



ETHIOPIA



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

Activities carried out by Focal Points

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

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Veterinary drug and feed administration and control authority



Outline



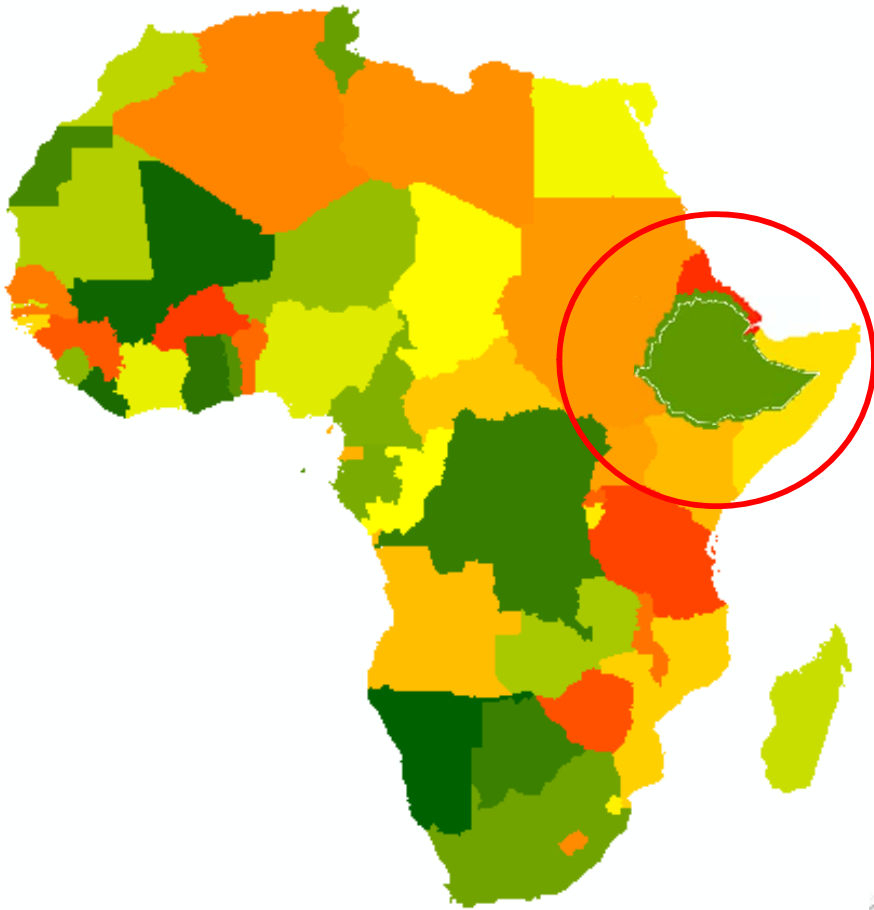
Ethiopia in Brief

Livestock production in Ethiopia

Veterinary drug regulation situation

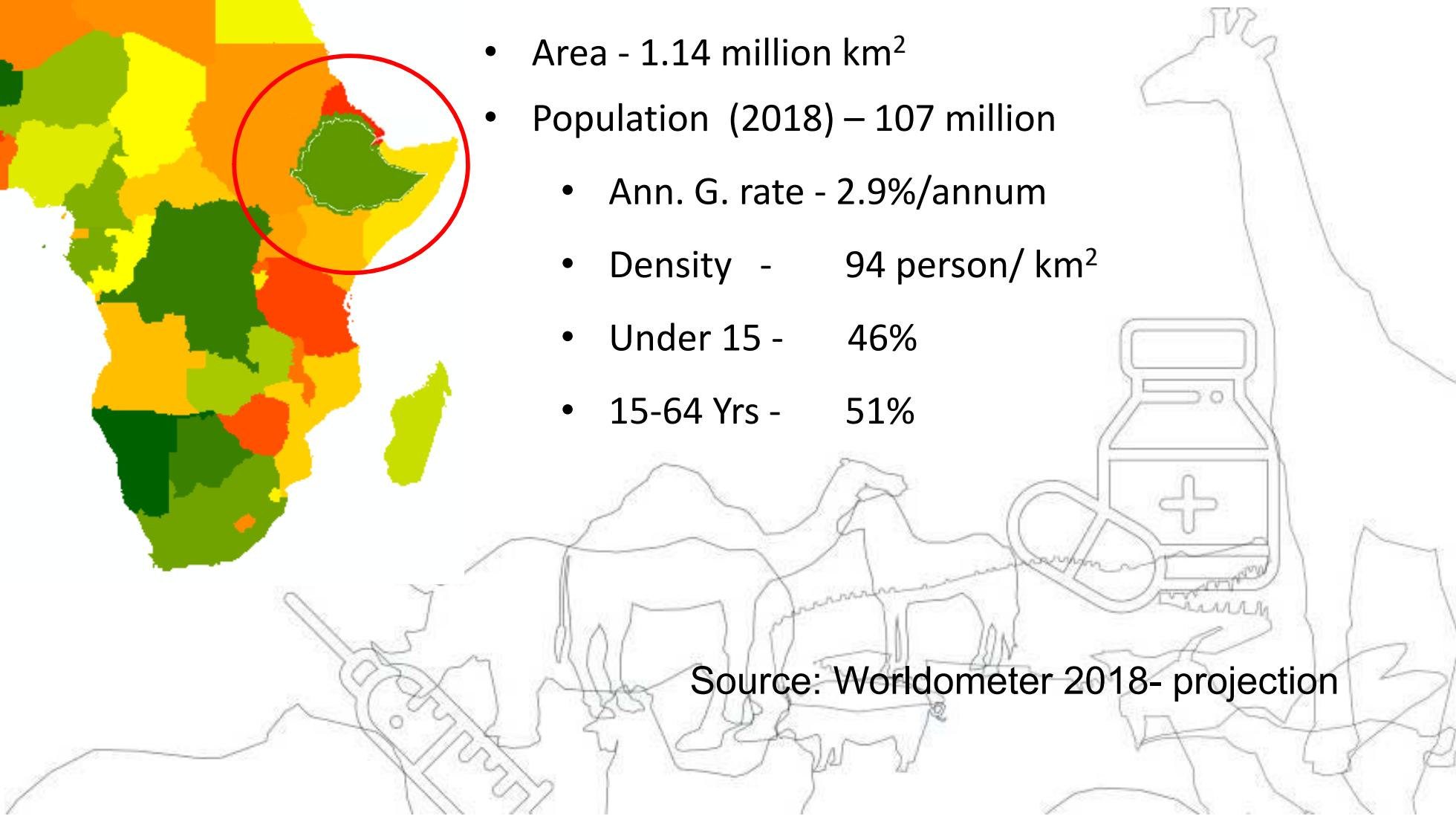
Challenges

1.1. Location, size and population



- Area - 1.14 million km²
- Population (2018) – 107 million
 - Ann. G. rate - 2.9%/annum
 - Density - 94 person/ km²
 - Under 15 - 46%
 - 15-64 Yrs - 51%

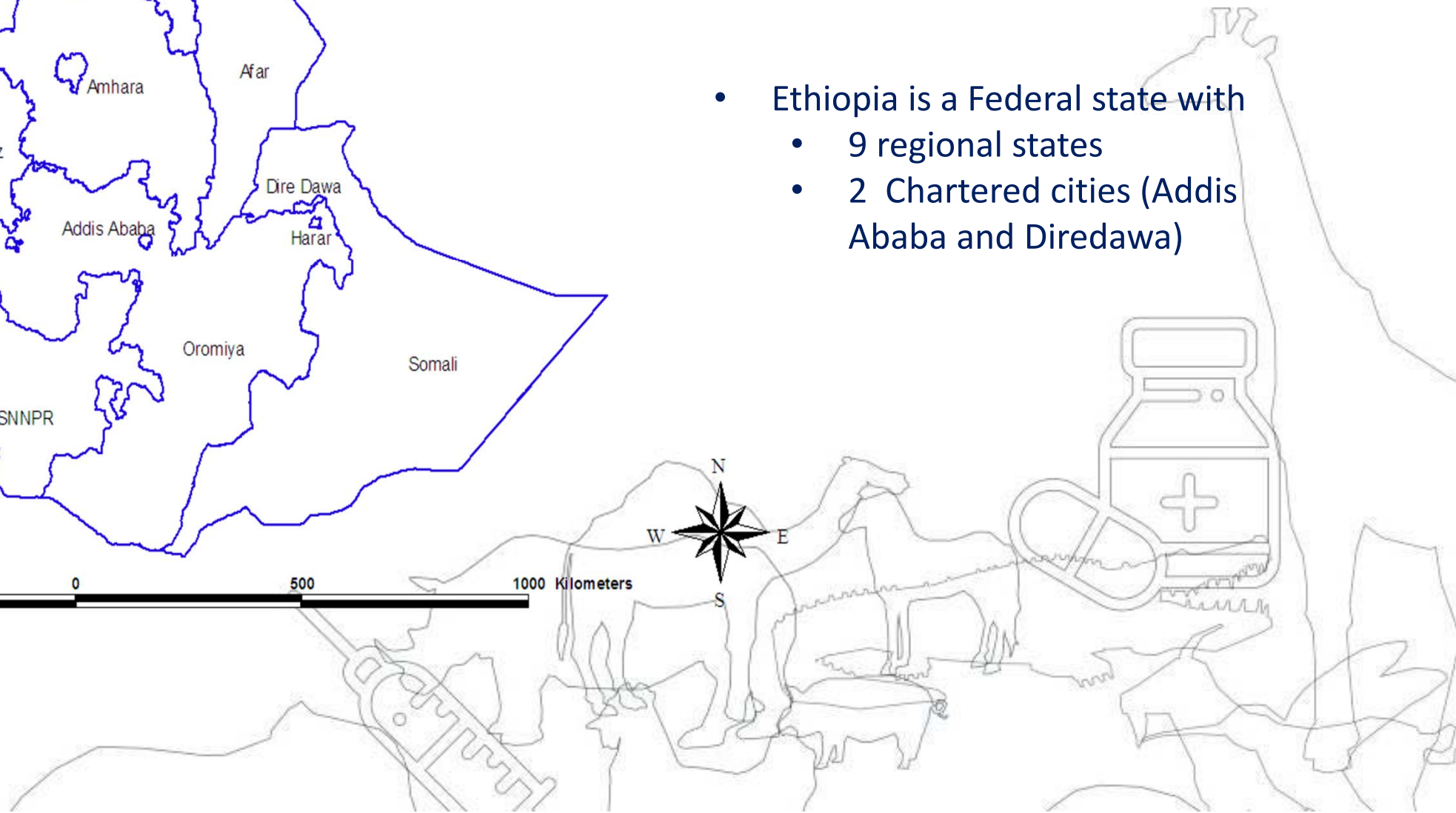
Source: Worldometer 2018- projection



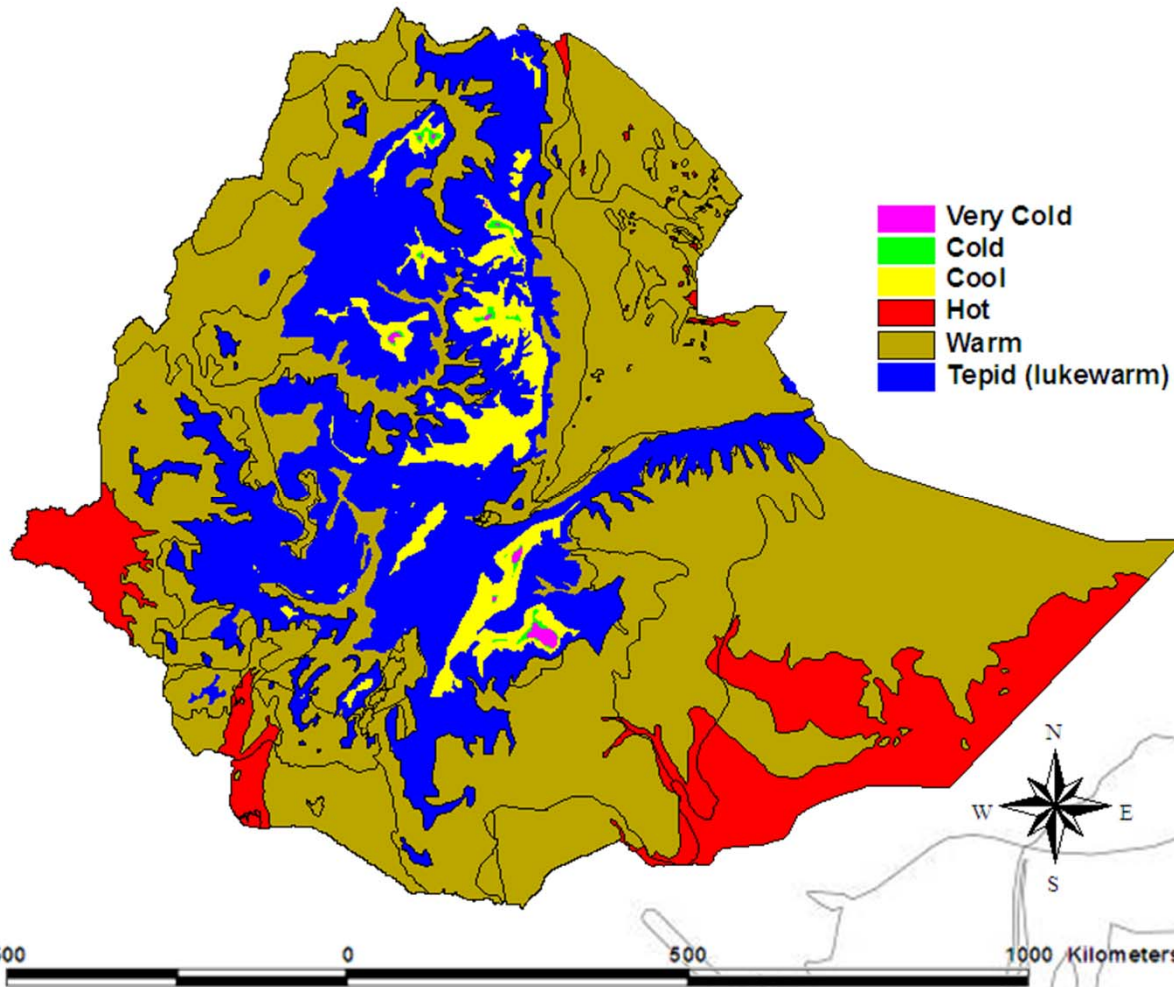
1.2. Administrative boundaries



- Ethiopia is a Federal state with
 - 9 regional states
 - 2 Chartered cities (Addis Ababa and Diredawa)



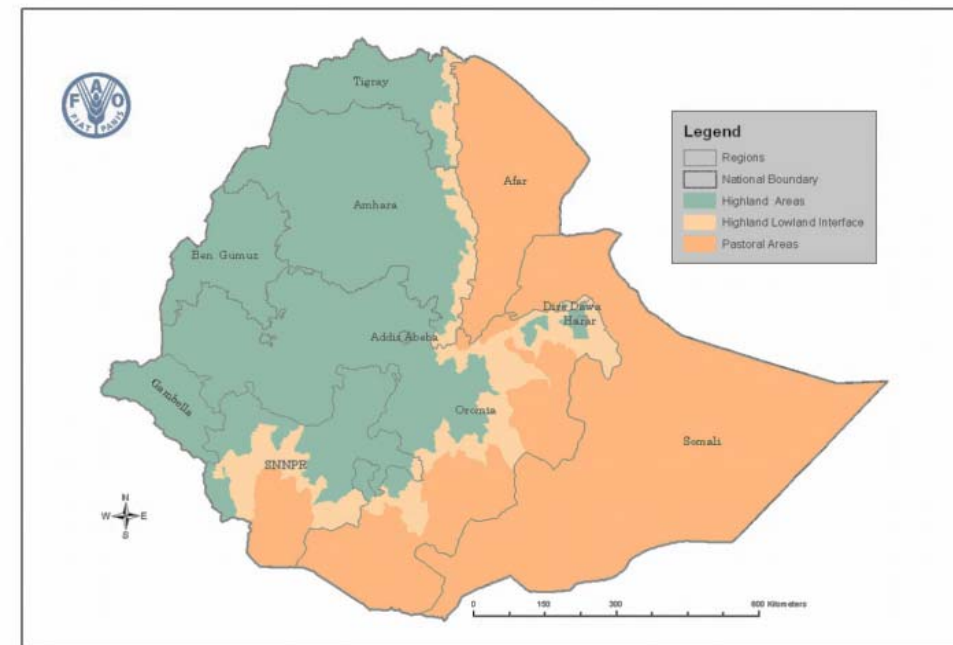
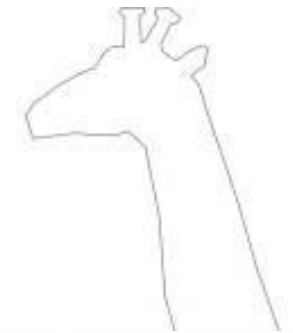
1.3. Agro-ecology



- Much of Ethiopia has a warm-lukewarm like climate
- Two major seasons
 - Dry : (October –May)
 - Wet: (June –Sept)
- Rainfall ranges from 200mm to 2000mm per year.
- With high surface and underground ground water potential

Agro-ecology cont.

- Classifies the country into **three geographic/agro-ecological zonation**:
 - **Pastoral agro-pastoral** – the focus is on **livestock development**
 - **Crop-livestock- moisture deficit** – the focus is on **livestock agriculture** –particularly **small stock and bee keeping**. Crop playing a subsidiary role.
 - **Crop-livestock- Sufficient moisture areas** – the focus is on **Crop Agriculture**. Except in some specialized **areas (dairy, poultry and feedlots)** livestock has **subsidiary role**



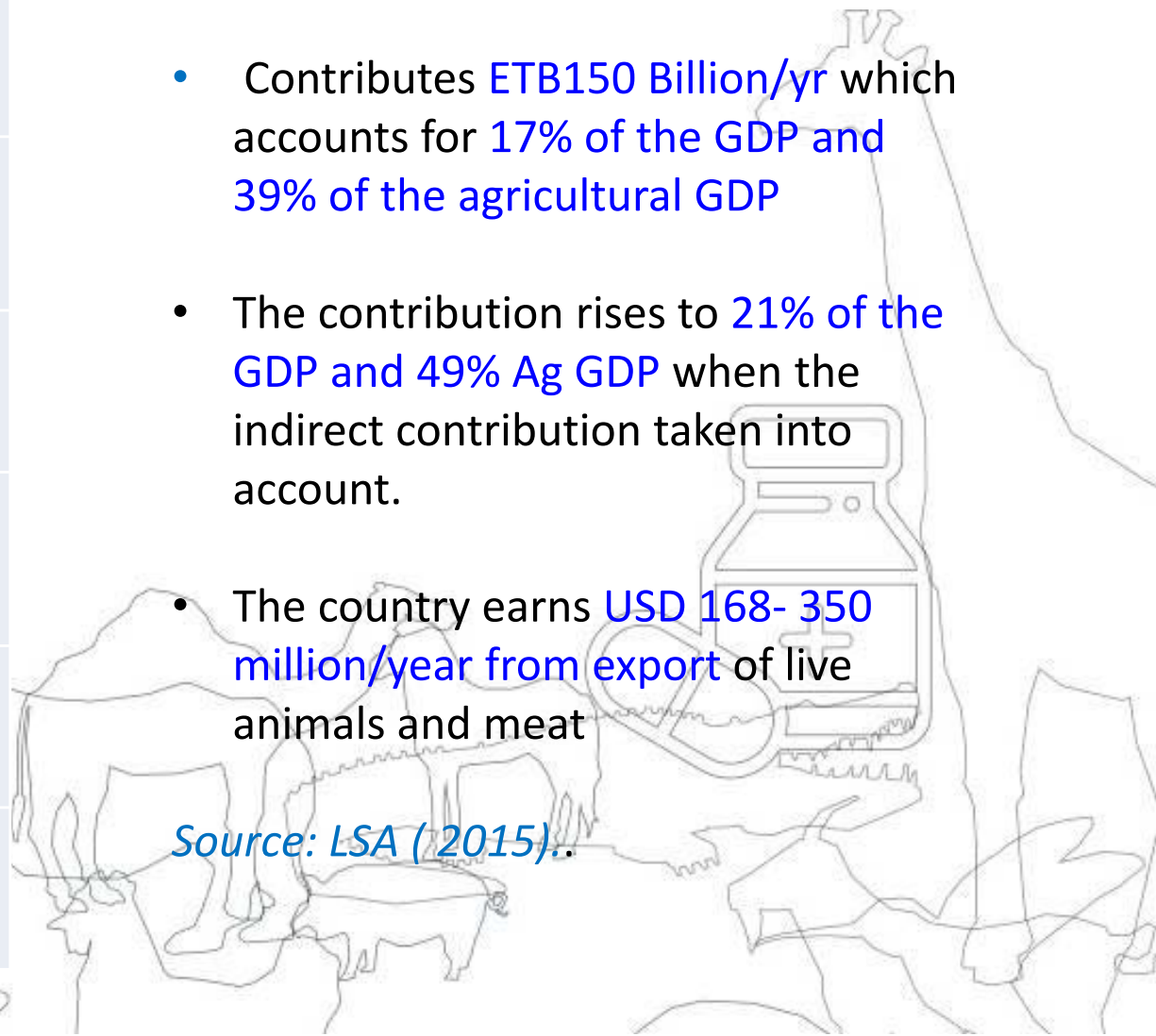
Pastoral, highland and interface areas

2. Livestock production in Ethiopia

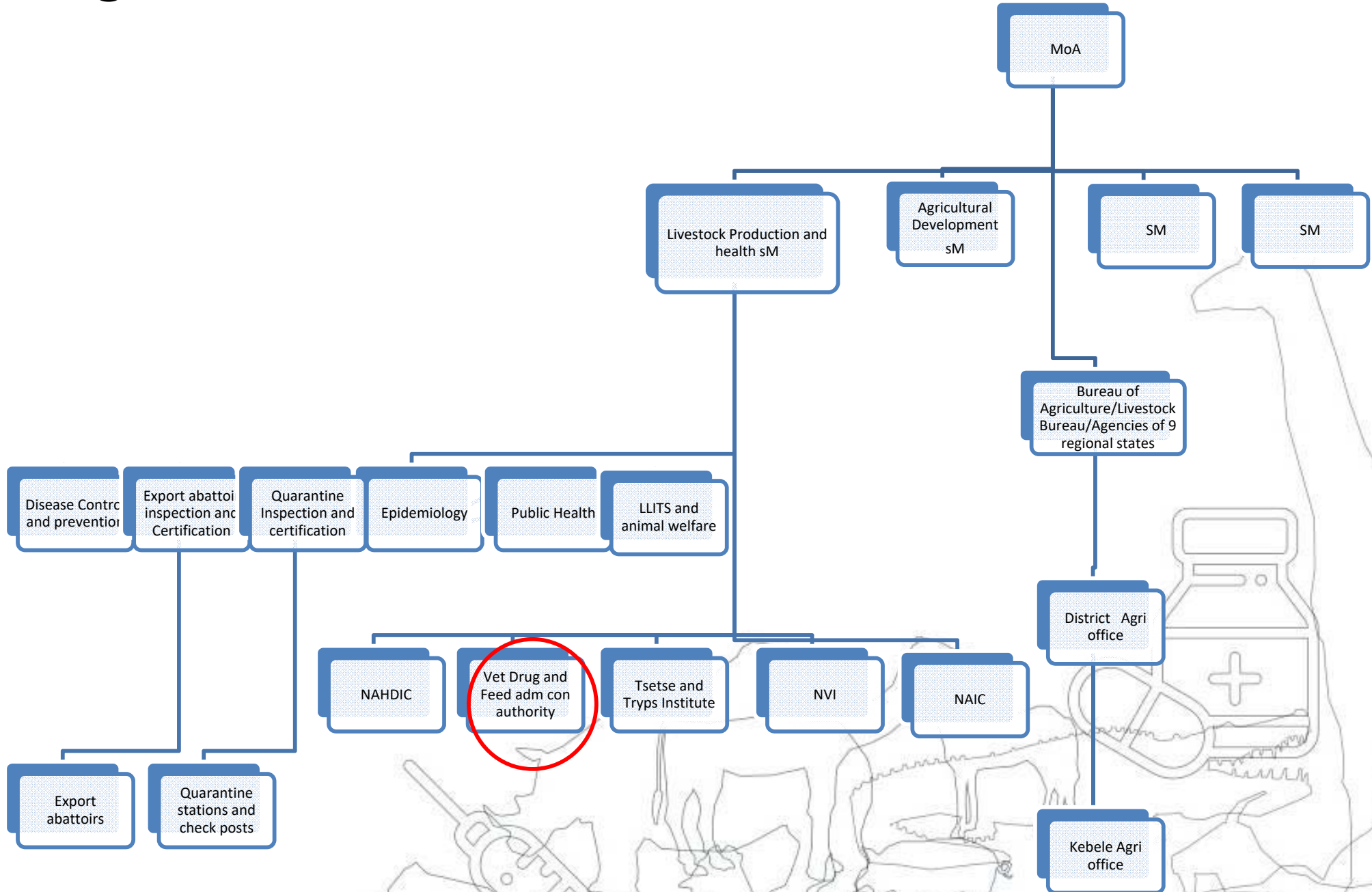
Species	Number in Million
Cattle	59.5
Sheep	30.7
Goat	30.2
Camel	1.2
Poultry	59.5

- Provides livelihood to 11.3 million (68%) rural HHs
- Contributes ETB150 Billion/yr which accounts for 17% of the GDP and 39% of the agricultural GDP
- The contribution rises to 21% of the GDP and 49% Ag GDP when the indirect contribution taken into account.
- The country earns USD 168- 350 million/year from export of live animals and meat

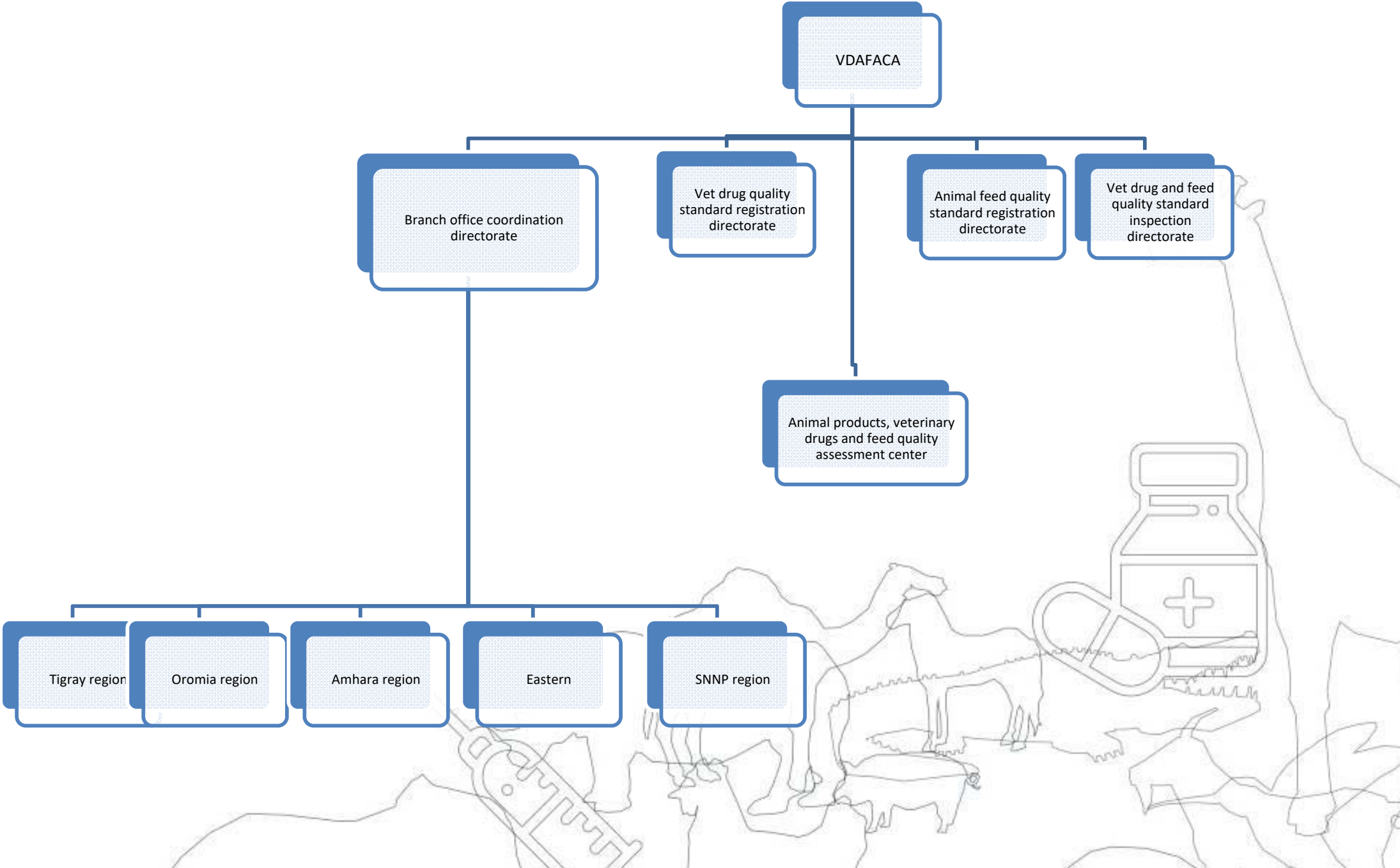
Source: LSA (2015).



Organizational Structure of the veterinary services



Organizational Structure of VDFACA



3. Veterinary drug regulation situation

□ VDFACA has two main strategic goals for veterinary drugs

1. Approval and maintenance of quality, safety and efficacy of veterinary Drugs

• VDFACA register **veterinary drug manufacturer, veterinary drug importer and veterinary drug wholesalers**

• There are **three veterinary drug manufacturer** registered by VDFACA

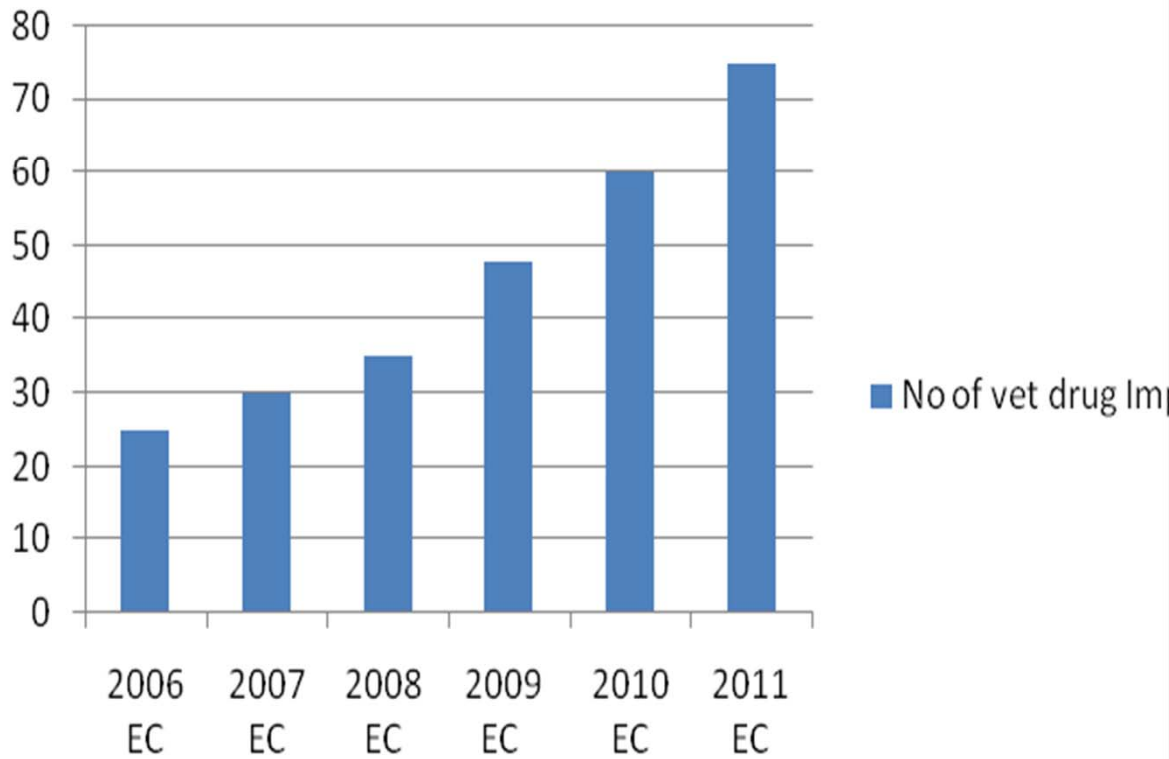
- National veterinary institute
- East Africa veterinary drug manufacturer
- Adomitulu Pesticides processing factory

• There are **75 veterinary drug importer, 80 veterinary drug wholesalers and 1427 veterinary drug retailer**

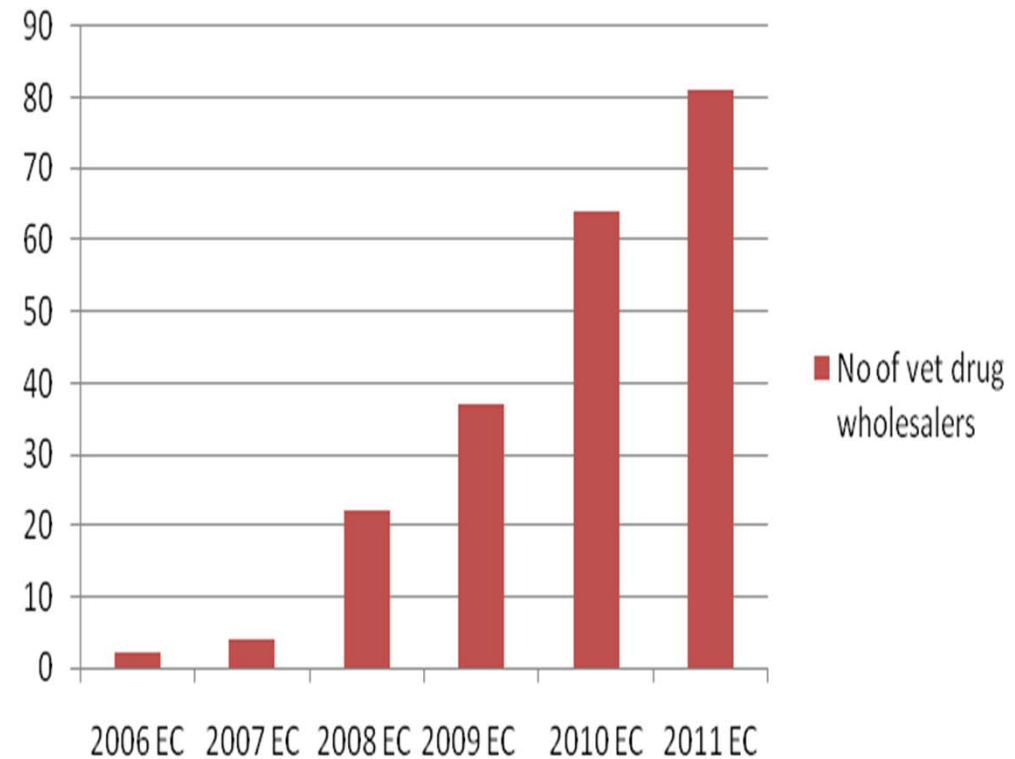


Number of registered veterinary drug importer and wholesalers

No of vet drug Importers



No of vet drug wholesalers

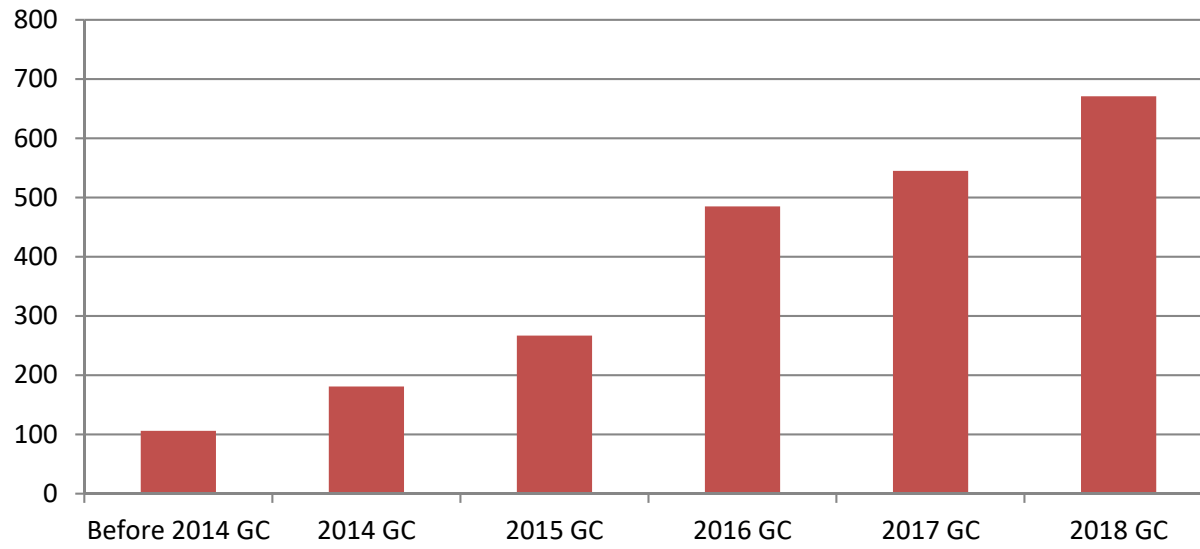


Veterinary drug regulation situation cont.

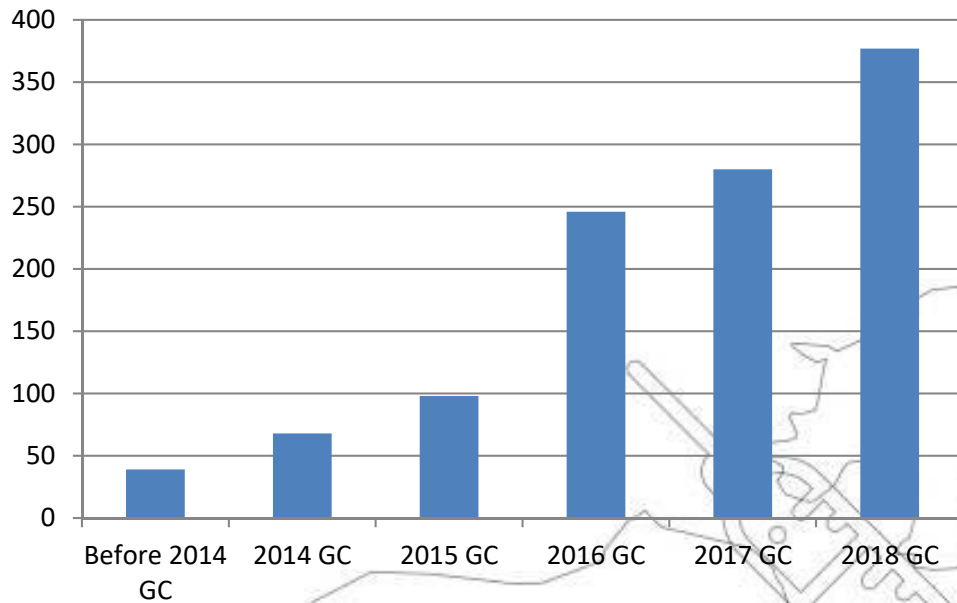
- VDFACA register veterinary drugs by
 - Dossier evaluation
 - Good manufacturing practice inspection for non stringent regulatory authority country (No need of GMP inspection for SRA country)
 - Laboratory analysis of pre registration sample
- After that we give **veterinary drug registration certificate valid for 5 years.**
- The registered veterinary drugs should be **renewed every 5 years**



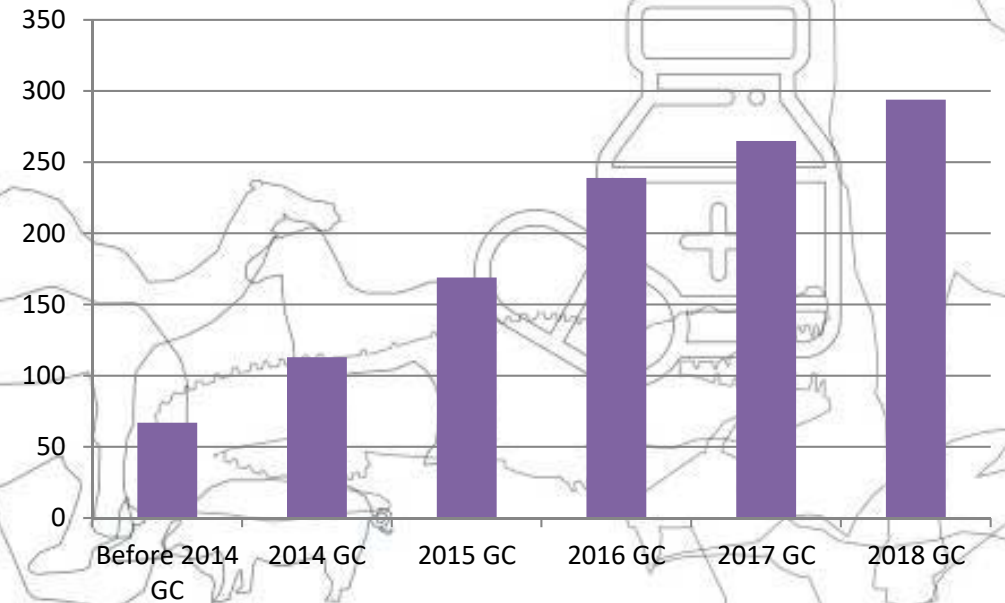
No of registered vet drug



No of new registered vet drug



No of Re registered vet drug



Veterinary drug regulation situation cont.

- Veterinary drug registration and certification directorate
 - Approve **pre import permit**
- Branch office coordination directorate
 - Approve **import release** at the port
 - Collect consignment sample from port (either randomly or when suspect)
- Veterinary drug and feed inspection directorate
 - Inspect the veterinary drugs** in the warehouse for about storage condition and distribution
 - Collect **PMS (Post Marketing sample)** from the market

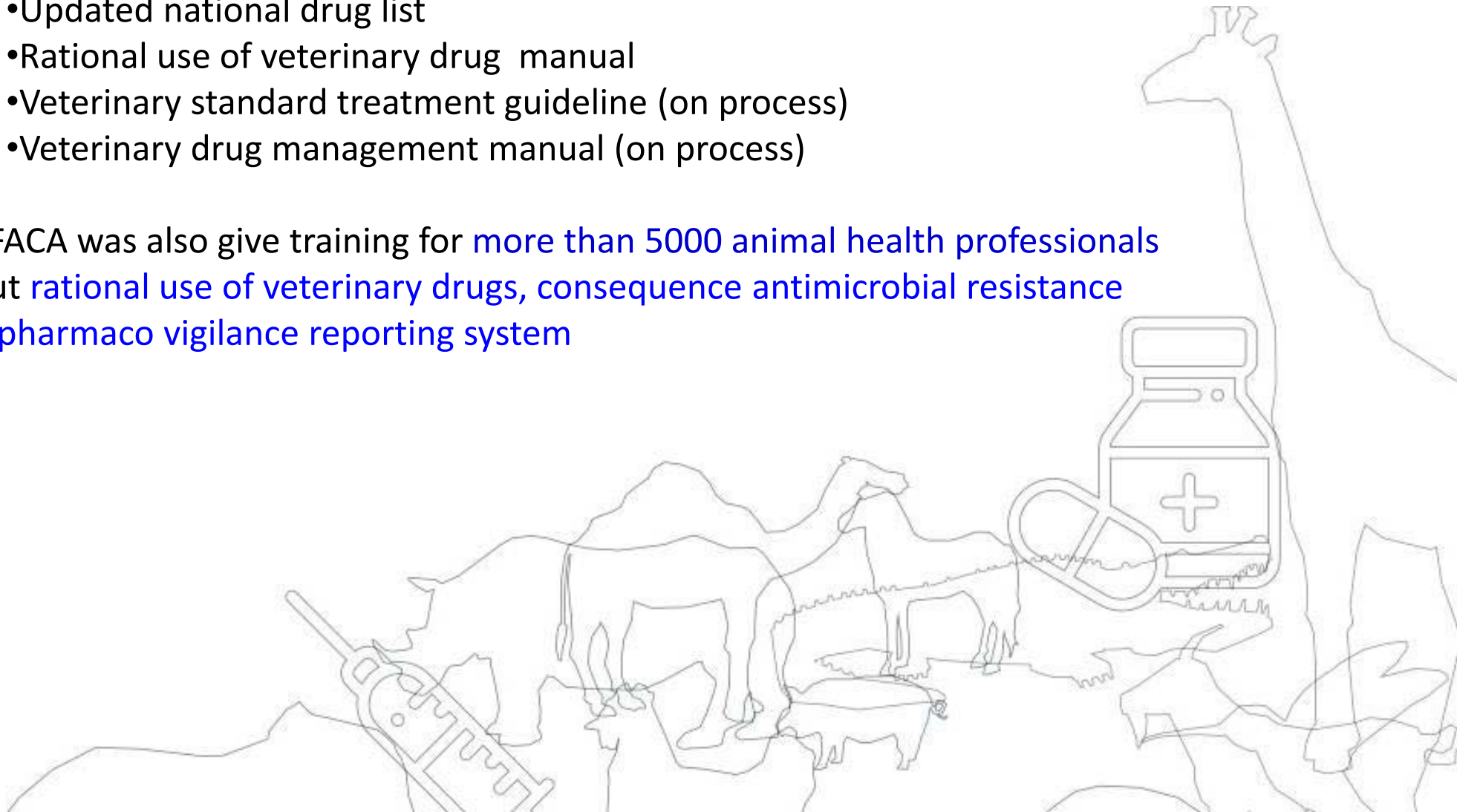


Veterinary drug regulation situation cont.

- Animal products, veterinary drugs and feed quality assessment center was check the quality of pre registration, consignment and PMS (Post Marketing sample)
- Tests done for veterinary drugs by quality control laboratory of VDFACA
 - Disintegration
 - Dissolution
 - Assay test/ API/
 - Friability
 - Sterility
 - Safety
 - Identity
- VDFACA outsource some of tests (vaccine analysis tests for AU-PANVAC)
- Up to now we have got 5 drugs(Like Tetramisole HCL, Albendazole 600mg, 300mg, 2500mg and Ivermectine 1% injection) below the standard by taking PMS and consignment sample ,
- VDFACA decided the failed veterinary drug should be collected by the importer and to be recalled to the manufacturer
- In addition the veterinary drug registration certificate was cancelled the registration certificate

Veterinary drug regulation situation cont.

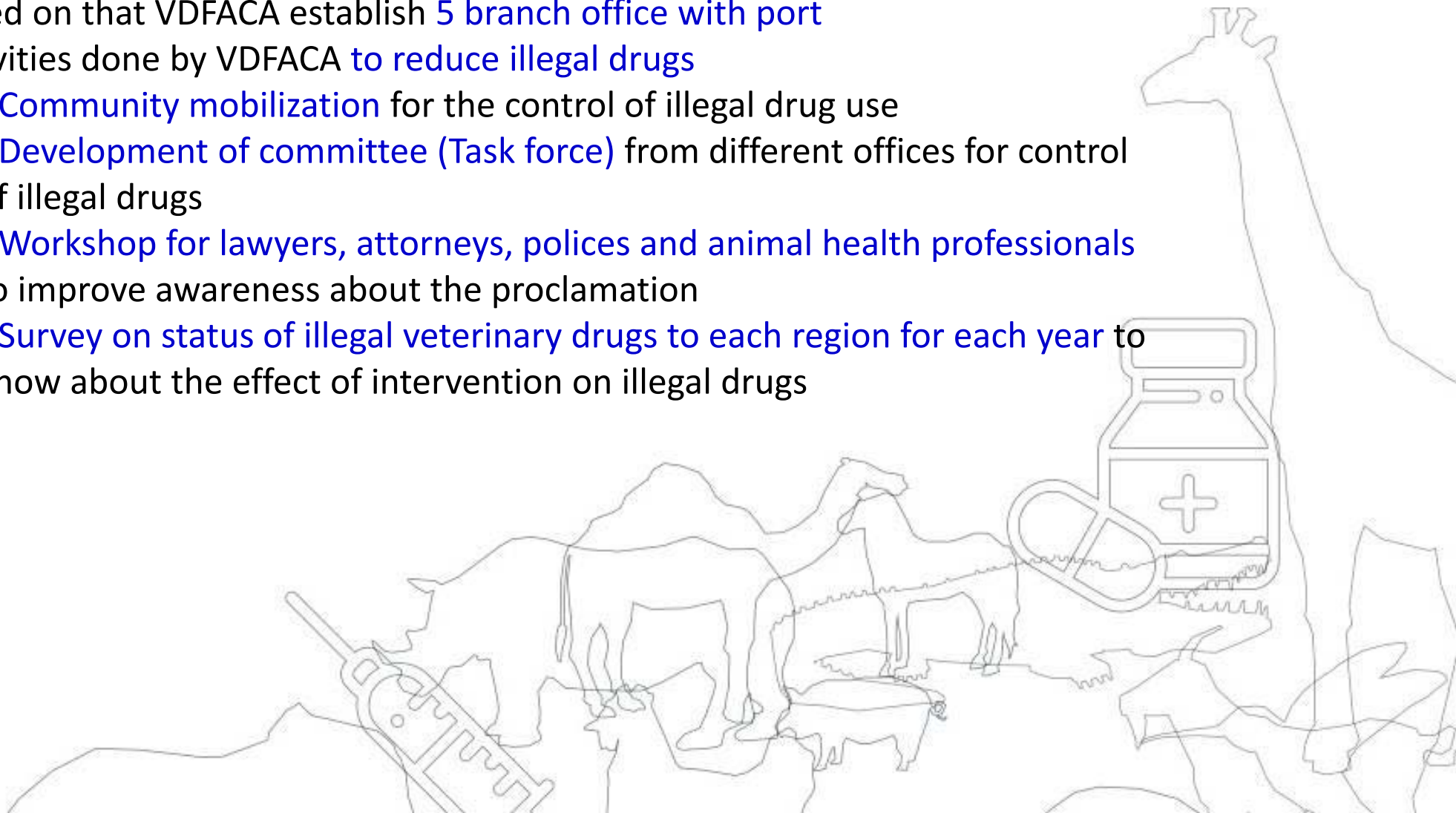
- VDFACA has also prepare important documents like
 - Number of directives
 - Updated national drug list
 - Rational use of veterinary drug manual
 - Veterinary standard treatment guideline (on process)
 - Veterinary drug management manual (on process)
- VDFACA was also give training for more than 5000 animal health professionals about rational use of veterinary drugs, consequence antimicrobial resistance and pharmaco vigilance reporting system



Veterinary drug regulation situation cont.

2. The second main strategic goal is **control of illegal drugs**

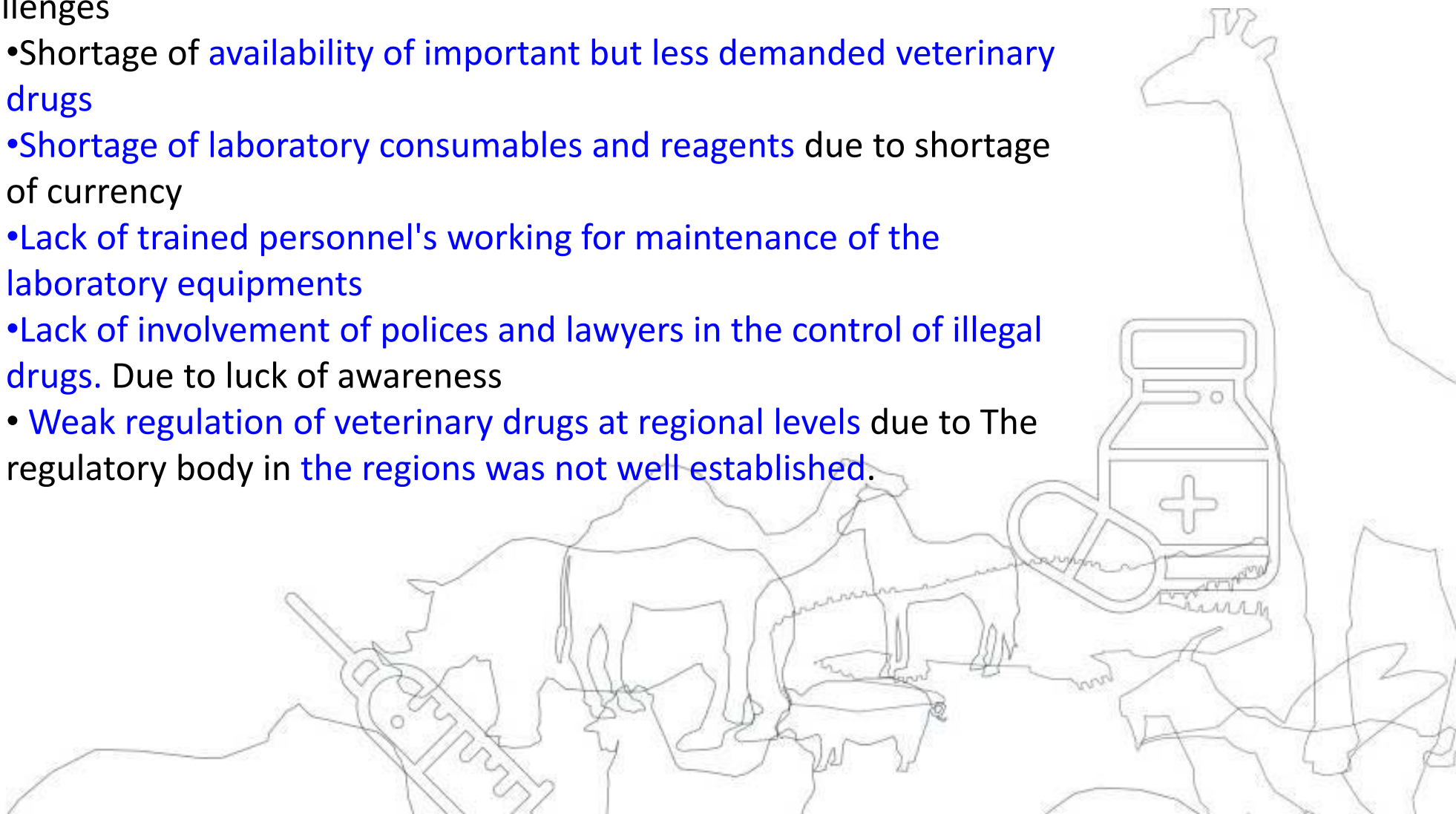
- VDFACA classify in to **three zones** based on status of illegal drugs
- Based on that VDFACA establish **5 branch office with port**
- Activities done by VDFACA **to reduce illegal drugs**
 - **Community mobilization** for the control of illegal drug use
 - **Development of committee (Task force)** from different offices for control of illegal drugs
 - **Workshop for lawyers, attorneys, polices and animal health professionals** to improve awareness about the proclamation
 - **Survey on status of illegal veterinary drugs to each region for each year** to know about the effect of intervention on illegal drugs



Veterinary drug regulation situation cont.

- Challenges

- Shortage of availability of important but less demanded veterinary drugs
- Shortage of laboratory consumables and reagents due to shortage of currency
- Lack of trained personnel's working for maintenance of the laboratory equipments
- Lack of involvement of polices and lawyers in the control of illegal drugs. Due to lack of awareness
- Weak regulation of veterinary drugs at regional levels due to The regulatory body in the regions was not well established.



thank You

