TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

THE NATIONAL PHARMACOVIGILANCE ROADMAP

2019 -2023

January, 2021

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FOREWORD

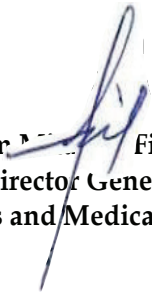
This Roadmap has been developed by the Tanzania Medicines and Medical Devices Authority (TMDA) which was formally known as Tanzania Food and Drugs Authority (TFDA) in collaboration with stakeholders with support from PROFORMA and PAVIA projects funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).

The roadmap is a product of the baseline situational analysis (BSA) which was conducted by using the EAC PV Performance Assessment tool to identify the gaps in PV system. The baseline assessment survey was conducted in the early phases of the PROFORMA and PAVIA projects in August 2018. The tool was categorized into the following areas: Policy, Laws and regulations; Systems, structures and stakeholders' engagement in PV activities; Signal generation and data management; Risk Assessment and Evaluation; Risk Management and Communication. In addition, the BSA also covered the assessment of training curricular in Medical Universities both for a long and short term. Respondents were from TMDA, Medical Universities, PHPs, MAHs and health facilities.

The identified gaps were incorporated to the draft Roadmap and shared to stakeholders in different workshops. The valuable inputs were received from the Ministry of Health Gender, Community development, Elderly and Children (MOHGCEC), Public Health Programs including; National Tuberculosis & Leprosy Program (NTLP), National Malaria Control Programme (NMCP), National AIDS Control Programme (NACP), Neglected Tropical Diseases Control Program and Immunization and Vaccine Development Program, Central Tuberculosis Reference Laboratory (CTRL), Muhimbili University of Health and Allied Sciences (MUHAS), Kilimanjaro Christian Medical University College (KCMUCo), Kilimanjaro Christian Medical Centre (KCMC), Kilimanjaro Clinical

Research Institute (KCRI), Temeke Hospital, Kibong'oto Hospital, Arusha Municipal Council and Kilimanjaro Municipal Council.

Due to rapid advancement in technology, new medical products are already on the market and other being invented every now and then for public use hence close monitoring of their safety, efficacy and quality to the consumer is of paramount importance. This roadmap provides guidance on the implementation of National PV activities in five (5) years period (2019-2023). All activities intend to strengthen the pharmacovigilance system in the country.



Adam [illegible] Fimbo
Director General
Tanzania Medicines and Medical Devices Authority

LIST OF ABBREVIATIONS

ADRs	Adverse Drug Reactions
aDSM	Active Drug Safety Monitoring and Management
BSA	Baseline Situational Analysis
DR-TB	Drug Resistance Tuberculosis
EAC	East African Community
EDCTP	European and Developing Countries Clinical Trials Partnership
ETL	Electronic Tuberculosis and Leprosy database
HCWs	Health Care Workers
HFs	Health facilities
IVD	Immunization and Vaccine Development
KCMC	Kilimanjaro Christian Medical Center
KCMUCo	Kilimanjaro Christian Medical University College
KCRI	Kilimanjaro Clinical Research Institute
MAH	Marketing Authorization Holder
MDR-TB	Multi-Drug Resistant Tuberculosis
MSD	Medical Stores Department
MUHAS	Muhimbili University of Health and Allied Sciences
NACP	National AIDS Control Programme
NMCP	National Malaria Control Programme
NMRA	National Medicines Regulatory Authority
NTDCP	Neglected Tropical Diseases Control Programme
NTLP	National Tuberculosis and Leprosy Control Programme
PAVIA	PharmacoVigilance Africa
PHP	Public Health Programme
PROFORMA	**P**ha**R**mac**O**vigilance infrastructure and post-marketing surveillance system capacity building **FOR** regional **M**edicine regulatory harmonization in East **A**fric**A**
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance

SOP	Standard Operating Procedure
SSA	Sub-Saharan Africa
TMDA	Tanzania Medicines and Medical Devices Authority
TWG	Technical Working Group

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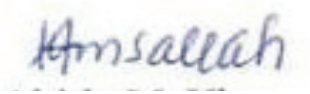
Special thanks to international collaborators from PAVIA and PROFOMA projects for their valuable inputs towards shaping this roadmap.

Special thanks also to the Government of Tanzania and development partners particularly EDCTP for financial support.



Akida M. Khea
Acting Director for Medical Products Control

1. BACKGROUND AND JUSTIFICATION

1.1. Pharmacovigilance in Tanzania

The World Health Organization (WHO) has defined Pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems."[1] The aim of the PV system is to protect the public from medicines-related harm. Currently few low- and middle-income countries have a well-functioning PV system to support the timely identification, collection, and assessment of medicine-related adverse events.

The PV system in Tanzania was introduced in 1989. The major purpose was to monitor and provide relevant information about the safety of medicines. Since its establishment, there have been a lot of interventions conducted to strengthen the system such as development of tools like electronic reporting systems, sensitization and training, establishment of PV zonal centers and active safety monitoring for some selected medicines. The Pharmacovigilance regulations were also developed and endorsed by the Minister responsible for Health, Community Development, Gender, Elderly and Children (MoHCDGEC) in the year 2018. The regulations require for mandatory reporting of all suspected adverse drug reaction by the Marketing Authorization Holders, healthcare works and consumers.

Despite all these efforts, the PV system in Tanzania did not achieve all of its planned goals due to inefficient functional regulatory and organizational structures, limited funds, unclear roles and responsibilities of all stakeholders on ensuring medicinal safety, ineffective active surveillance of Adverse Drug Reactions (ADRs),

[1] WHO 2009, The importance of pharmacovigilance. Safety monitoring of medicinal products. Geneva.

disconnected databases, lack of sufficient Human Resources as well as lack of PV relevant skills and competence among stakeholders

1.2. Why a roadmap?

The roadmap has been developed based on the gaps and challenges identified during the baseline situational analysis (BSA). The roadmap includes all the activities to be undertaken so as to overcome the identified gaps/challenges and hence improve the overall PV system. It states which activities to be done, when, how, by whom and sources of funds for the period 2019-2023.

1.2.1. Brief description of the roadmap development process

This roadmap is the product of the BSA of PV system conducted in August 2018 that was coordinated by the partnership of PAVIA/PROFORMA projects funded by the EDCTP.

The BSA identified the gaps and challenges which led to a workshop that was held in 2019 where stakeholders discussed the findings and defined the desired *'end state'* for the PV situation in the country. The roadmap outlines the areas for PV strengthening, with key activities.

1.2.2. Overview of key gaps identified from the baseline situational analysis

i. Inadequate linkage between the TMDA and the potential PV stakeholders e.g. healthcare workers and professionals, Public Health Programmes (PHPs), Marketing Authorization Holders (MAHs).

ii. Inadequate capacity to analyse aggregated safety information like Periodic Safety Update Reports (PSUR) from MAH
iii. Lack of a locally tailored short courses to train PHPs, MAHs and HFs on PV
iv. Lack of system to estimate the level of drug utilization i.e. size of the population exposed to a product with safety issue.
v. Lack of systematic and well-structured curriculum or stand-alone PV training in medical schools.
vi. Existence of parallel ADR database in various institutions/organizations not linked to TMDA.
vii. Lack of commitment by health facilities leadership and HCWs in ADR reporting
viii. PV being not part of the agenda for implementation for Hospital Drugs and Therapeutic Committees despite PV being one of their main objective (objective 3a-c).
ix. Inadequate awareness on PV among HCWs and management
x. Lack of a well-defined system for ADR risk management at MAH, health facilities and PHPs
xi. Poor connectivity between Multi Drug Resistance Tuberculosis (MDR-TB) PV team and the general hospital PV team.
xii. Lack of PV units and focal persons at MAH and health facilities for coordinating PV activities and liaising with TMDA.
xiii. Poor transfer of knowledge from PV trained staff within the same facility and high rate of PV trained staff turn over
xiv. Low reporting of quality defect issues, medication errors and therapeutic ineffectiveness.

1.3. Alignment of this roadmap with existing national strategic plans

This Roadmap aligns with the existing TMDA and PHP strategic plans in which monitoring of safety, efficacy and quality of medicines are part of their planned activities. It also aligns with the TMDA strategic plan (2017/18 – 2021/2022).

- *Tanzania Medicine and Medical Devices Authority Strategic plan*
  Among the objectives in TMDA strategic plan is monitoring safety, effectiveness and quality of medicines and medical devices. It also aims at; Strengthen the system for regulations of medicines including PV, promote voluntary reporting and management of adverse events and engage in regional collaboration and international harmonization initiatives for PV.

- *Strategic plan for PHPs*
  Each PHP in Tanzania has a strategic plan into which monitoring of safety, efficacy and quality of medicines and other medical products is among the stated objectives. For examples, PV activities for National Tuberculosis and Leprosy Programme (NTLP) are included in the annual operational plan and there is budget allocated for these activities. In addition, there is a national active drug safety monitoring (aDSM) committee that was officially appointed by the MoHCDGEC to deal with MDR - TB. Similarly, other PHPs have their own PV programmes that must be aligned with the National PV Roadmap.

2. GOALS AND STRATEGIC OBJECTIVES OF THIS ROADMAP

The Roadmap is meant to provide an activity plan to strengthen PV in the country over the coming 3-5 years. The strategic objectives are:

i. Improving the efficiency and functioning of regulatory and organizational structures of PV activities
ii. Defining and clarifying the roles and responsibilities for all stakeholders towards ensuring the safety, effectiveness and quality of medicines
iii. Increasing the effectiveness of active (sentinel) surveillance of ADRs
iv. Improving connectivity of databases and use of PV tools for event detection, reporting, analysis and dissemination to relevant stakeholders
v. Increasing resources to sufficiently exercise safety-monitoring activities throughout the country
vi. Improving PV-relevant skills and competencies at various levels
vii. Improving monitoring and evaluation of the performance of the PV system
viii. Enhancing national, regional and international initiatives and networking in relation to PV skills, knowledge and better resource mobilization and utilization

3. KEY MILESTONES AND ACTIVITIES PER STRATEGIC AREA

3.1. Improving the efficiency and functioning of regulatory and organizational structures of PV activities

a) Print and disseminate PV tools (Regulations, Guidelines, SOPs, Registers, and Bulletins).
b) Orient and sensitize on PV regulations to all PV stakeholders
c) Establish system to capture medicines utilization in the country in order strength PV system.
d) Conduct PV inspection as per the PV regulations, 2018
e) Raise awareness on PV to the public through different media (i.e, radio, televisions, bulletins, newspapers, brochures, posters, social medias, magazines), exhibitions events and school education
f) Conduct annual stakeholders meeting to sensitize and create awareness on safety monitoring of medicines
g) Conduct mentorship and supervision to TMDA Zones and health facilities

3.2. Defining and clarifying the roles and responsibilities for all stakeholders to ensure the safety of medicines

a) Establish a process for active surveillance data from PHPs for monitoring safety of newly introduced drug for PRD.
b) Establish standardized procedures for collecting information from PHPs on adverse drug reactions (ADRs) and sharing this information with the national PV Centre.

c) Establish standardized procedure for signal detection and signal communication between PHPs and PV Centres.
d) Train PHPs, MAH healthcare professionals to improve reporting of potential ADRs.
e) Establish collaborative approach in collecting, analyzing and exchanging information and sharing expertise

3.3. Increasing the effectiveness of active (sentinel) surveillance of ADRs

a) Establish a process for including active surveillance data from PHPs in data used by regulatory authorities for decision-making on (safety of) newly introduced drug for PRD.
b) Establish a process for analyzing and interpretation of aDSM data
c) Engage in active surveillance of MDR-TB treatment in collaboration with the NTLP

3.4. Improving connectivity of databases and use of PV tools for event detection, reporting, analysis and dissemination to relevant stakeholders

a) Create a link between TMDA electronic reporting system and electronic systems for NTLP, NMCP, NACP and IVD.
b) To harmonize current health management information systems and electronic ADR reporting systems
c) Ensure availability and public displaying of a toll-free phone number for reporting ADR

3.5. Increasing human resources to sufficiently exercise safety-monitoring activities throughout the country

a) Appoint PV focal persons in all health facilities, PHP, Medical Stores Department (MSD), MAH and community pharmacies.
b) Establish PV task force in all public and private hospitals
c) Sensitize health facilities and PHPs to plan and budget for PV activities
d) Revive seven (7) Zonal PV centers, establish 20 regional PV centers and providing working tools for PV activities

3.6. Improving PV-relevant skills and competencies at various levels

a) Training of staff at Msc and PhD levels on PV.
b) Develop and conduct PV training module/curricula for medical training institutions (MUHAS, UDOM, CUHAS and KCMUCo) for undergraduate and postgraduate programmes
c) Capacity building of TMDA and University staff through participation in regional and international training programmes.
d) Develop and conduct short course training curricula for healthcare professionals, PHPs and MAHs on PV
e) Sensitize HCWs at all levels and Community Advisory Boards on PV activities and the use of m-health in reporting ADRs.
f) Create awareness and sensitize Medicine and Therapeutic Committee (MTC) members on PV.
g) Mapping of the Health Training Institutions (MUHAS, UDOM, CUHAS and KCMUCo) for inclusion for PV module in their Curricula.

h) Dissemination of PV activities through publications and other means of communications.

3.7. Improving monitoring and evaluation of the performance of the PV system

a) Use existing PV indicators to monitor progress focusing on outputs and outcomes (ADR reports received and processed, improvements in active and passive reporting, reports to international databases) and impacts (signals detected, revisions of treatment guidelines); PV training curricula, analyze barriers (national as well as overarching); and adapt roadmaps where needed.
b) Conduct end-term evaluation on implementation of this Roadmap
c) Develop a tailored made tool for MAH, PHPs and health facilities for monitoring and evaluation of PV activities.
d) Use the developed M&E tool to conduct self-biannual monitoring of PV at MAH, PHPs and health facilities.
e) Conduct biannual PV centres workshops to discuss progress and sharing experiences from the best performers

3.8. Enhancing national, regional and international initiatives and networking in relation to PV skills, knowledge and better resource mobilization and utilization

a) Attend Regional and International meetings on PV.
b) Hold annual PV stakeholder meeting *(pharmacovigilance day).*
c) Harmonize PV activities within EAC region.

d) Engage with Regional and International stakeholders such as NEPAD, the African Medicines Agency (AMA), EDCTP, WHO, ISOP and the Uppsala Monitoring Center.
e) Complement/strengthen the supranational capacity for PV and comprehensive risk management of the regional centers of excellence for PV.

4. MONITORING AND EVALUATION FRAMEWORK AND MATRIX PLAN

The Roadmap provides information about the main organizations, responsible stakeholders, activities, timelines, funding source, contributing partners, process, output and outcome indicators, and how these will be measured as per monitoring and evaluation framework (Figure 1), monitoring and evaluation matrix plans (table 1 and 2).

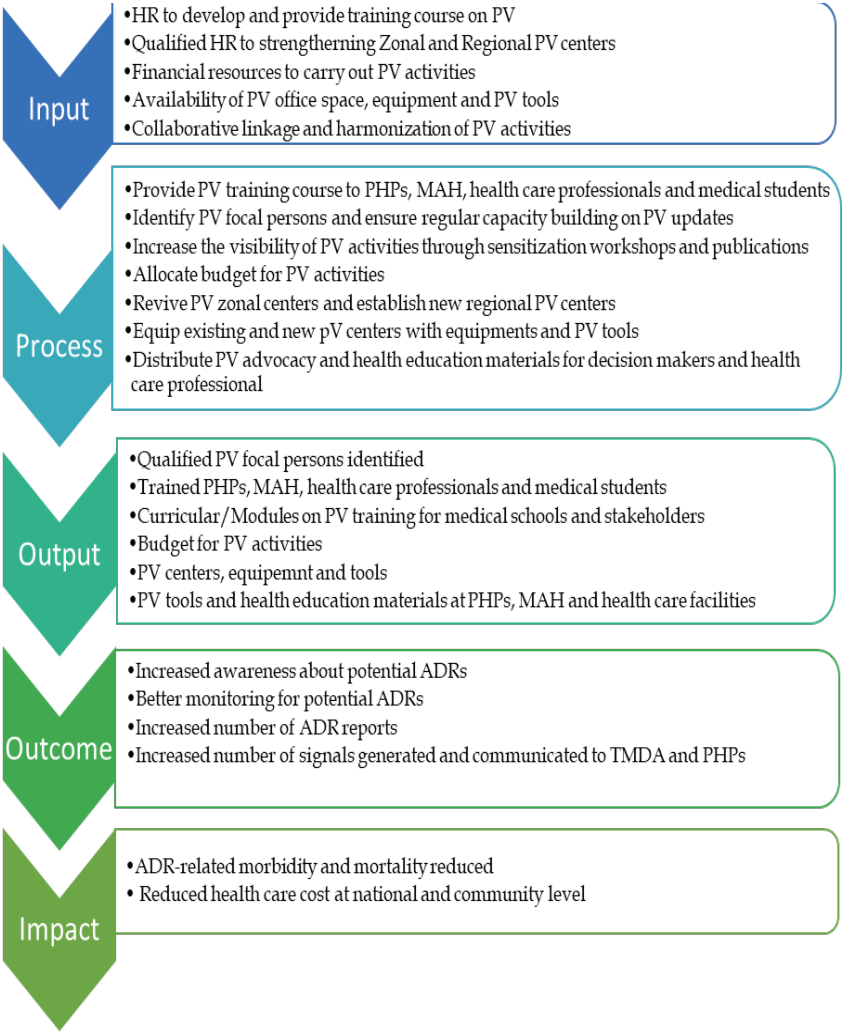

Input
•HR to develop and provide training course on PV
•Qualified HR to strengtherning Zonal and Regional PV centers
•Financial resources to carry out PV activities
•Availability of PV office space, equipment and PV tools
•Collaborative linkage and harmonization of PV activities
Process
•Provide PV training course to PHPs, MAH, health care professionals and medical students
•Identify PV focal persons and ensure regular capacity building on PV updates
•Increase the visibility of PV activities through sensitization workshops and publications
•Allocate budget for PV activities
•Revive PV zonal centers and establish new regional PV centers
•Equip existing and new pV centers with equipments and PV tools
•Distribute PV advocacy and health education materials for decision makers and health care professional
Output
•Qualified PV focal persons identified
•Trained PHPs, MAH, health care professionals and medical students
•Curricular/Modules on PV training for medical schools and stakeholders
•Budget for PV activities
•PV centers, equipemnt and tools
•PV tools and health education materials at PHPs, MAH and health care facilities
Outcome
•Increased awareness about potential ADRs
•Better monitoring for potential ADRs
•Increased number of ADR reports
•Increased number of signals generated and communicated to TMDA and PHPs
Impact
•ADR-related morbidity and mortality reduced
• Reduced health care cost at national and community level

Figure 1: Monitoring and evaluation framework

Monitoring and evaluation of activities will be done to ensure progress towards the intended objectives and to make sure that the resources allocated are being used efficiently. Depending on nature of activities, monitoring can be done Monthly, Quarterly or Yearly. Evaluation will be done at the end of the project to assess the impact of the two projects (PAVIA and PROFORMA) as compared to the baseline assessment.

Table 1: Monitoring and Evaluation Framework

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
Objective 1: Improving the efficiency and functioning of regulatory and organizational structures of PV activities												
a) Print and disseminate PV tools (Regulations, Guidelin	- Percentage of five (5) zonal referral hospital received PV tools	2018	-	20%	40%	60%	80%	100%	TMDA	Reports with list of health facilities	TMDA	TMDA GF WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
es, SOPs, Registers, and Bulletins).	- Percentage of regional referral hospitals received PV tools	2018	-	20%	40%	50%	60%	70%	TMDA	Reports with list of health facilities	TMDA	TMDA GF WHO
	- Percentage of district hospitals received PV tools	2018	-	10%	20%	30%	40%	50%	TMDA	Reports with list of health facilities	TMDA	TMDA GF WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
b) Orient and sensitize on PV regulations to all PV	- Percentage of sensitized PV stakeholders	2018	-	20%	40%	50%	60%	70%	TMDA	Sensitization reports and list of HFs sensitized	TMDA	PAVIA PROFOMA TMDA GF WHO
c) Establish system to capture medicines utilization in the country in order strength	- System in place	2019	-	-	-	-	√	√	TMDA MoHCDGEC	Reports	TMDA	TMDA /GF

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
PV system.												
d) Conduct PV inspection as per the PV regulations, 2018	- Percentage of health facilities inspected	2018	0%	-	10%	20%	25%	30%	TMDA	Reports	TMDA	TMDA GF WHO NORPAT
	- Percentage of MAH inspected	2018	0%	-	10%	40%	60%	70%	TMDA	Reports	TMDA	TMDA GF WHO NORPAT

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	- Percentage of PHPs inspected	2018	0%	-	-	50%	80%	100%	TMDA	Reports	TMDA	TMDA GF WHO NORPAT
e) Raise awareness on PV to the public through different media (i.e, radio, televisio	- Number of sessions delivered through radio and televisio n	2018							TMDA	Reports	TMDA KCRI MUHAS	TMDA GF PAVIA PROFOMA NORPAT

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
ns, bulletins, newspapers, brochures, posters, social medias, magazines), exhibitions events and school education	- Number of bulletin issued	2018							TMDA	Reports	TMDA KCRI	TMDA GF PAVIA
	Number of exhibitions/ events	2018							TMDA	Reports	TMDA KCRI	TMDA GF PAVIA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
f) Conduct annual stakeholders meeting to sensitize and create awareness on safety monitori	- Stakeholders meeting conducted	2018	√	-	-	√	√	√	TMDA	Reports	TMDA KCRI	TMDA GF WHO PAVIA ASCEND
	-Number of stakeholders sensitized	2018	√	-	-	√	√	√	TMDA	Reports	TMDA	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
ng of medicines												
g) Conduct mentorship and supervision to TMDA Zones and health facilities	- Number of TMDA zones supervised/ mentored	2018	7	7	7	7	7	7	TMDA	Reports	TMDA KCRI MUHAS	TMDA GF PAVIA PROFOMA NORPAT
	- Number of health facilities supervised/	2018	38	27	20	20	20	20	TMDA	Reports	TMDA KCRI MUHAS	TMDA GF PAVIA PROFOMA NORPAT

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	mentored											
Objective 2: Defining and clarifying the roles and responsibilities for all stakeholders to ensure the safety of medicines												
a) Establish a structural link between the PV Center and	- Number of joint meetings between PV center and	**2018**	**-**	**-**	**-**	**Objective 2: Defining and clarifying the**	**2**	**2**	**TMDA**	Reports	**TMDA**	**TMDA**

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
PHPs (NTLP, NACP, NMCP, NPCNTD and IVD)	PHP					roles and responsibilities for all stakeholders to ensure the safety of medicines						

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
b) Establish standardized procedures for collecting information from PHPs on adverse drug reactions (ADRs) and sharing this informat	- Standardized procedures (SOPs) for collecting information from PHP in place	2018	-	-	-	√	√	√	TMDA	SOPs	TMDA	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
ion with the national PV Centre.												
c) Establish standardized procedure for signal detection and signal communication between PHPs	- Standardized procedures (SOPs) for signal detection and communication between PHPs	2018	-	-	-	√	√	√	TMDA	SOPs	TMDA	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
and PV Centres.	and PV centers											
d) Train PHPs, MAH healthcare professionals to improve reporting of potential ADRs.	- Number of in-service training and workshops conducted	2018				4	4	4	TMDA	Reports	TMDA	TMDA GF PAVIA PROFOMA ASCEND
	- Number of HCWs trained	2018				100	100	150	TMDA	Reports	TMDA	PAVIA PROFOMA ASCE

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
												ND
	- Number of MAH personnel trained	2018				25	25	25	TMDA	Reports	TMDA MUHAS KCRI	TMDA GF PAVIA PROF OMA
e) Establish collaborative approach in collecting, analyzing	- Number of reports analyzed and exchanged	2018	-	-						Reports		

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
g and exchanging information and sharing expertise	- Number of feedback meetings/sessions held	2018	-	-								
Objective 3: Increasing the effectiveness of active (sentinel) surveillance of ADRs												

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
a) Establish a process for active surveillance data from PHPs for monitoring safety of newly introduced drug for PRD	- SOP for active surveillance in place	2018				√	√	√	TMDA	SOPs	TMDA	TMDA GF

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
b) Establish a process for analyzing and interpretation of aDSM data	- SOP for aDSM data analysis and interpretation	2018				√	√	√	TMDA	SOPs	TMDA	TMDA GF
c) Engage in active surveillance of MDR-TB treatment in collabora	- Number of ADRs reported through aDSM	2018	-	-		√	√	√	TMDA NTLP	Reports	TMDA NTLP	TMDA PAVIA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
tion with the NTLP												
Objective 4: Improving connectivity of databases and use of PV tools for event detection, reporting, analysis and dissemination to relevant stakeholders												
a) Create a link between TMDA electronic reporting system	- Number of electronic ADR reports received from NTLP	**2018**	**-**	**-**	**-**	√	√	√	**TMDA NTLP**	Reports	**TMDA NTLP**	**TMDA PAVIA**

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
and electronic systems for NTLP, NMCP, NACP and IVD.												
	Number of electronic ADR reports received from NMCP	2018	-	-	-	√	√	√	TMDA NMCP	Reports	TMDA NMCP	TMDA GF
	Number of electronic ADR reports	2018	-	-	-	√	√	√	TMDA NACP	Reports	TMDA NACP	TMDA GF

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	received from NACP											
	Number of electronic AEFI reports received from IVD	2018	-	-	-	√	√	√	TMDA IVD	Reports	TMDA IVD	TMDA WHO UNICEF
b) To harmonize current health management informat	- Request sent to MoHCDGEC for harmonizing the	2018	-	-	-	√	√	√	TMDA MoHCDGEC	Reports Letter to MoHCDGEC	TMDA MoHCDGEC	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
ion systems (HMIS) and electronic ADR reporting systems	HMIS											
c) Ensure availability and public displaying of a	- Toll-free phone number for PV in place	2018	-	-	-	-	√	√	TMDA	Reports	TMDA	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
toll-free phone number for reporting ADR	- Number of ADRs received through toll-free phone number	2018	-	-	-	-	20	100	TMDA	Reports	TMDA	TMDA
Objective 5: Increasing human resources to sufficiently exercise safety-monitoring activities throughout the country												

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
a) Appoint PV focal persons in all health facilities, PHP, Medical Stores Department (MSD), MAH and community pharmacies.	- Number of health facilities, PHP, Medical Stores Department (MSD), MAH and community pharmacies with PV focal	2018	31	31	31	40	50	50	TMDA	Appointment letter	TMDA	TMDA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	persons											
b) Establish PV task force in all public and private hospitals	- Number of public and private hospitals with PV task force	**2018**	**-**	**-**	**-**	**5**	**20**	**31**	**TMDA HFs**	Terms of reference, minutes	**TMDA HFs MUHAS**	**TMDA PAVIA GF PROF OMA**
c) Sensitize health facilities and	- Number of PHPs sensitized	**2018**	**1**	**1**	**1**	**5**	**5**	**5**	**TMDA PHPs**	Reports	**TMDA**	**TMDA GF PAVIA PROF**

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
PHPs to plan and budget for PV activities												OMA
	- Number of councils sensitized	2018	-	-	-	10	15	15	TMDA Councils	Reports	TMDA	TMDA GF PAVIA PROF OMA
d) Revive seven (7) Zonal PV centers, establish 20 regional	- PV regional centers functioning	2018	7	3	4	7	7	7	TMDA	Correspondences Number of ADRs	TMDA	TMDA PAVIA GF WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
PV centers and providing working tools for PV activities	- Number of regional PV centers established	2018	-	17	20	20	20	20	TMDA	Letter Distribution tools	TMDA	TMDA PAVIA GF WHO
	- Number of tool supplied	2018			10000	10000	10000	10000	TMDA	Register	TMDA	TMDA PAVIA GF WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	- Number of ADR reports received from new PV centers	2018				200	200	200	TMDA	VigiFlow	TMDA	TMDA PAVIA GF WHO
Objective 6: Improving PV-relevant skills and competencies at various levels												

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
a) Training of staff at Msc and PhD levels on PV	- Number of staff trained for MSc and PhD on PV	2018	-	-	-	1	-	3	TMDA	Certificate of completion	TMDA	TMDA PROFOMA SMERT ASCEND
b) Capacity building of TMDA and University staff through participation in regional	- Number of staff attended training programmes	2018	3	6	6	12	12	12	TMDA	Reports	TMDA MUHAS	TMDA PROFOMA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
and international training programmes.												
c) Develop and conduct PV training module/ curricula for	- PV training curriculum in place	2018	-	1	1	2	3	4	TMDA Medical universities	Curricula/ module document TCU accreditation letter	TMDA Medical universities	TMDA PROFOMA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
medical training institutions (MUHAS, UDOM, CUHAS and KCMUCo) for undergraduate and postgraduate programmes	- Number of universities implementing the curriculum	2018	-	1	1	2	3	4	**TMDA Medical universities**	Curricula/ module document TCU accreditation letter	**TMDA Medical universities**	**TMDA PROFOMA**

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
d) Develop and conduct short course training curricula for healthcare professionals, PHPs and MAHs on PV	- Number of short course curricular in place	2018	1	1	2	5	5	5	TMDA	Approved curricular	TMDA Universities	TMDA PROFOMA PAVIA NORPAT WHO
	- Number of PHPs trained	2018	-	-	-	5	5	5	TMDA	Reports	TMDA Universities	TMDA PROFOMA PAVIA NORPAT WHO
	- Number of MAH trained	2018	-	-	-	25	25	25	TMDA	Reports	TMDA Universities	TMDA PROFOMA PAVIA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
												NORPAT WHO
	- Number of health care workers trained	2018	-	-	-	100	100	150	TMDA	Reports	TMDA Universities	TMDA PROFOMA PAVIA NORPAT WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
e) Create awareness and sensitize Medicine and Therapeutic Committee (MTC) members on PV	- Number of MTCs sensitized	2018				10	15	27	TMDA	Reports	TMDA PSU	TMDA GF PAVIA PROFOMA WHO USAID

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
f) Mapping of the Health Training Institutions (MUHAS, UDOM, CUHAS and KCMUCo) for inclusion for PV curricular/module	- Number medical training institution mapped	2018	0	1		2	-	5	TMDA	Reports	TMDA Universities	TMDA GF PAVIA PROFOMA WHO USAID
	- Number of medical training institution with PV curriculum	2018	0		1	1	3	5	TMDA	Reports	TMDA Universities	TMDA GF PAVIA PROFOMA WHO USAID

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
g) Dissemination of PV activities through publications and other means of communications.	- Number of publication and communication sessions	2018	1	1	2	5	6	8	TMDA	Peer reviewed publications Conference abstracts Conference proceedings Policy brief	TMDA KCMUCo KCRI MUHAS	TMDA GF PAVIA PROFOMA WHO USAID
Objective 7: Improving monitoring and evaluation of the performance of the PV system												

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
a) Update the national M&E tool using existing PV indicators to monitor progress focusing on outputs, outcomes and impacts.	- M&E tool developed	2018	√	√	√	√	√	√	TMDA	M&E tool in place	TMDA	TMDA PROFORMA PAVIA WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
b) Conduct end-term evaluation on implementation of this Roadmap	- M&E conducted	2018	√	-	-	-	√	√	TMDA KCRI MUHAS	Report	TMDA	TMDA PROFORMA PAVIA WHO
c) Develop and disseminate a tailored	- M&E tool for MAH developed and	2018	-	-	-	√	√	-	TMDA	Report	TMDA	TMDA PROFORMA PAVIA WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
made tool for MAH, PHPs and health facilities for monitoring and evaluation of PV activities.	disseminated											
	- M&E tool for PHPs developed and disseminated	**2018**	**-**	**-**	**-**	√	√	**-**	**TMDA**	Report	**TMDA**	**TMDA PROFORMA PAVIA WHO**
	- M&E tool for HFs developed and	**2018**	**-**	**-**	**-**	√	√	**-**	**TMDA**	Report	**TMDA**	**TMDA PROFORMA PAVIA WHO**

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	disseminated											
d) Conduct self-biannual M&E of PV at MAH, PHPs and health facilities.	- Two M&E conducted by MAH, PHPs and HFs	2018	-	-	-	-	√	√	TMDA	Report	TMDA	TMDA PROFORMA PAVIA WHO

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
e) Conduct biannual PV centres workshops to discuss progress and sharing experiences from the best performers	- Number of workshops conducted	2018	1	-	-	2	2	2	TMDA	Report	TMDA	TMDA PROFORMA PAVIA WHO
	- Number of people and facilities attended	2018	-	-	-	25	25	25	TMDA	Reports	TMDA MUHAS KCRI	TMDA PROFORMA PAVIA WHO GF

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
Objective 8: Enhancing national, regional and international initiatives and networking in relation to PV skills, knowledge and better resource mobilization and utilization												
a) Attend Regional and International meetings on PV	- Number of regional and international meetings attended	2018	2	2	-	2	2	2	TMDA	Reports	TMDA MUHAS KCRI	TMDA PROFORMA MUHAS PAVIA EAC NEPAD

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
b) Hold annual PV stakeholder meeting (pharmacovigilance day).	- Number of PV stakeholders meetings conducted	2018	1	1	1	1	1	1	TMDA	Reports	TMDA MUHAS KCRI	TMDA PROFORMA MUHAS PAVIA
c) Domesticate the EAC harmonized guidelines for PV	- EAC harmonized guidelines for PV disseminated to stakehol	2018	-	√	√	√	√	√	TMDA	TMDA Website	TMDA	TMDA EAC

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
	ders											
d) Engage with Regional and International stakeholders such as NEPAD, the African	- Number of PV regional and international initiatives and collaborations engaged	2018	2	4	4	4	4	4	TMDA	Reports	TMDA MUHAS KCRI	TMDA WHO EAC PROFORMA MUHAS PAVIA

Activity	Indicator and indicator description	Baseline		Indicator target value					Data Source	Means of verification	Responsible	Fund
		Date	Value	Y1 (2019)	Y2 (2020)	Y3 (2021)	Y4 (2022)	Y5 (2023)				
Medicines Agency (AMA), EDCTP, WHO, ISOP and the Uppsala Monitoring Center.	- Number of collaborative grant applications submitted	2018	3	3	3	3	3	3	TMDA	Reports	TMDA MUHAS KCRI	TMDA WHO EAC PROF ORMA MUH AS PAVIA

Table 2: Evaluation Matrix Plan

SN	Evaluation Study	Description Evaluation	Study Questions	Methodology	Timeframe	Responsible Person
1.	Baseline Situational Analysis	The BSA aimed at assessing the existing gaps on PV systems	a) Is there adequate regulatory framework for PV? b) Are the stakeholders aware of PV tools and activities? c) Are training institutions having modules/ curricula (short- and long-term courses) on PV related activities?	i. Questionnaires and interviews ii. Checklist	August 2018	TMDA KCRI MUHAS PAVIA PROFORMA
2.	Stakeholders self-assessment	The self-assessment will	a) Are the stakeholders	i. Questionnaires and interviews	January 2023	PHPs, MAHs,

	on PV	be conducted within health facilities, PHP, MAHs and medical universities to ascertain PV activities implementation	having tools for PV activities? b) Are the stakeholders aware of PV tools and activities? c) What kind of reporting systems are used by stakeholders for PV reporting? d) Is there any increase in ADR reporting from stakeholders? e) Are the training modules/ curricula	ii. Checklist		HF MUHAS

			developed and implemented?			
3.	End term evaluation on implementation of the PV Roadmap completed	The evaluation aims to measure performance of PV Roadmap	a) Have the objectives of the PV Roadmap been achieved? b) What were the limitations? c) Has the ADR reporting improved? d) What lessons can be learnt from PV Roadmap implementation?	i. Questionnaires and interviews ii. Checklist	January 2023	TMDA KCRI MUHAS PAVIA PROFORMA

5. CONCLUSION

This Pharmacovigilance roadmap has been developed basing on the findings of the baseline assessment conducted in August 2018. It outlines strategic areas and all activities that will be implemented in five years to achieve the stated project objectives. The expectation is to have an improved and efficient Pharmacovigilance system in Tanzania.

This is a general country PV road map that will need funds from different sources for the implementation of various activities. Finance is always a major issue to address. The existing projects i.e. PAVIA, PROFORMA will select the areas of interest for implementation according to the focus of the projects and the remaining activities will be implemented using Government funds allocated at the regulatory Authority and other funds from development partners such as Global Funds, WHO and others who will have PV activities component.