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 Census)

<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](image-url)
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
Process flow

Application for Registration Dossier, Samples & SMF

Screening

Application accepted for assessment

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

Information requested

Assessment

Information requested

Accepted

Corrective and preventive actions

Manufacturer

Accepted

Final decision on Registration: CNF & Authority

Listing on National Register

Retention
Variations
Pharmacovigilance
Import & Export control
Post market surveillance

NDA Website

NDA website

NATIONAL DRUG AUTHORITY-UGANDA
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

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
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
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
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
• 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
THANK YOU

NDA ready for MRP