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

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

How to set-up a simple PHARMACOVIGILANCE system for your country or region: country experience

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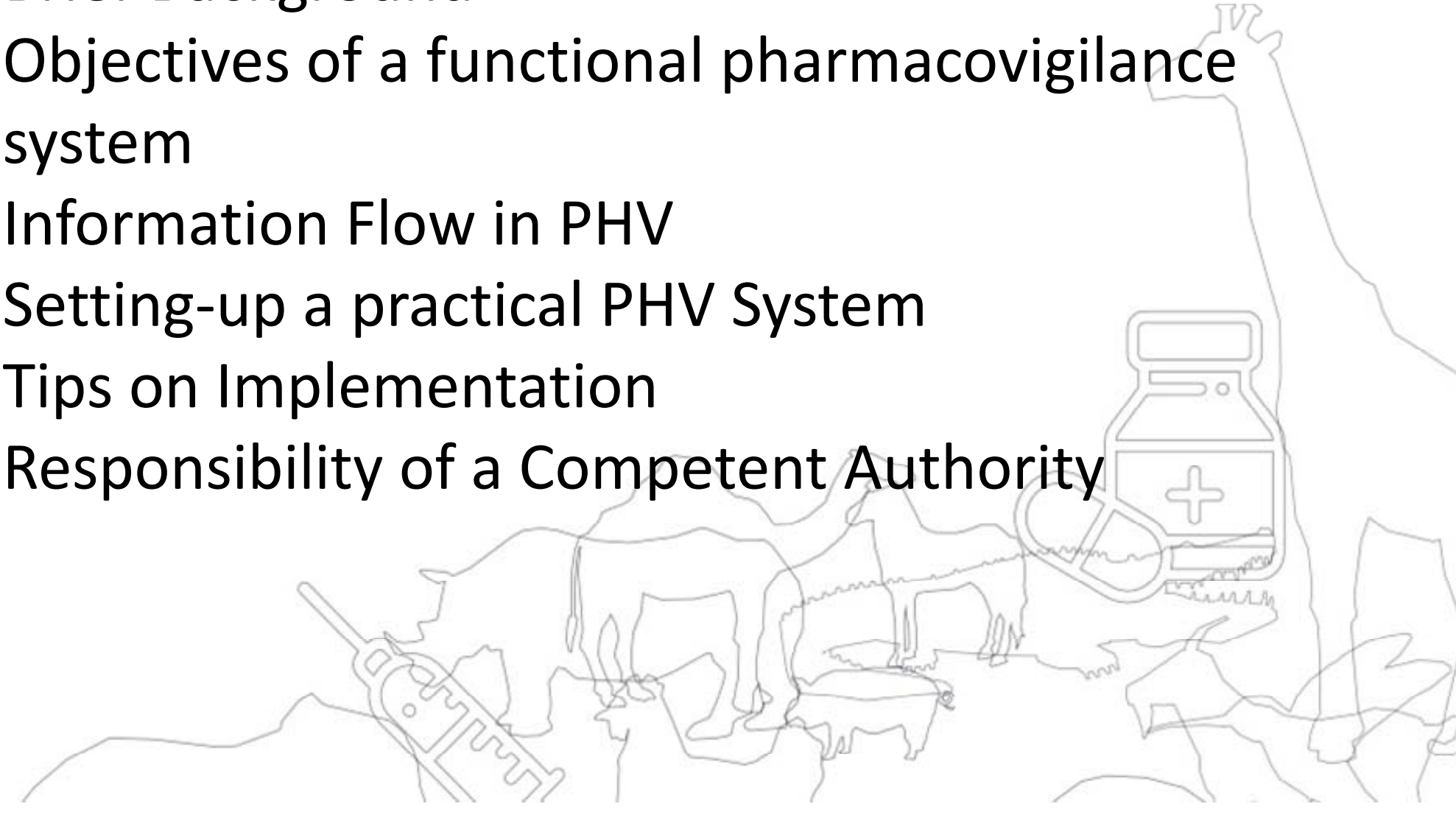
OiE National Focal Point for Veterinary Medicinal Products

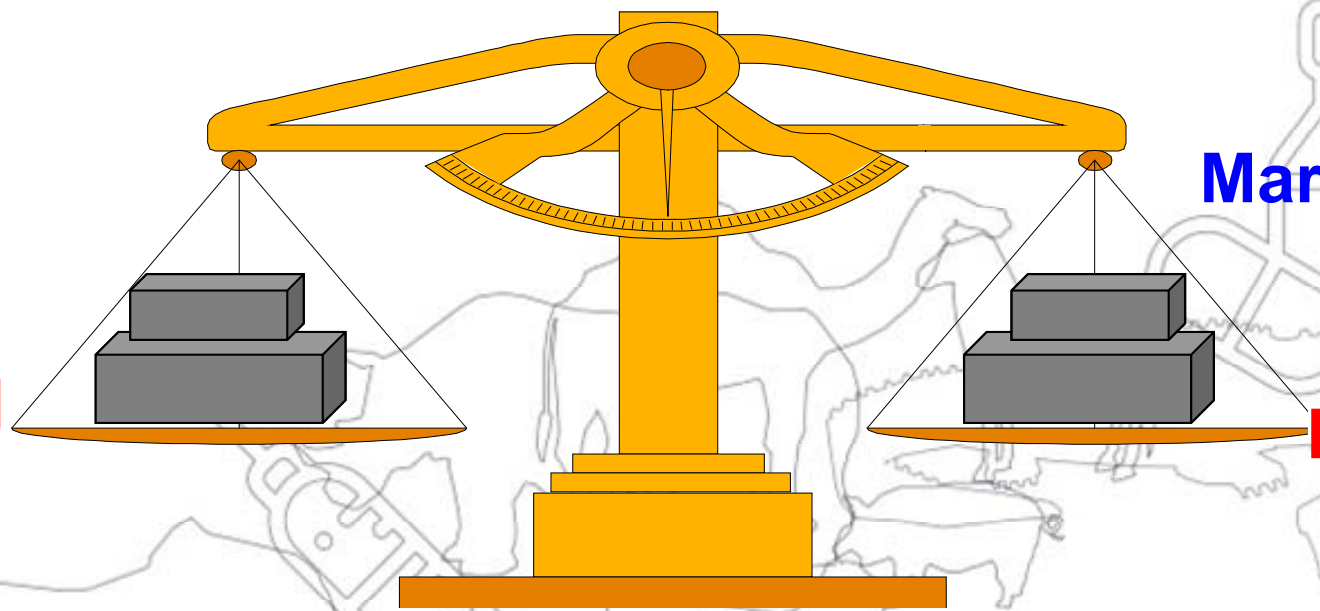
PRESENTATION OUTLINE

- Brief Background
- Objectives of a functional pharmacovigilance system
- Information Flow in PHV
- Setting-up a practical PHV System
- Tips on Implementation
- Responsibility of a Competent Authority

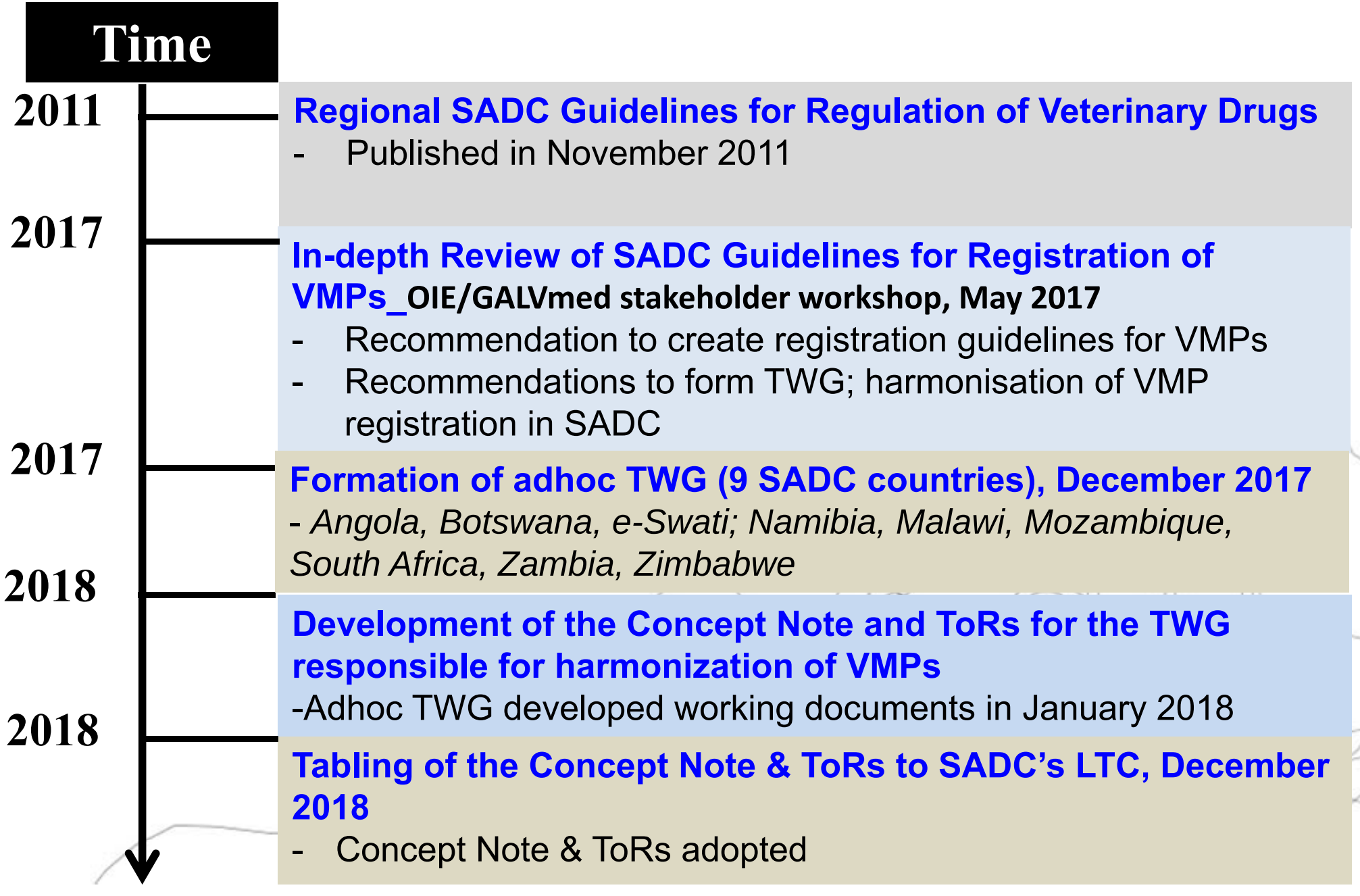


BACKGROUND

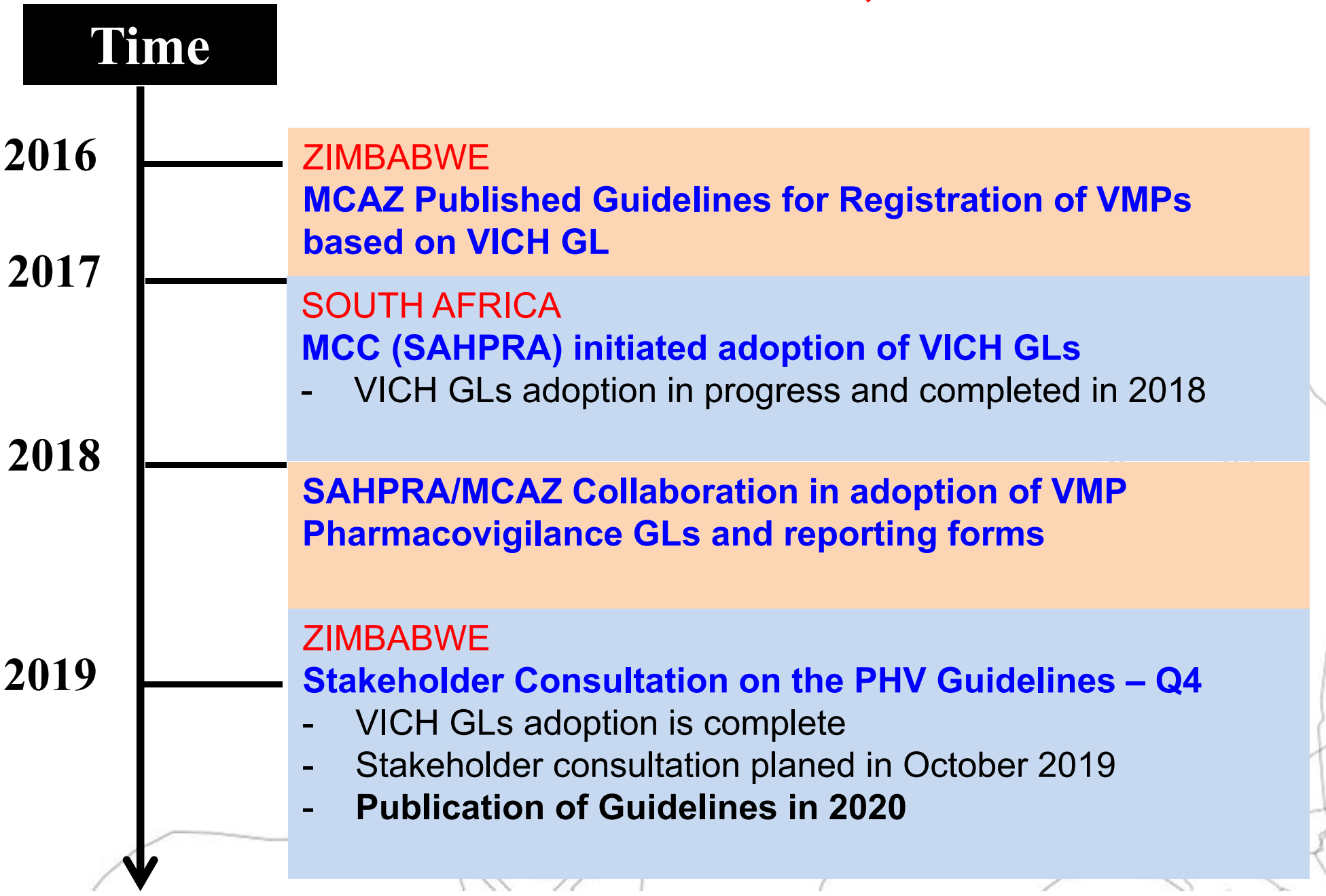
- Regulation of VMPs in Africa is skewed towards ensuring that available medicines are **safe**, **efficacious** and of **good quality** (pre-registration checks)
- Post-registration issues pertaining to **pharmacovigilance**; very little to no attention



EVOLUTION OF HARMONISATION IN SADC



Harmonisation of VMP Pharmacovigilance Guidelines– SOUTH AFRICA; ZIMBABWE

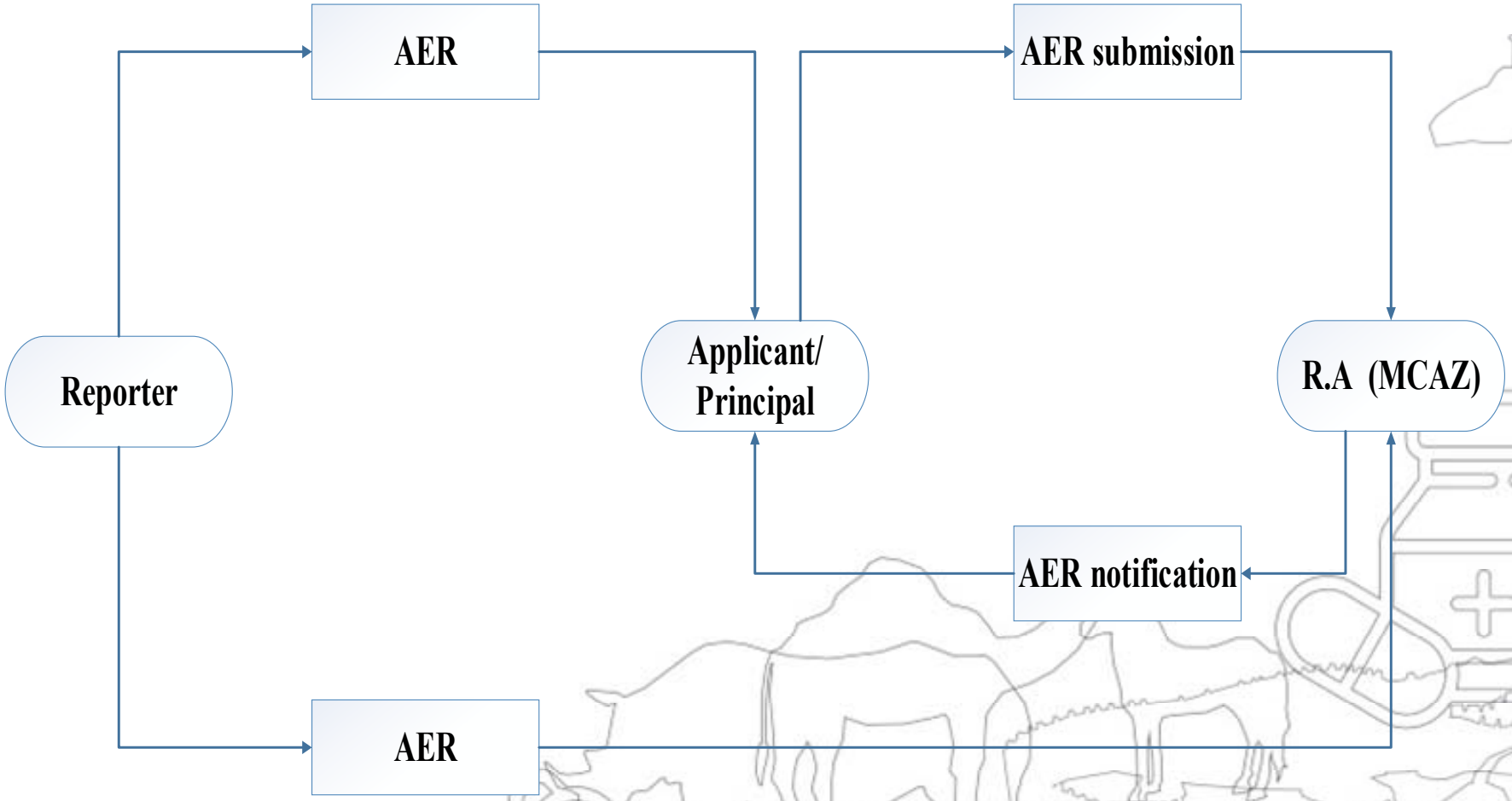


Objectives of a Functional PHV System

TO Provide:

- Surveillance of all authorised (*registered*) VMPs
- Ensure **Quality**, **Safe** and **Effective** products on the market
- Feedback to regulators, manufacturers, animal keepers and vets on product performance

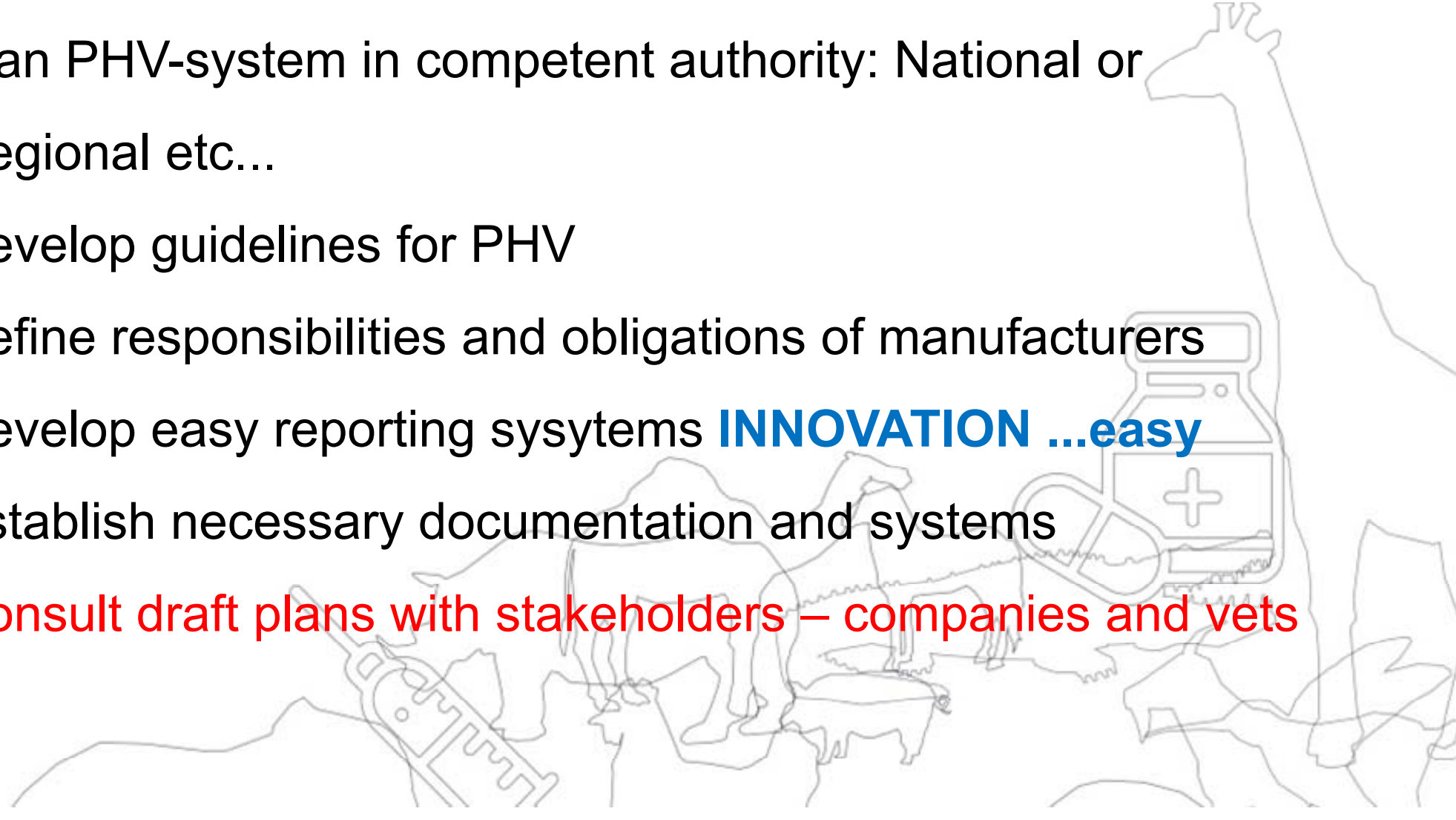
Information Flow in the Pharmacovigilance System



Adopted from the *VICH GL24 (PHARMACOVIGILANCE: AERS), 2007*

HOW to Set-Up a PHV System

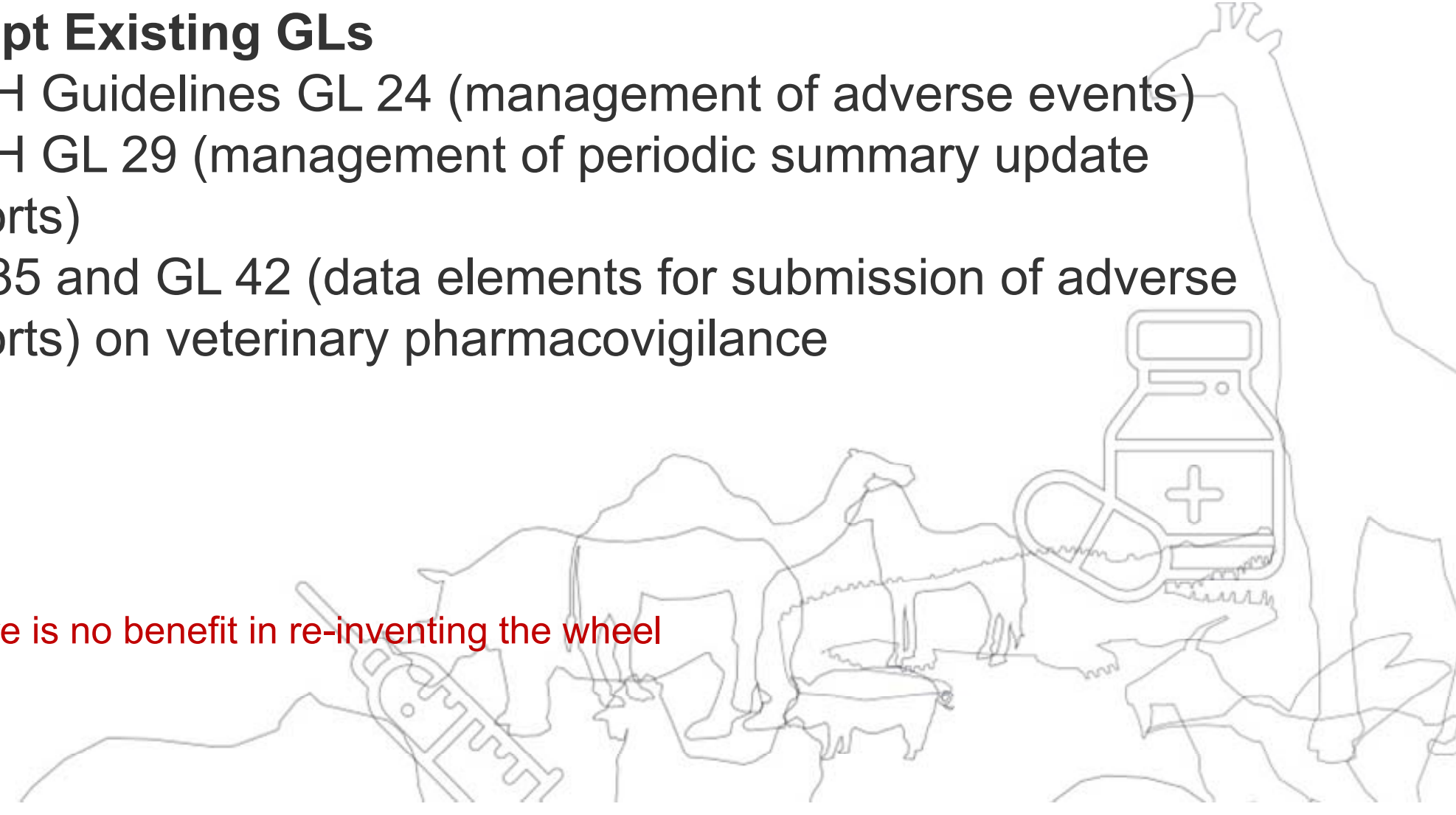
1. Legislation Framework for Pharmacovigilance
2. Plan PHV-system in competent authority: National or Regional etc...
3. Develop guidelines for PHV
4. Define responsibilities and obligations of manufacturers
5. Develop easy reporting sysytems **INNOVATION ...easy**
6. Establish necessary documentation and systems
7. Consult draft plans with stakeholders – companies and vets



HOW to Set-Up a PHV System

Adapt Existing GLs

VICH Guidelines GL 24 (management of adverse events)
VICH GL 29 (management of periodic summary update reports)
GL 35 and GL 42 (data elements for submission of adverse reports) on veterinary pharmacovigilance



There is no benefit in re-inventing the wheel

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Drag a column header and drop it here to group by that column

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Trade Name	Generic Name	Registration No	Form	Categories for Distribution	Strength
				All	
ASHIENRO 10% ORAL LIQUID	ENROFLOXACIN	2017/80.12.11/9758	LIQUID; ORAL	VETERINARY PRESCRIPTION PREPARATION, P.P.(VET)	100MG
BAYTRIL	ENROFLOXACIN	90/80.22.11/9244	SOLUTION	VETERINARY PRESCRIPTION PREPARATION, P.P.(VET)	10%
BAYTRIL 5%	ENROFLOXACIN	92/80.22.11/9325	INJECTABLE; INJECTION	VETERINARY PRESCRIPTION PREPARATION, P.P.(VET)	5%
COLIFLOX ORAL	ENROFLOXACIN; COLISTIN SULPHATE	2014/80.22.11/9693	SOLUTION	VETERINARY PRESCRIPTION PREPARATION, P.P.(VET)	100 MG
ENROCIN	ENROFLOXACIN	2014/80.22.11/9699	SOLUTION	VETERINARY PRESCRIPTION PREPARATION, P.P.(VET)	100 MG/ML

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ZAZIBONA Collaborative Medicines Registration Process

06 January 2016

REPORTING FORM.

Reporting Veterinarian/Practice/Owner				
Tel: +263772 145191 (MCAZ) Fax: +263-4-736980 E-mail: vetevr@mcaz.co.zw	Facility/Practice			
	District		Tel	
	Province		E mail	

Patient Details									
Patient Name		File/Reference Number			Owner				
Sex	▫ M ▫ F ▫ Neutered	Species		Breed		Age		Pregnant?	▫ N ▫ Y
Allergies				Estimated Gestational Age at time of reaction					

Suspect Medicine(s) [Medicines suspected to have caused the ADR]

Trade Name and Manufacturer	Route	Dose (mg) and Interval	Date Started/Given	Date Stopped	Reason for use	Batch Number	Expiry Date

All other Medicines Patient was taking at time of reaction [Including over-the-counter and complementary medicines]

Trade Name and manufacturer	Route	Dose (mg) and Interval	Date Started/Given	Date Stopped	Reason for use	Batch Number	Expiry Date

Adverse Drug Reaction/Product Quality Problem

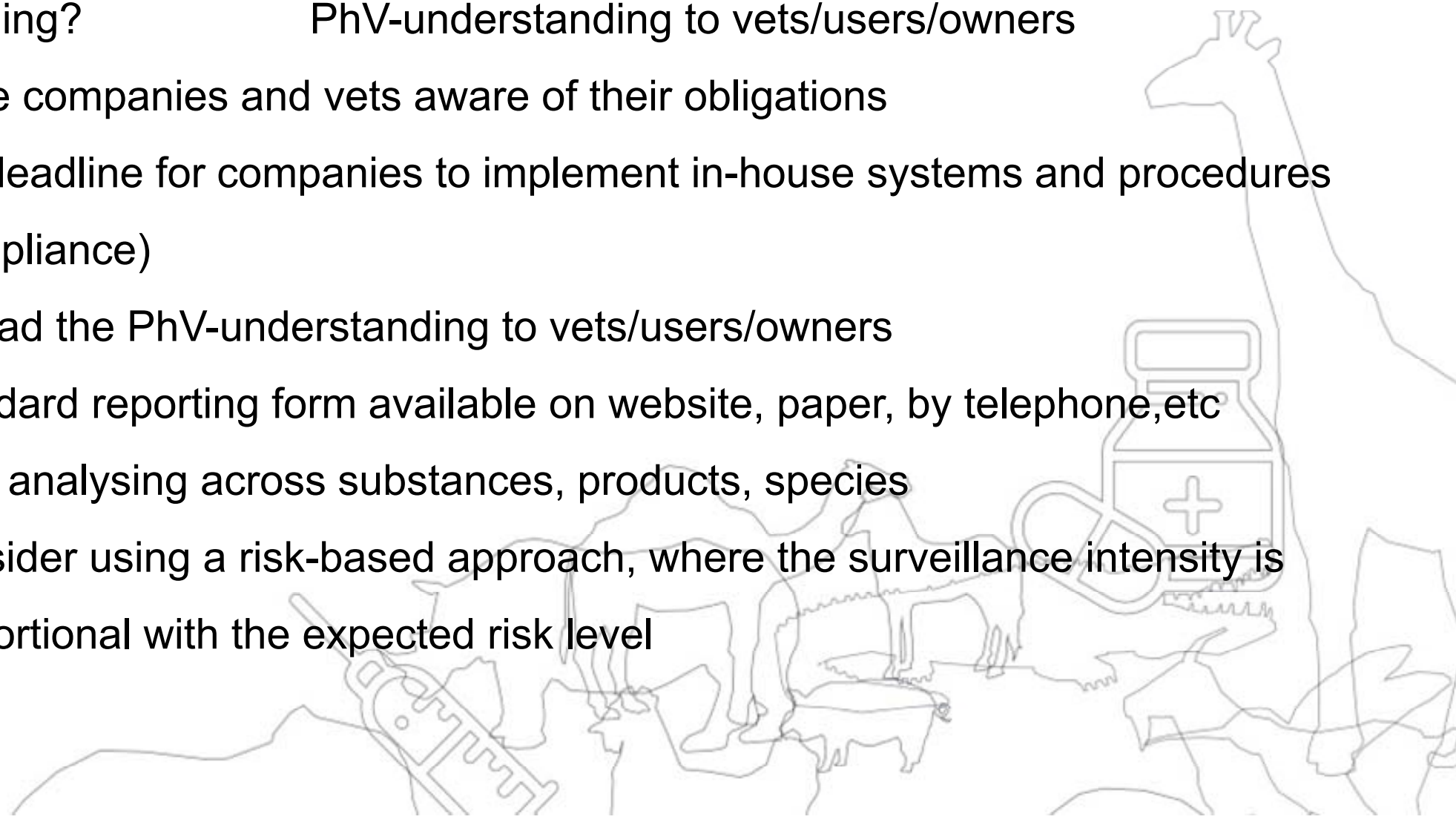
Date and time of onset of reaction		Date reaction resolved/duration	

Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)

Intervention(tick applicable boxes)	Patient Outcomes (tick applicable boxes)
▫ No intervention ▫ Intervention unknown ▫ Owner informed ▫ Discontinued Suspect Drug; **Replaced with:**_____ ▫ Decreased Suspect Drug Dosage; **New Dose:**_____ ▫ Treated ADR - with:_____ ▫ Referred to veterinarian: **Name**_____ ▫ Other Intervention: _____	▫ ADR recovered/resolved ▫ recovering/resolving ▫ not recovered/not resolved ▫ Patient Died: Date of death:_____ ▫ Impairment/Disability ▫ Congenital Anomaly ▫ Patient Hospitalised or Hospitalisation prolonged ▫ Life Threatening ▫ Other:_____ ▫ ADR reappeared after restarting suspect drug/similar drug/re-challenge?: ▫ N ▫ Y ▫ Not done ▫ Unknown
Laboratory Results and name of Lab	**Additional Laboratory Results**

TIPs - IMPLEMENTATION

- Communication and awareness plan
- Training? PhV-understanding to vets/users/owners
- Make companies and vets aware of their obligations
- Set deadline for companies to implement in-house systems and procedures (compliance)
- Spread the PhV-understanding to vets/users/owners
- Standard reporting form available on website, paper, by telephone,etc
- Start analysing across substances, products, species
- Consider using a risk-based approach, where the surveillance intensity is proportional with the expected risk level



Responsibility of a Competent Authority

- **Immediately after AE-report is received:**

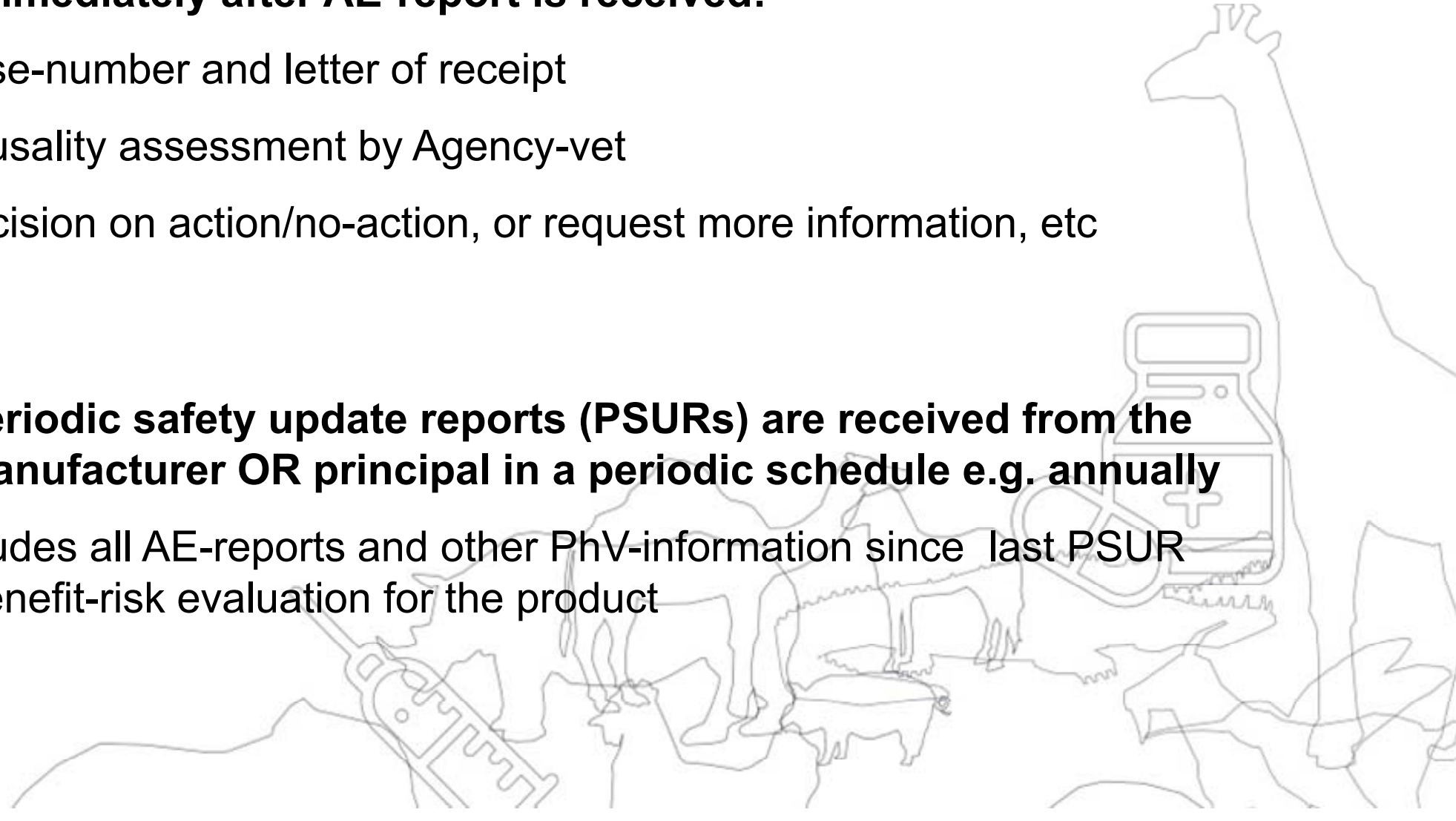
- case-number and letter of receipt

- causality assessment by Agency-vet

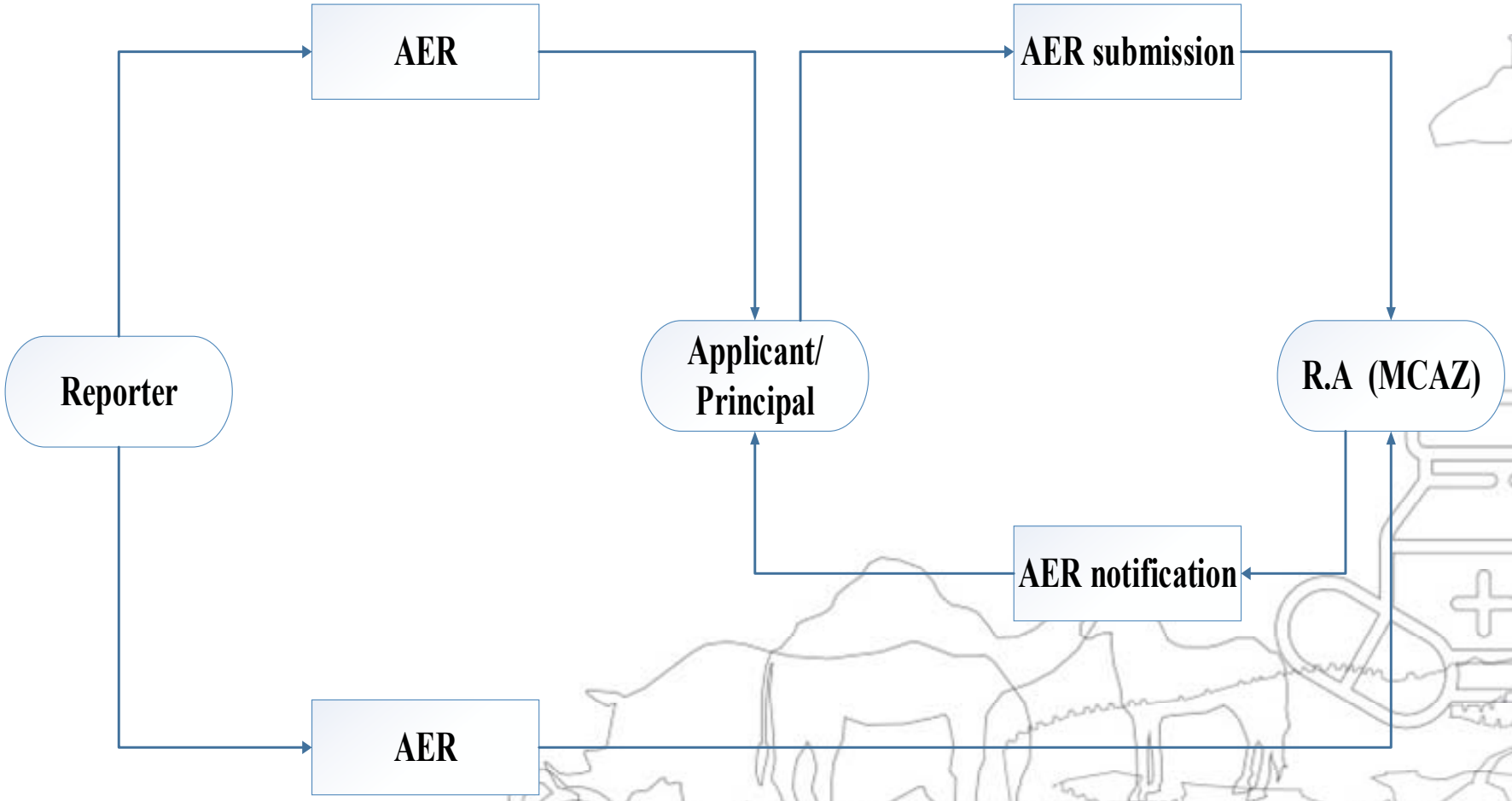
- decision on action/no-action, or request more information, etc

- **Periodic safety update reports (PSURs) are received from the manufacturer OR principal in a periodic schedule e.g. annually**

- includes all AE-reports and other PhV-information since last PSUR
- a benefit-risk evaluation for the product



AER & PSUR



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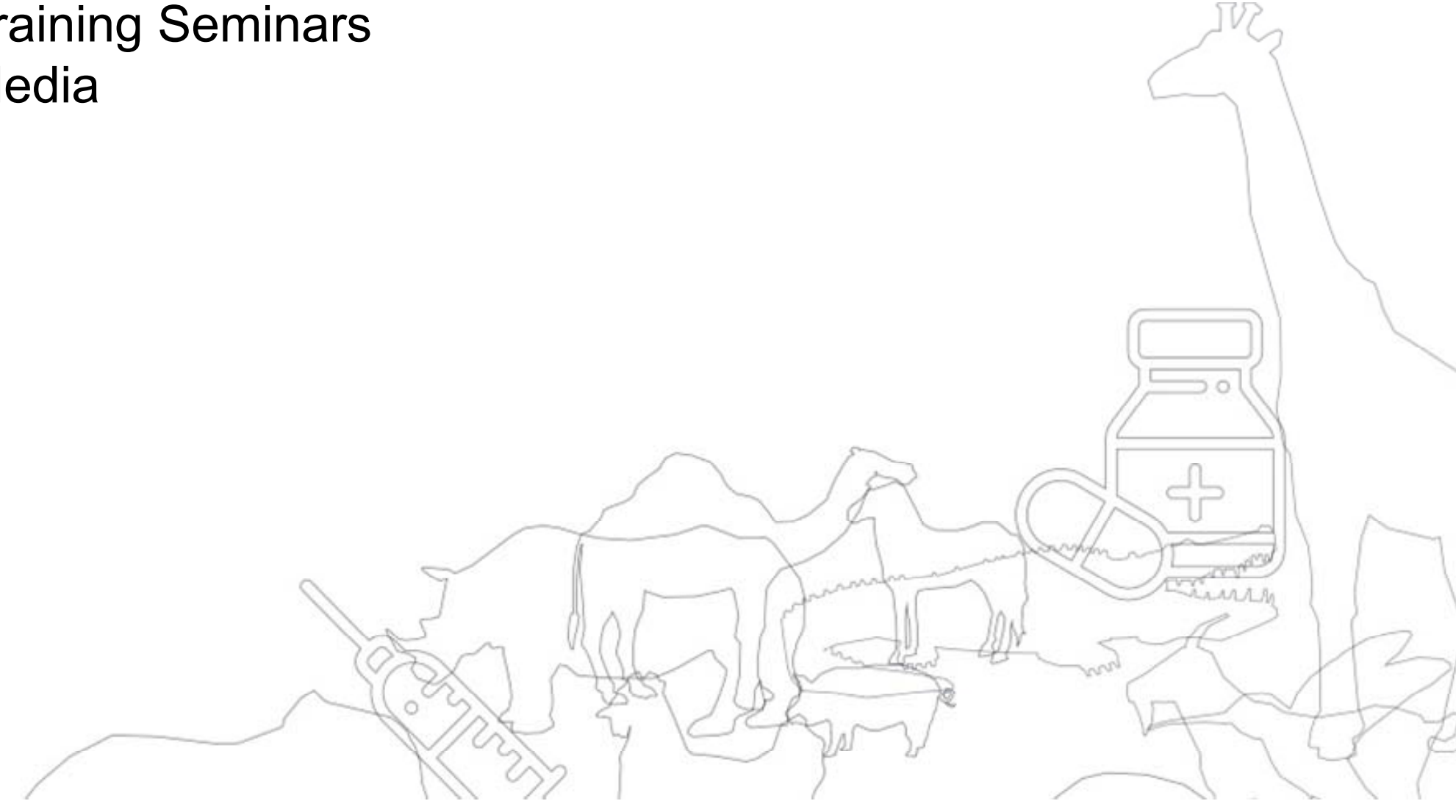
Feed back, Very Important

- ❑ Newsletters
- ❑ Training Seminars
- ❑ Media



Thank you for Listening!

Questions?