WHO **formal benchmarking** of Medicines Control Authority of Zimbabwe (MCAZ)

14 – 15 May 2024

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SUSTAINABLE DEVELOPMENT GOALS
1 NO POVERTY
2 NO HUNGER
3 GOOD HEALTH
4 QUALITY EDUCATION
5 GENDER EQUALITY
6 CLEAN WATER AND SANITATION
7 RENEWABLE ENERGY
8 GOOD JOBS AND ECONOMIC GROWTH
9 INNOVATION AND INFRASTRUCTURE
10 REDUCED INEQUALITIES
11 SUSTAINABLE CITIES AND COMMUNITIES
12 RESPONSIBLE CONSUMPTION
13 CLIMATE ACTION
17 PARTNERSHIPS FOR THE GOALS
SDG 3 – Target 3.8
Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

Resolution WHA 67:20 – RSS for medical products

- **Adopted in May 2014**
  - ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

WHO supports Member States in reaching and sustaining effective regulatory oversight of medical products through the regulatory systems strengthening (RSS) programme

Objectives of the RSS programme

- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance*

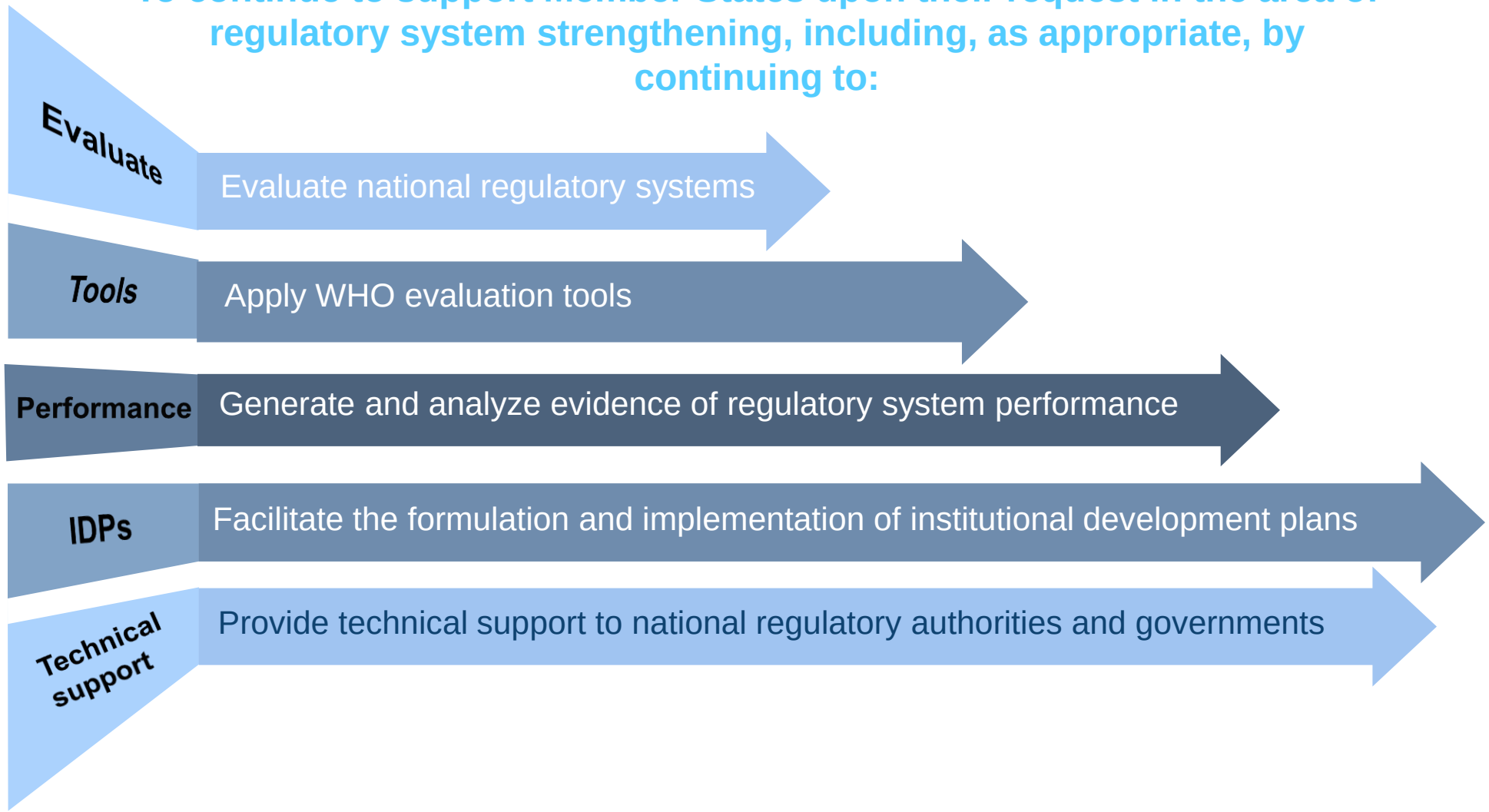
Ultimate goal

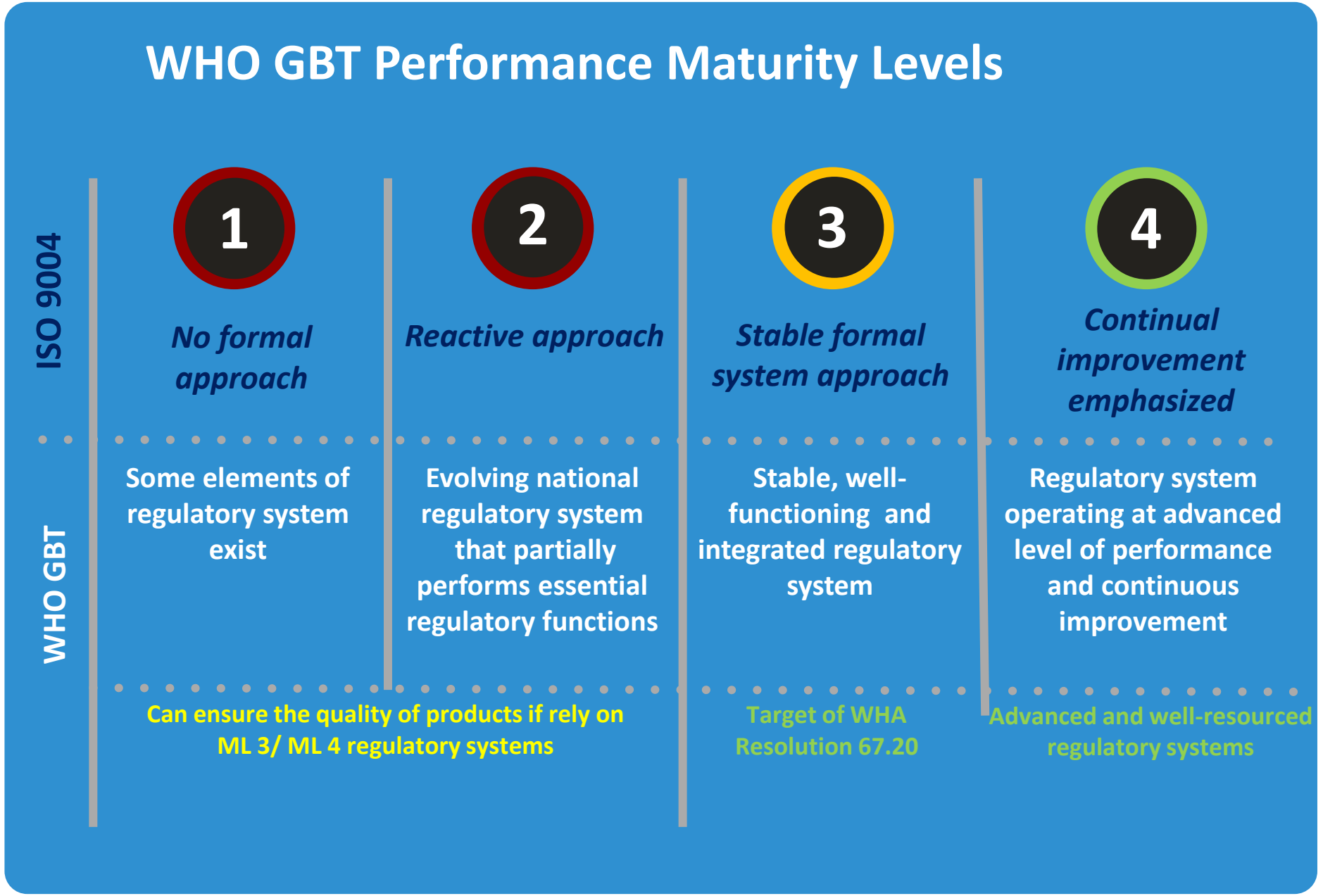
- ***Promote access to quality assured medical products***

WHA Resolution 67.20

What WHO should do

To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:




WHO GBT Performance Maturity Levels
ISO 9004
WHO GBT
1
2
3
4
No formal approach
Reactive approach
Stable formal system approach
Continual improvement emphasized
Some elements of regulatory system exist
Evolving national regulatory system that partially performs essential regulatory functions
Stable, well-functioning and integrated regulatory system
Regulatory system operating at advanced level of performance and continuous improvement
Can ensure the quality of products if rely on ML 3/ ML 4 regulatory systems
Target of WHA Resolution 67.20
Advanced and well-resourced regulatory systems

Status of Regulatory Functions (May 2024)

NRA Function assessed	Nov 2021		May 2023		May 2024	
	Sub indicators implementation %	Maturity level	Subindicators implementation %	Maturity level	Sub indicators implementation %	Maturity level
01-NATIONAL REGULATORY SYSTEM (RS)	93.0%	1	94.0%	2	97.0%	3
02-REGISTRATION AND MARKETING AUTHORIZATION (MA)	84.0%	1	93.0%	2	94.0%	3
03-VIGILANCE (VL)	85.0%	1	94.0%	3	94.0%	3
04-MARKET SURVEILLANCE AND CONTROL (MC)	85.0%	1	93.0%	3	93.0%	3
05-LICENSING ESTABLISHMENT (LI)	80.0%	2	92.0%	3	92.0%	3
06-REGULATORY INSPECTION (RI)	83.0%	2	82.0%	2	88.0%	3
07-LABORATORY TESTING (LT)	93.0%	2	96.0%	2	98.0%	3
08-CLINICAL TRIAL'S OVERSIGHT (CT)	98.0%	3	98.0%	3	98.0%	3

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Overall Maturity Level =

KEY FINDINGS

Strengths

- Solid and comprehensive legal basis defining the regulatory framework
  - ✓ Clear mandate for national regulatory system and functions
  - ✓ complemented with well established regulations and guidelines
- Regulatory framework
  - ✓ Requirements, guidelines, and processes in line with WHO and other internationally recognized guidance
    - ➢ Taking into account the country and region-specific policies and guidelines
- Robust strategic plan with well defined performance measurements and ambitious targets
- Good Infrastructure to facilitate regulatory activities, upgrade of the Laboratory including new equipment

KEY FINDINGS …

Strengths

- Committed leadership and dedicated staff of MCAZ
- Well established quality management system supporting different regulatory and management functions
- Clear roles and responsibilities of different units within MCAZ
- Expanding automation of regulatory activities
- Support to other NRAs at regional and continental level (e.g., ZAZIBONA, AMRH).
- Communication and outreach to the stakeholders including general public (e.g., communication policy, MCAZ website)
- WHO Prequalification of the Laboratory

KEY FINDINGS

Major areas for improvement

- Continued implementation of the framework for renewal of Marketing Authorization of medical products.
- Continued increase of human resources – in terms of number and competencies to efficiently perform regulatory activities.
- Maintenance and sustainability plan for continuous improvement of the regulatory performance by measuring and monitoring performance through KPIs
- Recruitment of competent staff and training dedicated to the new laboratory
- Continued implementation of a Risk-based postmark surveillance plan

Roadmap for the formal benchmarking of MCAZ 2011 to 2024

Mar 2011

WHO vaccine assessment of MCAZ

Nov 2012

IDP follow up visit of MCAZ by WHO

Sep 2014

WHO prequalification of MCAZ laboratory

May 2019

Regional self-benchmarking workshop

Aug 2021

WHO formal benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ

May 2023

WHO formal [re-] benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ

May 2024

Finalization of WHO formal benchmarking of the medical products national regulatory system of Zimbabwe

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Roadmap for the formal benchmarking of MCAZ, 2024 to 2027

May 2024

Finalization of WHO formal benchmarking of the medical products national regulatory system of Zimbabwe

June 2024

Official announcement of the result and WHO/MCAZ press release

Q1-Q2 2027

Formal re-benchmarking of the medical products national regulatory system of Zimbabwe MCAZ

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JUNE 2024

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Zimbabwe becomes the sixth country in Africa to reach WHO maturity level 3 in regulation of medicines

Zimbabwe becomes the sixth country in Africa to reach WHO maturity level 3 in regulation of medicines

14 June 2024 | Departmental update
|Reading time: 1 min (381 words)

Towards ML 4 for Marketing Authorization

- MA04.05- The use of advisory or scientific committees, including external experts, in the review of registration or MA applications is documented and supported by adequate regulations- Implemented already
- MA05.03 -The summary technical evaluation reports of those medical products registration applications that have been approved, are published and made available to the public,
- MA05.04 -The summary technical evaluation reports of those medical products registration applications that have been deferred or rejected is published and made available to the public
- MA06.02 -The existence and implementation of performance indicators for different activities included under the registration and MA functions.
- MC01.05- The availability of legal provisions and regulations setting the rules for placement of a unique identification number on the outer package of each medical product

Regulatory Performance Indicators

2. Registration and Marketing Authorization (MA)

SN	Performance indicator	Target	Rating
2.1	Percentage of completed screened applications for new MA applications within defined days		
2.2	Average timeline for completed assessment of new MA applications Sub-KPIs if applicable:		
	• *Percentage of completed screened applications for changes/variation applications within defined days* • *Percentage of completed quality assessment of applications for registration of medicines within defined days* • *Percentage of completed efficacy/safety assessment of applications for registration of medicines within defined days* • *Percentage of completed quality assurance of completed assessments of applications for registration of medicines within defined days*		

Regulatory Performance Indicators

2.3	Average timeline for registration or denial for new MA applications		
2.4	Average timeline for completed assessment of MA renewal application		
2.5	Average timeline for approval of renewal of MAs		
2.6	Percentage of completed assessment of applications for variations to registered health products within defined days		
2.7	Percentage of decisions made to approve or deny the grant of MA for health products within defined days		
2.8	Percentage of the new and generic drug applications to be processed within the target turn-around-time.		
2.9	Percentage of published public assessment reports (PAR) for MA approvals		
2.10	Percentage of MA approvals granted within defined days for standard pathways		
2.11	Percentage of MA approvals granted within defined days for fast-track/expedited pathways		
2.12	Percentage of MA approvals granted within defined days through reliance/recognition pathways		