UGANDA

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

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

Regulatory perspective on harmonization

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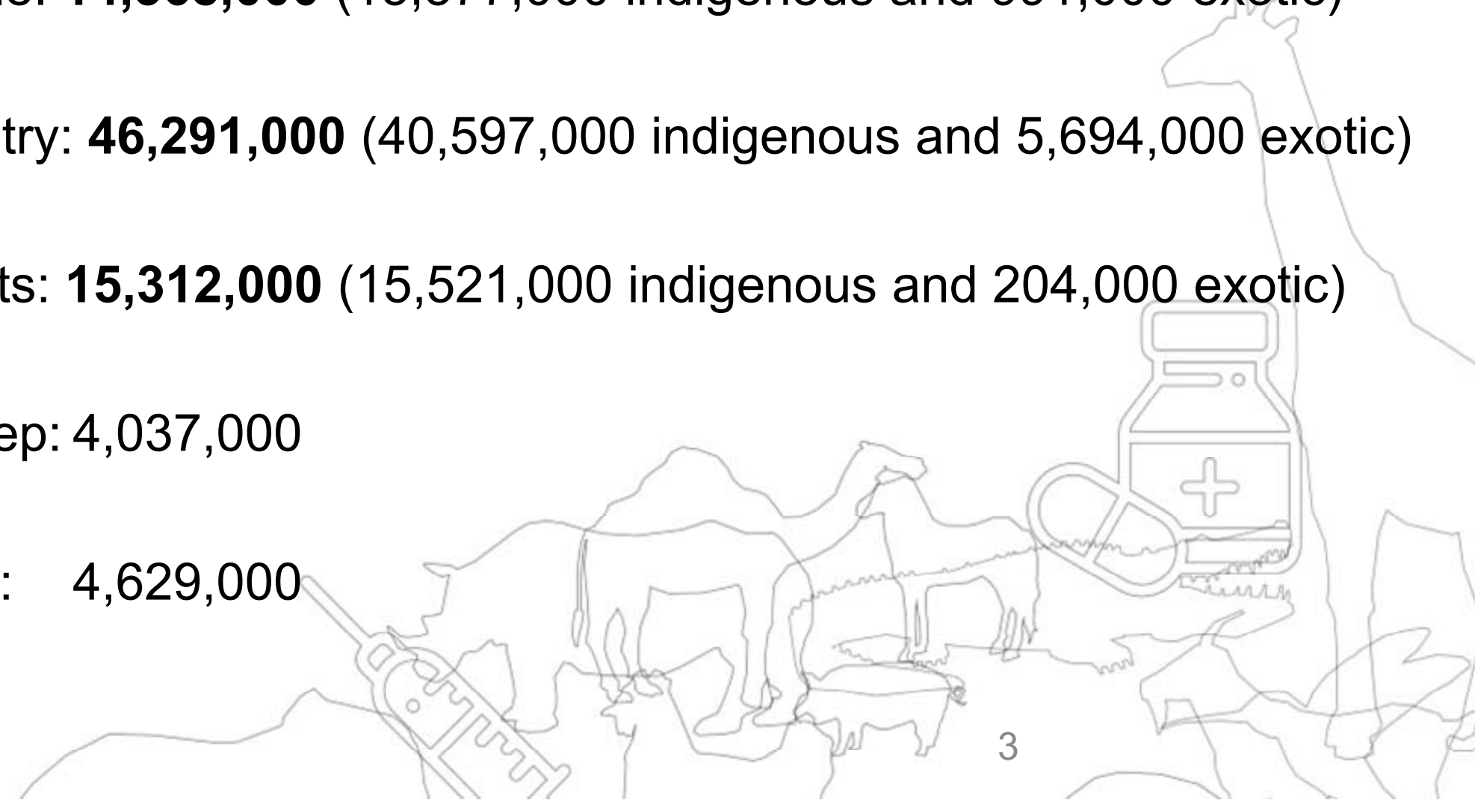
Uganda

Key facts and figures about Uganda

- Area: 241,038 sq.km
- Human Population: 42 million (2016)
- Official Language: English
- Capital City: Kampala

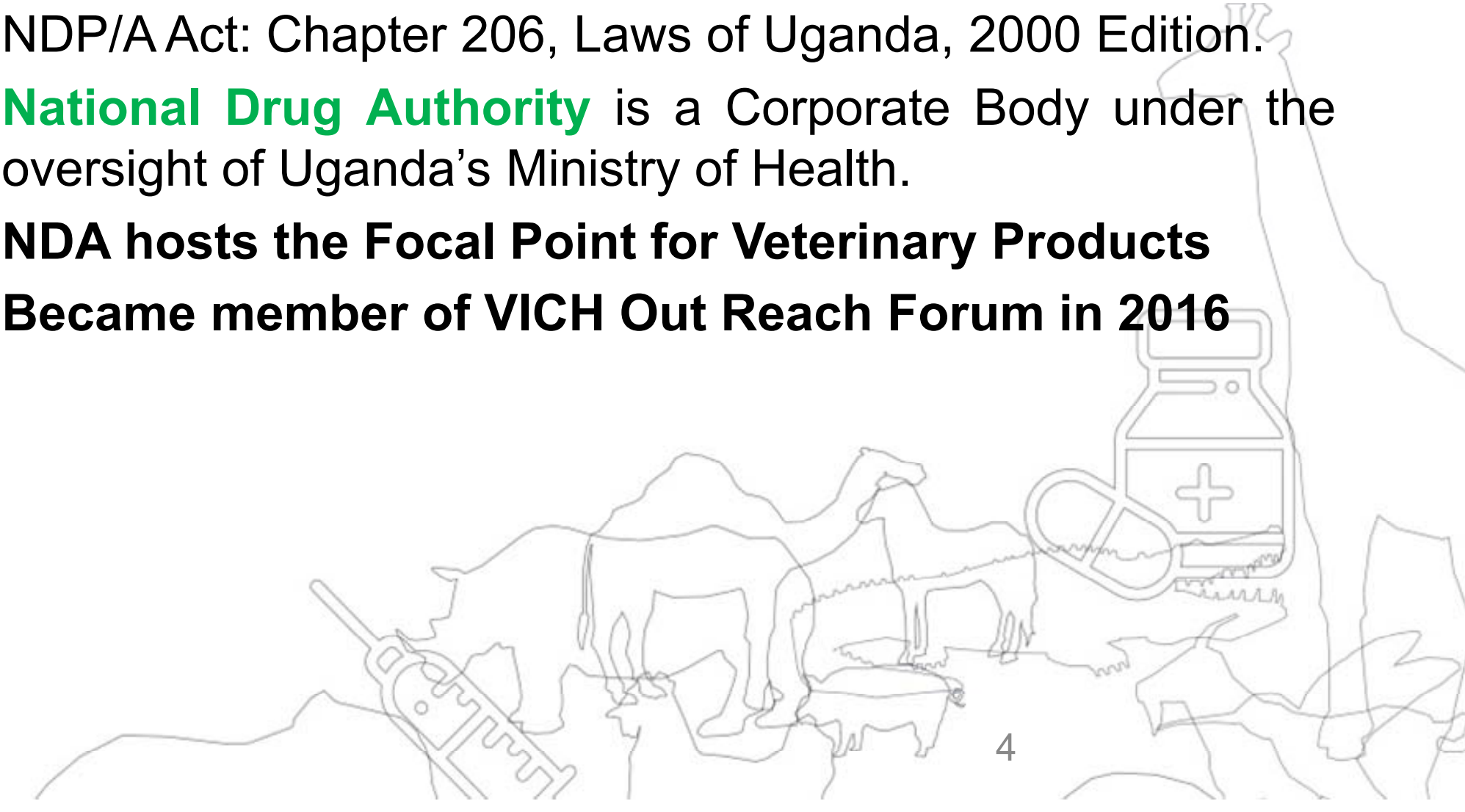
Animal population in Uganda (UBOS, 2017)

- Cattle: **14,368,000** (13,377,000 indigenous and 991,000 exotic)
- Poultry: **46,291,000** (40,597,000 indigenous and 5,694,000 exotic)
- Goats: **15,312,000** (15,521,000 indigenous and 204,000 exotic)
- Sheep: 4,037,000
- Pigs: 4,629,000



History and establishment of NDA

- National Drug Authority was established by a Statute of Parliament in 1993:
- NDP/A Act: Chapter 206, Laws of Uganda, 2000 Edition.
- **National Drug Authority** is a Corporate Body under the oversight of Uganda's Ministry of Health.
- **NDA hosts the Focal Point for Veterinary Products**
- **Became member of VICH Out Reach Forum in 2016**



Safe Drugs Save Lives

MANDATE

To ensure *availability*, at all times, of *essential*, *efficacious* and *cost-effective* drugs (human and animal) to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

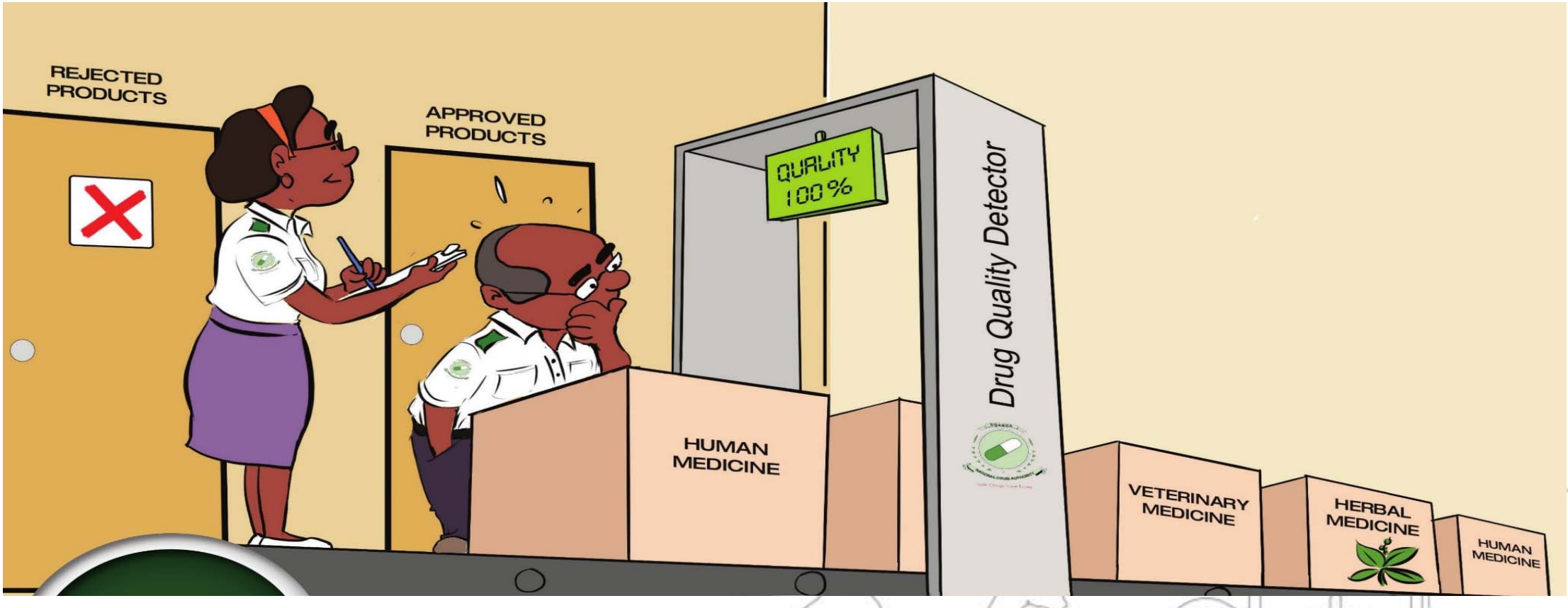
VISION:

A Uganda with safe, effective, quality medicines and healthcare products.

MISSION:

Promoting and protecting public health through the effective regulation of human, and animal medicines and healthcare products

NDA's regulatory scope

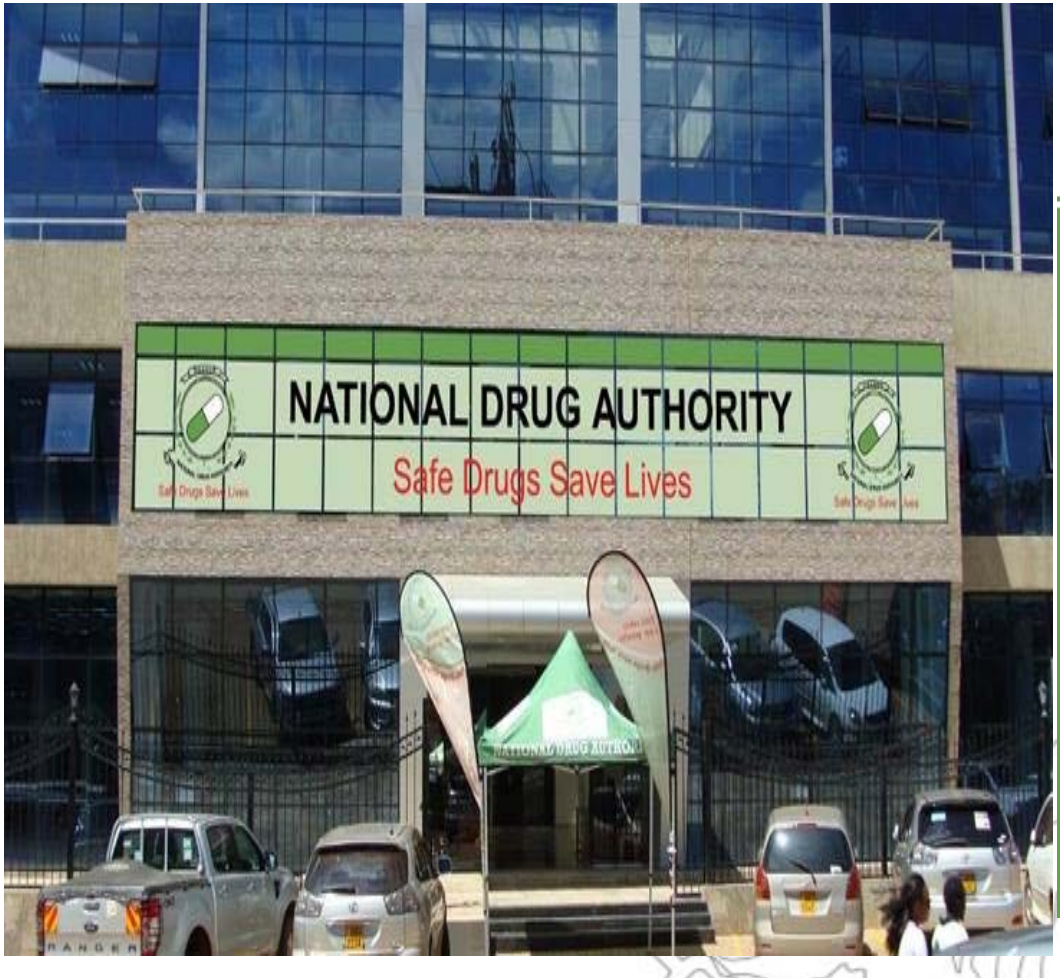


- ✓ Human drug products (conventional and herbal)
- ✓Veterinary drug products (conventional and herbal)

NDA offices across the country

Headquarter

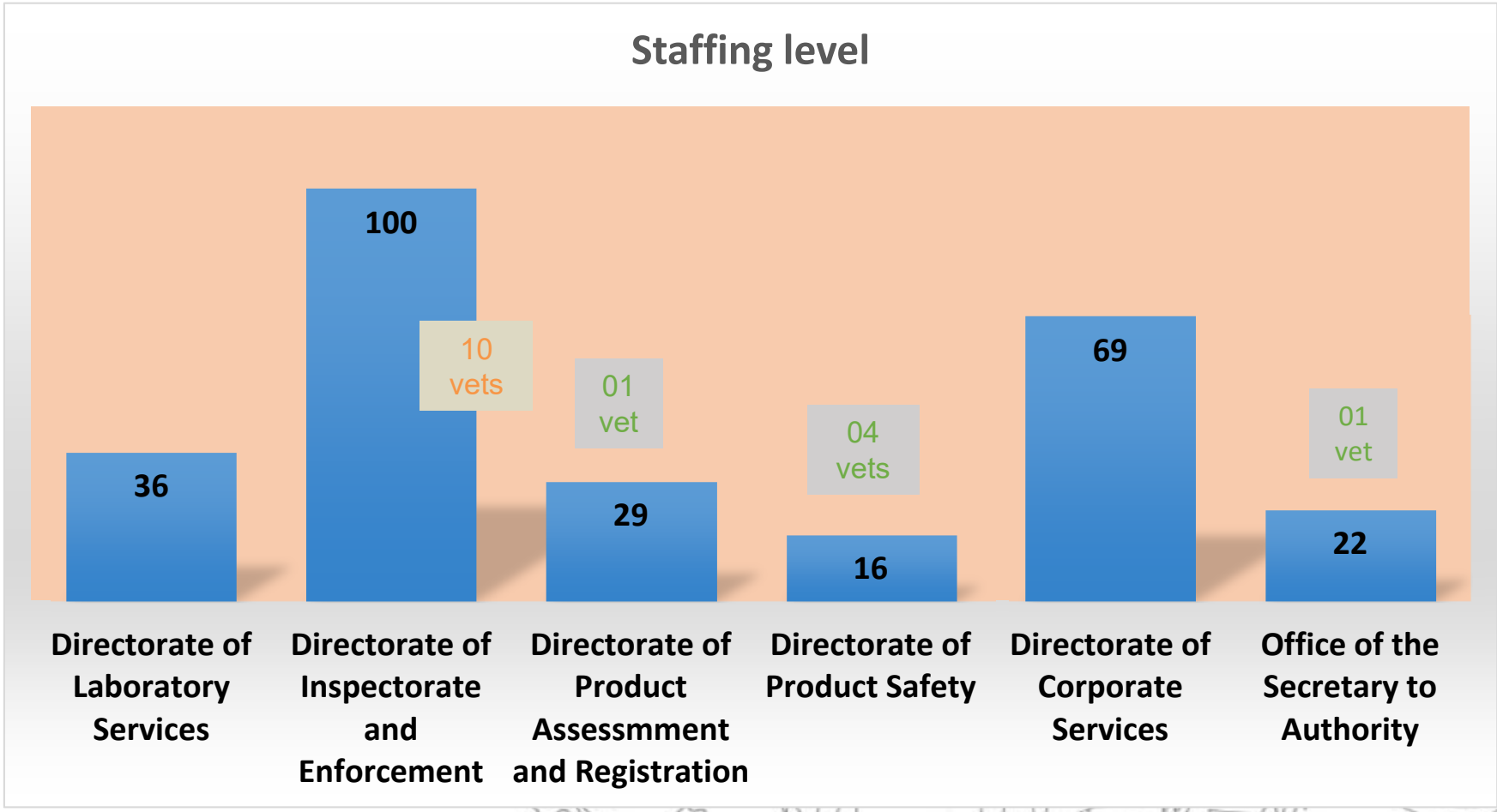
Plot 19, Lumumba Avenue-Kampala



7 regional offices

Staff establishment

Currently NDA has 272 employees distributed across the country of which 16 are veterinarians



Strategic goal and priority areas 2016-2021

"To transform NDA into a high performing regulatory agency that maximizes protection and promotion of public and animal health while delivering value to its clients"

Key strategic outcomes

Expected Outcomes	Actions Undertaken
Quality products	Quality control Testing of regulated products from; a) The Port of Entry, b) Pre-market and c) Post market surveillance.
Efficacious products	Assessment of dossier applications for Market authorizations, clinical trials and post marketing surveillance.
Safety of Products	Continuous monitoring of clinical trials, drug reaction - Paharmacovigilance, Post marketing surveillance, and monitoring and approval of promotional drug materials.
Availability of Products	Approval of drug manufacturing sites, drug registration, licensing of drug outlets and promoting local production.
Affordability of Products	Licensing of drug outlets across all parts of the country and drug registration.

• 24 VICH Guidelines have been adopted for Use in NDA regulatory processes

- Guidelines for MA of Veterinary Pharmaceutical Products :

VICH GL 18, 10, 39, 1, 2, 5, 3, 34, 31, 37, 23, 28, 27, 32, 33, 36, 6, 38 and 43

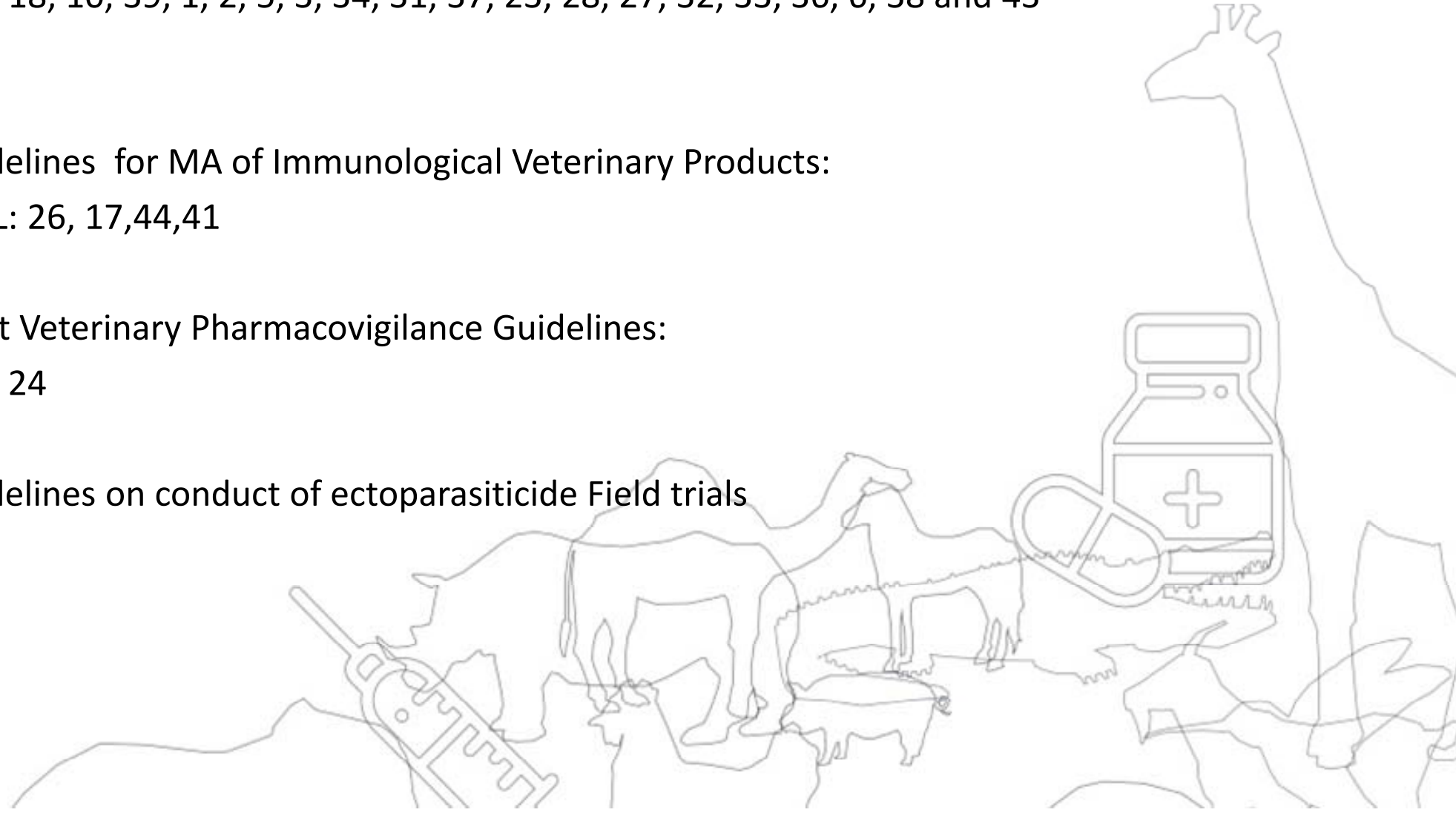
- Guidelines for MA of Immunological Veterinary Products:

VICH GL: 26, 17,44,41

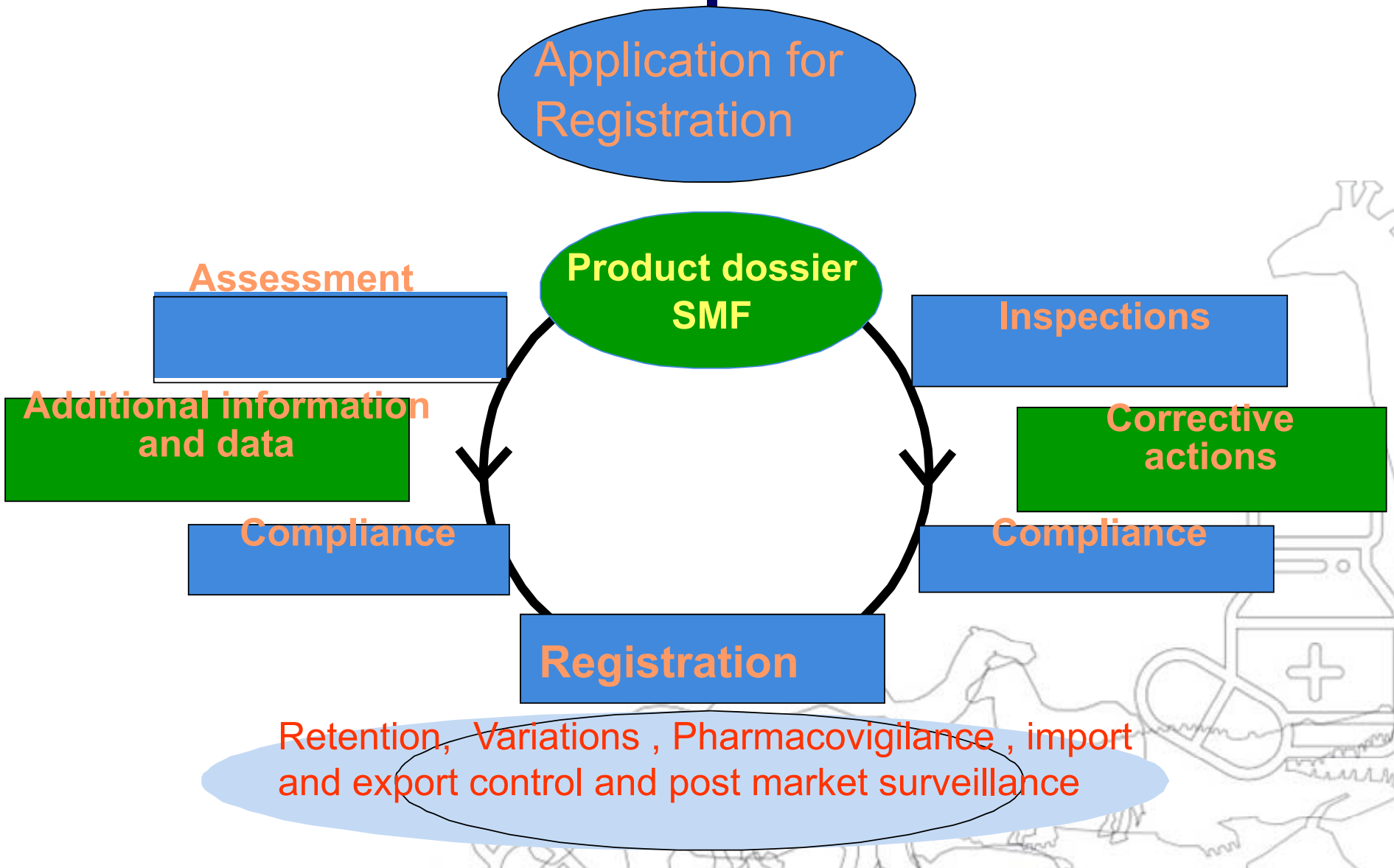
- Draft Veterinary Pharmacovigilance Guidelines:

VICH GL 24

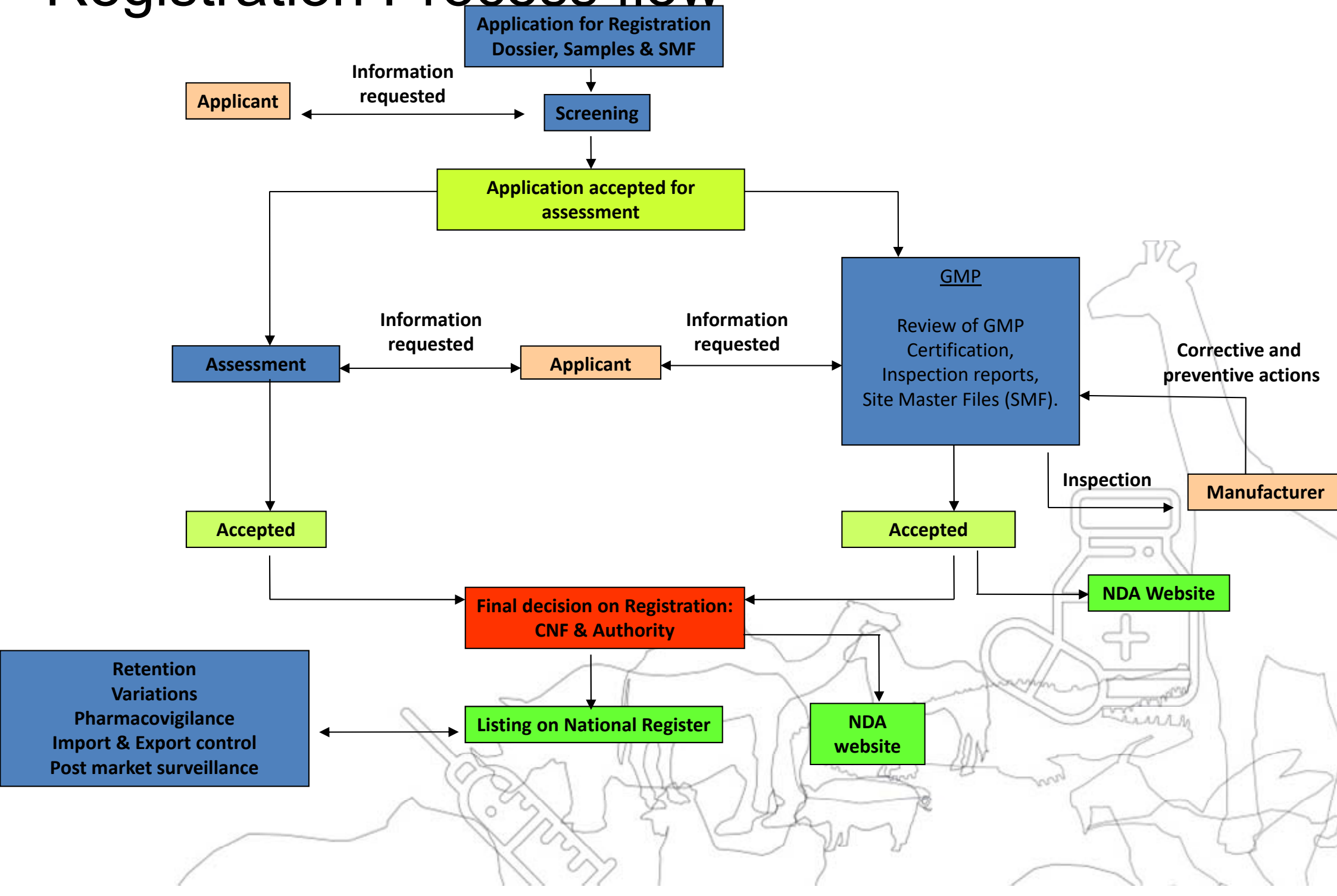
- Guidelines on conduct of ectoparasiticide Field trials



Steps in REGISTRATION



Registration Process flow



AUTHORITY REGULATORY PROCESSES

Registration & Market Authorisation

- **Legal Provisions are in place that define market authorisation & Registration.**
- **S.I. No. 29 of 2014**
- **Guidelines and SOPs exist**
- **Key outputs :**

❑ Registered: 4729

- Human: 4,045
- Veterinary: 476
- Human Herbal: 207
- Vet. Herbal: 1

Licensing Premises

- Legal provisions are in place.
- S.I. No. 36 of 2014
- Guidelines and SOPs exist

❑ Licensed premises:

- Vet Local manufacturers: 02
- Vet pharmacies: 79
- Vet drug shops: 1005

Imports and Exports inspections

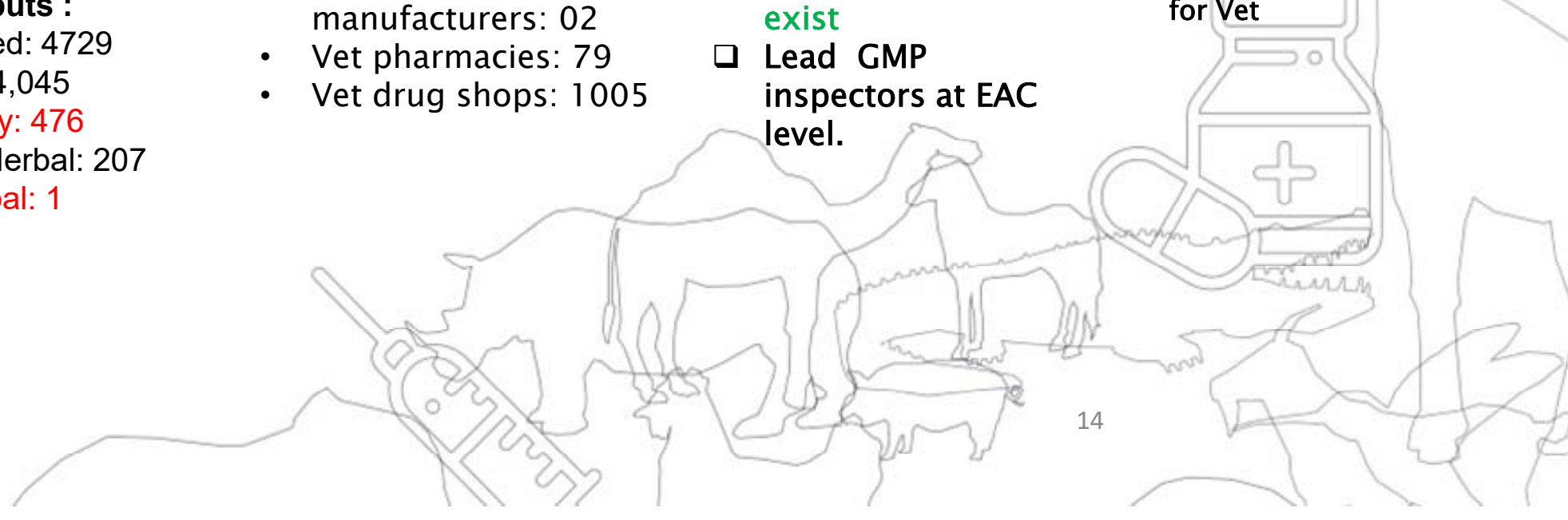
- Legal provisions, regulations &guidelines exist for inspection and enforcement.
- S.I. No. 34 of 2014
- Guidelines and SOPs exist

❑ Lead GMP inspectors at EAC level.

Laboratory Services

- Legal provisions
- The NDP/A Act, CAP 206.
- Guidelines and SOPs in place for laboratory access and testing.

❑ Mandatory testing of some drugs based on risk assessment eg acaricides for Vet



AUTHORITY REGULATORY PROCESSES CONT'D…

Pharmacovigilance

- Legal Provisions are in place that define pharmacovigilance.
- Statutory Instrument 2014, NO.37
- Draft Guidelines and strategies for Vigilance exist

Market Surveillance and Control

- Legal provisions, regulations for Market surveillance and control exist.
- SI 2014, NO.37
- Draft PMS strategy exist

Clinical/Field Trials

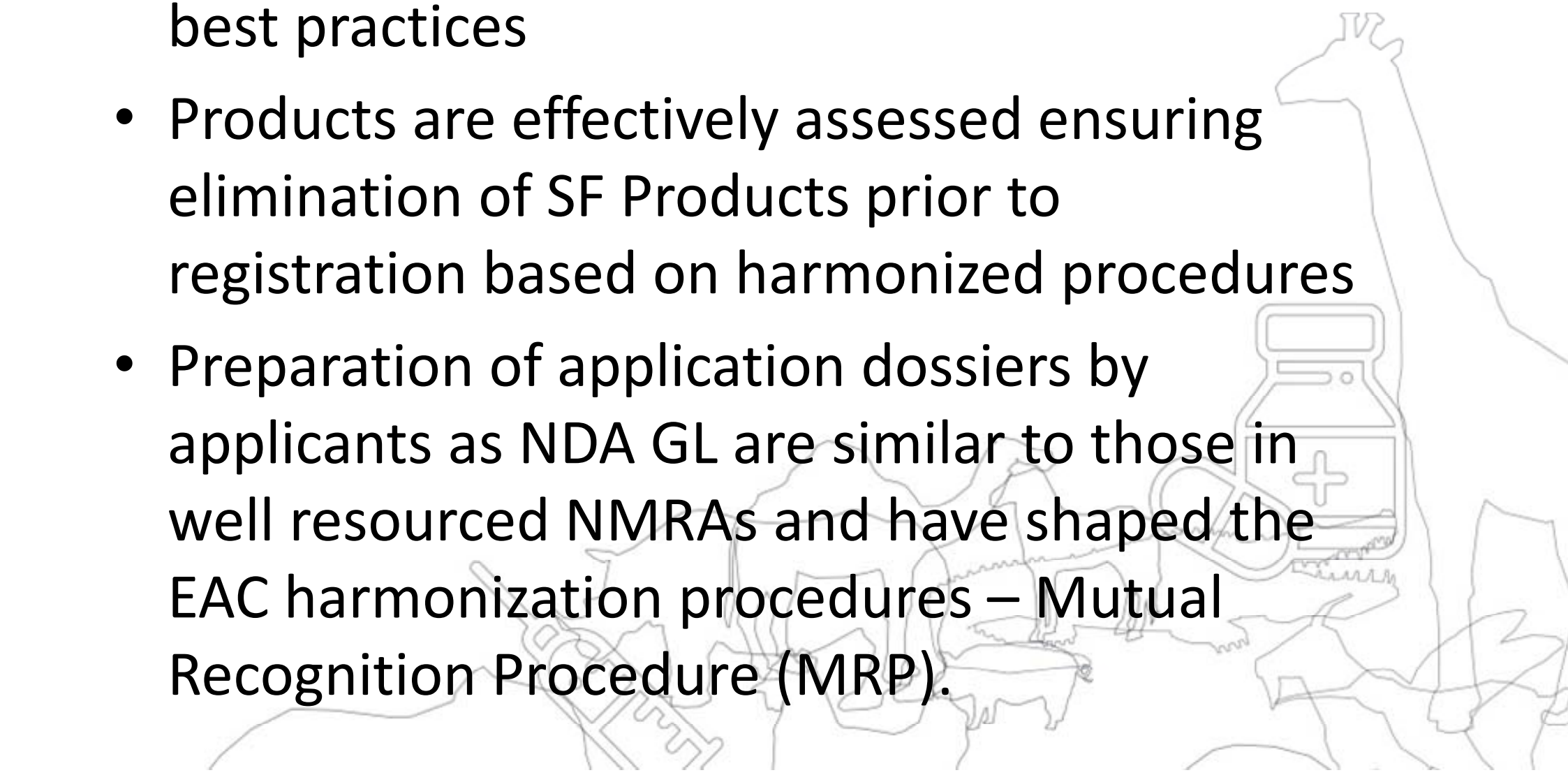
- Legal provisions, regulations for ectoparasiticides field trial exist.
- SI 2014, NO. 30
- Guidelines & SOPs exist for Ectoparasiticides field trials exist.

NDQCL ACCREDITATION

- World Health Organization (WHO) prequalified
- ISO 17025: 2005 accredited
- Collaboration with PANVAC for vaccine testing

VICH GL: BENEFITS

- NDA GL based on internationally accepted best practices
- Products are effectively assessed ensuring elimination of SF Products prior to registration based on harmonized procedures
- Preparation of application dossiers by applicants as NDA GL are similar to those in well resourced NMRAs and have shaped the EAC harmonization procedures – Mutual Recognition Procedure (MRP).



Regional Mutual Recognition Procedure (MRP) in the East Africa Community (EAC) Experience;

Member countries included; - Burundi, Kenya, Rwanda, Tanzania, Uganda and South Sudan

Back Ground

Workshop for African regulators organized by GALVmed was held in Cape Town in 2010. Requested for;

- ❑ Development of a harmonized registration system for immunologicals
- ❑ Training for their regulators in registration of veterinary vaccines
- ❑ Establishment of a system of Mutual Recognition

PROGRESS TOWARDS MRP

1. **Article 108** of the EAC Treaty forms the legal basis for harmonization of regulations for veterinary medicines registration within the EAC Partner States

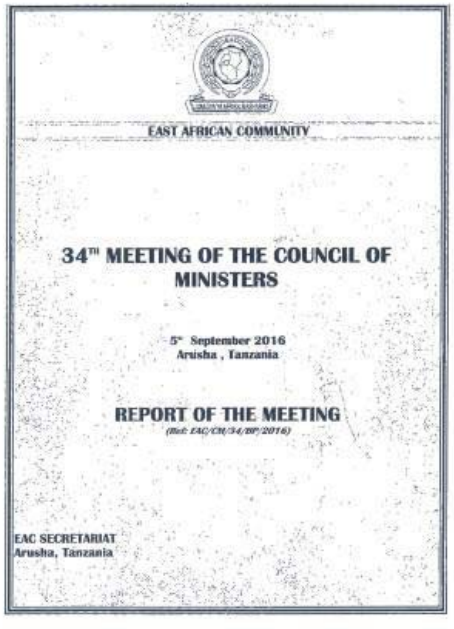
2 The Sectoral Council on Agriculture and Food Security **adopted the Concept of Mutual Recognition Procedures** on the 5th September, 2014, in Kigali, Rwanda

3. These **decisions were adopted by the EAC Council of Ministers** on the 28th of November, 2014 in Nairobi, Kenya resulting in a Decision Number: EAC/CM 30/Decision 34.

4. The 34th meeting of the Council of Ministers on 5th September 2016 Ministers **directed Partner States to implement the Mutual Recognition Procedure (MRP) for IVPs & develop harmonised GMP guidelines for conducting joint assessments**: EAC/CM 34/Decision 35

5. The 10th Meeting of the Sectoral Council on Agriculture and Food Security **directed the EAC Secretariat and Partner States to convene stakeholder sensitization meetings** on MRP in all Partner States and **directed the Secretariat to set up a coordination office and mobilize resources to finance MRP activities**

Progress towards MRP …. Contd



EAST AFRICAN COMMUNITY

34TH MEETING OF THE COUNCIL OF MINISTERS

5th September 2016
Arusha , Tanzania

REPORT OF THE MEETING

EAC SECRETARIAT
Arusha, Tanzania

EAC letter to Partner States, 17th February 2017:
"At the 34th meeting of the Council of Ministers on 5th September 2016, Ministers directed Partner States to implement the Mutual Recognition Procedure (MRP) for IVPs (EAC/CM34/Decision 35). EAC calls upon all heads to the medicines regulatory agencies to make arrangements to initiate MRPs upon request by applicants."

ATPS Report 2017:
"The MRP is legally binding on Partner States as anchored in the Council of Ministers' decision with reference to the functions and the effects of the Council of Ministers' decision as spelt out in *Chapter 5* of the EAC Treaty."

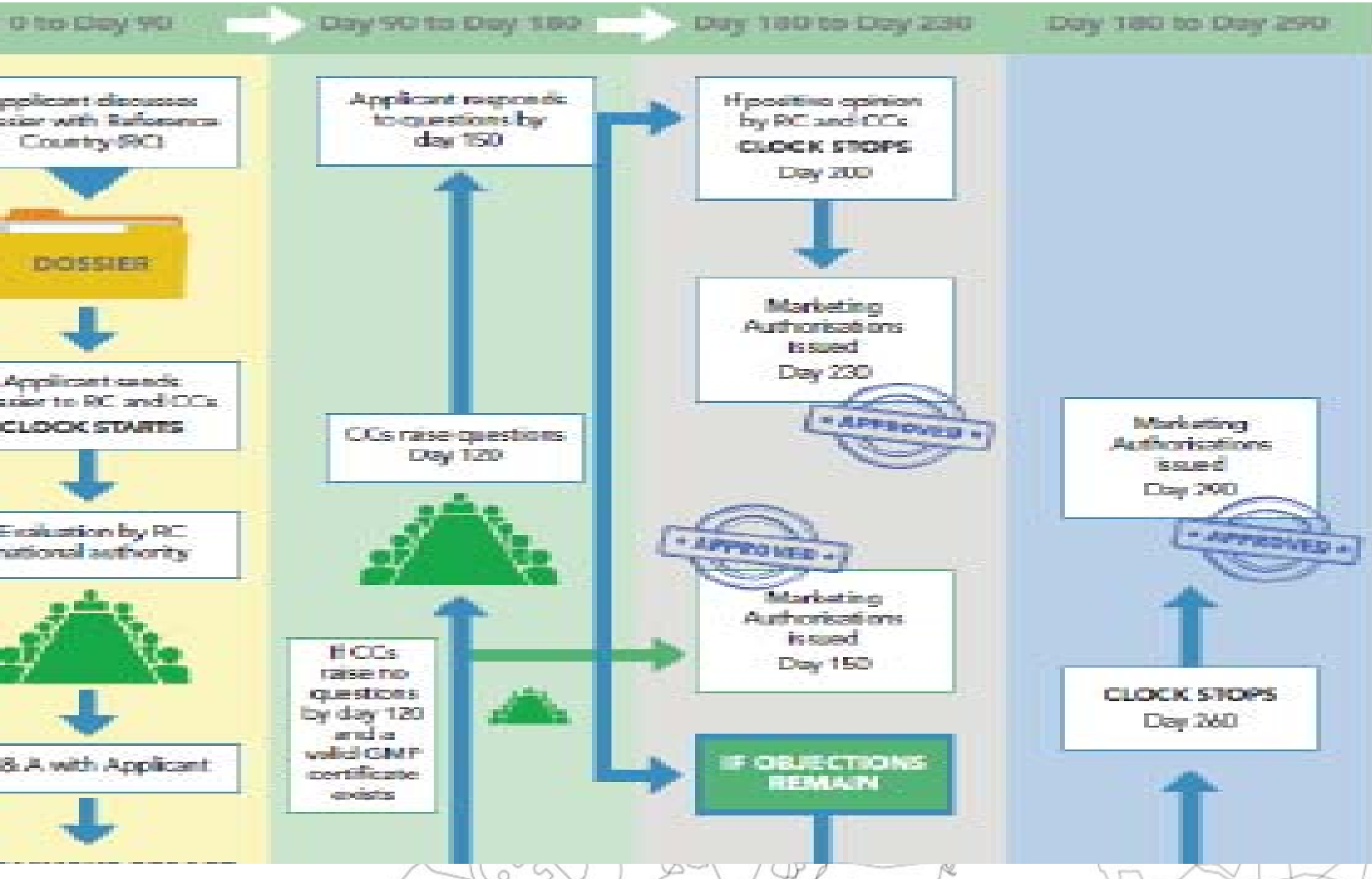
Progress towards MRP …. Contd

- **EAC Countries with their National Regulatory Authorities;**

Burundi - Ministry of Health
Kenya – Pharmacy and Poisons Board (PPB) and later Veterinary Medicines Directorate(VMD
Rwanda - RAB
Tanzania – Tanzania Food and Drug Authority (TFDA)
Uganda – National Drug Authority (NDA)
S. Sudan - Ministry of Health

- **The system is now open for business**

- 1st MRP application was completed in June 2018 and **to date 3 immunological products have been registered under the MRP.**
- EAC MRP Coordinator office is being established
- Plans to expand MRP to cover pharmaceuticals are underway- Draft guidelines are ready
- There are Interests by other Regional Economic Blocks (Res) – SADC & ECCAS/CEMAC


0 to Day 90
Day 90 to Day 180
Day 180 to Day 230
Day 180 to Day 290
Country RC)
DOSSIER
CLOCK STARTS
Evaluation by RC
national authority
Q & A with Applicant
Applicant responds to questions by day 150
CCs raise questions Day 120
If CCs raise no questions by day 120 and a valid CMP certificate exists
If positive opinion by RC and CCs
CLOCK STOPS
Day 200
Marketing Authorisations issued
Day 230
APPROVED
Marketing Authorisations issued
Day 150
IF OBJECTIONS REMAIN
Marketing Authorisations issued
Day 290
APPROVED
CLOCK STOPS
Day 260

Uganda is a member of the East African Community (EAC) Harmonization - MRP initiative & has realized the following Benefits:

- Improved operational efficiencies : **after regulatory gap analysis, Secure electronic platform for sharing of reports/comments**
- Potentially faster and more consistent review and approval process.
- Regulatory convergence, promotion of regulatory science and the strengthening of RAs through Staff exchange, workshops and training .
- Greater regulatory oversight and peer review.
- Reduction in overall regulatory burden and less duplication of effort e.g. No parallel registrations.
- Lower regulatory and product development costs/times thus reduced price of IVP
- Greater alignment of industry submission practices
- Mutual learning and consistency in applying international guidelines such as VICH, EU, OIE and WHO

CURRENT CHALLENGES IN VETERINARY DRUGS REGULATION IN UGANDA

- Legislative gaps:

❖ No legal categorization of the classification & distribution of veterinary drugs in the drug schedules – Drug schedules are under review in the NDPA Act

❖ No statutory instrument on the establishment and oversight of a residue surveillance system – NFDA Bill is covering this area

- Gaps in the institutional governance/organization structure that implement VICH guidelines

- Weak linkages with veterinary stakeholders particularly other government agencies in implementing VICH guidelines

OPPORTUNITIES IN VETERINARY DRUGS REGULATIONS

- The NFDA Bill
- The Veterinary Practitioners' Bill
- Formation of veterinary medicines desk at MAAIF
- The drugs schedules are currently under review
- Commitment by the NDA Board and Management to improve veterinary drugs regulation

Transition from NDA to NFDA

NDA's regulatory scope:

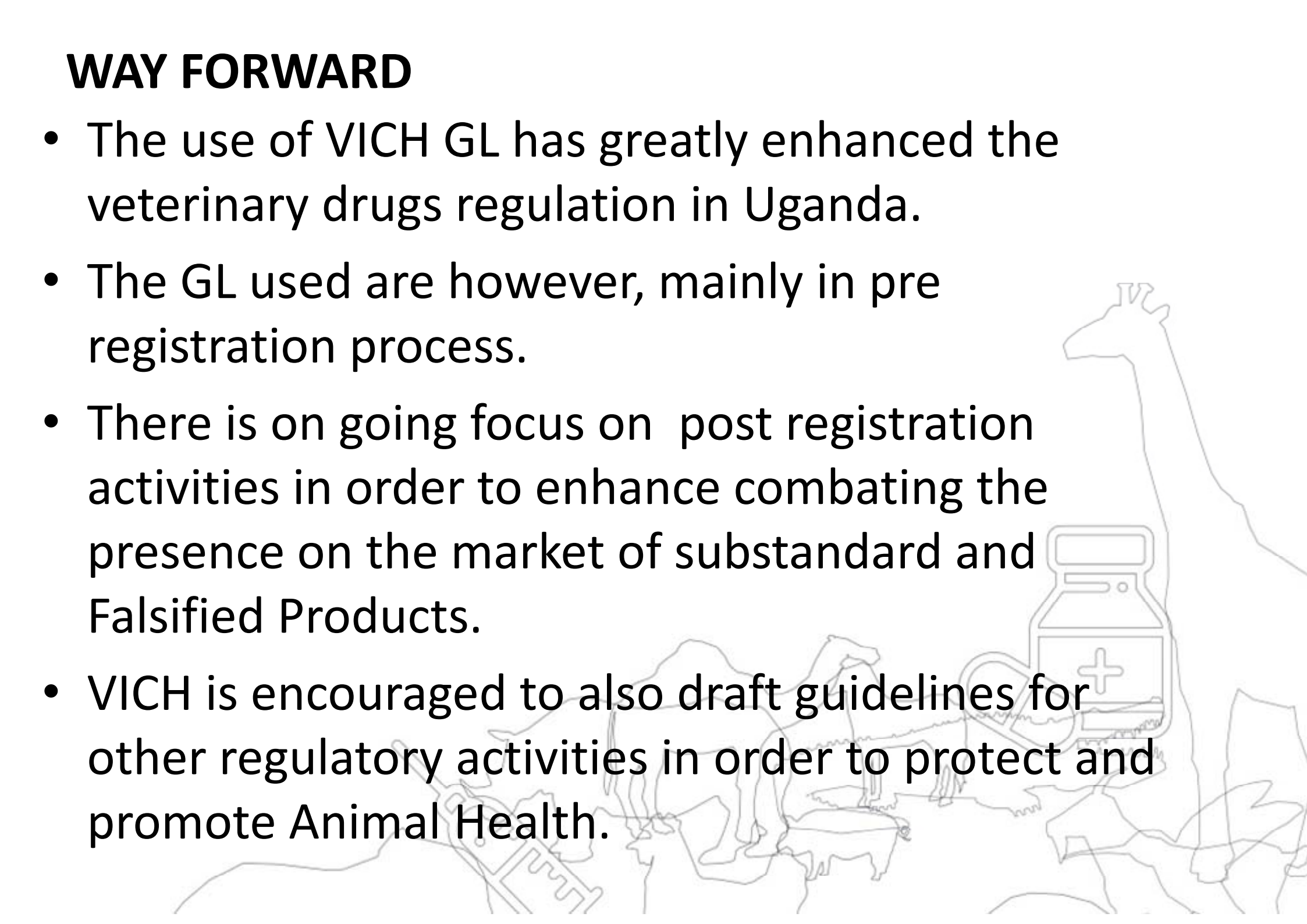
- Human and Veterinary drugs

NDFA's regulatory scope to include:

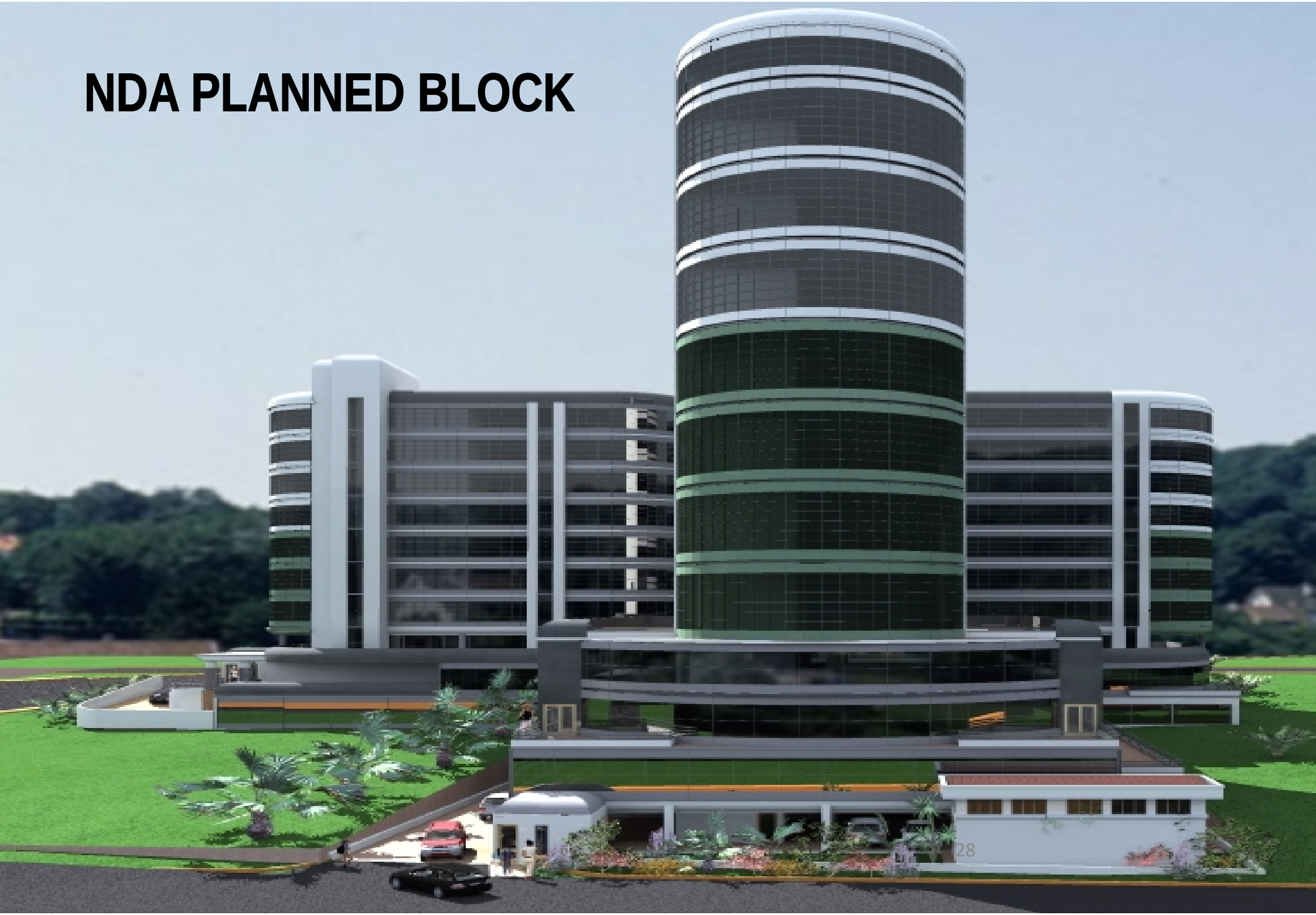
- Human and Veterinary drugs
- Food
- Cosmetics
- Medical/Veterinary devices
- Public health chemicals

WAY FORWARD

- The use of VICH GL has greatly enhanced the veterinary drugs regulation in Uganda.
- The GL used are however, mainly in pre registration process.
- There is on going focus on post registration activities in order to enhance combating the presence on the market of substandard and Falsified Products.
- VICH is encouraged to also draft guidelines for other regulatory activities in order to protect and promote Animal Health.



NDA PLANNED BLOCK



End

But did you know

#1Uganda is crossed by the Equator

#2: The charm of the Rwenzori- crossed by the equator, hot all

#3: Uganda is home to the world's largest food varieties

#4: The worldwide population of mountain gorillas is just about 1000, but Uganda owns over three quarters of this number!

#5: Uganda is home to the species of climbing lions!

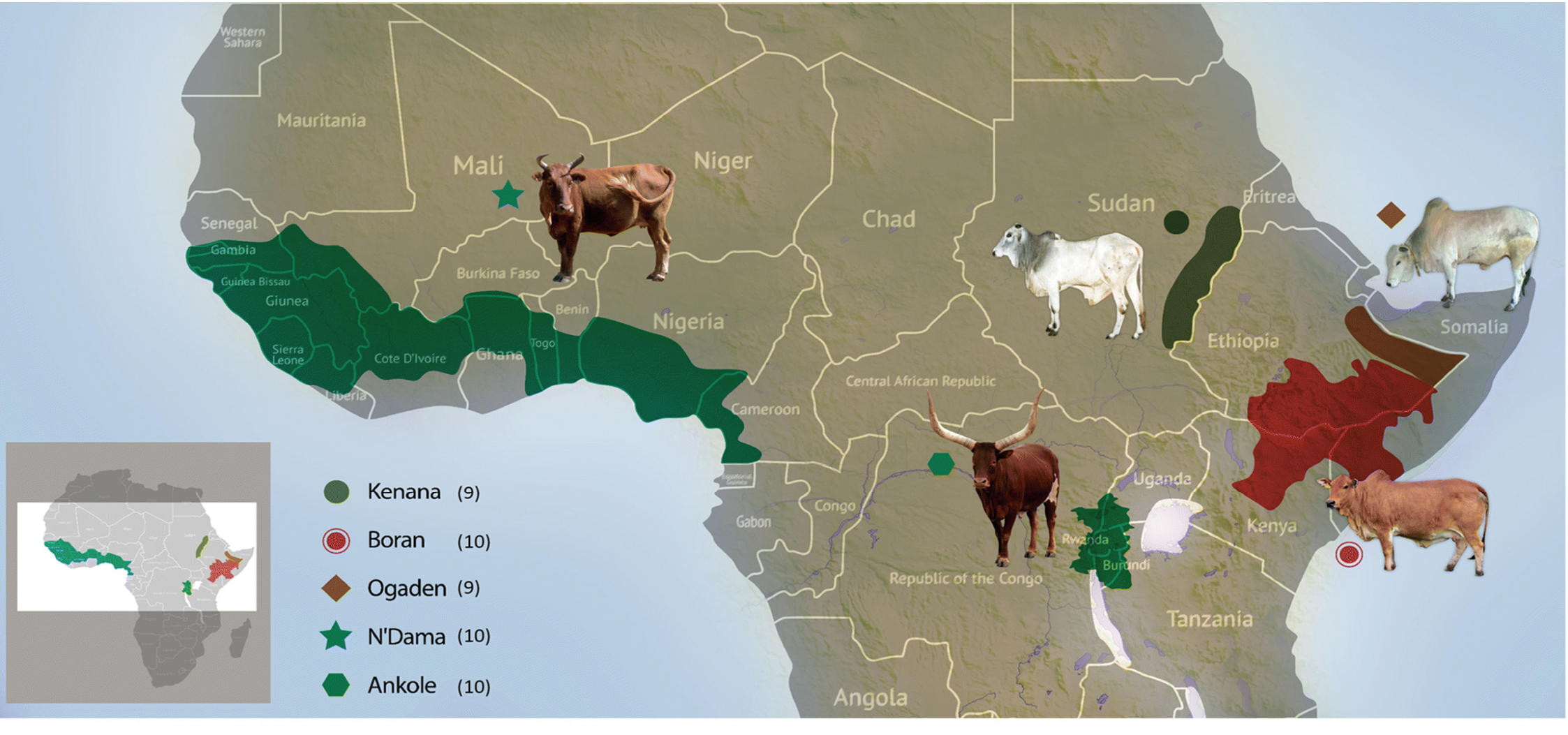
#6: Uganda is home to the 3rd largest lake in the world- Lake

#7: Uganda is home to the longest river in the World- The Nile!

#8 The Crested Crane is the official bird of Uganda

- The three colors of Uganda; **black, yellow and red** are contained in its plumage.
- It is friendly, gentle and a peace loving bird, x-tics which are true of Ugandan people.
- It is a crime punishable by imprisonment to kill a Crested Crane.

#10 Uganda is home to the Ankole Long Horn Cattle



The Ankole Long Horn Cattle

Thank You For Your Attention!