A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Outline of the presentation

- Brief introduction to the ZAZIBONA MRH initiative
- The milestones since inception
- The ZAZIBONA inspection process
- Where we are now
- The challenges/ opportunities for improvement
- The future
THEY HAD A VISION

COMING TOGETHER IS A BEGINNING; KEEPING TOGETHER IS PROGRESS; WORKING TOGETHER IS SUCCESS.

Henry K Ard
ZAZIBONA BRIEF INTRODUCTION

Zazibona in the Nyanja language of Zambia means ‘look to the future’.

It is also the contraction of the first two letters in the names of the four founding countries – Zambia, Zimbabwe, Botswana, Namibia

Primary motive
- to assure quality, safety, efficacy of products marketed in our SADC region

Secondary motive
- Work sharing among regional regulators
- Mutual confidence (long-term reliance)
- Regulatory capacity building in the region
<table>
<thead>
<tr>
<th>13 Participating SADC Member States- As at 30 August 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
</tr>
<tr>
<td>D. R. Congo</td>
</tr>
<tr>
<td>Namibia</td>
</tr>
<tr>
<td>South Africa</td>
</tr>
<tr>
<td>Zambia</td>
</tr>
<tr>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Malawi</td>
</tr>
<tr>
<td>Mozambique</td>
</tr>
<tr>
<td>Tanzania</td>
</tr>
<tr>
<td>Angola</td>
</tr>
<tr>
<td>Seychelles</td>
</tr>
<tr>
<td>Kingdom of Eswatini</td>
</tr>
<tr>
<td>Madagascar</td>
</tr>
</tbody>
</table>

*Contribute to the assessments and inspection activities [ACTIVE MEMBERS]*
ZAZIBONA: Real Work Sharing in Practice!

2 meetings/Year of Heads of Agencies (HOA)

# of Assessment Sessions: 4/year

15 Training Sessions

Manufacturers inspected for GMP compliance: 4 schedules/year

38

12 Average # of products per session

12

77 Pending Responses from Manufacturers or responses being reviewed

59% Positive

16% Negative

25% Withdrawn

258 in Total (March 2019)

+ 181 Product Finalised

Since 2013
THE INSPECTIONS TRAJECTORY SINCE 2014

FIRST INSPECTION – 4 COUNTRIES
NOVEMBER 2014

CRO INSPECTION
DECEMBER 2017

DESK REVIEWS STARTED
JUNE 2017

CAPACITY BUILDING/ TRAINING

ZAZIBONA GMP INSPECTIONS
MILESTONES OCTOBER 2019

38 SITES INSPECTED AS OF SEPTEMBER 2019
Av 2 sites/quarter

ONE CRO INSPECTION, with TA from WHO

19 DESK REVIEWS DONE SO FAR

1. ANNUAL MANAGERS POLICY MEETINGS
2. QUARTERLY GMP TWG MEETINGS
3. BI-ANNUAL INSPECTORS MEETINGS
4. BI-ANNUAL INSPECTORS TRAINING

A decade of regulatory harmonization
• Planning and scheduling centrally done through the implementing agency.
• Inspections done to support product registrations. Advanced policy discussions on risk-based routine inspections.
• Product-based inspections supported by dossier assessment reports/QIS.
• Inspections to encourage GMP compliance and assure product safety and quality.
• Continuous QMS development- SOPs for all processes, code of conduct, information sharing.
• 4 inspections per year target. Team comprised of Lead, Co- and Observer
• Annual GMP inspections calendar, rotational basis.
• Interim and final report according to agreed format
• Collaborative peer review of reports and CAPAs.
• Reliance on outcome of collaborative process.
• Fully adopted the WHO GMP guidelines
• TWG working on guidance documents on grey areas in the guidelines and from inspection experiences
ZAZIBONA INSPECTIONS STATISTICS – as at 09/2019

- PASS
- FAIL
- PENDING
- TOTAL

Categories:
- OSD
- GEN. STERILE
- BIOSIMILAR
- cephalosporin & penicillin
- oncology
With manufacturers

• Perception that the initiative is at mutual recognition stage yet it’s a work sharing initiative.
• ZAZIBONA does not issue certificates of GMP compliance, it’s not an authority
• Difficult to agree to proposed inspection slots which affect downstream logistics.
• Low uptake by regional local manufacturers. They were supposed to benefit according to the Pharmaceutical Manufacturing Plan for Africa, PMPA.

Within Member states

• Differing timelines for finalization of inspections at country level which affect uptake of routine inspections by companies.
• Apathy during peer review meetings of inspection reports and CAPAs
• Varied travel policies from the member states and partners.
• Language barrier with some members
• Brain drain at NMRAs, loss of key trained staff.
• As more countries join, the issue of the most appropriate inspection fees continue to be discussed. Also affordability among regional smaller manufacturers.
WHERE ARE WE NOW?

• Logistically much better planning & scheduling and coordination centrally. 2 inspections per quarter/ 8 in a year

• Rotational inspections team calendar comprised of 3 team members, Lead, Co-inspector and observer. Twinning of competences.

• Great Partner support of the inspections activities (World Bank, NEPAD, WHO, +), but the actual inspections remain on cost recovery (great for sustainability). We need the support to continue

• Unwavering support from the implementing agency- MCAZ
IMPACT

• Great inspectors networking through inspectors meetings, and social media platforms. Each discussion is a mini technical GMP psymposium.

• Member states which had never gone on inspection have now been given a chance by twinning with experienced inspectors. This, together with many other trainings, has hugely improved the regional body of knowledge on GMP inspections and medicines Quality Assurance footprint.

• One regional company inspected through the initiative, more encouraged.

• ZAZIBONA has provided a better route for manufacturers to avert the in-country back logs and at times longer timelines.

• The market base is widening with each new member state joining actively.

• Many products successfully registered since 2013.
THE FUTURE

- QMS
  - Main SOPs to be approved by year end
  - Quality Manual proposed
  - Monitoring of timelines
  - MeDNET access for all focal persons as an information repository
- Increased scope of inspections in the future
  - Biologicals and biosimilars
  - CROs
  - APIs
  - Blood and blood products
  - Routine-inspections

- Competency framework implementation in all NMRAs. Focus on Technical depth and efficiency
- Training
  - Advanced training for inspectors and continued elementary training for fresh inspectors.
Harmonization is possible

Thank You

Washington Dengu
+263 719 998 970
denguwashington@gmail.com
LinkedIn @washington dengu