The ZAZIBONA Work Sharing Experience in the SADC Region
Case study: South Africa and Zimbabwe Experience in Work sharing using VICH GLs

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Presentation Outline

• Brief Background
• Objectives of the Collaborative procedure
• Achievements
• ZAZIBONA Process
• The Future
Brief Background

• SADC is a regional economic group with 16 Member States (MS)
• Varying regulatory capacities in the region
  – 11/16 MS actively issue marketing authorizations
• Harmonisation of registration of medicines
  – Directive issued by SADC Ministers of Health in 1999
  – Work focused on development of technical guidelines (> 22 guidelines developed)
The challenge is to achieve balance

Access

Economic and industrial interests

Market Control

Public health
A single stick may smoke, but it will not burn. ~ African proverb
Objectives

• Initiative to collaborate in assessment and inspections for medicines registrations with objectives to:
  – Reduce workload
  – Reduce timelines to registrations
  – Develop mutual trust and confidence in regulatory collaboration
  – Platform for training and collaboration in other regulatory fields
Initiation of Work Sharing!

- ✔ 4 Countries
- ✔ 1 Joint Session
- ✔ 4 Products

ZA, ZI, BO, NA

October 2013
13 Participating SADC Member States

Botswana  Angola
Malawi  Seychelles
Mozambique  Swaziland
Namibia
South Africa
Tanzania
Zambia
Zimbabwe

*Contribute to the assessments and inspection activities [ACTIVE MEMBERS]

As at 30 November 2018
Real Work Sharing in Practice!

- ✔ 13 Countries
- ✔ 20 Joint Sessions
- ✔ 230 Products Received & Assessed

Since 2013
Human Medicinal Products Finalised 2013 to 2018

- Positive Opinion
- Negative Opinion
- Withdrawn
The distribution of the applications assessed for 2018

<table>
<thead>
<tr>
<th>Zazibona hosting country/city and month of session</th>
<th>Number of new products assessed</th>
<th>Number of responses reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaborone February 2018</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td>Lusaka June 2018</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Harare August 2018</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Johannesburg November 2018</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td><strong>Total # of applications considered</strong></td>
<td>44</td>
<td>67</td>
</tr>
</tbody>
</table>
Secret to success in ZAZIBONA Work Sharing Platform

Planned meetings - 4 meetings p.a.

Primary Assessment

CAR & CLOQ
How does this work?

Consensus

Common Pending Products

Manufacturer’s Consent

180 days

Consolidated Assessment reports (CAR)

Consolidated list of Q to applicant (CLOQ)

Median Time to Recommendation?

1 Primary Assessment + 4 Countries = 4 CAR + Happy Face

180 days
Can anything good come out of Africa?

Why Not?
“The recommendation received provides a **very in-depth CMC review of the dossier.** Please clarify which regulatory authority criteria were followed, i.e. ICH, WHO, South African MCC, etc.”
The future...is bright!

• Veterinary Zazibona is on its way
• Sharing Outcomes
• Participation of others (observers/full participation)
• Adopt sustainable financing
• Publish an Expression of Interest
• Model can be applicable elsewhere
Manufacturers

Patients

Regulators
Casestudy: VMP harmonisation initiative – SOUTH AFRICA & ZIMBABWE

**Time**

2011

Regional SADC Guidelines for Regulation of Veterinary Drugs
- Published in November 2011

2017

In-depth Review of SADC Guidelines for Registration of VMPs_OIE/GALVmed stakeholder workshop, May 2017
- Recommendation to create registration guidelines for VMPs
- Recommendations to form TWG; harmonisation of VMP registration in SADC

2017

Formation of adhoc TWG (9 SADC countries), December 2017
- Angola, Botswana, e-Swati; Namibia, Malawi, Mozambique, South Africa, Zambia, Zimbabwe

2018

Development of the Concept Note and ToRs for the TWG responsible for harmonization of VMPs
- Adhoc TWG developed working documents in January 2018

2018

Tabling of the Concept Note & ToRs to SADC’s LTC, December 2018
- Concept Note & ToRs adopted
Harmonisation of VMP Pharmacovigilance Guidelines— SOUTH AFRICA; ZIMBABWE

2016
ZIMBABWE
MCAZ Published Guidelines for Registration of VMPs based on VICH GL

2017
SOUTH AFRICA
MCC (SAPRA) initiated adoption of VICH GLs
- VICH GLs adoption in progress and almost complete

2018
MCC/MCAZ Collaboration in adoption of VMP Pharmacovigilance GLs and reporting forms
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• WHO Prequalification Team – Medicines
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• BMGF
• World Bank