Feedback on SADC Workshop of Industry & Regulators

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Consultant
SADC WORKSHOP ON REGISTRATION OF MEDICINES & GOOD MANUFACTURING PRACTICE STANDARDS

11TH – 13TH APRIL 2016, SOUTH AFRICA
Brief Background

• SADC has harmonised CTD and registration guidelines – approved in January 2015
• Product information and labelling not harmonised
1 Public Health

SADC Protocol on Health 1999
- SADC Pharmaceutical Business Plan 2015 - 2019

2 Economic & Industry Interests

SADC Industrialization Strategy and Roadmap 2015 – 2063
- Strategy on Regional Manufacturing of Essential Medicines and Health Commodities (2016-2020)
At the end of the workshop, specific recommendations on harmonization of labelling requirements & product information, and SADC GMP Roadmap
Concept

Product Information

Summary of Product Characteristics
  For healthcare professional

Patient Information Leaflet
  For user/patient

Product Labelling
Accessibility of Product Information-SmPC

4. SmPC to be submitted separately.
Product Information & Labelling
Recommendations

• Proposed Structure of the SmPC & PIL
• Minimum information on the product labelling
  • Secondary packaging
  • Primary packaging
## Way forward

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<td>Consultation with regulators &amp; Industry – develop drafting instructions</td>
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| Step 4  | 1. In – country consultations  
2. Circulation of the Guideline for comments                                                                                                                                                    | 1. TWG / MS NMRA  
2. SADC Secretariat |
| Step 5  | Consideration and adoption of the guideline                                                                                                                                                           | SADC Medicine Regulators Forum      |
| Step 6  | Regional level validation                                                                                                                                                                               | SADC Secretariat                    |
| Step 7  | Submitting the finalized guideline to the PAC                                                                                                                                                           | SADC Secretariat                    |
| Step 8  | Submission to Joint meeting of Ministers of Health and Ministers responsible for HIV and AIDS for approval                                                                                       | SADC Secretariat                    |
| Step 9  | Printing and publication                                                                                                                                                                                | SADC Secretariat                    |
| Step 10 | Regional level: Training of NMRA on the guideline                                                                                                                                                       | Center of specialization             |
| Step 11 | Implementation: National level  
1. MS received approved hard and soft copies  
2. Training at national level  
3. MS adopt /adapt  
4. Notice to applicants with effective dates                                                                                                  | MS NMRA                             |
SADC Good Manufacturing Practice (GMP) Roadmap
Common Standards and norms

• Region to adopt WHO GMP guidelines
• Additional regional specific requirements or clarification on GMP (*Q & A document on GMP*)
• Capacity building of regulators and industry
• Risk based application
• Information and work-sharing for NMRAs
Time frame for compliance with priority GMP principles

1. QMS
2. Documentation
3. Facilities
4. Processes
5. Quality Control (In-process/FPP)
Outline of the SADC GMP Roadmap

1. Agreeing on basic principles/standards i.e. on scope of commodities; co-operation; legal/regulatory policy – industry and regulators; Proposed time frame 2016

2. Mapping of conditions by 2017 of the existing inspectors’ competences and manufacturers against the standard;

3. Implementation of standards by manufacturers to be done in a timeline of three (03) years;

4. Enforcement of standards in line with the agreed by 2020;
Regulators Input in the GMP Roadmap

• Information exchange
• Documents to be shared
• Process towards mutual confidence (reduction of duplication)
• Capacity building/training
• Partners and Responsibilities
• Organisation of inspections
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<tr>
<td><strong>Current Status</strong></td>
<td>Survey of industry and NMRAs – inspector’s availability and competency, GMP status of manufacturers (self-evaluation and regulators evaluation). Criteria – any manufacturer that exports to at least 1 country should be targeted</td>
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<tr>
<td><strong>Guidelines</strong></td>
<td>Adopt WHO and develop “living” explanatory schedule</td>
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<td><strong>Manufacturers compliance with GMP</strong></td>
<td>Sterile product manufacturers to be compliant within 24 months</td>
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<td>From “2017” any new site should be fully compliant</td>
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<td>Others (Industry comments required):</td>
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<td>Quality system – 24 months’</td>
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<td>Facility – 60 months</td>
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<td>Processes – 48 months</td>
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<td>Documents – 36 months</td>
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<td>Equipment – 60 months</td>
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<td>QC – 36 months</td>
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| Information sharing            | What? – Inspection reports, GMP Status, SSFFC, Inspection outcomes (e.g. Notices of concern/suspension), withdrawals, Inspection plans/schedules  
How – SADC regulators forum, Secure Repository  
Sources of information – Regulators and Industry (for inspections conducted by extra-regional inspectorates)  
- Reports should be owned by NMRAs rather than manufacturers (legal matter)  
- Member states should be available to formally validate any posted information  
Annual meeting back to back with industry. In between Webex sessions encouraged |
<p>| Document format alignment      | To use WHO format for final reports and CAPAs + review of outcomes to be shared on secure platform. WHO draft currently circulating for comments. Members to access and review. |</p>
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<td><strong>Process towards mutual confidence</strong></td>
<td>Training (including categorization of deficiencies)</td>
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<td>Similar processes and information on inspectorate structures</td>
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<td>Joint Inspections following shared schedules. Encourage joint inspections.</td>
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<td>Inspections schedules to be updated regularly</td>
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<td><strong>Capacity building and training</strong></td>
<td>Training to be of three types</td>
<td>24 months</td>
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<td>Specialists to be identified and capacitated in areas of 36 months GMP</td>
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<td>Institutionalize capacity building of inspectors within the region i.e. at least one regional center of specialization / center of regulatory excellence.</td>
<td>Immediate</td>
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<td></td>
<td>The Zazibona GMP coordinator to map out and determine availability of expertise</td>
<td>Immediate</td>
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<td></td>
<td>Training extended to industry.</td>
<td>Yearly</td>
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<td><strong>Organization of inspectorate functions</strong></td>
<td>Each inspectorate to have QMS.</td>
<td>24 months</td>
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<td>SADC to develop/adapt draft guidance for appropriate QMS based on e.g. PICs, WHO, ISO 17020</td>
<td>6 months</td>
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<td><strong>Worksharing</strong></td>
<td>See joint inspections</td>
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SADC Collaborative Medicines Registration Process (Zazibona)
Acknowledgements

• NRAs in Southern Africa (Zazibona initiative)
• DFID Funded SARPAM Programme
  – Co-financing the 2014 Work Plan
• WHO Prequalification Team – Medicines
  – Technical & financial Support
• AMRH Partners
• SADC Secretariat, NEPAD Agency
The challenge is to achieve balance between access, economic and industrial interests, market control, and public health.
WHO prequalified

Approved by well-resourced Authorities

Reviews & inspection by each NMRA

Duplication of effort

#1
If you want to go quickly, go alone. If you want to go far, go together. ~ African proverb
A single stick may smoke, but it will not burn. ~ African proverb
Specific 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
Analytical Framework for Collaborative Models

- **Phase Analysis** | formation, implementation and maintenance.
- **Results Analysis** | outputs, outcomes or impact.
- **Networking analysis** | partner participation, relationship support, efficiency, resources, leadership and management, communication, governance, structure or the external environment.
ZAZIBONA: Real Work Sharing in Practice!

Since 2013

2 | Nos. of HoA meetings/Year

10 | # of Assessment Sessions: 4/year

6 | Joint GMP inspections: 4/year

12 | Average # of products per session

55% vs 33% vs 12%
Positive vs Negative vs Withdrawn
How does this work?

- Common Submission
- Essential medicine
- Manufacturer’s Consent

Consensus

Consolidated Assessment reports (CAR)
Consolidated list of Q to applicant (CLOQ)

1 Primary Assessment + 5↑ Countries = 5 CAR + 😊
• WHO PQT-m performs QA on the Assessment Reports

• Outcomes of Assessments and Inspections would be made available (Transparency on Decision Making)
What ZAZIBONA is not...

• Replacement of the NMRAs
  – Only focuses on the review and inspection process
  – Actual registration is done at the national level i.e., requires actual submission of product application to the countries following applicable national requirements i.e. application fees etc.,

• Centralised procedure
  – There is no central single submission (…yet)
  – But same dossier submission to all the countries based on the SADC CTD and registration guidelines
Concluding Points

• Potential mechanism for improving the regulatory systems in LMICs
  – Efficiency & effectiveness
• Sustainability
• Risk based approach
• Transparency
• Regulatory capacity
Q & A