MARKETING AUTHORIZATION KPIS

Scope: Human Medicines

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).

For TMDA

Signature: Signed by: Felchism Apolinary 02D0E1905651414...

Name: Felchism Apolinary

Title: Manager, Medicines Registration

Date: Jun 16, 2025

For Ethiopia FDA

Signature: Signed by: Seble Shambel 5479B5E2DEB24E3...

Name: Seble Shambel

Title: Head, Medicines Registration

Date: Jun 23, 2025

For Rwanda FDA

Signature: Signed by: 0C1697629CD44C5...

Name: George Ntaganda

Title: Chief Finance Officer

Date: Jun 25, 2025

For Uganda NDA

Signature: Signed by: Dr David Nahamya 31E10EE479E14A3...

Name: Dr David Nahamya

Title: secretary to the Authority

Date: Jun 25, 2025

Contents

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.

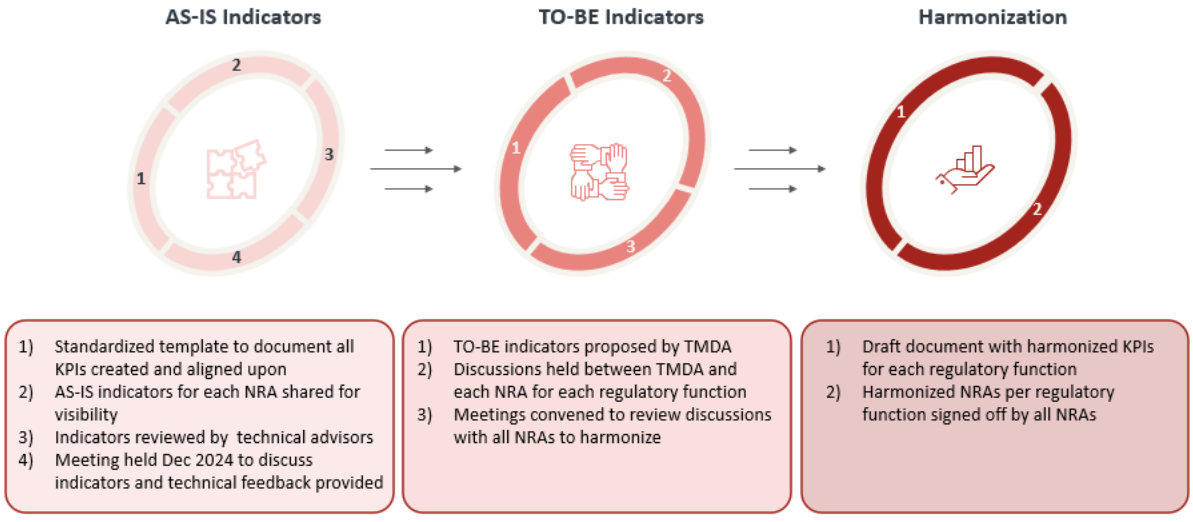

Figure 1: KPI harmonization approach

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.

Disaggregations

All NRAs agreed to monitor the below list of KPIs at the apex aggregated level but also to provide disaggregates where possible across the below disagg categories. Greater granularity will provide increased transparency and facilitate decision-making by quickly identifying bottlenecks. NRAs will work towards increasing the ability to monitor the variety of disaggs within their regulatory information management systems.

Current Disagg Tracking Capability

Table 1: Disaggs the NRA systems can currently track

MA profile categories	TMDA	EFDA	Rwanda FDA	UNDA
Product categories (within human medicines)	• Biologics & Vaccines • Generics • New Chemical Entities • Herbal Medicines •	• New Chemical Entities • Generics • Biologics • Vaccines • Biosimilar • Radiopharmaceuticals	• Generics • Biologics • Vaccines • Biosimilar • Traditional / Herbal Medicinal Preparation • Radiopharmaceuticals & Radiotherapy products •	• Biologics & Vaccines • Generics & New Chemical Entities • Complementary Medicines *(Traditional / Herbal)* • Priority Products *(any medicine type required to address current public health priorities)*
Internal Regulatory Pathway	• Standard • Abbreviated • Emergency Use • Priority (Orphan Medicines) •	• Standard/regular • Fast Track • Emergency Use • Conditional	• Full Assessment • Abbreviated •	• Standard • Priority • Fast Track
Reliance Pathway	• WHO PQ • EAC •	• WHO PQ • SRA	• Reliance /Recognition *(all reliance pathways are incorporated in this currently)*	• Reliance *(UNDA does not split this out further – all reliance pathways are incorporated in this currently)*
Regulatory Outcome	• Granted • Rejected • Revoked • Suspended	• Approved • Rejected • Cancelled • Suspended	• Authorized • Refused • Additional Data Requested	• Granted • Additional Information Requested

	• Additional Information Requested	• Further information request Requested	• Withdrawn • Suspended/Revoked	

FUTURE FOCUSED DISAGG TRACKING CAPABILITY TO BE BUILT

Table 2: Disaggs the NRA systems will aim to track in the next few years

MA profile categories	TMDA	EFDA	Rwanda FDA	UNDA
Product categories (within human medicines)		• Traditional / Herbal • Plasma Derived Medical Products	• Innovator Products • Blood and Blood Products •	*To split out and track these separately:* • New Chemical Entities • Generics • Biologics • Vaccines *To start tracking:* • Biosimilar
Internal Regulatory Pathway		• N/A	• Emergency Use/Conditional Use • Innovator Product Pathway	• N/A
Reliance Pathway	• WLAs/SRA • Continental (AMA)	• Regional (IGAD MRH) • Continental (AMA) • Article 58	• WLA - WHO-Listed Authorities • WHO transitional Listed Authorities (B category), • WHO PQ - Pharmaceutical products Prequalified by World Health Organization under the framework of the • WHO Collaborative Registration Procedure (CRP) • Products recommended by EMA, AMA, and EAC through the Joint Dossier	• WHO PQ • SRA • Article 58 • Regional (EAC MRH) • Continental (AMA)

			Assessments *(with each being tracked separately*) • Products registered by at least ML3 functioning regulatory Authorities having Memorandum of • Understanding (MoU) with Rwanda FDA.	
Regulatory Outcome of MA process		• Withdrawn		• Withdrawn • Rejected • Suspended • Cancelled Timing is dependent on when all processes for MA are digitalized

Harmonized set of KPIs for Marketing Authorization

Five KPIs were proposed by TMDA under the Marketing Authorization function for harmonization across the four NRAs. Post discussions, the following set of eight KPIs was aligned upon among the four NRAs. Where relevant, specific nuances and exceptions have been noted.

Two of these indicators have specific variations at the request of AMRH that each NRA will report on. 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 New MA Applications Completed Within a Specified Time Period

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of new MA applications completed within a specified time period**	3	Process	Number of new MA applications completed within the specified time period	Total number of new MA applications received* within the specified time period **See note on UNDA version in "Alignment" section*	(N/D)*100	%	Quarterly
Notes	• Time is measured from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • Specified timelines to be as per the NRA's public charter.							
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 use the denominator "Total number of new MA applications planned to be completed within the specified period" as UNDA uses a target based approach.							

AMRH Requirement	• **KPI 1.1: The indicator will be qualified for the positive outcomes via the regulatory reliance pathway "Regional"**
	  ○ Denominator: the MA Applications received via regional reliance pathways
	  ○ Numerator: the portion of these applications that have been **granted MA** within the specified time period (i.e., 90 working days)
	  ○ Regional pathway refers to the cases where REC joint assessment has been completed
	• **KPI 1.2: The indicator will be qualified for the positive outcomes via the regulatory reliance pathway "Continental"**
	  ○ Denominator: the MA Applications received via continental reliance pathways
	  ○ Numerator: the portion of these applications that have been **granted MA** within the specified time period (i.e., 90 working days)
	  ○ Continental pathway refers to the cases where continental joint assessment has been completed
	Note that the above two indicators are combinations of two sets of the disaggs (Reliance pathway + Regulatory outcome) discussed earlier. While all NRAs may not be able to report on this immediately, they will work on incorporating these disaggs into their systems / processes / SOPs.

KPI #2: Percentage of Renewal MA Applications Completed Within a Specified Time Period

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of renewal MA applications completed within a specified time period**	3	Process	Number of renewal MA applications completed within the specified time period	Total number of renewal MA applications received within the specified time period	(N/D)*100	%	Quarterly
Notes	• Time is measured from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • Specified timelines to be as per the NRA's public charter							
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. Renewal applications for MA is currently not a priority area for the NRA. To be able to report on this, staffing will need to be augmented and the NRA must define targets for each period							

KPI #3: Percentage of Minor Variation MA Applications Completed Within a Specified Time Period

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of minor variation MA applications completed within a specified time period**	3	Process	Number of minor variation MA applications completed within the specified time period	Total number of minor variation MA applications received* within the specified time period **See note on UNDA version in "Alignment" section*	(N/D)*100	%	Quarterly
Notes	• <u>Time is measured</u> from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • Specified timelines to be as per the NRA's public charter							
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 will use the denominator "Total number of minor variation MA applications planned to be completed within the specified period" as UNDA uses a target based approach.							

KPI #4: Percentage of Major Variation MA Applications Completed Within a Specified Time Period

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of major variation MA applications completed within a specified time period**	3	Process	Number of major variation MA applications completed within the specified time period	Total number of major variation MA applications received* within the specified time period **See note on UNDA version in "Alignment" section*	(N/D)*100	%	Quarterly
Notes	• <u>Time is measured</u> from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • Specified timelines to be as per the NRA's public charter where relevant							
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 will use the denominator "Total number of major variation MA applications planned to be completed within the specified period" as UNDA uses a target based approach.							

KPI #5: Percentage of Queries / Additional Info / FIRs Completed Within a Specified Time Period

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of queries / additional info / FIRS completed within a specified time period**	3	Process	Number of queries / additional info / FIRS completed within the specified time period	Total number of queries / additional info / FIRS received* within the specified time period **See note on UNDA version in "Alignment" section*	(N/D)*100	%	Quarterly
Notes	• Time is measured from the date of applicant response to the query / FIR to the date the query / FIR was marked as being completed. Periods during which the application is on hold pending applicant action (e.g., applicant responding to additional information request) are excluded.							
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 use the denominator "Total number of queries / additional info / FIRS planned to be completed within the specified period" as UNDA uses a target based approach.							

KPI #6: MEDIAN TIME TAKEN TO COMPLETE A NEW MA APPLICATION

	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 new application**	3	Process	Arrange all 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 is measured from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • While NRAs are more comfortable with measuring the mean / average rather than the median, it was agreed that the median is a statistically better measure as the mean / average can be highly skewed with the presence of outliers. AMRH also raised that other NRAs have already started to adopt the median and as a point of continental harmonization, it is important to adopt the median as a measure. All NRAs agreed to measure the median going forward, although not all will be able to do so immediately					
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					
AMRH Requirement	• **KPI 6.1: The indicator will be qualified for the regulatory reliance pathway "Regional"** o Regional pathway refers to the cases where REC joint assessment has been completed • **KPI 6.2: The indicator will be qualified for the regulatory reliance pathway "Continental"** o Continental pathway refers to the cases where continental joint assessment has been completed Note that the above are two of the reliance pathway disaggs listed above.					

KPI #7: AVERAGE TIME TAKEN TO COMPLETE A NEW MA APPLICATION

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the average time taken by the NRA to review and make a decision on a new application**	3	Process	Sum of all times taken to complete new MA applications in the specified time period	Total number of new MA applications completed in the specified time period	N/D	Days	Annually
Notes	• Time is measured from the start of regulatory processing (screening or validation) to the issuance of a final decision. Periods during which the application is on hold pending applicant action (e.g., for additional information) are excluded. • As mentioned in the previous KPI, NRAs are currently more comfortable using the mean. It is to be noted that before using the mean, NRAs will need to examine the dataset for outliers to determine if the mean / average is representative and sufficient for decision making purposes. If it is not, the median should be used.							
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: PERCENTAGE OF PUBLIC ASSESSMENT REPORTS PUBLISHED WITHIN SPECIFIED TIMELINES

	Objective	Maturity Level	Indicator Type	Indicator calculation rules			Unit of Measure	Reporting Frequency
				Numerator (N)	Denominator (D)	Formula		
Definition	**Measures the proportion of final assessment reports for approved medicines made publicly available within the specified time period**	4	Output	Number of public assessment reports published within the specified time period	Total number of MAs granted within the specified time period	N/D	Days	Quarterly

Notes	• Only those MAs that were successfully granted are in scope here
	• Time is measured from the point the regulatory decision to grant the MA has been made to the date of PAR publication
	• Specified time period as follows:
	  ○ EFDA: 60 days
	  ○ TMDA: 90 days
	  ○ Rwanda FDA: TBD as not yet implemented
	  ○ UNDA: TBD as not yet implemented							

Alignment	**Legend** ✓ Alignment achieved on all fronts ○ Alignment achieved, but with some differences ✗ NRA will not be taking up this ✓ Aligned across TMDA, EFDA, Rwanda FDA, UNDA – to note, Rwanda FDA and Uganda NDA have not yet implemented these within their guidelines							

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 MA 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.