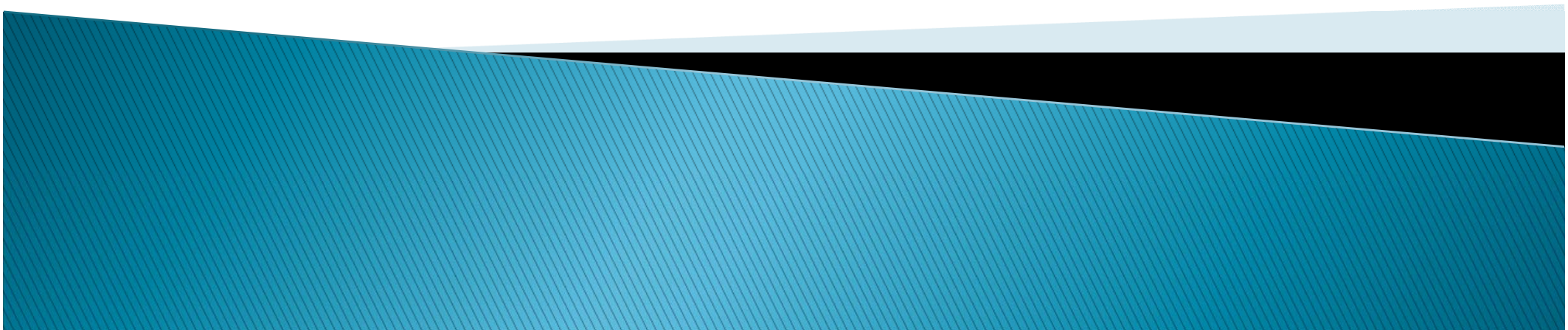
REPUBLIC OF SUDAN

Ministry of Animal Resources

General Directorate of Animal Health and EpizooticDiseases Control

Dr.Sabah Hassan Abdelgadir
Sudan Focal Point for Veterinary products

Sudan experiences in prudent and responsible use of antimicrobials

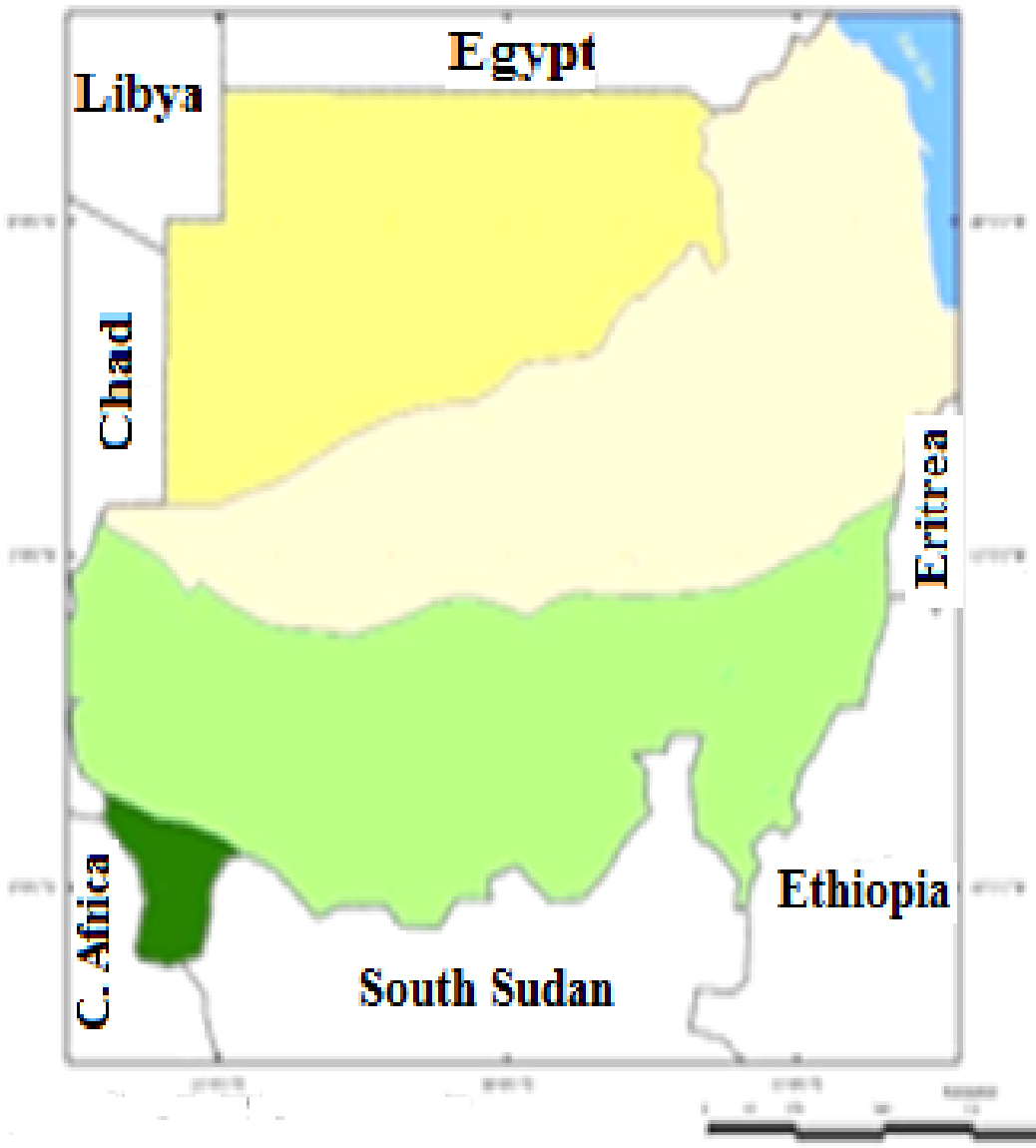


❑ overview

- Introduction
- Legislation of medicines in Sudan.
- Regulatory Control system of medicines in Sudan
- Current Available Data on AMU

INTRODUCTOIN

- Republic of Sudan is a country in Northern Africa. It is bordered by Egypt to the north, the Red Sea, Eritrea and Ethiopia to the east, South Sudan to the south, the Central African Republic to the southwest, Chad to the west and Libya to the northwest.
- It is the third largest country in Africa. The River Nile divides the country into eastern and western halves.
- Its predominant religion is Islam.



Country border
desert
semi desert
low rain fall woodland savannah
high rain fall woodland savannah

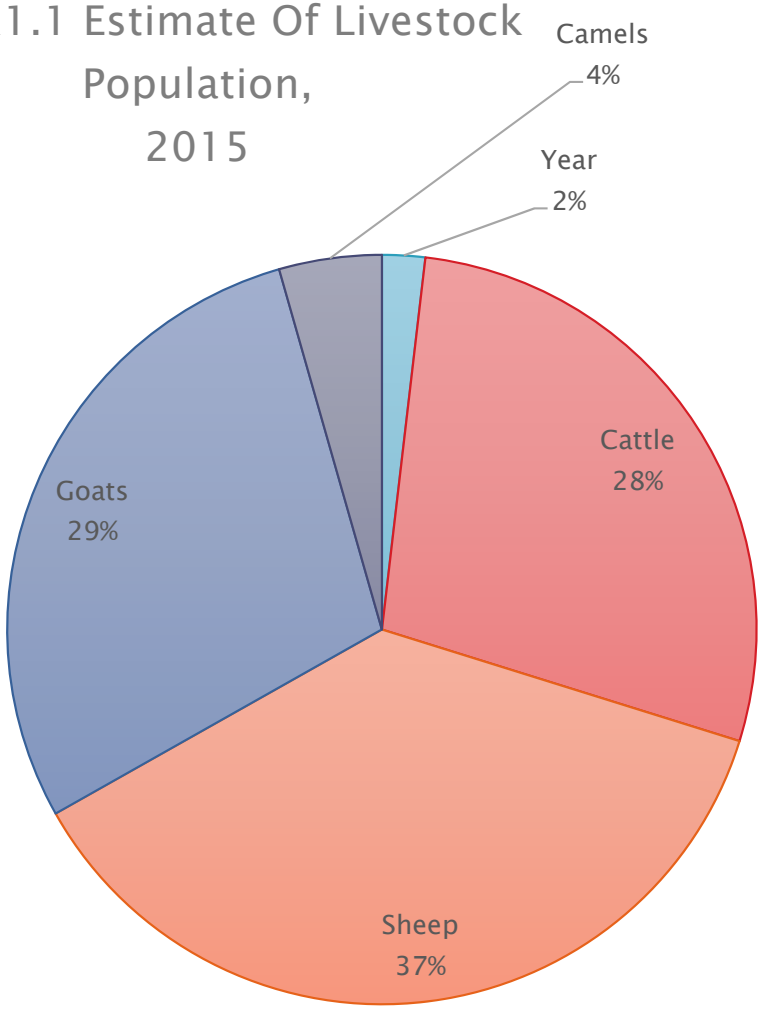
Source : RS Administration Forest National Corporation
(Khartoum, Nov. 2014 adopted from Harrison & Jackson, 1958)

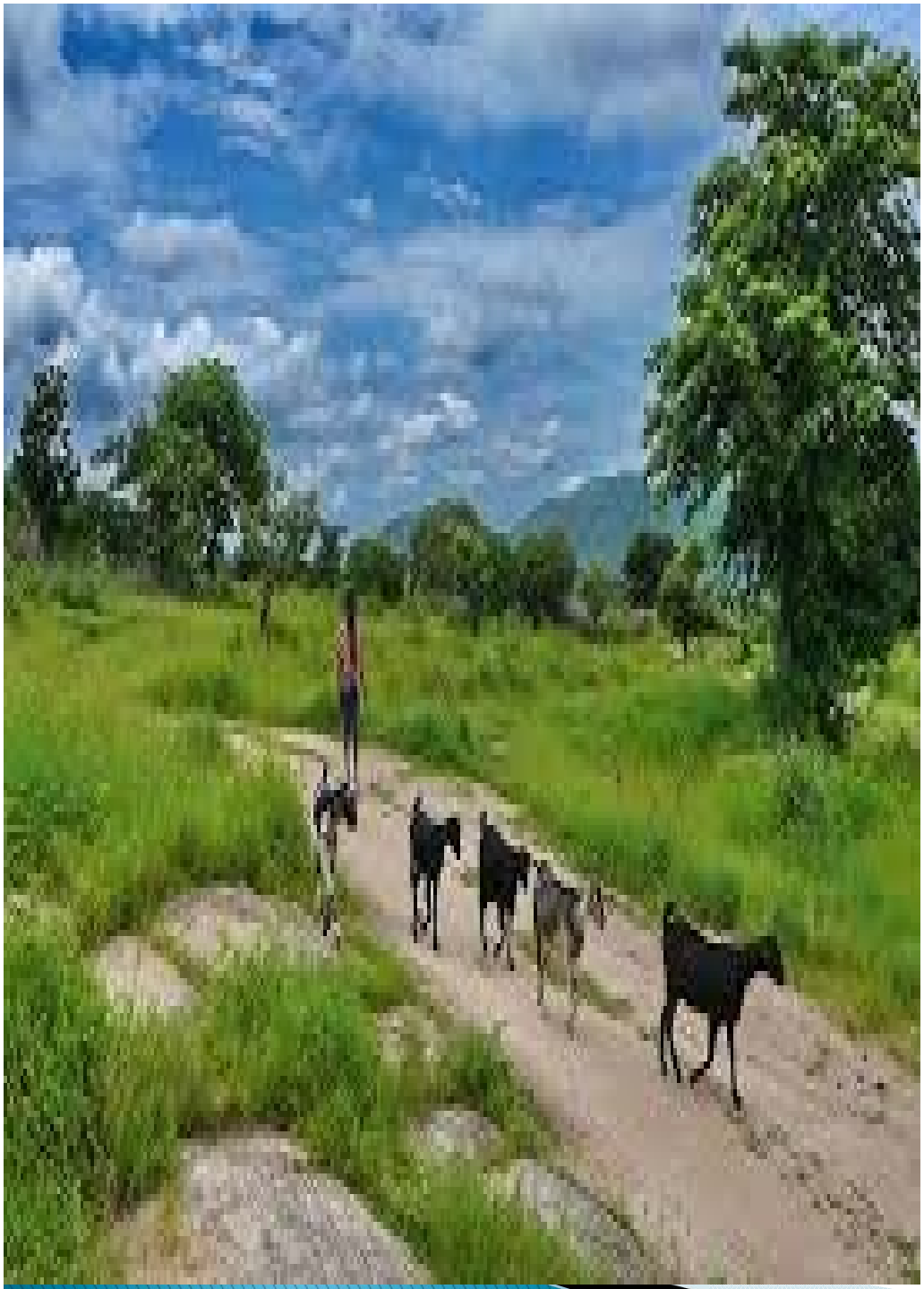
- Sudan has an area of 1,861,484 sq. km and about 107 million head of cattle, sheep, goats and camels, of which five million live animals and 8,100 tons of meat were exported to the kingdom of Saudi Arabia, Egypt and Jordan in 2016.

Animal resources population by thousands of head, 2015-2016
Ministry of Livestock -Information Center

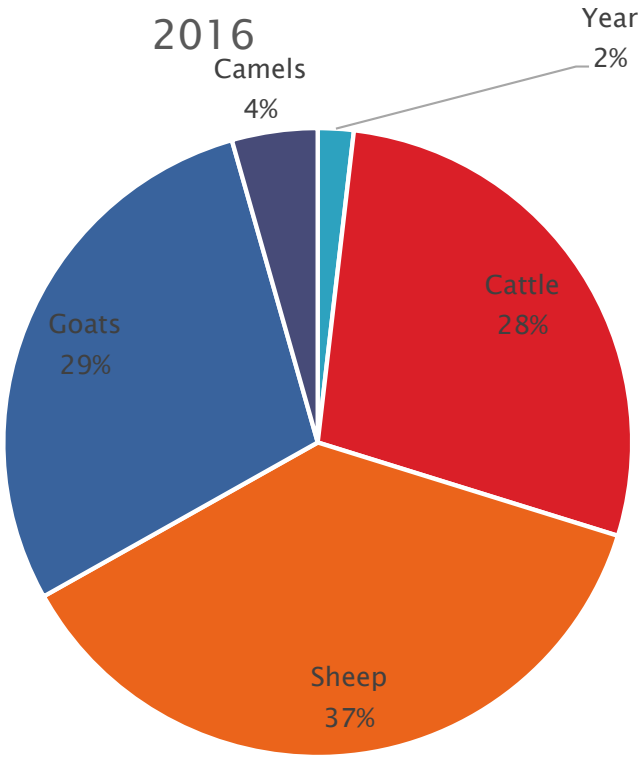
Year	Cattle	Sheep	Goats	Camels	Total
2015	**30376**	**40210**	**31227**	**4809**	**106622**
2016	**30632**	**40612**	**31481**	**4830**	**107555**

nnex1.1 Estimate Of Livestock Population, 2015





Annex 1.2 Estimate of livestock population, 2016



Legislation of medicines in Sudan

- veterinary supply department was Established in 1901 and was responsible for importing all kinds of veterinary medicines.
- The private sector began importation of veterinary medicines since1974
- the Veterinary Authorities represented by the Ministry of Agriculture and Natural Resources in provided the Veterinary Drugs Act 1995, which was approved by the Council of Ministers

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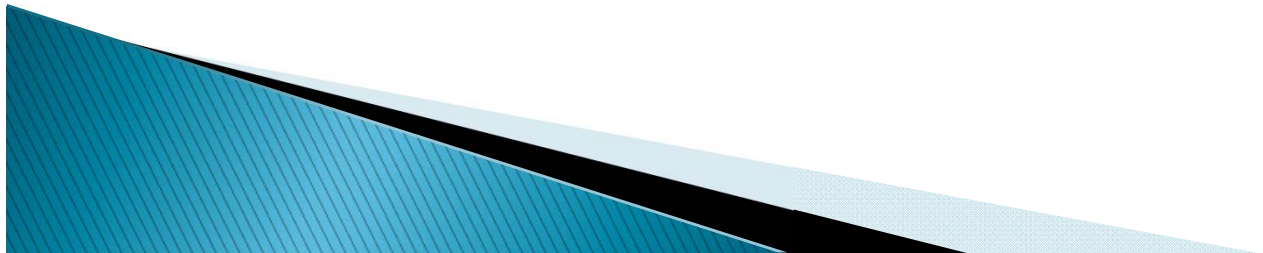
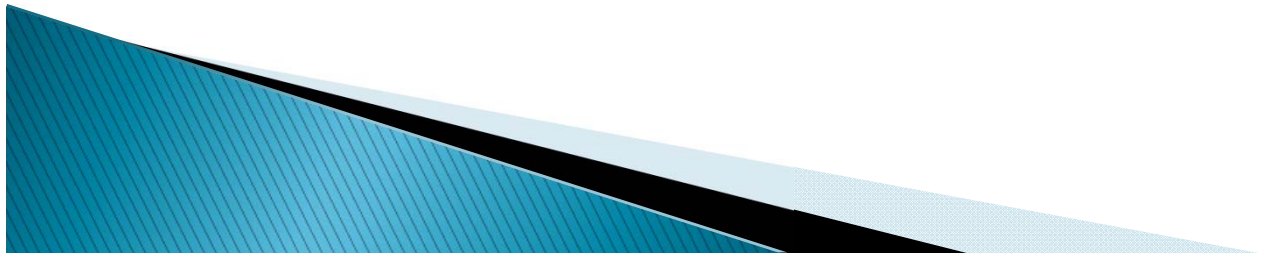


- The VS was responsible for regulation of veterinary medicine sincs2000 under Act2001 for pharmacy and poison
- The regulation of VMP was under responsibility of national board for drugs and poisons since 2007

- Medicines and poison Act 2009
- The Act regulates the registration of all medicines both human and veterinary, cosmetics and medical devices
- Provisions
- inspection, registration, distribution and pricing were created and implemented to assure quality, safety and efficacy of medicines and health products.

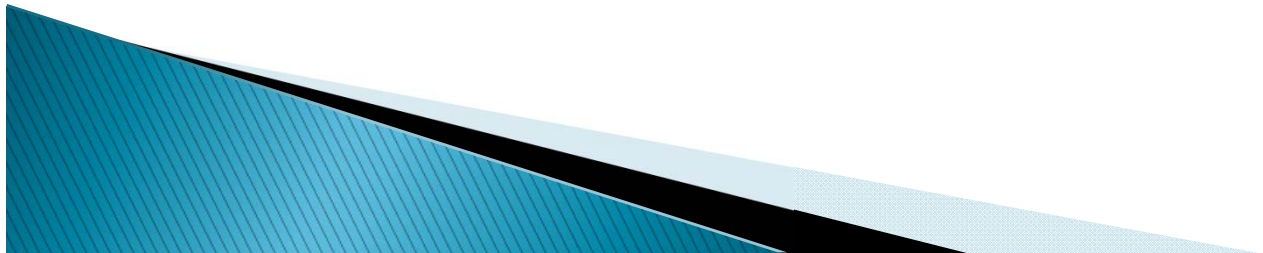
REGULATERY CONTROL OF VETERINARY MEDCINE

- Control system of medicines is done through :
- Inspection of pharmaceutical plants
- Registration of medicines
- Regulation of medicines importation .
- Post marketing surveillance



Inspection of pharmaceutical plants

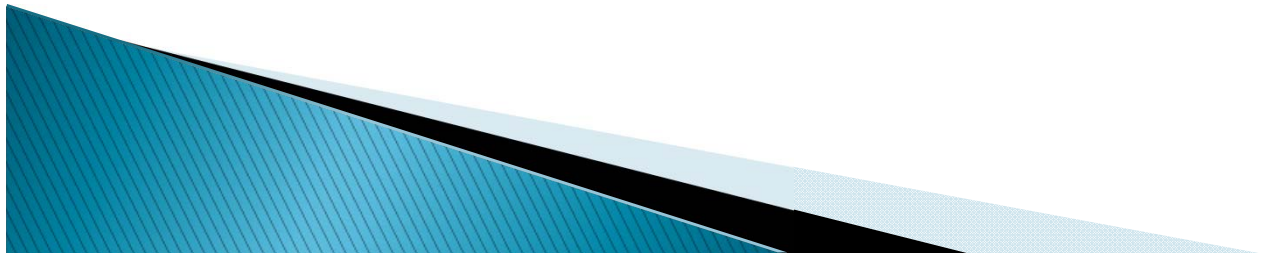
- Regular Inspection visits conducted to evaluate adherence of the plants to GMP
- Inspection is referenced to WHO guidelines on GMP
- Technical specialized committee is responsible of registration of the plants inspected
- Inspection of plants is mandatory before registration of the product.



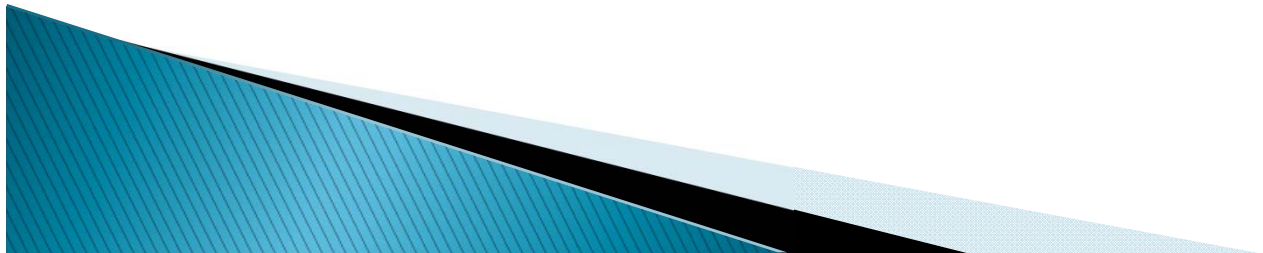
REQUIREMENTS FOR LICENSING OF LOCAL DRUG MANUFACTURING COMPANY

- 1.Ministry of Investment approval letter
- 2. Licensing form of local drug manufacturing company
- 3. Full information and details about the pharmaceutical plant

4. Quality Manual
5. Evidence of any internationally recognized awards or certifications of excellence or compliance with international standards, e.g. ISO 9000, 9001.
6. List of main research studies performed by the manufacture during the last 5 to 10 years.

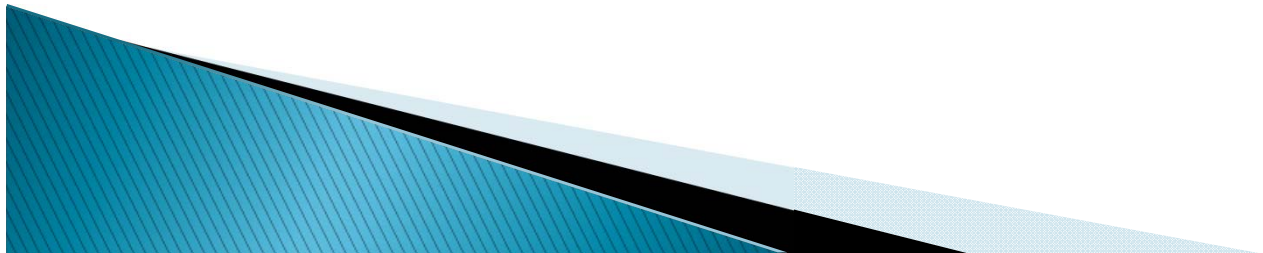


7.Pharmaceutical products released to the market based on that research.
8. Validation Master Plan (VMP)
9. Copy of permanent registration and qualifications of the technical manager of the
local manufacturing company.



Registration of medicines

- Registration of medicines (veterinary and human) started since 1964
- Technical committee for registration of veterinary medicines and anther committee for the human medicines
- They held meeting regulary



General Requirements for the Registration of Veterinary Pharmaceutical Products

The application form for registration of a pharmaceutical available on the web of NMPB.

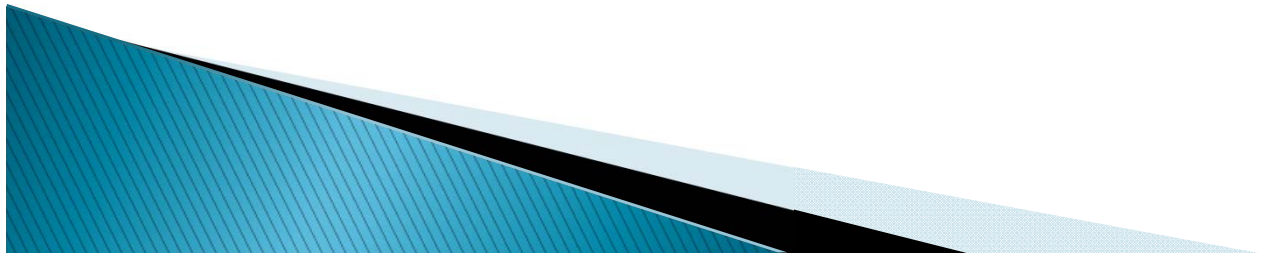
2. The applicant should be:

2.1. Holder of a valid wholesales pharmaceutical license and an agency agreement

2.2. A public sector establishment authorized to deal with Veterinary Pharmaceutical Products.

3.The applicant should also pay the prescribed registration fees (non refundable) and attach the receipt to the application form.
4. The form certifying the accuracy of documentation and information submitted for registration should be signed by responsible person specified by the applicant.
5. A motivation letter and not more than 500 words as to why the product should registered in Sudan.

6.The applicant should present with the application form and the specified documentation.
7. All documents should be in English and/or Arabic.
8. All documents are to be submitted typewritten or computer printed.
9. Application for registration is accepted only for products produced in registered manufacturing plants.
10. Any incomplete or incorrect documents will not be accepted.
11. Any documents that not properly arranged and filed will not be accepted.
12. The documents should be submitted in two files (volume I and volume II).



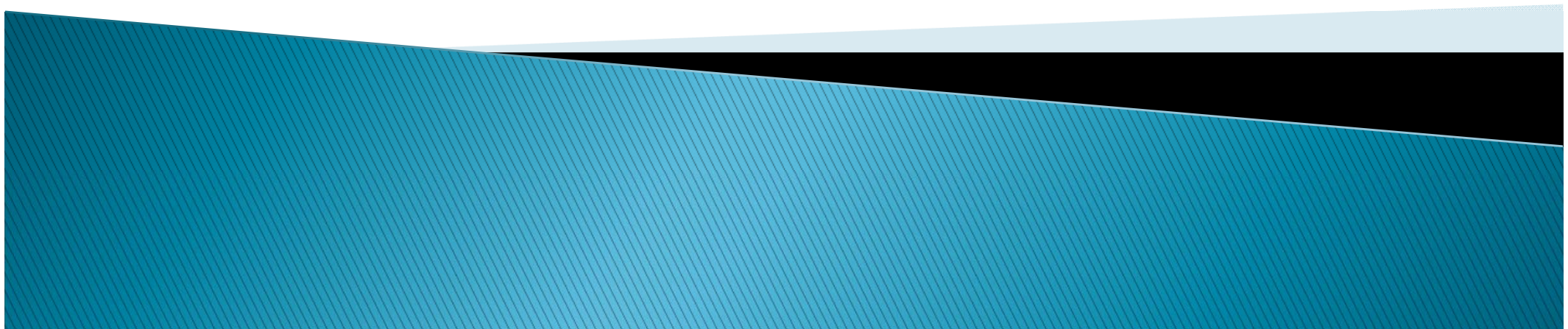
Importation of medicines

- All medicines imported to Sudan are under control of NMPB
- Visual inspection to all imported medicines to Sudan is mandatory before releasing the product into the market.
- Complying of every consignment documents with the information of the product on data base system is essential to permit importation.
- Pricing of every batch issued upon importation

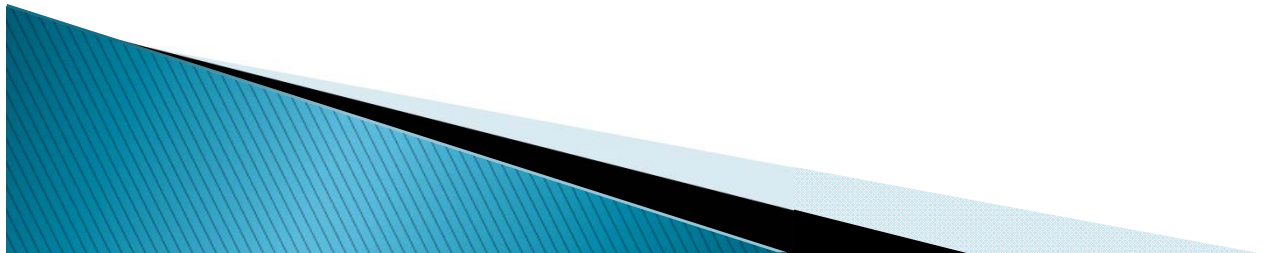
- Batch testing before releasing a product into the market to complete the registration procedure for the products imported for the first time (pre-market quality testing).

inspection of pharmaceutical premises

- Regular inspection conducted for store of Importer and retail sellers owned by both public and private sectors
- Licensing and inspection of pharmacy premises (that is for Importer , distributors and retail pharmacies)-delegated from NMPB to state authorities according to NMPB GDP guidelines.

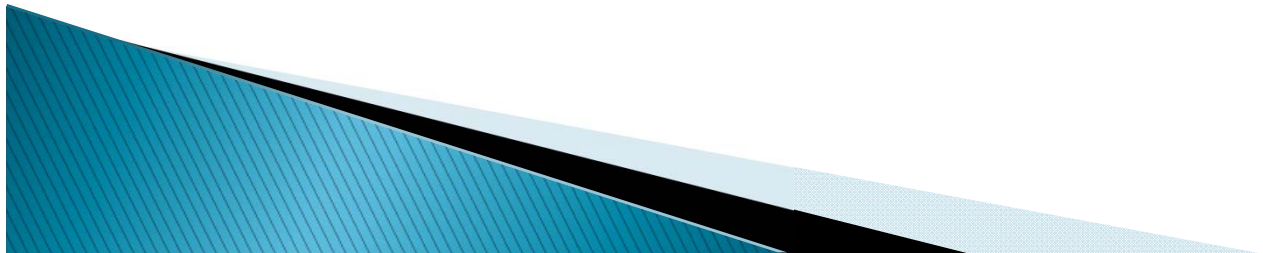


- Reports from states are submitted to NMPB monthly and supervision visits are carried by NMPB to the states
- NMPB undertake regular inspection of local pharmaceutical plants



POST Market surveillance activities

- Post-marketing surveillance activities involve:
  - Collection of samples for selected medicines from the public, private, sectors or in response to complaints according to NMPB policy for post-marketing.
  - Receiving and handling of complaints



- Monitoring of medicines prices and availability of medicines
- NMPB maintain drug analysis laboratories for the pre- and post- marketing analysis of medicines

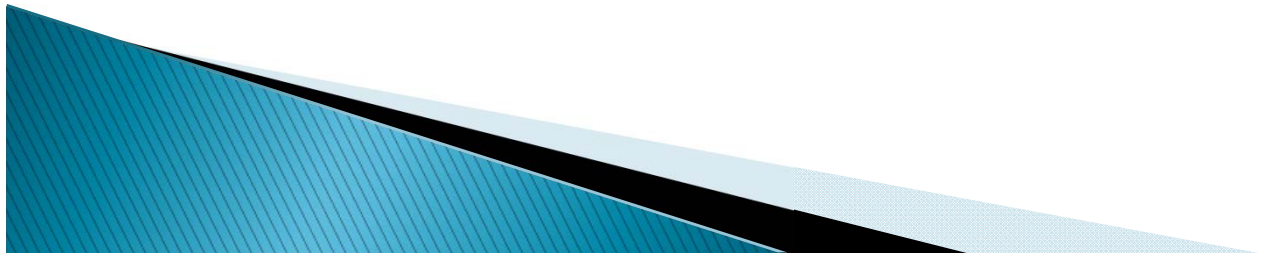
NATIONAL LAB

- The lab was established in 1924
- The lab is well equipped with necessary equipments to carry on testing for medicines and health products including microbiological, physical and chemical tests.

Curren Available Data on AMU

- The availability and the use of antimicrobial drugs in terrestrial and aquatic animals production is essential to both health and productivity.
- They contribute to food security, food safety, and animal welfare and in turn, to the protection of livelihood and sustainability of animal.

- In Sudan as well as in many other developing countries the use of antimicrobial drugs for human and animal treatment is weakly regulated
- Antibiotics are frequently misused or overused
- AMs are still wrongly used as disease preventive and growth promoting agents
- There is need for national framework of antimicrobials use
- The NMPB role is need to be more stronger to implement the antimicrobial provisions under act 2009



Animal spp.	Antimicrobial	Antimicrobial class
Cattle, Sheep, and Goat	Penicillin	Penicillin
	Ampicillin	
	Amoxicillin	
	Chloramphincol	Amphenicols
	Florfenicol	
	Enrofloxacin	Quinolone
	Gentamicin	Aminoglycosides
	Sulphadimedine	Sulphonamide s
	Tylosin	Macrolide
	Oxytetracycline	Tetracycline
Chickens	Chloramphincol	Amphenicols
	Florfenicol	
	Colistin	polypeptide
	Erythromycin	Macrolides
	Tylosin	
	Oxytetracyclin	Tetracycline
	Chlortetracycline	
	Doxycycline	
	Neomycin	Aminoglycosides
	Dexoquinolone	Quinolone


Thank you for your attention