6th VICH Conference
UNLOCKING AFRICA’S POTENTIAL
26 - 28 February 2019, Capetown

Animal Health Product
availability and accessibility

Guillaume Agède – Ceva santé Animale
“The level of Transparency, Predictability and Efficiency of relevant regulatory systems is critical to private sectors decisions to supply a market with VMP, and thus can affect the availability of effective and safe VMPs in the market.”
Transparency

- Format of the dossier
  - EU: Notice to Applicants
  - CTD, Other format, Application form

- Type of studies
  - Specific studies for AM
  - Specific studies for Antiparasitics

- GL acceptances
  - VICH studies
  - Non VICH Studies
  - GCP/non GCP studies
Transparency

- **GL Acceptances : Stability**
  - VICH GL3
    Stability Testing of New Veterinary Drug Substances and Medicinal Products
  - VICH GL4
    Requirements for New Dosage Forms
  - VICH45
    Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products

- **VICH GL4**
  Requirements for New Dosage Forms
  - Difficulties for multiple API suppliers

- **VICH45**
  Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
  - Difficulties for specific packaging for specific market
Predictability

Timeline of registration
Predictability

<table>
<thead>
<tr>
<th>Region</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Africa</td>
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<td></td>
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<td>24 months</td>
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<tr>
<td>Middle East</td>
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<tr>
<td>UEMOA</td>
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<td>24 months – Act 36</td>
<td></td>
<td>48 months – Act 101</td>
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<td>Asia</td>
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<td>FSC</td>
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<td>Eastern Europe</td>
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<td>18 months</td>
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<td>Latin America</td>
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<td>12 to 24 months</td>
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<td>36 months</td>
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<td>Colombia</td>
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<td>12 months for Innovation</td>
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</tbody>
</table>

92 countries

6
Predictability

Life is not so simple

Variation

Strategic change

– New products

Administrative Burden

Unclear rules

Small markets

Companion animals

New Competitors

Multiple Projects

FSC

FSC

FSC

FSC

12 to 24 month

12 month

18 month

18 month

12 month

36 month

36 month

24 month

24 month

48 month

48 month

30 month

30 month

24 month

24 month

15 month

15 month

1 Year

3 Year

4 Year

Year

Africa

Middle East

UEMOA

Asia

Eastern Europe

Latin America

– Act

101

Health for Animals
global animal medicines association
Predictability

5 to 10 years
Efficiency

Time for registration = Time to market
- Fast track system in BR for innovation
- Fixed Time line in EU - Centralised Procedure, MRP/DCP
  - Support Innovation

Access to larger market in one registration process
- UEMOA – 8 Unified countries
- EAC – Tanzania, Kenia, Uganda, Burundi, Rwanda
- EU – 28 member states
- CAMEVET : Tomorrow ?
  - Better ROI, save resources

Market protection
- Only legally authorized or imported products
- Avoid black market, counterfeit
- Non controlled quality products,
  - Animal Health & Welfare
Efficiency

Submission process

From Paper time

To electronic submission

1. DUNS number
2. Digital certificate
3. Prepare electronic submission
4. Set up the computer
5. Letter of Non-repudiation
Submission process

Tomorrow a full ?

Web Hosted
Efficiency & flexibility for National Competent Authorities and applicants
Conclusion

Key drivers for availability and accessibility to new markets

*It is important that regulations are streamlined and efficient in order not to discourage suppliers from entering and operating in markets*

**Transparency**
- Better knowledge of regulatory environment
  - Convergence and harmonization

**Predictability**
- Remove some barriers (Geographic or administrative)
- More mutual recognition
  - Association network

**Efficiency**
- Time to market, secure the market
- Innovate with new technologies
  - Reduce the cost

Better value to Society
Thank you for your attention