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

- Introduction
- Marketing Authorization
- MRP
- Benefits of MRP
- Role of International bodies
- GALVmed/OIE SADC meeting update
Map of Africa showing the location of Uganda
### Livestock Population (2008 Cens.)

<table>
<thead>
<tr>
<th>Species</th>
<th>Number (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>11.4</td>
</tr>
<tr>
<td>Goats</td>
<td>12.4</td>
</tr>
<tr>
<td>Sheep</td>
<td>3.4</td>
</tr>
<tr>
<td>Pigs</td>
<td>3.2</td>
</tr>
<tr>
<td>Chickens</td>
<td>37.4</td>
</tr>
<tr>
<td>Ducks</td>
<td>1.5</td>
</tr>
<tr>
<td>Turkeys</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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
Introduction

Major Business Processes:
- Inspectorate & Enforcement
- Drug Assessment & Registration
- Pharmacovigilance
- Quality Control
- Support functions- Legal, PR, Finance, IT, Procurement etc.
MARKETING AUTHORIZATION

Application for Registration

Product dossier SMF

Assessment

Additional information and Data

Compliance

Inspections

Corrective actions

Compliance

Registration

Retention, Variations, Pharmacovigilance, Import and export control and post market Surveillance

NATIONAL DRUG AUTHORITY-UGANDA
Process flow

Application for Registration Dossier, Samples & SMF

Screening

Application accepted for assessment

GMP
Review of GMP Certification, Inspection reports, Site Master Files (SMF).

Corrective and preventive actions

Inspection

Manufacturer

Accepted

Final decision on Registration: CNF & Authority

Retention
Variations
Pharmacovigilance
Import & Export control
Post market surveillance

Listing on National Register

NDA website

NDA Website

国家战略

国家药物管理局-乌干达
Vaccine Imports (Million Doses)

- Rabies
- Mycoplasma gallisepticum
- Newcastle/Infectious Bronchitis
- Infectious Bursal Disease (IBD)
- Salmonella
- Fowl Pox
- Mareks
- Infectious Bronchitis (IB)
- Newcastle Disease (ND)
- FMD
- CCPP
- 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
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 35.
MRP

Progress in Uganda

- Domesticated the EAC Technical Documents
- Received nearly 100 applications, 16 IVPS registered
- Sensitization seminars scheduled for June 2017
- NDA ready for MRP
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 $\rightleftharpoons$ Reduced cost of the IVP
Obstacles to MR

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

- OIE
- VICH
- AU PANVAC
OIE Terrestrial Manual

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

Available in full and up to date online 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
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
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
SADC Meeting

• Held May 9-11 2017 in Johannesburg, RSA
• Participants included Regulators, DVS, Industry reps, International bodies
• Meeting considered establishing MRP for VMP in SADC
• A harmonized system appreciated as it simplifies regulatory workload, increases predictability, enhances compliance and encourages access to small markets.
SADC Meeting

• Willingness to harmonize- different but disjointed initiatives ongoing in the region
• Lack of a champion to offer leadership
• Challenges observed include outdated Technical Documents, lack of consistency in interpretation of requirements, lack of a common labeling language and GMP compliance
SADC Meeting- Recommendations

• SADC to establish a Technical Working Group (TWG) to drive the harmonization process
• The TWG to draft a common set of Technical Documents by 2018
• SADC TWG to collaborate with the EAC TWG
• Stakeholder Sensitization to generate political will and acceptance of the process.
• Implementation of the MRP to start by 2020
THANK YOU