



Country Presentation: Activities carried out so far  
in regulation of veterinary products, Ethiopia

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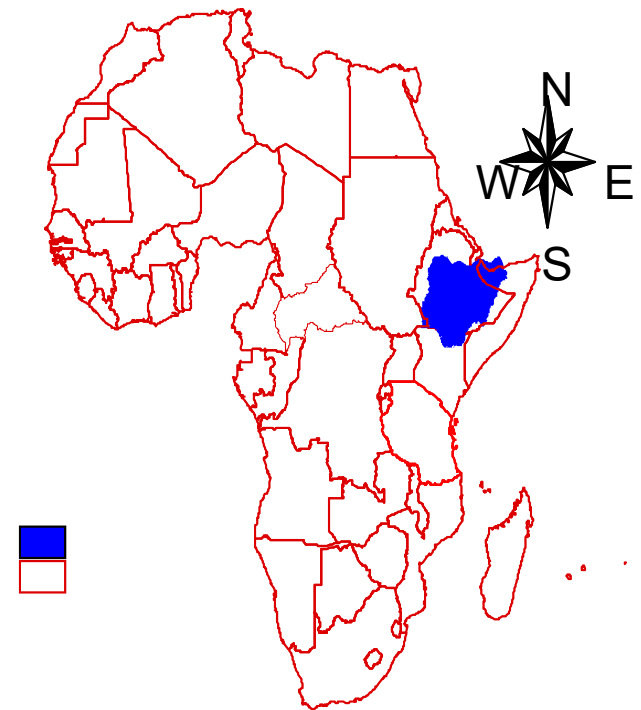
Regional Seminar for OIE National Focal Points for Veterinary Products – 5<sup>th</sup> Cycle  
Ezulwini, Swaziland. 6 - 8 December, 2017

# outline

- Background
- Introduction
- Terms of Reference for OIE National Focal Points for Veterinary Products
- Activities
- Collaboration
- Regulation of veterinary medicinal products
- Challenges

# Background on Ethiopia

- Location – East Africa
- Shares border with Djibouti, Somali, Kenya, South Sudan, Sudan and Eritrea
- Size – 1.1millionsq Km
- Human Population – over 102million
- Federal System – Federal, States (10)



# Continued

- The animal population census gives national populations of Ethiopia.
  - ▶ 44.3 million cattle,
  - ▶ 23.6 million sheep,
  - ▶ 23.3 million goats,
  - ▶ 2.3 million camels
  - ▶ over 50 million poultry

# Introduction

- 2<sup>nd</sup> cycle training focal points were to work to improve registration, distribution and quality control of VMP nationally and other responsibilities in their ToRs
- 3<sup>rd</sup> cycle training focus was on establishment of monitoring plan for veterinary drug residue and AMR
- 4<sup>th</sup> cycle focus on antimicrobial stewardship and antimicrobial resistance ,as well as quality of veterinary drugs taking into account the WHO global action plan on AMR

# Terms of Reference for Focal Points

- ToR - the responsibilities of the focal points are under the authority of the OIE Delegate. Any information transmitted to the OIE from the different focal points needs to be transmitted under the designated authority of the OIE Delegate
  - to establish a network of veterinary product experts within his country or to communicate with existing networks;
  - to establish and maintain a dialogue with the Competent Authority for veterinary products in his country, and to facilitate cooperation and communication among several authorities where responsibility is shared;
  - under the authority of the OIE Delegate of his country, to monitor legislation on and control of veterinary products to ensure that these are in support of OIE international standards, guidelines and recommendations;
  - to act as a contact point with the OIE on matters related to veterinary products;

## TOR Cont....

- to receive from the OIE Headquarters information on VICH activities and copies of the reports of the Biological Standards Commission and other relevant reports, should they address discussion points on veterinary products;
- to conduct, on request, the in-country consultation process with recognised veterinary product experts on draft texts of standards and/or on guidelines and recommendations proposed in those reports; and
- to prepare comments for the Delegate on each of the relevant meeting reports reflecting the scientific view and position of the individual OIE Member and/or the region, including comments on the proposals for new or revised OIE standards and guidelines and recommendations related to veterinary products.

# Activities

- Stakeholders meeting
  - To establish a network of stakeholders in the regulation of veterinary medicinal products.
  - To harmonize activities of stakeholders and agree on channels for information sharing.
- Antibiotics Awareness Week; Banner and Brouchers
- Completion of questionnaires
  - Monitoring of quantities of antimicrobial agents used in animals
- Data collection on antimicrobial use in animals, with some limitations on the calculations



# World Antibiotic awareness week in Ethiopian national language&calendar



# Collaboration

- All of TOR activities for veterinary products are carried out together with the Ethiopian Veterinary Drugs and Animal Feed Administration and Control Authority(VDFACA)

# Regulation of Veterinary products

- Initially Both human and veterinary drugs in Ethiopia were regulated by the Drug Administration and Control Agency, established in 1999,
- regulation of veterinary drug import was not so well developed as humans , probably because veterinary import was done by the government itself till the mid-90s, because the veterinary private sector within the country was much less well developed

## Cont....

- Following the passage of proclamation No.728/2011, the veterinary products regulation was transformed to an independent drug control authority named “*Veterinary Drug and Animal feed Administration and control Authority (VDFACA)*” which became operational on 2011 G.C.
- Then after regulation number 272/2012 was approved by ministers council for the establishment of authority.

## Cont...

- According to article 4 of the proclamation 728/2011,
- ‘No veterinary drug may be produced locally or imported and put in use unless it is **registered** by the Authority after being tested for its safety, efficacy and quality’.
- Notwithstanding sub-article (1) of the above Article, the Authority may authorize, in compelling circumstances of natural disaster causing high animal migration such as drought, flood and earth quake, or in cases of epidemic of exotic animal disease, or for animal health research, or for pre-registration test.

## Cont....

- The import of veterinary drugs is a key sub-sector for Ethiopia, one of Africa's largest livestock producers.
- The country's requirement of veterinary medicines is mainly met through import.
- In 2012 demand for veterinary medicines was estimated to be about:
  - ❖ 416 tons of solid drugs
    - ✓ 100 tons of antibiotics
    - ✓ 282 tons of anthelmintics and
    - ✓ 34 tons of antiprotozoal
  - ❖ 692.38 thousand liters of acaricides.

## Cont.....

The demand for veterinary medicines will projected to reach by year 2022.

- 1,131 tons of solid drugs
  - 272 tons of antibiotics
  - 767 tons of anthelimentics
  - 92 tons of antiprotozoals
- 1.88 million liters of acaricides .

# Importing Companies

- The import of veterinary pharmaceuticals to Ethiopia was a monopoly of government until the mid-1990s,
- the early years of the present government, at which point it was liberalised and import licenses were given to a number local companies.
- the number of licensed importers which have contact with the authority so far appears to be around 30.
- Veterinary medicinal products wholesalers around 3.
- the national drug list serve as useful guide for, registration, procurement, distribution and prescription of drugs in the country.



# Type of veterinary medicinal products imported

- Anthelmintics
- Antibiotics
- Antiprotozoals
- Accarcide
- vaccines
- Veterinary instruments
- Vitamines
- Hormones
- Lab equipments and reagents

Cont.....

Import of veterinary medicinal products done by the:

- **governmental sector :**

e.g. NVI, AISCO, Universities, Ethiopian Wild life agency)

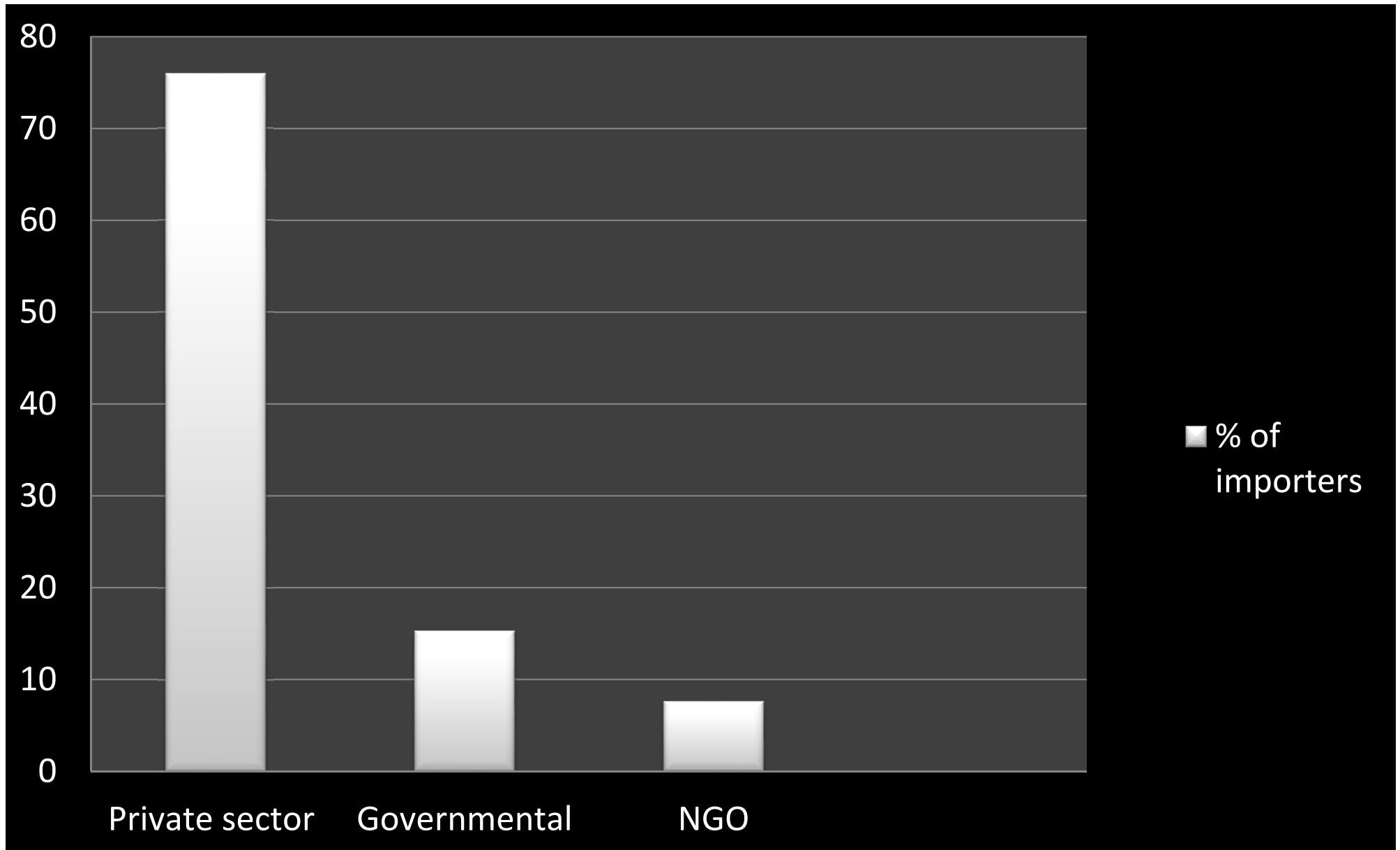
- **private sector:**

licensed importers, private animals farms

- **NGO's :**

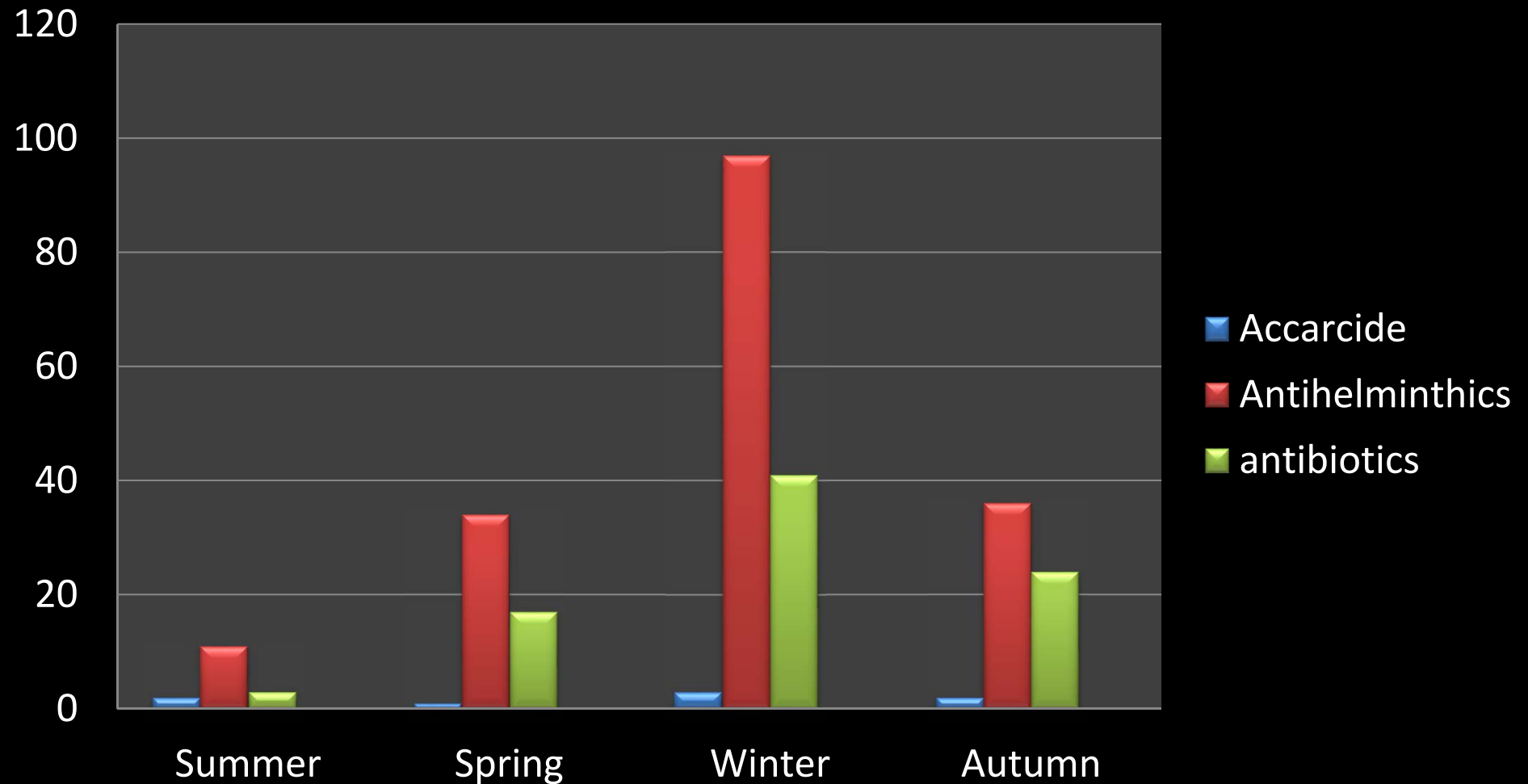
e.g. PANVAC, ILRI, Donkey sanctuary

# Types of organizations involved in drug importing in Ethiopia since the establishment of authority



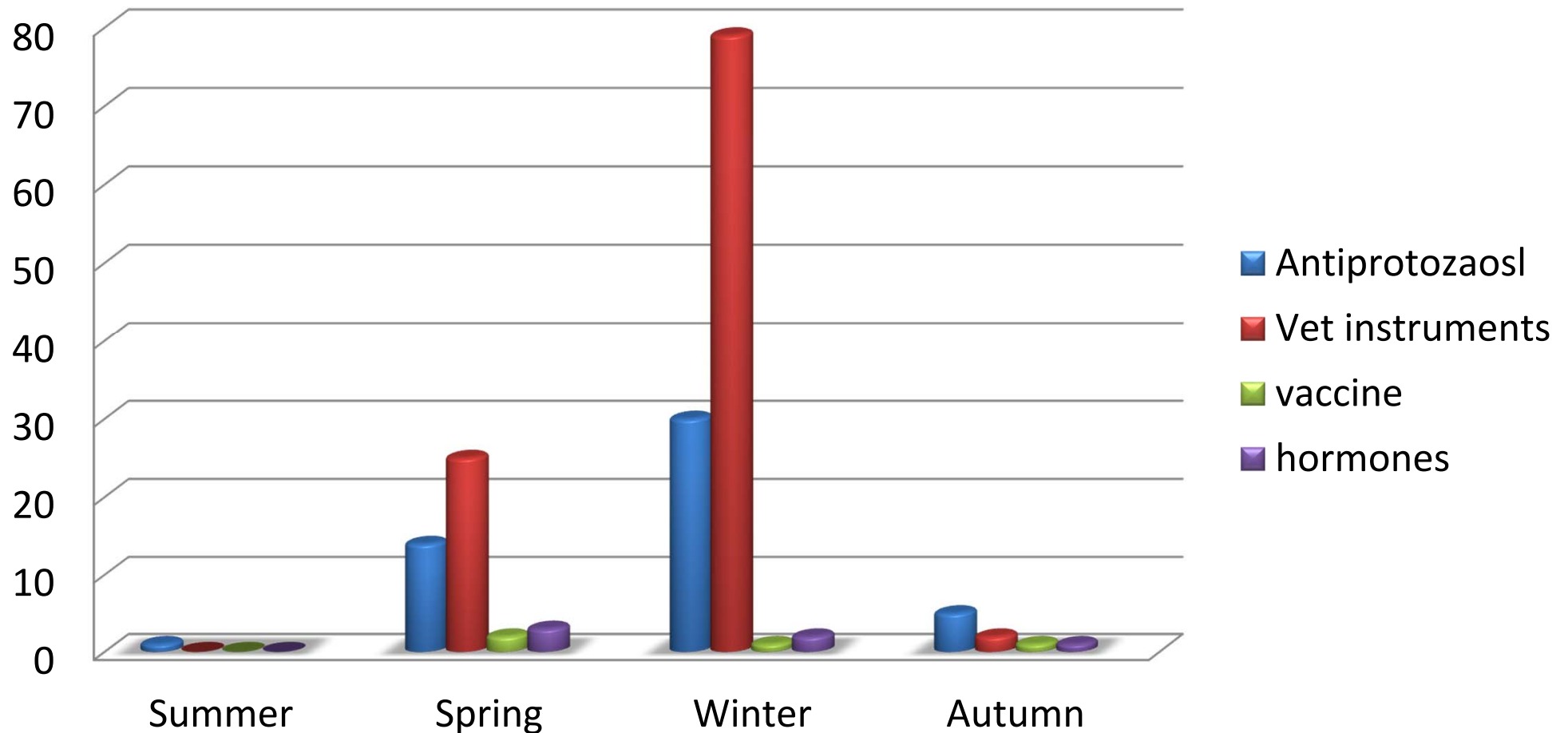
# Purchase order requested....

The frequency of Purchase request permitted for importation of accarcide ,antihelminthics and antibiotics in different seasons 2013/14



# Purchase order requisited...Cont....

The frequency of Purchase request permitted for antiprotozoals, Vet instruments, vaccines and hormones since the authority become functional



# *Manufacturing of veterinary medicinal products in Ethiopia*

In addition to the veterinary importers, there are some companies manufacturing veterinary pharmaceuticals:

- East African pharmaceuticals Plc. ( both human and vet drugs)
- **Adamitulu pesticides processing Sh.co**  
**( ectoparasitides)**
- National Veterinary Institute(Vaccines)

## The list of registered medicinal products since establishment of the authority

No	Brand name	Generic Name	presentation	Type	Manufacturer	Country
1	oxyTTC LA 20%	OxyTTC 20% inj	100ml vial	Re	Shanghai Tongdon	China
2	OxyTTC 10%	OxyTTC 10%	100ml vial	Re	Shanghai Tongdon	China
3	Ivermectine 1%	Ivermectine 1% inj	50ml vial	Re	Shanghai Tongdon	China
4	Yz-Albendazole 600mg	Albendazole 600mg Bolus	Blister of 5 or 6 boli	New	Hebey yoanzheeng	China
5	Yz-Albendazole 2500mg	Albendazole 2500mg Bolus	Blister of 5 or 6 boli	New	Hebey yoanzheeng	China
6	Yz-Albendazole 300mg	Albendazole 300mg Bolus	Blister of 5 or 6 boli	New	Hebey yoanzheeng	China
7	Multi-vitamine	Mlti vitamine inj	Vial of 100ml	Re	Norbrook Lab. Ltd	UK
8	Defensor-3-Rabis vaccine	Defensor-3-Rabis vaccine 10 <sup>35</sup> /dose	Vial of 1,10,25ml	New	PF12ER Animal Health	USA
9	Lerafox	Rafoxanide 1gm+levamisole HCl	Strip of 1boli	New	Ashish life science	India
10	Vet instrum	Vet instrum		Re	MLD vet supply	China

# List of Cont...

No	Brand name	Generic Name	presentation	Type of registration	Manufacturer	Country
11	Ashiver	Ivermectine 5mg		New	Ashish life science	India
12	Levamisole 600mg		12strip of 5boli	New	Ashish life science	India
13	Flukazash cattle	Oxuclozanide 2700mg	Blister of 4boli	New	Ashish life science	India
14	Diminazine 1.05g	Diminazin acetu 1.05g	Sachet of 2.36g	Re	Shangai Tongren	China
15	Veridium 1gm	Isomethamidium chloridehydrochloride	sachet	Re	Ceva santé Antihel	France
16	Veridium 125mg	Isomethamidium chloridehydrochloride	Ssachet	Re	Ceva santé Antihel	France
17	Oxytetracycline	OxyTTC 10%	Vial of 100ml	Re	Kulipers wEga-314	India
18	Smash 20%	Deltamethrine 20%	1 Lit	Re	Tagros Chemicals	France
19	Smash 1%	Deltamethrine 1%	1 Lit	Re	Tagros Chemicals	France
20	MULTIVET	MULTIVIT	100ML	Re	KELA LABORATORIA	UK



# List of cont...

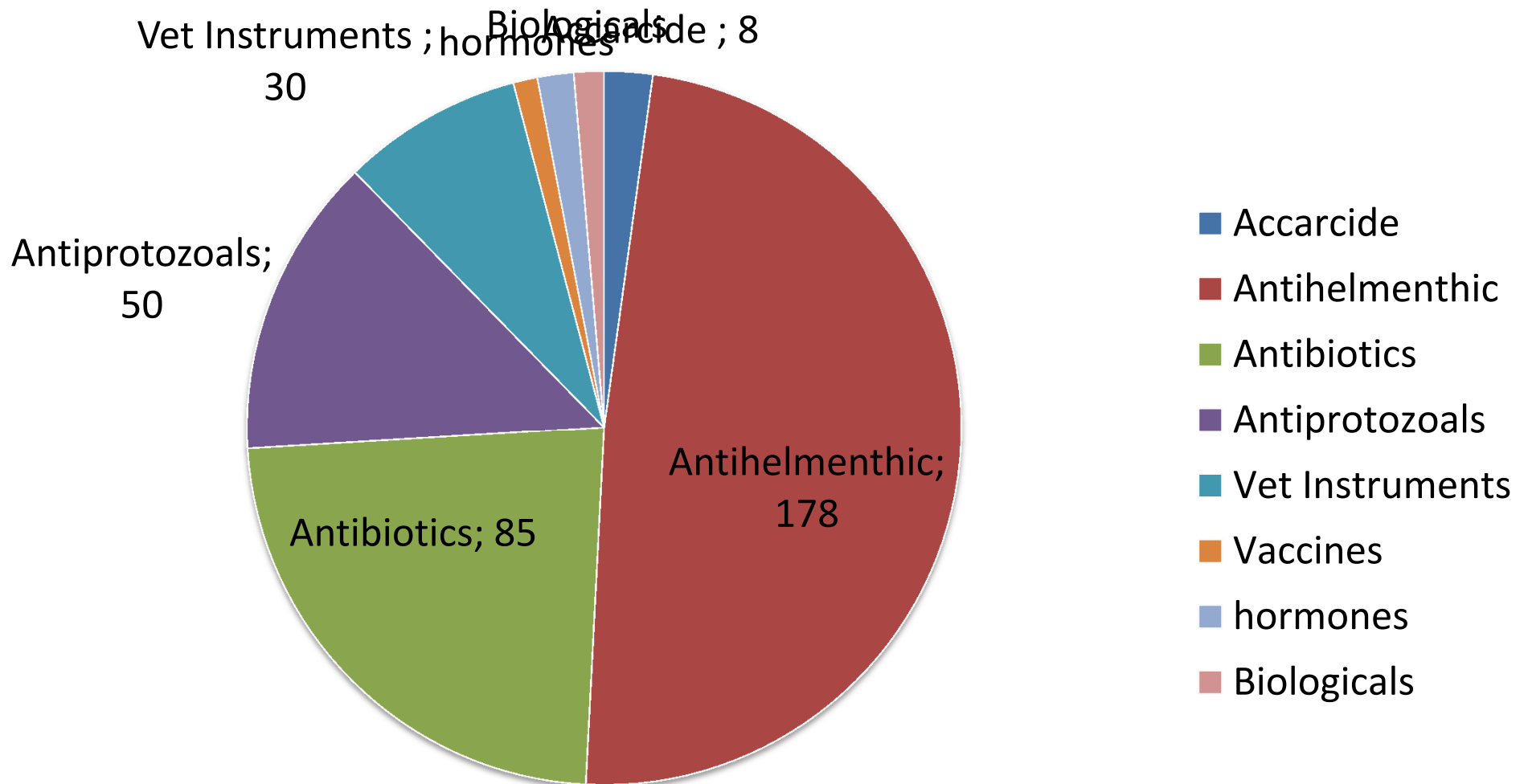
No	Brand name	Generic Name	presentation	Type of registration	Manufacturer	Country
21	Ethio-miraz	Amitraz	1 Lit	New	Adamitulu pesticides processing sh.Co	Ethiopia
22	Ashoxy	Oxytetracycline	Sachet of 1g	Variation	Ashish life Science	India
23	Tetracozash	Oxyclozanide450+ Tetramisole450mg	13x4+ 12x4	variation	Ashish life Science	India
24	Levaoxynide	Levamisole HCl 450mg +Oxyclozanode 450mg	12x Blister of 5 Boli	New	Chong quing Fengtong Animal Pharmace.	China
25	Mastitis-2	Benzylepenicillinu m procai um 300mg+ Neomycine sulfate	Prefiled syringe	Variation	KELA laboratory	UK

# List of cont...

<b>N o</b>	<b>Brand name</b>	<b>Generic Name</b>	<b>presenta tion</b>	<b>Type of registratio n</b>	<b>Manufacturer</b>	<b>Countr y</b>
26	Veterinary Instrument	-	-	Re	HANGUF Interational	UK
27	Triquin	Quinapiraine sulfat e B Quinapiramine chloride BV	50 ml of 1 vial	Re	Vetoquinol Indian Animal health	India
28	Ashialben 2500	Albendazole 2500mg		variation	Ashish life science	India
29	Vet Instrument	Vet Instrument	Different	Re	ARAAZ	India
30	Bovidium	Homodium chloride		Re	KELA laboratoriy	UK
31	Vet- Instrument	Vet- Instrument	Different	Re	TRUETECH	UK

# Supply of veterinary pharmaceuticals

The frequency (rate) of VMPs in Purchase order requested to import



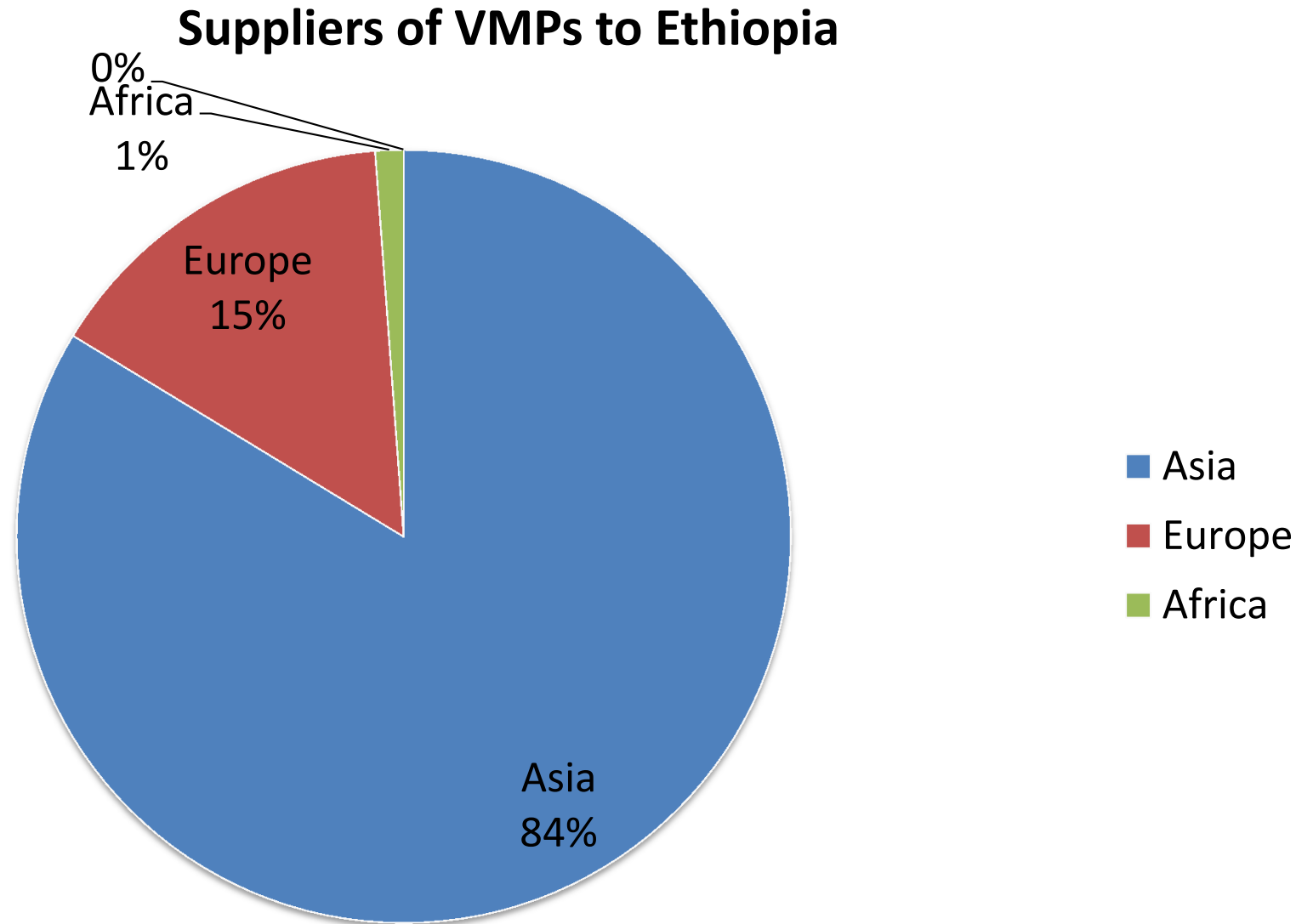
# Major suppliers of VMPPs to Ethiopia

Asia :China, India, Korea, Pakistan

Europe :Uk,France, Greece, Belgium, Czech

Africa :South Africa,Kenya,Egypt

# Cont..



# ***Drug financing***

Sources of drug financing include :

- government finance
- private expenditure
- external assistance,
- loan,

# Stakeholders meeting

- Problems were identified and discussed
- Solutions proposed and agreements reached to work together towards the solutions

# Challenges

- Enforcement of laws and regulations
- Illegal drug sellers in the community
- Illegal and unethical practice of some professionals especially in remote rural areas



# Thank you!

