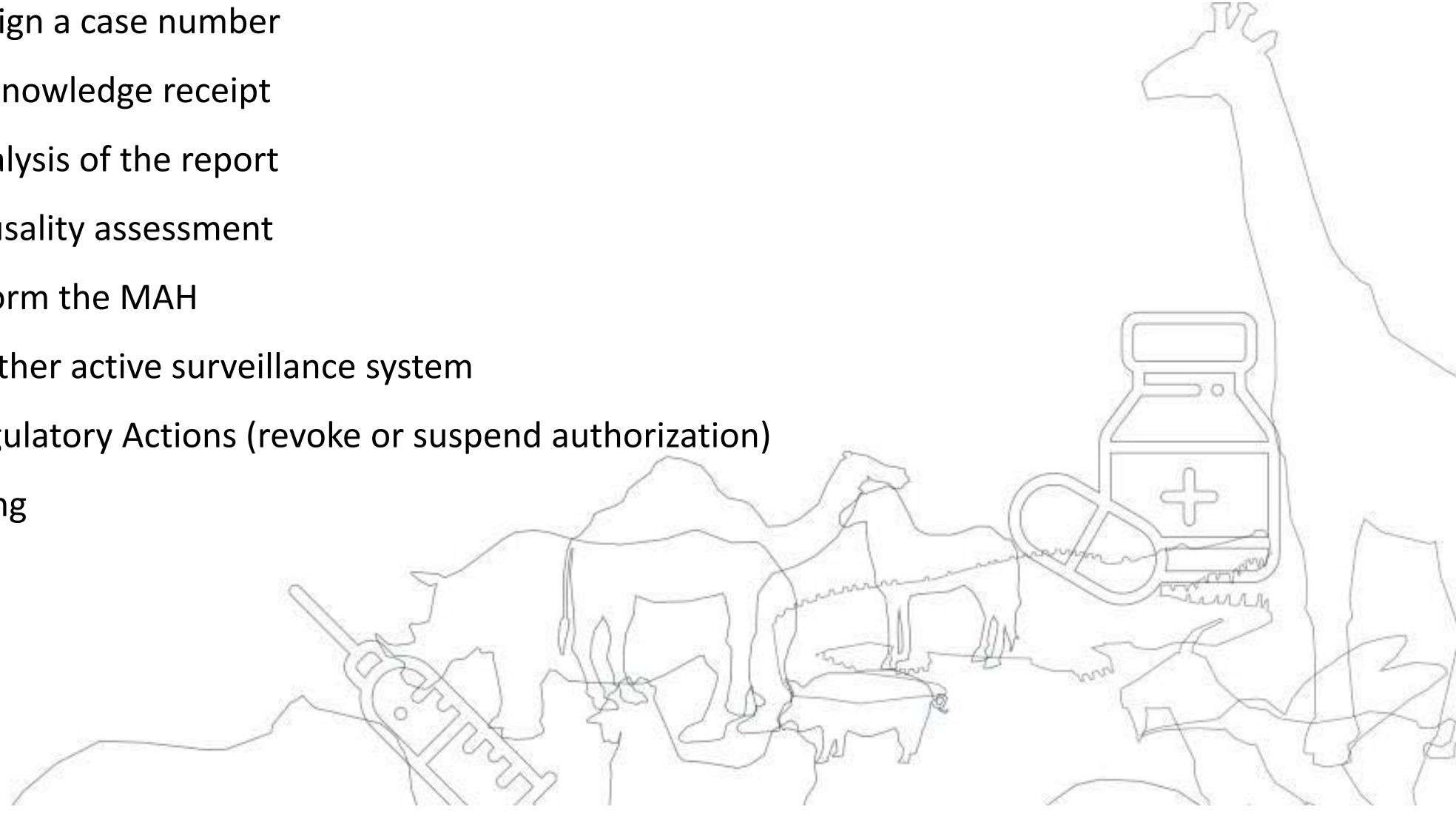
•Telephone: 8083 (free call)

•ADE reports may be faxed in cases of perceived urgency



Report Management and Regulatory Actions

- Assign a case number
- Acknowledge receipt
- Analysis of the report
- Causality assessment
- Inform the MAH
- Further active surveillance system
- Regulatory Actions (revoke or suspend authorization)
- Filing



1. Animal Information

Species/Breed	Sex	age	weight	Physiological condition (eg. Pregnancy)	Number of animals treated on this	Number of animals reacted	Number of deaths

2. The Adverse Drug Event

Date of onset of an adverse event		Description of the adverse event:
Duration of the event		

laboratory findings (if done)			**Postmortem findings (if any)**
Lab test	Result	test date	

3. Drugs suspected to have caused the adverse event

Trade and Generic Name:	Manufacturer:	Batch Number:	Expiry Date:

Route of Administration	Dose and Frequency	Date Started/Given	Date Stopped	Reason for use

Details of products given concurrently		Drugs given after onset of the adverse event	

4. Product Quality Problems (Color change, change of odor, caking, precipitation, incomplete packs, poor packaging/labeling, etc.)	
5. Lack of Expected Efficacy	

6. Reported by:

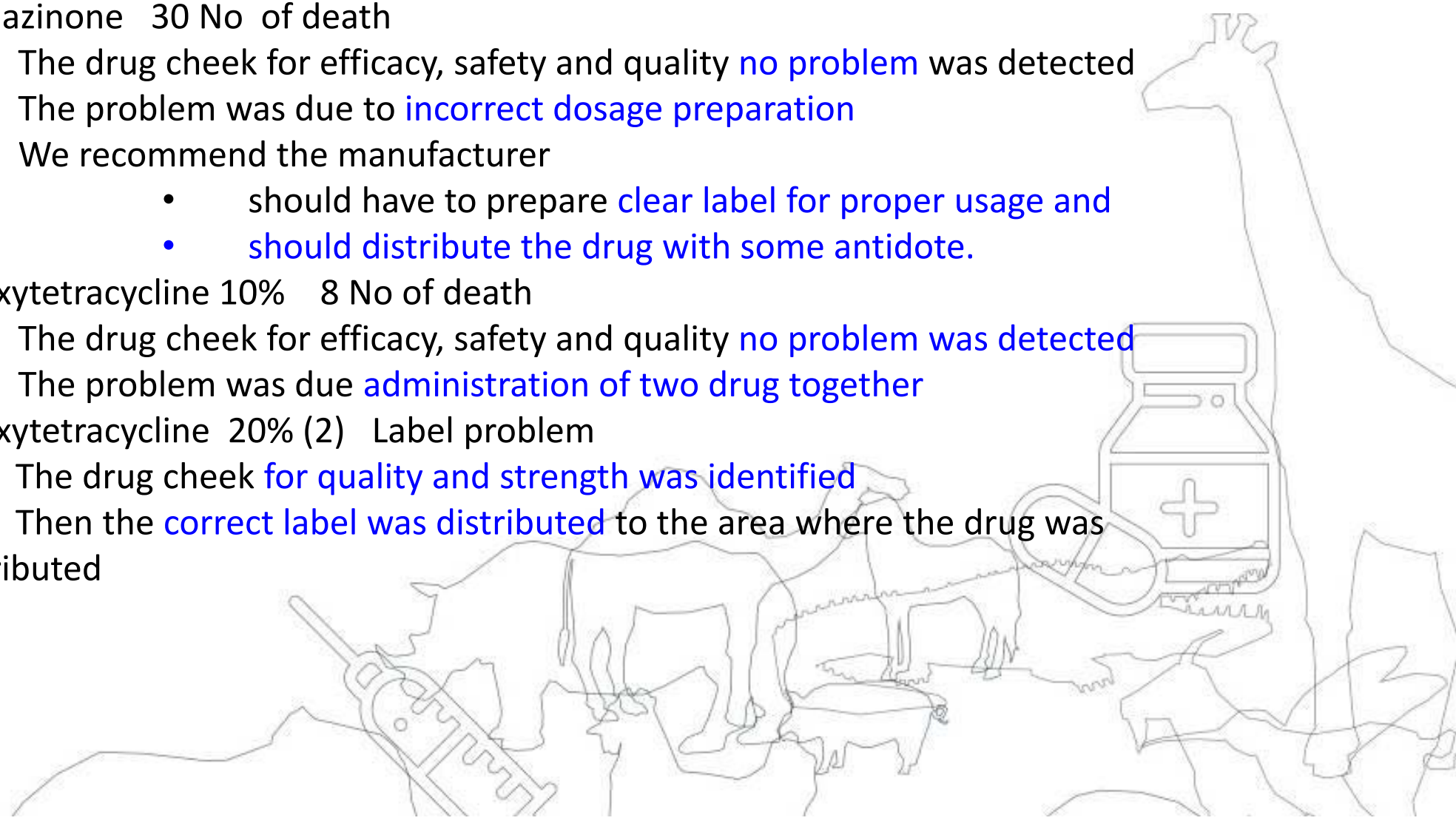
Name		e-mail		Phone No.	
Profession/Qualification					
Working institution/office					
Date reported		Signature:			

ADE reported drugs

1. Diazinone 30 No of death
- The drug cheek for efficacy, safety and quality no problem was detected
- The problem was due to incorrect dosage preparation
- We recommend the manufacturer
    - should have to prepare clear label for proper usage and
    - should distribute the drug with some antidote.

2. Oxytetracycline 10% 8 No of death
- The drug cheek for efficacy, safety and quality no problem was detected
- The problem was due administration of two drug together

3. Oxytetracycline 20% (2) Label problem
- The drug cheek for quality and strength was identified
- Then the correct label was distributed to the area where the drug was distributed



please Report ADE s!!

thank You