Vaccine Deployment in the Field: The Uganda Experience

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Uganda National Drug Authority
Scope of the presentation

- Introduction
- Marketing Authorisation (MA)
- Post Registration Activities
- VICH Guidelines in use
- Way Forward
Map of Africa showing the location of Uganda
Uganda’s Livestock Population

<table>
<thead>
<tr>
<th>Species</th>
<th>Number (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>14.2</td>
</tr>
<tr>
<td>Goats</td>
<td>16.0</td>
</tr>
<tr>
<td>Sheep</td>
<td>4.4</td>
</tr>
<tr>
<td>Pigs</td>
<td>4.1</td>
</tr>
<tr>
<td>Poultry</td>
<td>47.6</td>
</tr>
</tbody>
</table>

Source: UBOS, MAAIF (2017)
National Drug Authority (NDA) regulates veterinary medicinal products in addition to human medicines.

The NDP Act governs the operations, a number of statutory instruments are also in force including The National Drug Policy And Authority (Registration) Regulations, 2014 No 29 that provides:

- All products shall be registered in Uganda before sale or distribution.
- A person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product (Marketing Authorisation).

Other regulatory functions carried out include regulation of Clinical Trials, Vigilance, Inspection of Premises and GMP Market Surveillance and Control and Laboratory Testing.
Marketing Authorisation

> National Procedure

> East African Community Harmonised Procedure

> Authorisation of vaccines use in special circumstances (Section 8/4 of the NDP Act)
All applications received at the National level; the process service delivery timeline is 120 days for vaccines, overwhelming majority of applications are handled through the National Procedure. The details of the procedure are provided below.
Steps in REGISTRATION

Application for Registration

Product dossier SMF

Assessment

Additional information and data

Compliance

Registrations

Inspections

Corrective actions

Compliance

Retention, Variations, Pharmacovigilance, import and export control and post market surveillance

NATIONAL DRUG AUTHORITY - UGANDA
Mutual Recognition Procedure in the EAC (Burundi, Kenya, Rwanda, Tanzania, Uganda and lately South Sudan). Started in 2017 following the drafting of common technical registration requirements.
Post Registration Activities

- Inspection of Premises
- Import Control
- Vigilance
- Market Surveillance and Control
- Laboratory Testing
VICH Guidelines in Use

> Guidelines for MA of Veterinary Pharmaceutical Products:
VICH GL 18, 10, 39, 1, 2, 5, 3, 34, 31, 37, 23, 28, 27, 332, 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
Way Forward

> The use of VICH GL has greatly enhanced the MA of vaccines in Uganda
> The GL however are mainly in pre registration activities
> 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 these activities in order to protect and promote Animal Health.
Acknowledgements

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