



Benefits of Mutual Recognition Procedure (MRP) in East African Community (EAC) for regulators – Ugandan experience

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Scope of presentation

- Introduction
- Marketing Authorization
- MRP
- Benefits of MRP
- Role of International bodies





**Map of Africa
showing the location
of Uganda**



Livestock Population(2008 Cens.)

Species	Number (millions)
Cattle	11.4
Goats	12.4
Sheep	3.4
Pigs	3.2
Chickens	37.4
Ducks	1.5
Turkeys	0.3



Long horned Ankole Cattle





Introduction

- NDA was established in 1993
- The National Drug Authority And Policy Act(NDPA), Cap. 206, Laws of Uganda is the enabling law
- Governed by an Authority(Board of Directors) appointed by the Minister of Health
- Secretariat headed by the Executive Director carries out all activities





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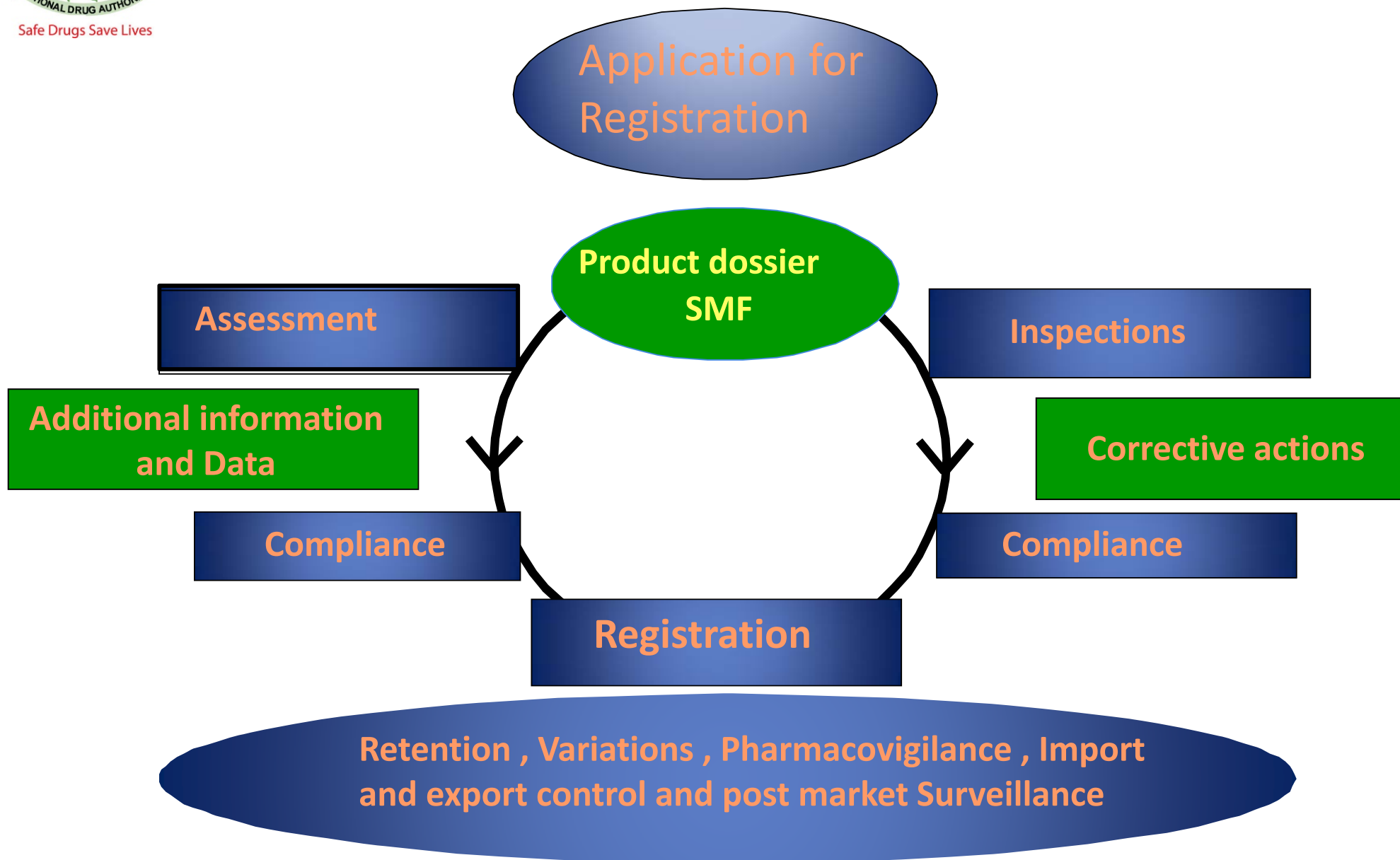
Introduction

Major Business Processes:

- Inspectorate & Enforcement
- Drug Assessment & Registration
- Pharmacovigilance
- Quality Control
- Support functions- Legal ,PR, Finance, IT, Procurement etc

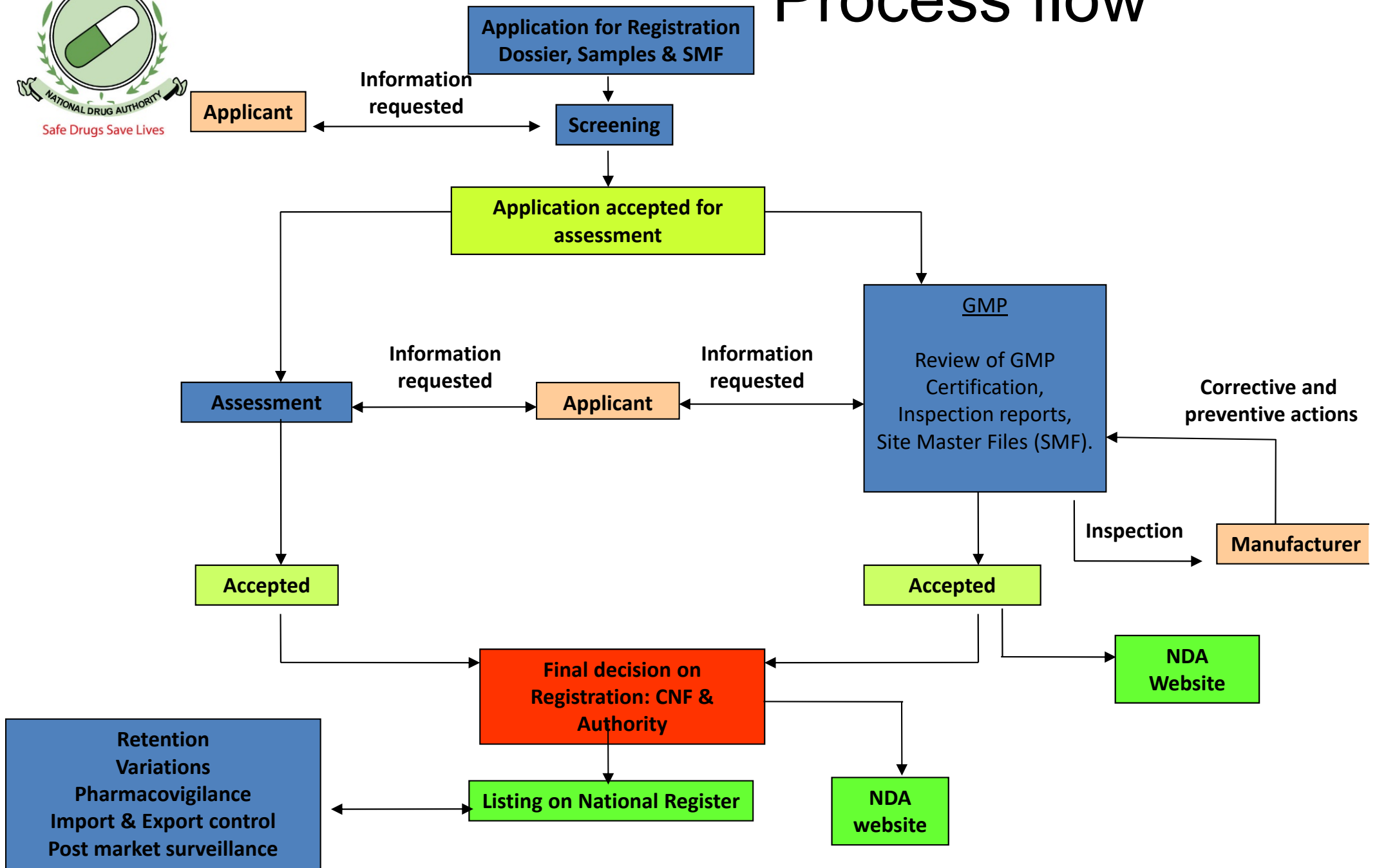


MARKETING AUTHORIZATION





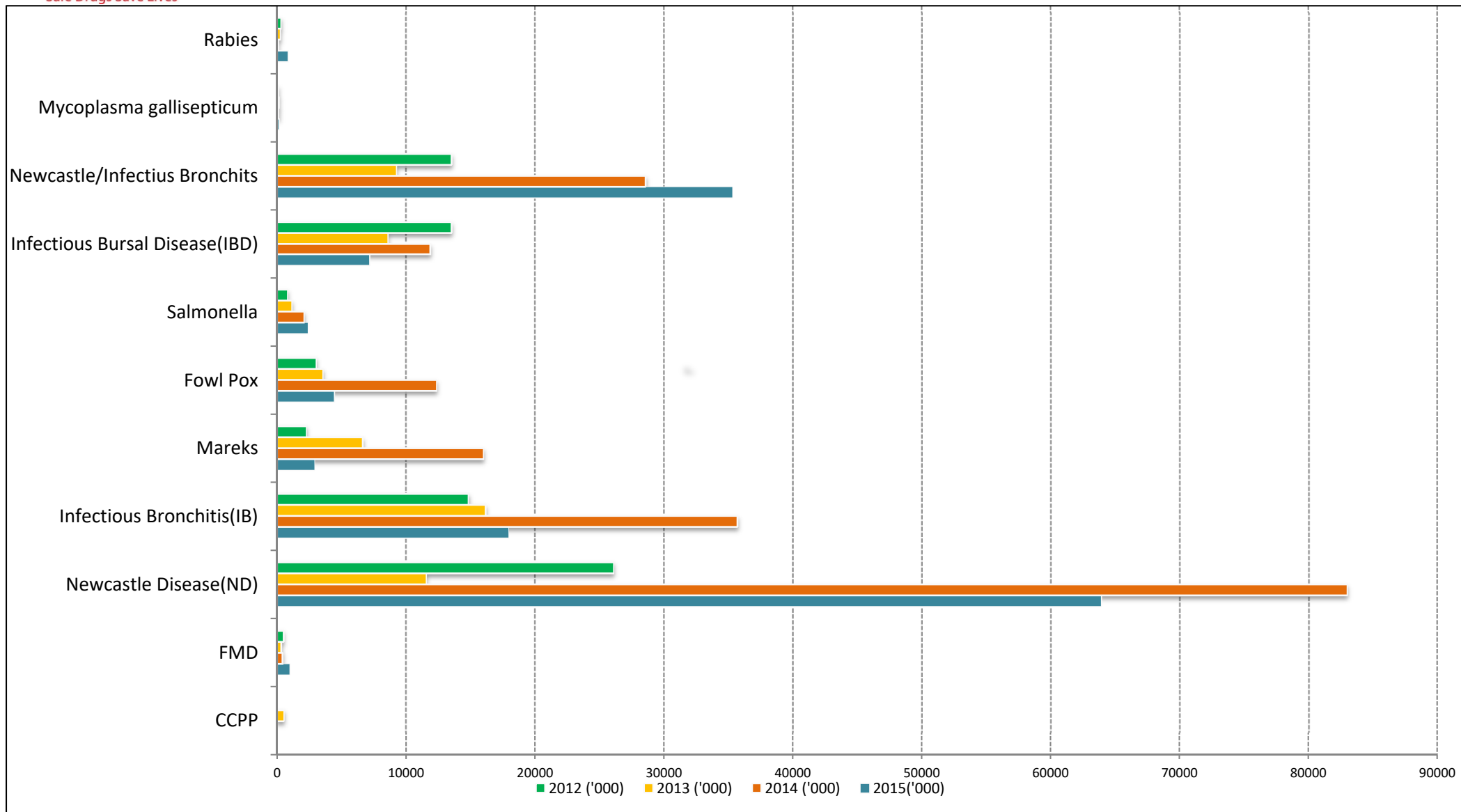
Process flow





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Vaccine Imports(Million Doses)





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MRP

- Initiated at the OIE/GALVmed workshop held in South Africa, 2010
- Formation of EAC TWG, 10 meetings held so far
- Formation of CGMR
- Various training sessions in dossier evaluation and GMP inspection
- Drafting of working documents to effect MRP

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MRP

Legal Mandate

- ❑ The EAC Sectoral Council of Ministers adopted the Concept of MRP and the TORs of the TWG and the CGMR in Kigali, Rwanda in, 2014,
- ❑ This was 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.



MRP

Progress in Uganda

- Domesticated the EAC Technical Documents
- Received nearly 100 applications, 16 IVPS registered
- Sensitization seminars scheduled for May 2017
- NDA ready for MRP





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Benefits of MRP

- **Reduced timelines**
- **Since applicants prefer stringent NRAs, this will promote excellence**
- **Improved collaboration between NRAs**
- **More applications expected due to improved transparency**

Reduced regulatory costs → **Reduced cost of the IVP**



Obstacles to MR

- Regulatory capacity among the different NRAs is not uniform
- Language barrier- English Vs. French
- Different regulatory framework: Ministries Vs. DRAs
- Political Obstacles- National Pride/Sovereignty





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Role of International Bodies

OIE

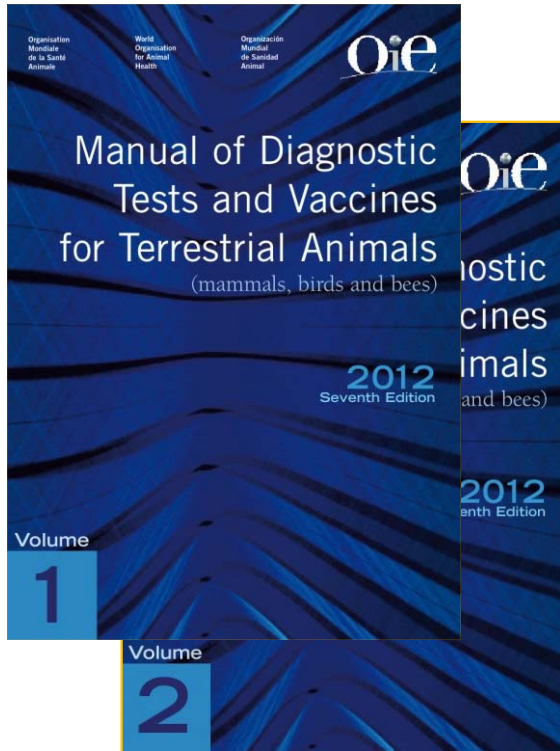
VICH

AU PANVAC



NATIONAL DRUG AUTHORITY-UGANDA

OIE Terrestrial Manual



Requirements for the production and control of vaccines and other biological products

Available in full and up to date on line at:

<http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/>



VICH

- NDA became a member of the VICH Outreach Forum in 2016
- Participate in the Outreach Forum meetings
- Propose new priority topics for elaboration
- Provide feedback on the relevance of and on the implementation of VICH guidelines in your country and region



VICH

- Where relevant, participate in VICH Expert Working Groups
- Submit comments to draft guidelines during the public consultation phase (step 4 of the VICH process)
- Make suggestions for discussion at the VICH Outreach Forum meetings
- Provide feedback on the usefulness of the VICH Outreach Forum and the VICH webpages

VICH GLs very useful during Pre market Assessment of application dossiers

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AU PANVAC

- NDA implementing directive of AU Ministers' Directive on mandatory testing of all Vaccine consignments prior to use
- AU PANVAC also instrumental in training of NDA staff





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THANK YOU



NDA ready for MRP



NATIONAL DRUG AUTHORITY-UGANDA