Feedback on SADC Workshop of Industry & Regulators

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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

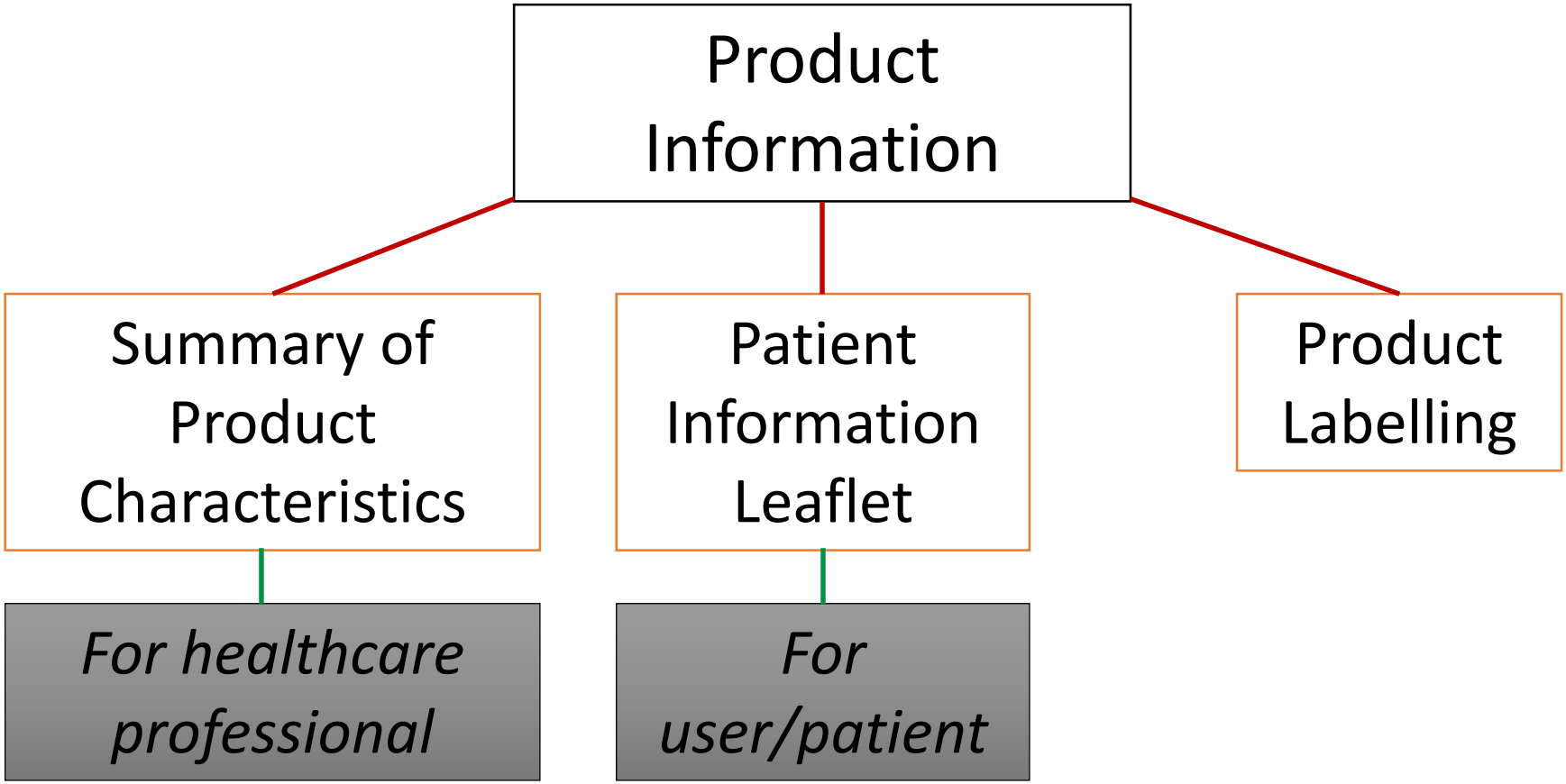
Economic & Industry Interests

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

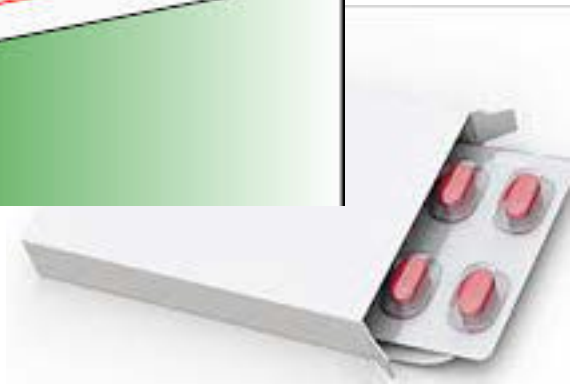

Product Information
Summary of Product Characteristics
Patient Information Leaflet
Product Labelling
For healthcare professional
For user/patient

Accessibility of Product Information-SmPC

1

2

3



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

Steps	Description	Responsibility
Step 1	Consultation with regulators & Industry – develop drafting instructions	SADC Secretariat
Step 2	Drafting the Guideline	TWG on Registration Guidelines
Step 3	Workshop (Industry representatives & TWG) to review the draft Guideline	TWG on Registration Guidelines/SADC Secretariat
Step 4	o In – country consultations o Circulation of the Guideline for comments	o TWG / MS NMRA o 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

Activities	Notes
Current Status	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
Guidelines	Adopt WHO and develop "living" explanatory schedule
Manufacturers compliance with GMP	Sterile product manufacturers to be compliant within 24 months
	From "2017" any new site should be fully compliant
	Others (Industry comments required): Quality system – 24 months' Facility – 60 months Processes – 48 months Documents – 36 months Equipment – 60 months QC – 36 months

Activities	Notes
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
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.

Activities	Notes	Time Frame
Process towards mutual confidence	Training (including categorization of deficiencies)	
	Similar processes and information on inspectorate structures	
	Joint Inspections following shared schedules. Encourage joint inspections.	
	Inspections schedules to be updated regularly	
Capacity building and training	Training to be of three types	24 months
	Specialists to be identified and capacitated in areas of GMP	36 months
	Institutionalize capacity building of inspectors within the region i.e. at least one regional center of specialization / center of regulatory excellence.	Immediate
	The Zazibona GMP coordinator to map out and determine availability of expertise	Immediate
	Training extended to industry.	Yearly
Organization of inspectorate functions	Each inspectorate to have QMS.	24 months
	SADC to develop/adapt draft guidance for appropriate QMS based on e.g. PICs, WHO, ISO 17020	6 months
Worksharing	See joint inspections	

Way Forward

Steps	Description	Responsibility
Step 1	Consultation with regulators & Industry – develop drafting instructions	SADC Secretariat
Step 2	Drafting the GMP Roadmap	TWG on GMP plus Industry representatives
Step 3	Workshop (Industry representatives & TWG) to review the draft Guideline	TWG on GMP/ SADC Secretariat
Step 4	o In – country consultations o Circulation of the Roadmap for comments	o TWG / MS NMRA o SADC Secretariat
Step 5	Consideration and adoption of the Roadmap	Health: SADC Medicine Regulators Forum Industry:
Step 6	Regional level validation	SADC Secretariat
Step 7	Submitting the finalized Roadmap	SADC Secretariat
Step 8	Approval of the GMP Roadmap by SADC Ministers	SADC Secretariat
Step 9	Printing and publication	SADC Secretariat
Step 10	Implementation	MS NMRA Pharmaceutical Industry

SADC Collaborative Medicines Registration Process (Zazibona)

NEPAD
TRANSFORMING AFRICA

WORLD BANK GROUP

World Health Organization

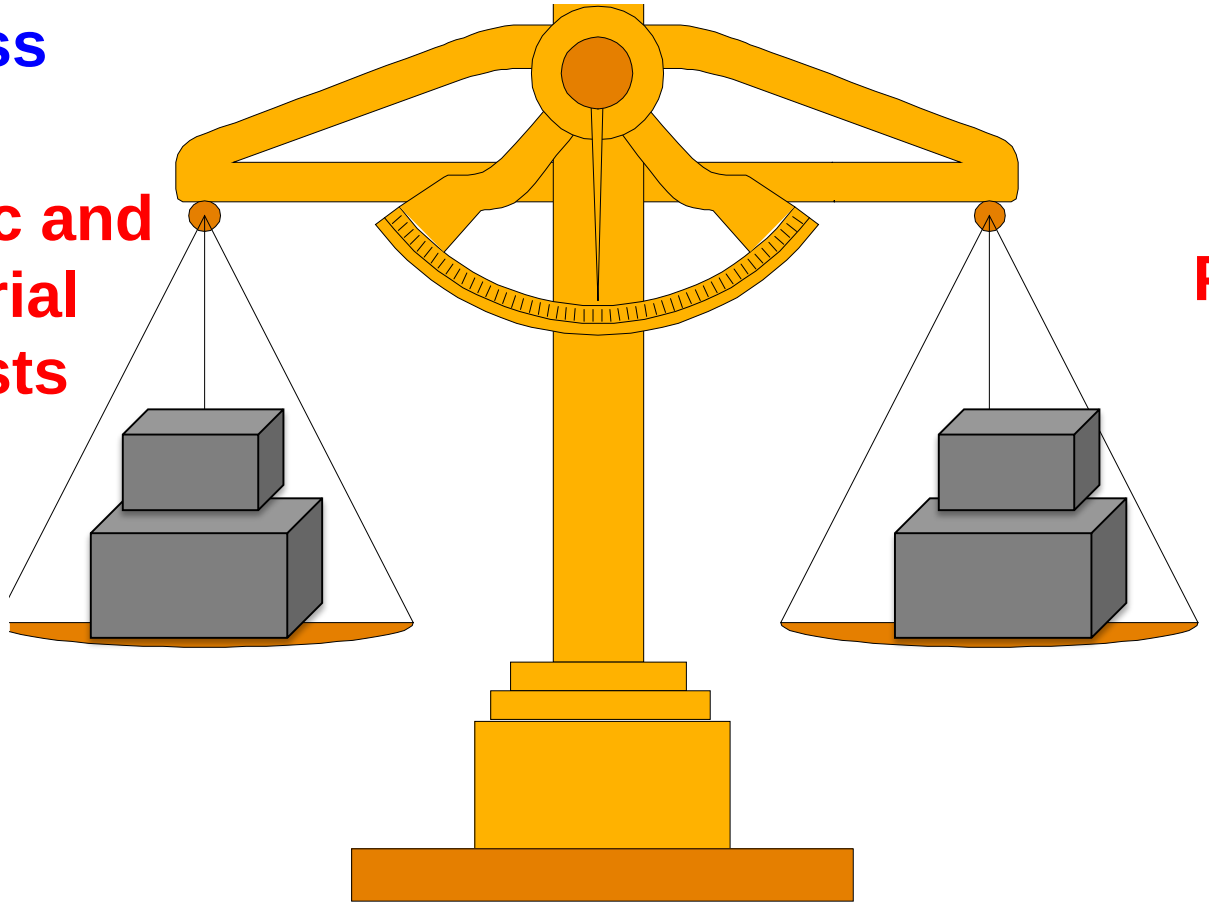
Acknowledgements

- 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

Access

Economic and industrial interests



Market Control

Public health

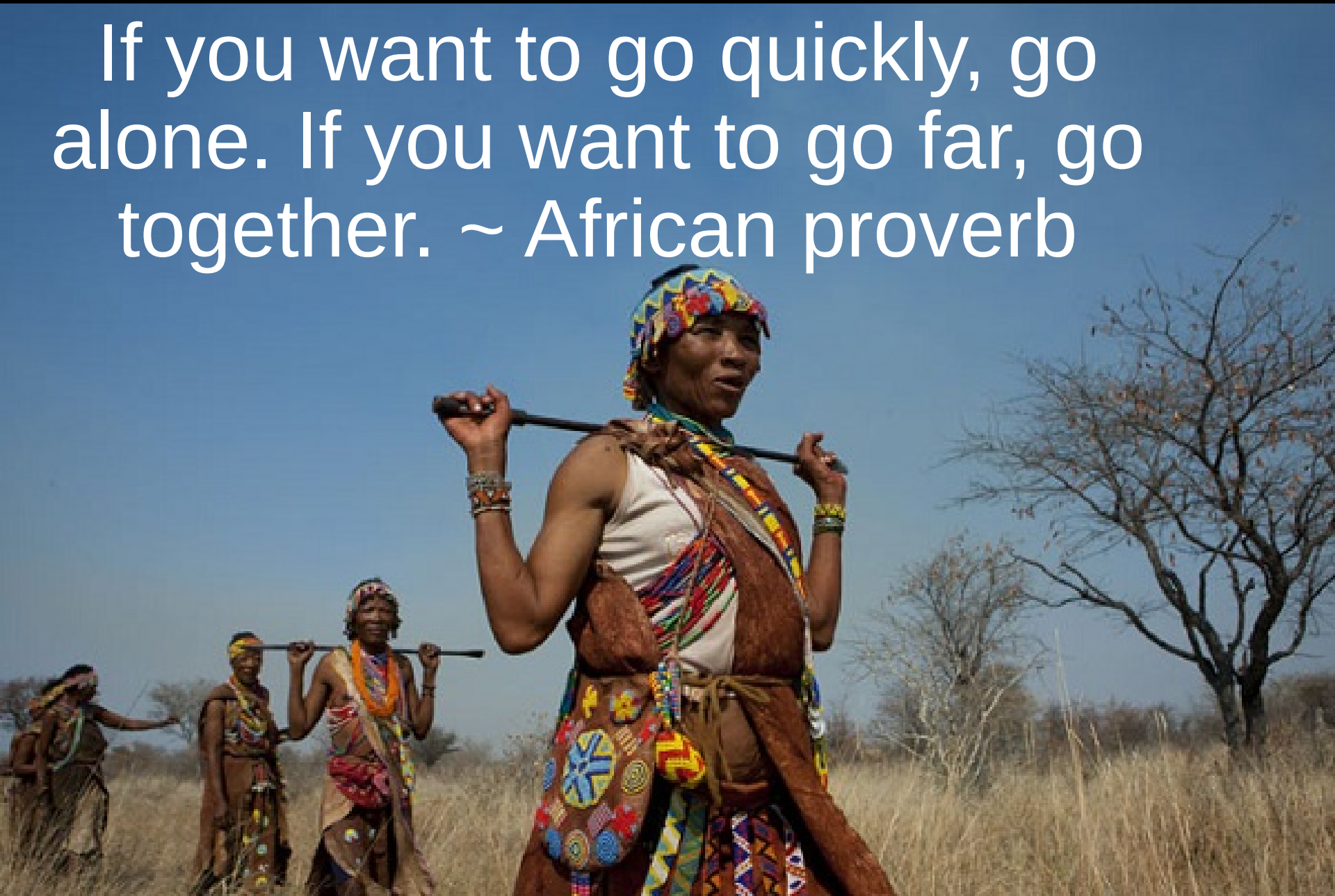
WHO prequalified

Reviews & inspection by each NMRA

Duplication of effort

#1

Approved by well-resourced Authorities


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

8

Training Sessions

10

# of Assessment Sessions: 4|year

6

Joint GMP inspections: 4|year

12| Average # of products per session

ZAZIBONA

55% Positive

vs

33% Negative

vs

12% Withdrawn

How does this work ?

Common Submission

Essential medicine

Manufacturer's Consent

Consensus

Consolidated Assessment reports (CAR)

Consolidated list of Q to applicant (CLOQ)

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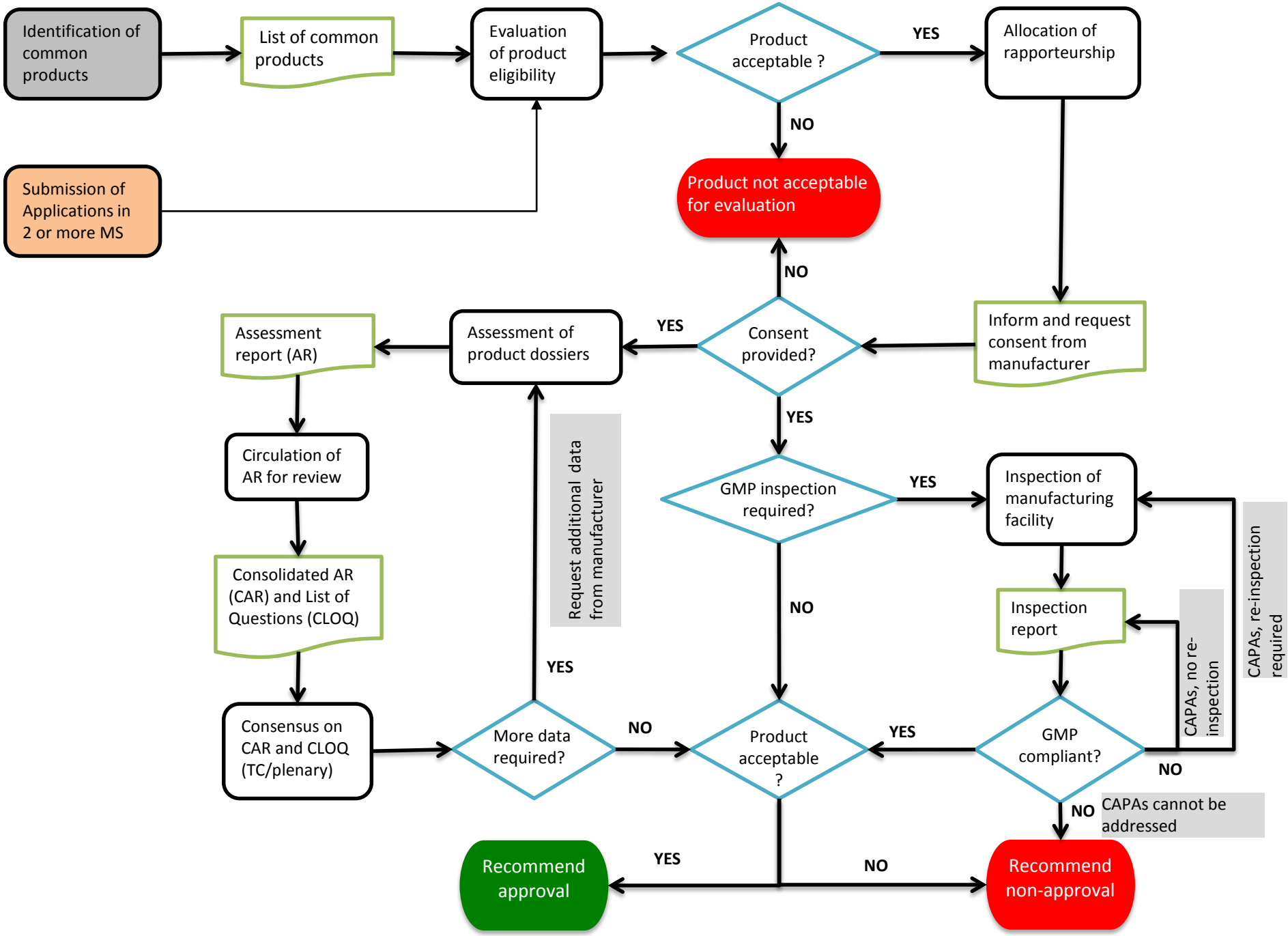
1 Primary Assessment + 5↑ Countries = 5 CAR + 


Identification of common products
List of common products
Evaluation of product eligibility
Product acceptable ?
YES
Allocation of rapporteurship
NO
Product not acceptable for evaluation
Submission of Applications in 2 or more MS
NO
Inform and request consent from manufacturer
Consent provided?
YES
Assessment of product dossiers
Assessment report (AR)
Circulation of AR for review
Consolidated AR (CAR) and List of Questions (CLOQ)
Consensus on CAR and CLOQ (TC/plenary)
YES
Request additional data from manufacturer
More data required?
NO
YES
GMP inspection required?
NO
Product acceptable ?
YES
Inspection of manufacturing facility
Inspection report
GMP compliant?
CAPAs, no re-inspection
CAPAs, re-inspection required
NO
NO
CAPAs cannot be addressed
YES
Recommend approval
NO
Recommend non-approval

- **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