GOOD MANUFACTURING PRACTICES KPIS

Harmonization across TMDA, Ethiopia FDA, Rwanda FDA, Uganda NDA

a part of the

Grand Challenges: Enhancing Data Systems of African National Regulatory Agencies

Confirmation and Approval

The contents of this document have been reviewed, confirmed and approved by each of the four National Regulatory Agencies in Tanzania (TMDA), Ethiopia (EFDA), Rwanda (Rwanda FDA) and Uganda (UNDA).

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Background

As part of the Gates Foundation's Grand Challenges program ***Enhancing Data Systems of African National Regulatory Agencies***, the East African group of National Regulatory Agencies (NRAs) participating in this program committed to working together to arrive at a subset of Key Performance Indicators (KPIs) across Marketing Authorization (MA), Clinical Trials (CT) and Good Manufacturing Processes (GMP) that they could all align around towards the goal of achieving harmonization. The East African NRAs are as follows:

- **TMDA:** Tanzania Medicines and Medical Devices Authority Home
- **EFDA:** Ethiopia Food and Drug Authority
- **Rwanda FDA:** Rwanda Food and Drugs Authority
- **UNDA:** Uganda National Drug Authority

On the basis of maturity level seniority, TMDA was elected to lead this group of NRAs in the technical discussions and collaborations. Providing additional support were technical advisory specialists from the African Medicines Regulatory Harmonization (AMRH) initiative, Global Health Analytics Group and the BroadReach Group, who also provided the Program Management Office (PMO) to oversee all efforts.

Approach

The teams utilized a highly collaborative approach based on mutual trust, transparency and integrity.

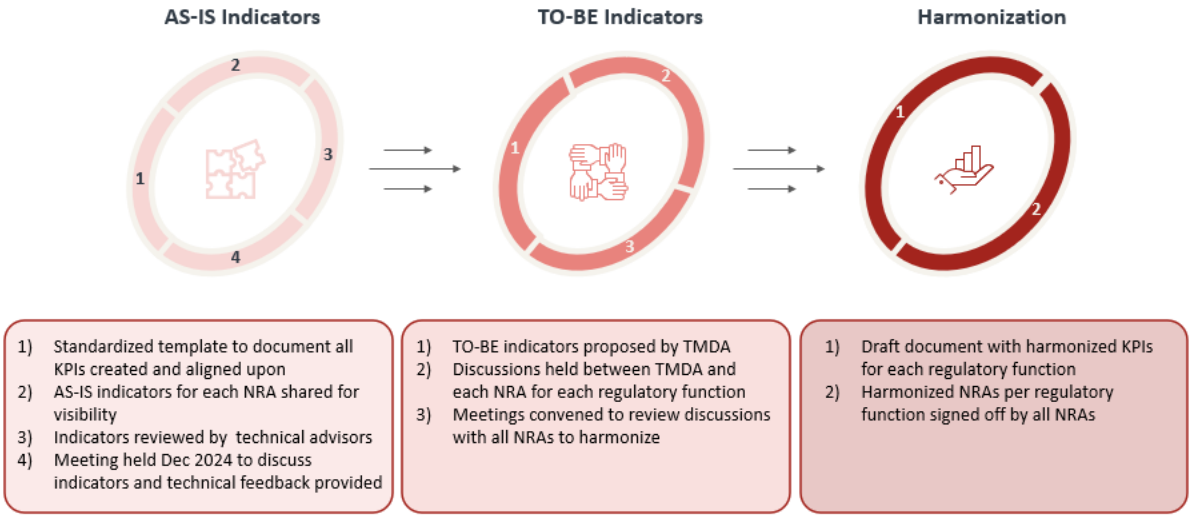

Figure 1: KPI harmonization approach

Each NRA initially shared their key indicators for the regulatory functions (MA, CT, GMP) which were reviewed by Global Health Analytics Group, BroadReach and AMRH's M&E Community of Practice representatives. Based on the feedback, TMDA then proposed a set of KPIs that could be harmonized across the countries. As the KPIs fall across three different regulatory functions, the NRAs agreed to follow a staggered manner. CT KPIs would be harmonized first, followed by MA and then GMP.

The group then reported back on their individual discussions with TMDA and with BroadReach and Global Health Analytics Group advisory support, aligned on a final set of KPIs for the regulatory function. Nuanced differences between NRAs have been noted.

These KPIs are designed to meet a minimum maturity level of 3, as outlined in the WHO Global Benchmarking Tool (GBT) framework. To achieve this, National Regulatory Authorities (NRAs) will as a part of this program, undertake a review of their processes to harmonize them and align with the Level 3 requirement, which emphasizes the standardization and documentation of processes. Additionally, clear process owners will be established to ensure accountability, and the effectiveness of these processes will be monitored through the identified KPIs. Following this, NRAs will focus on ensuring that staff receive regular training on these processes, enabling consistent execution across the organization.

Harmonized set of KPIs for Good Manufacturing Practices

Five KPIs were proposed by TMDA under the GMP function for harmonization across the four NRAs. Post discussions, the following set of nine KPIs was aligned upon among the four NRAs. Where relevant, specific nuances and exceptions have been noted. Not all indicators can be measured and monitored immediately. Where this is not possible currently because of system limitations, the NRAs have committed to improving their regulatory systems to allow them to monitor these variations in the near future.

KPI #1: PERCENTAGE OF PHARMACEUTICAL MANUFACTURING FACILITIES INSPECTED FOR GMP AS PER PLAN

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Assesses how well the regulator is executing its planned GMP inspections**	3	Output	Number of pharmaceutical manufacturing facilities inspected for GMP as per plan	Total number of pharmaceutical manufacturing facilities planned for inspection	(N/D)*100	%	Quarterly
Disaggs	• On-site domestic inspections • On-site foreign inspections (direct physical inspections)				**Reliance specific:** • Joint on-site foreign inspections			
Notes	• Remote / desktop-based reviews are not done as per plan and thus are not included as a disagg. They are measured under KPI #3 • For EFDA and TMDA both, the annual domestic plan is to inspect all domestics facilities every year.							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA O UNDA's IRIMS does not capture plans or targets currently. They will look at adding this as an indicator in the future.							

KPI #2: PERCENTAGE OF COMPLAINT-TRIGGERED GMP INSPECTIONS CONDUCTED AT PHARMACEUTICAL MANUFACTURING FACILITIES

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the regulator's responsiveness to public or stakeholder complaints by conducting special GMP inspections**	3	Process	Number of GMP inspections conducted in response to complaints.	Total number of complaints received requiring GMP Inspection	(N/D)*100	%	Quarterly
Disaggs	• Domestic inspections • Foreign inspections (all modes)							
Notes	• This is an important indicator. However, it is to be noted that it is an adhoc indicator that cannot be planned for							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✘ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA ✘ UNDA will not be reporting on this indicator.							

KPI #3: PERCENTAGE OF GMP ON-SITE INSPECTIONS WAIVED FOR PHARMACEUTICAL MANUFACTURING FACILITIES

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Monitors the extent to which the NRA leverages reliance or risk-based approaches to waive on-site GMP inspections**	3	Process	Number of pharmaceutical manufacturing facilities for which on-site GMP inspections were waived	Total number of GMP inspections completed within the set timelines	(N/D)*100	%	Quarterly
Notes	• An inspection is deemed "completed" when the decision has been communicated to the applicant • GMP inspections included in the denominator may be done through physical inspections or remote / desk-based inspections. In the numerator, only the GMP inspections done by remote / desk-based inspections are to be included.							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA, Uganda NDA							

KPI #4: PERCENTAGE OF PHARMACEUTICAL MANUFACTURING FACILITIES COMPLIANT WITH GMP REQUIREMENTS

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the overall GMP compliance level among manufacturing facilities**	3	Outcome	Number of pharmaceutical manufacturing facilities compliant with GMP requirements	Total number of pharmaceutical facilities inspected for GMP	(N/D)*100	%	Annually
Disaggs	• On-site domestic inspections • On-site foreign inspections (direct physical inspections)				**Reliance specific:** • Joint on-site foreign inspections • Remote / desk-based inspections			
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA, Uganda NDA							

KPI #5: PERCENTAGE OF FINAL CAPA DECISIONS ISSUED WITHIN A SPECIFIED TIMELINE

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures efficiency in reviewing manufacturers' corrective actions post-inspection**	3	Process	Number of final CAPA decisions issued within specified timeline	Total number of CAPA responses received from pharmaceutical manufacturing facilities	(N/D)*100	%	Quarterly
Disaggs	• Direct: Domestic + Foreign inspections done by the NRA • Reliance: REC Joint inspections							
Notes	• When determining if a decision was made within the specified timeline, any time where the process was waiting for the applicant should be excluded. • Ability to report on the REC Joint inspections will mean that the EAC system and/or other relevant systems / platforms will need to be integrated into the KPI monitoring tool, in addition to the Regulatory Information Management System.							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA, Uganda NDA							

KPI #6: PERCENTAGE OF GMP INSPECTION APPLICATIONS FOR PHARMACEUTICAL MANUFACTURING FACILITIES COMPLETED WITHIN THE SET TIMELINE

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Monitors efficiency of GMP application processing**	3	Process	Number of GMP inspection applications for pharmaceutical manufacturing facilities completed within the set timeline	Total number of GMP applications for pharmaceutical manufacturing facilities received.	(N/D)*100	%	Quarterly
Disaggs	• Domestic applicant • Foreign applicant undergoing review by the NRA (direct review) • Foreign applicant being reviewed by reliance mechanism (reliance)							
Notes	The stop-clock for the applicant process starts from the time payment is made by the applicant. This is as follows for each NRA: • TMDA, EFDA, UNDA: Payment is done after screening • Rwanda FDA: Payment is done prior to screening The stop-clock ends when the final decision has been made. Thus this includes the time to review the application, carry out the inspection, and make the final decision. The *set timeline* is as per the NRA's Service Level Agreement.							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA, Uganda NDA							

KPI #7: AVERAGE TURNAROUND TIME (IN DAYS) TO COMPLETE GMP APPLICATIONS FOR PHARMACEUTICAL MANUFACTURING FACILITIES

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Assesses overall efficiency and speed of GMP application process**	3	Process	Sum of the days taken to process each GMP inspection application completed during the period	Total # of GMP applications completed during the period	N/D	Days	Quarterly
Disaggs	• On-site domestic inspections • On-site foreign inspections (direct physical inspections)			**Reliance specific:** • Joint on-site foreign inspections • EFDA will also measure: Document review for waiver-based reference regulatory authority				
Notes	• <u>Time measured</u> is from the time of payment to the point where the first decisions has been communicated to the applicant. The first decision may be "compliant", "non-compliant", or "requires CAPA". Time that the application is with the applicant will be excluded.							
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA, UNDA							

KPI #8: MEDIAN TURNAROUND TIME (IN DAYS) TO COMPLETE GMP INSPECTION APPLICATIONS FOR PHARMACEUTICAL MANUFACTURING FACILITIES

	Objective	Maturity Level	Indicator Type	Indicator calculation rules	Unit of Measure	Reporting Frequency
Definition	**Measures the median time taken by the NRA to review and make a decision on a GMP Inspection application**	3	Process	Arrange all completion times in ascending order. If the number of applications (say n) is: Odd: median = value at position (n+1)/2 Even: median = average of values in positions (n/2) and ({n/2} + 1)	Days	Annually
Notes	• Time measured is from the time of payment to the point where the first decisions has been communicated to the applicant. The first decision may be "compliant", "non-compliant", or "requires CAPA". Time that the application is with the applicant will be excluded. • NRAs can report manually (but not real-time) until the monitoring tools have been built out to calculate this.					
Alignment	**Legend** ✓ Alignment achieved on all fronts O Alignment achieved, but with some differences ✖ NRA will not be taking up this ✓ Harmonized across TMDA, Rwanda FDA ✓ EFDA and UNDA will take on this indicator in the future.					

KPI #9: PERCENTAGE OF GMP INSPECTION REPORTS PUBLISHED ON THE REGULATOR'S WEBSITE WITHIN A SPECIFIED TIMELINE

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Tracks the transparency and timeliness of publishing GMP inspection outcomes**	4	Output	Number of GMP inspection reports published on the NRA website within the specified timeline	Total number of GMP inspections completed within the time period	(N/D) * 100	%	Annually
Disaggs	• On-site domestic inspections • On-site foreign inspections (direct physical inspections)			**Reliance specific:** • Joint on-site foreign inspections • Remote / desk-based inspections • EFDA will also measure: Document review for waiver-based reference regulatory authority				
Notes	• Time measured is from the time of payment to the point where the first decisions has been communicated to the applicant. The first decision may be "compliant", "non compliant", or "requires CAPA". Time that the application is with the applicant will be excluded. • TMDA notes that their goal is not to publish ***all*** completed GMP inspection reports, but only those that are of public interest which is determined based on set criteria. This will be reflected in the target they set for this indicator. As their capacity to publish greater volumes increases, the target will be increased.							
Alignment	**Legend** ✓ Alignment achieved on all fronts ○ Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Harmonized across TMDA, EFDA, Rwanda FDA ○ UNDA will take this on as a future-focused indicator. They will need to develop a SOP to clearly define what aspects of the inspection reports can be published for the public, given that some aspects of the report are bound by confidentiality / privacy. Resources (human or systems) will need to be sorted out to ensure that redactions are done as per the SOP.							

Way Forward

Following the acceptance of this document that lays out the indicators that have been aligned upon between the four NRAs, TMDA will take the lead in developing the User Requirement Specifications (URS) and thereafter the Design Specification for the GMP component of the KPI Monitoring Tool that all NRAs have committed to building out as an enhancement to their existing Regulatory Information Management System (RIMS). While the tool will not be the exact same across all NRAs, given that their RIMS are all at different levels of customization, aligning on the URS and Design will help to further the goals of harmonization of KPIs across NRAs. This will also be shared with other NRAs beyond this group as needed.