Roadmap toward a strengthened national pharmacovigilance systems [Kingdom of Eswatini], [[Timespan: 2019 – 2022]]

25 February 2020

Preface

This roadmap was developed in response to the need to strengthen Pharmacovigilance activities in the country and ensure the safety of our patients. The roadmap addresses the key strategic areas and prioritized activities namely:

1. Coordination, Policy and Implementation Development System
2. Adverse Events/Serious Adverse Events Recording and Reporting
3. Health Care Workers Capacity Development
4. Clinical Management
5. Data Management and Analysis (Data management system, Electronic system, and Causality assessment)
6. Pharmacovigilance Awareness Activities

The PV Roadmap was developed based on the outcome of the baseline assessment which details the strategic objectives, strategies, activities and expected outcomes following the implementation of the identified priority strategic policy areas. The roadmap also includes a detailed and timed action plan to facilitate its operationalization. The Roadmap was developed through a widely consultative process involving all relevant stakeholders.

The Ministry is committed to implementing this roadmap; I therefore encourage all stakeholders to fully participate in the successful implementation of this roadmap and for the improvement of pharmacovigilance in the kingdom of Eswatini.

This roadmap was developed as a product of the PAVIA project[1], which is part of the EDCTP2 programme supported by the European Union (grant number CSA2016S-1627-PAVIA)

Thank You

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EDCTP

PAVIA PhArmaco Vigilance Africa

[1] PAVIA (Pharmacovigilance Africa) envisions to strengthen the PV systems in four countries: Ethiopia, Nigeria, Eswatini and Tanzania, to have more effective drug safety reporting mechanisms for new products introduced and to gain a better understanding of their safety profiles. PAVIA's objectives are:
I) To strengthen governance of Pharmacovigilance (PV) systems, by strengthening regulatory and organizational structures and defining clear roles and responsibilities for all stakeholders
II) To improve efficiency and effectiveness of national surveillance systems, by strengthening active (sentinel) surveillance of adverse drug reactions and implementation of tools and technologies for their detection, reporting, analysis and dissemination
III) To build capacity and skills to sufficiently conduct safety-monitoring activities throughout the country
IV) To improve readiness of health systems within Sub-Saharan Africa by improving performance assessment of PV systems allowing identification of enablers and barriers for implementation.
PAVIA's strategy is to strengthen national PV systems in a collaborative effort with Public Health Programs (PHPs), building up medicines safety surveillance activities in the context of the introduction of new drugs for multidrug-resistant tuberculosis. Capacity at the national PV Centre/national medicines regulatory authority will be built gradually taking the PV activities for tuberculosis as the "building and training ground" for a generic PV system including data collection, database entry, data analysis, signal identification and causality assessment. The results and lessons learned will be transferred by PAVIA to the PHP for HIV and malaria. Combined with identified enablers and barriers in addressing regional differences and needs, a blueprint will be developed that can guide other countries in strengthening their PV systems.

List of abbreviations

ADR	Adverse Druga reaction
aDSM	Active TB Drug Safety and Monitoring system
AE	Adverse Event
BLA	Baseline Assessment
CEM	Cohort Event Monitoring
CMS	Central Medical stores
DR-TB	Drug resistant TB
GDF	Global Drug Facility
MOH	Ministry of Health
MRU	Medicine Regulatory Unit
NAHSAR	National Health Semi-Annual Review
NPVU	National Pharmacovigilance Unit
PAVIA	PhArmacovigilance Africa
PEPFAR	President's Emergency Plan for AIDS Relief
PHP	Public Health Programmes
PV	Pharmacovigilance
REHSAR	Regional HIV Semi-Annual Review
RHMTs	Regional Health Management Teams
SC-PASS	Supply Chain and Pharmaceutical Assistance for Sustainable System
TB QRMs	TB Quarterly data Review Meetings
UMC	Uppsala Monitoring Center

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1. Background and justification

1.1. Pharmacovigilance in Eswatini

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."[2] The aim of PV system is to protect the public from medicines-related harm. Currently only a limited number of low- and middle-income countries have a well-functioning PV system to support the timely identification, collection, and assessment of medicine-related adverse events.

Eswatini has been engaged in PV activities to assess the impact of adverse drug reactions on public safety and health since 2009. These activities have evolved from spontaneous reporting to encompass active surveillance systems initiated in 2015 for patients receiving TB and/or HIV medicines in sentinel sites. As it is indicated on the current PV structure (figure 1), National Pharmacovigilance unit (NPVU) coordinates all pharmacovigilance activities in the country. The National Patient Safety Monitoring Committee (NPSMC) was established to provide technical assistance to the NPVU on data analysis and validation including causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication. Notwithstanding the efforts that have been invested on PV in the country aspects of its development have been notably limited.

A baseline assessment (BLA) was conducted in June 2018; this was to present the situational analysis of the various aspects and needs of the PV systems in Eswatini at the start of the PAVIA project. One of the recommendations of the BLA was for the direct entry of PV data into existing ADR data management software, such as VigiFlow, that was already being used by the NPVU. This was encouraged in order to ensure proper coding of ADRs and medicines into internationally accepted standard dictionaries, such as MedDRA and WHO-DD, that are built into the software. These programs also make it possible to provide separate and complete information on both suspected medicines and concomitant medicines used by patients. It was also recommended that NPVU should be strengthened to routinely undertake causality/relationship assessment on collected ADR reports, such as through a work-sharing mechanism with members of the NPSMC. Results of the causality assessment are necessary for providing meaningful feedback on reports. Reporting of ADRs and other medicine-related problems should be expanded to include health care providers in the private sector as well as those at lower levels of health care delivery by training and actively engaging them in the PV process.

It was envisioned that these and a number of other recommendations from the BLA would assist in strengthening the PV systems in the country and therefore it was against this background that a country roadmap for PV has been developed.

1.2. Strength and challenges of pharmacovigilance in Eswatini

Strengths:

1. The political goodwill of government is a great strength for the growth of PV in Eswatini coupled with the enthusiasm of the available personnel
2. The legal framework envisaged is likely to position PV and integrate it into the healthcare system
3. The existent Law though not activated provides a potential enabling environment and a substrate for various facets of PV to build on

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

Challenges

1. A great weakness and limitation relates to the personnel disposition in numbers and expertise. Despite being a small country there are too few personnel to deal with the PV activities at the national level and around the country
2. The lack of resources to facilitate the growth of PV is a hindrance that have to be addressed
3. The lack of training platforms for PV locally and the inability to fully factor into external opportunities is yet another weakness
4. The country also lacks basic infrastructure to provide visibility for PV providing space to allow for PV function.

1.3. The roles and responsibilities of all stakeholders towards ensuring the safety of medicines

A key component of developing a strong PV system is the integration of pharmacovigilance activities into public health programmes (PHPs), such as HIV/AIDS, Tuberculosis, Immunization and Malaria programmes. Multiple ADR reporting structures tend to evolve when a country has vertical public health programs operating; however, such fragmentation ultimately weakens the system. Conversely, a public health program that has a well-established ADR collection and reporting structure can serve as a model and a starting point for a national system.

1.3.1. Public Health programmes

The Public health programmes issue guidelines for use of the new medicine(s) and ADR reporting, provides the drugs and other treatment components (e.g. laboratory monitoring), and oversees the implementation of the treatment including ADR reporting (e.g. clinical monitoring, laboratory investigations, follow-up of patients). Generally, the PHP will provide the drugs and other treatment components (e.g. laboratory monitoring) for free.

1.3.2. Health facilities

The health facilities provide treatment to the patients, monitor patients for ADRs and report ADRs to the NPVU.

1.3.3. National Pharmacovigilance Unit (NPVU)

In close collaboration with the PHP NPVU oversees and monitors the ADR reporting by the health facilities. It receives, collates and analyses the ADR reports entered in the PV database. In consultation with the National Patient safety and monitoring committee (NPSMC) and PHPs it interprets the data, detects signals and provides risk-benefit evaluations. Finally, it reports the findings back to health facilities and PHP. NPVU is also responsible for coordinating all PV activities, collecting ADR reports, developing and adapting procedures, developing training modules, training health workers, promoting rational use of drugs and reporting ADRs to the UMC

1.3.4. WHO collaborating center- UMC

Some of the responsibilities of WHO collaborating center (UMC) initiating, organizing, carrying out, advising and guiding a number of clinical programmes in PV; it also supports member states in assuring the safe use of medicinal products, encourages all clusters within WHO to advise member states on how to monitor the safe use of these products and encourages initiatives to conduct operational research on PV.

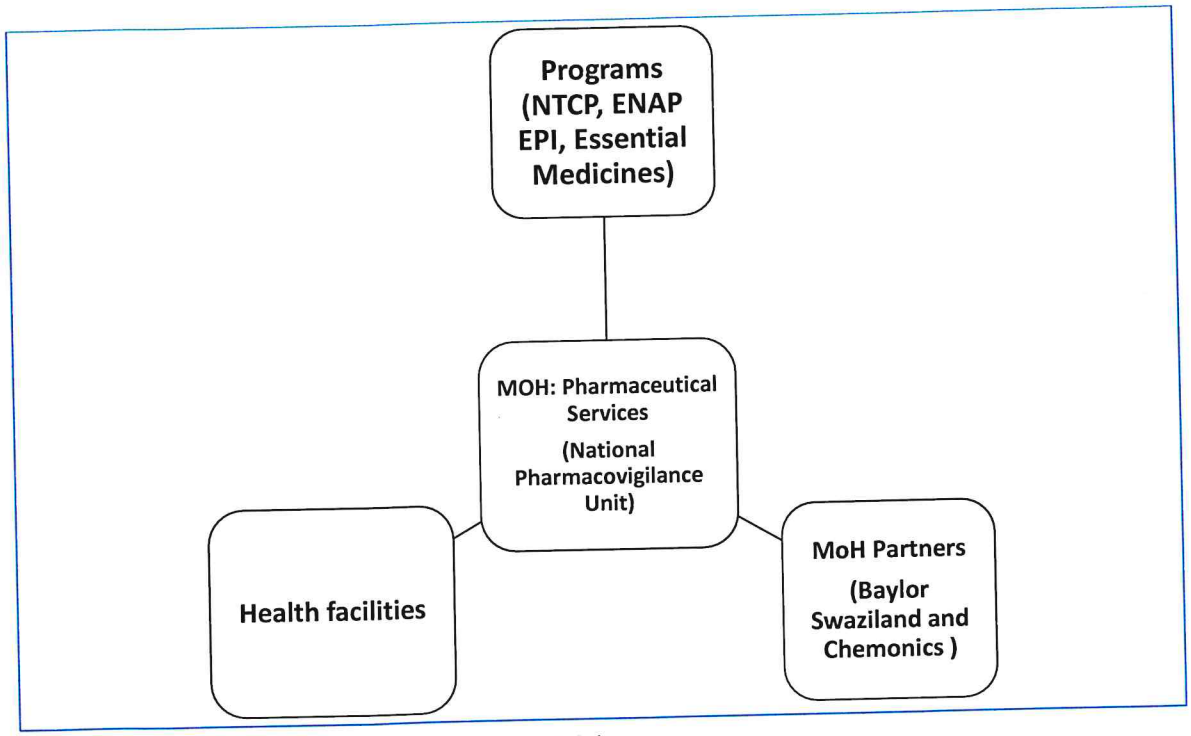

Figure 1: Structure of Pharmacovigilance in Eswatini

1.4. Why a roadmap?

1.4.1. Brief description of the roadmap development process

This roadmap was developed based on a baseline situational analysis that assessed the various aspects and needs of the PV system in Eswatini at the start of the PAVIA project.
Based on the gaps and challenges identified during the baseline situational analysis and the recommendations thereof, a workshop with all key PV stakeholders in the country was held to discuss the findings and define the desired 'end state' for the PV situation per country.

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

- ✓ There is inadequate legal provisions for PV or medicine safety in the Medicines and Related Substance Control Act.
- ✓ Since the Act does not prioritize PV it can only be expected that the subsequent Regulations will address issues concerning the monitoring of medicines post licensure.
- ✓ The Medicine Regulatory Authority (MRA) has not been established due to constraints in funding.
- ✓ There are no marketing authorization holders in the country; all medicines are imported from international manufacturers so there are no provisions requesting Marketing Authorization Holders to submit any Pharmacovigilance Plans, Risk Management Plans, Risk Minimization/Mitigation Plans, Periodic Safety Update Reports, report adverse drug reactions/medicine safety related issues, etc.
- ✓ The NMRA with a PV unit formally does not yet exist
- ✓ PV funding is mainly donor-driven which makes the national PV work vulnerable to international donors' focus areas and threats its long-term sustainability
- ✓ None of academic institutions included PV training curriculum like reporting, assessment and analysis of adverse drug reactions.

- ✓ Although the clinical management of adverse events is addressed, the formal and standardized TB and HIV training curriculum does not include a specific section for PV in any of in-service training
- ✓ There is no website for dissemination of PV information.
- ✓ Only in 2015, reports were entered in VigiFlow and submitted to VigiBase at the UMC.
- ✓ There is no dedicated computer available for the national PV database.
- ✓ Reports that are entered in Excel and not also entered in VigiFlow; theyare stored on one person's laptop only.
- ✓ There is no strong reporting practice due to high workload and copying of patient information prevents reporting to be a priority.
- ✓ In most health facilities reports of adverse event are collected monthly.
- ✓ Acknowledgement of receipt is not given consistently.
- ✓ Feedback is not given on individual reports, but summaries of adverse events and signals are presented through different platforms like: the PV newsletter, DR-TB expert group meetings, and emails.
- ✓ No causality assessment has been done for spontaneous reporting so far and The last causality assessment meeting happened towards the end of 2016 for CEM
- ✓ There is a lack of resources and capacity for data analysis and causality assessment
- ✓ The NPSMC discusses the management of adverse events but is not very active in driving causality assessment.

1.5 Alignment of this roadmap with existing national strategic plans

Both Eswatini National Pharmaceutical Policy[3] and Strategic plan (2012-2016)[4] support the establishment of pharmacovigilance unit. Despite the guidance of the two documents in the establishment of the pharmacovigilance unit, most of strategic objectives included in this roadmap are not part of the National strategic plan. Both Pharmaceutical Policy and Strategic plan are due for review.

2. Goals and strategic objectives of this roadmap

The overall goal is to implement activities that are listed under the following strategic plan to generate local, evidence-based information to improve patient care and safety through the identification, management, and prevention of medicine-related morbidity and mortality in patients.

1. Coordination, Policy and Implementation Development System
2. Adverse Events/Serious Adverse Events Recording and Reporting
3. Health Care Workers Capacity Development
4. Clinical Management
5. Data Management and Analysis (Data management system, Electronic system, and Causality assessment)
6. Pharmacovigilance Awareness Activities

3. Methodology and team

3.1. Stakeholder workshop

Several stakeholders like senior government officials, public health programmes, HMIS, MoH partners were invited to the Baseline assessment dissemination and roadmap development workshop. After presenting the findings, the participants suggested possible interventions to the gaps identified during the BLA.

[3] Swaziland National Pharmaceutical Policy 2nd Edition March 2011, pp9
[4] Swaziland Pharmaceutical Strategic Plan 2012–2016, pp13

3.2. Developing the roadmap

Based on the preliminary BLA findings, NPVU in collaboration with ENAP, NTCP and SC-PASS prepared a draft annual PV work plan. After finalizing the BLA different stakeholders were invited the roadmap development workshop. The purpose of this workshop was to disseminate PV baseline assessment findings with broader stakeholder involvement to analyze the findings and propose country-customized solutions and activities to address the gaps identified. Based on the proposed solution, a roadmap was developed, containing the targets and anticipated approach to strengthen the organizational framework, a supportive financial model, a PV action plan as well as a customized communication & dissemination plan.

3.3. Relationship between this roadmap and the annual work plans

This roadmap will be accompanied by annual work plans, detailing the activities to be implemented in the first following 12 months. These annual work plans will provide information about the main organization and focal person responsible for each activity, contributing partners, detailed timelines, budget needed and funding source, process, output and outcome indicators, and how these will be measured (Figure 1).

The workplans will be published as separate documents annually, referring to this roadmap that outlines the overall strategy for PV strengthening and the links with other existing strategic plans.

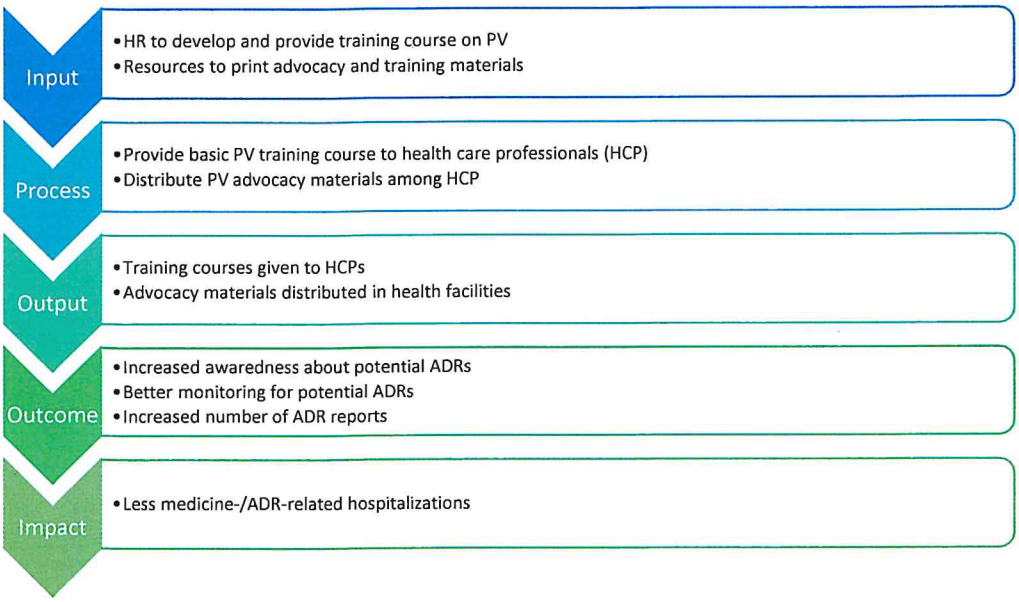

Figure 1. Monitoring and evaluation framework.

4. Key milestones and activities per strategic area

4.1. Strategic objective 1: Coordination, Policy and Implementation Development System Sub-objective 1.1. To Strengthen Coordination of PV Activities in Eswatini

A pharmacovigilance system should include all entities and resources that protect the public from medicine related harm, whether in personal health care or public health services. The pharmacovigilance system aims to achieve this protection through efficient and timely identification, collection, and assessment of ADEs, and by communicating risks and benefits to support decision

making about medicines at various levels of the health care system. The responsibility for pharmacovigilance should be shared among multiple stakeholders, including Medicine Regulatory Unit, public health programs, MoH partners, WHO, academic researchers, donor organizations, the health care delivery sector, and the public and patients. This collaborative approach creates synergy and better coordination in creating and sustaining advocacy and actions that support pharmacovigilance.[5]

To Strengthen Coordination of PV Activities in the kingdom the following activities will be accomplished with the coordination of NPVU:

- ✓ Finalize PAVIA Annual Work Plan and National Work plan
- ✓ Establish National PV Centre within MRU
- ✓ Conduct quarterly PV work plan meetings
- ✓ Establish aDSM Task Team and TOR
- ✓ Conduct aDSM Task Team quarterly meeting
- ✓ Conduct PAVIA Project Annual Meeting
- ✓ Review composition and Revive National Patient Safety Monitoring Committee (NPSMC)
- ✓ Review and update terms of reference (TORs) of NPSMC
- ✓ Conduct NPSMC quarterly meetings
- ✓ Conduct PV stakeholder sensitization meeting (PAVIA project national kick-off meeting)
- ✓ Conduct PV baseline situational analysis (including aDSM)
- ✓ Disseminate situational analysis results and PV road map
- ✓ External for travel to PAVIA Annual Meetings and face to face trainings

Sub-Objective 1.2. To Strengthen Legislative, Policy and Operational Environment for Pharmacovigilance in Eswatini

NVPU through PAVIA project will develop a National standalone PV policy that will provide the policy direction on medicines patient safety in the country. This document provide guidance for to setting up and sustaining an efficient surveillance mechanism for the early detection of adverse reactions to medicines administered to man and other medicine related problems, the receipt and processing of reports from a safety-conscious population of healthcare providers and consumers and the taking of appropriate measures to prevent or limit medicine-induced harm. It will also provide an enabling environment for effective planning, implementation, monitoring and evaluation of the pharmacovigilance system by the NPVU, partners, private health sectors, and health programmes. The policy addresses issues related to the systems and structures that are required for pre and post-authorization monitoring of safety and effectiveness of health products in Eswatini. The policy will also assist to facilitate the identification of suspected products of poor quality, cases of therapeutic ineffectiveness, medication errors and overall monitoring for safety and effectiveness after the registration of a medicine. Additionally, the policy document will also forge a way to finance PV system in the country.

Under this sub objective, PV guidelines and standard operating procedures will also be developed. The development of these documents will provide an enabling environment for the operational side of the PV system in Eswatini. They will allow all stakeholders to have a common understanding of what is expected of them at an operational level when it comes to PV in the country.

Establishing a national PV system requires a strong legal framework and political commitment. The legal basis for pharmacovigilance is in Eswatini is laid down in the Medicine and Related Substance

[5] Strengthening Pharmaceutical Systems (SPS). Supporting Pharmacovigilance in Developing Countries: The Systems Perspective. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.

Act. The PAVIA project will contribute in the finalization of the regulations for the Medicines and Related Substances Act that will provide legal framework for pharmacovigilance.

Another activity to be done under this sub-objective is; an advocacy for the inclusion of clear policy statements on PV in all national health policy and strategic health documents in Eswatini as well as advocate for the establishment of NMRA

Sub-objective 1.3. Financing PV

Funding of Pharmacovigilance activities remains a major challenge. Although the MoH pays the salaries of PV staff from the consolidated fund, currently PV funding is mainly donor-driven. This makes the national PV work vulnerable to international donors' focus areas and threats its long-term sustainability. To ensure steady and sustainable support to PV in the country, NPVU will advocate for resource mobilization and recruitment of additional staff for NPVU.

4.2. Strategic Objective 2: Adverse Events/Serious Adverse Events Recording and Reporting

Sub-objective 2.1. To streamline PV (including aDSM) recording and reporting

Under this sub-objective NPVU in collaboration with other stakeholders will review, print and disseminate ADR data collecting forms to facilities.

Sub-objective 2.2. To Strengthen PV Reporting in Eswatini

To establish a mechanism to ensure that adverse drug reactions are systematically reported and reviewed, NPVU in collaboration with PAVIA project and programmes:

- will develop SOP(s) for data clerks on handling and capturing reports into Vigiflow
- review and develop PV Job Aids
- define aDSM intermediate package
- explore on WEB-RADR mob app usage and adapt in the country's context,
- Renew subscription of Vigiflow® with UMC
- Establish global aDSM (GDF and aDSM global database) reporting for the country.

4.3. Strategic objective 3. Health Care Workers Capacity Development

Sub-objective 3.1. Incorporate PV into pre-service training

NPVU will engage academic institutions to provide undergraduate PV training, ensuring that all new healthcare professionals to know their role in documenting, reporting and learning from experience of medicine-related harm, including medication errors. The targeted training institutions are those that provide health science trainings like Nursing and Pharmacy.

Sub-objective 3.2. To Improve the Capacity of Health Care Workers on PV knowledge, reporting and data analysis.

The importance of (PV) for safe medicines and their safe use has increasingly been recognized during the last few years. PV has been subject of intense research and regulation. In particular, it has earned more and more importance and attention in low-resource countries. This is largely due to the globalization of trade and the availability of new, highly effective but potentially harmful chemical medicinal products in those parts of the world where traditional treatments, in particular herbal or other complementary remedies, used to prevail.

NPVU in collaboration with PAVIA and TB care II will develop a structured PV training for health care professionals. Developing a structured PV curriculum would pave the way to strengthen Pharmacovigilance and assure the safety of patients.

The sub activities of this objectives are:

- Establish PV training needs (use PAVIA baseline assessment report)
- Develop a National PV (including aDSM) training curriculum

- Conduct Training of Trainers on Causality Assessment, Signal Detection and Risk Identification (for NPVU)
- Develop PV Support Supervision (SS) and Mentoring Tools
- Sensitization and onsite support supervision of Active PV
- Conduct PV (NTCP, SNAP and NPVU) Quarterly SS and Mentoring Visits

4.4. Strategic objective 4: Clinical Management

Successful management of adverse drug reactions requires early identification and prompt treatment. As a country, the following sub activities are planned to improve the clinical management of patients who have experienced ADRs:

- ✓ Follow up of adverse events for patients on new drugs
- ✓ advocate for common ancillary drugs to be in Essential drug list for management of adverse effects
- ✓ Advocate for procurement of visual monitoring tools (Snellen chart, ishihara chart, ophthalmoscopes) in DR-TB sites, hospitals and health centers.
- ✓ Routine monitoring using ECG machine or visual screening tools for patients on QTc prolonging drugs or visual impairing drugs as defined by DR-TB guidelines
- ✓ Annual refresher offsite training and ongoing onsite training.
- ✓ Monthly collection of data on ECG and visual for patients on QTc prolonging or visual impairing drugs
- ✓ Routine monitoring of ototoxicity using audio equipment for patients on injectable drugs
- ✓ Annual refresher offsite training and ongoing onsite training.
- ✓ Monthly collection of data on ototoxicity for patients on injectable drugs

4.5. Strategic Area 5: Data Management and Analysis (Data Management Systems, Electronic System, and Causality Assessment)

The pharmacovigilance data management starts with identifying ADR, recording, ADR management, reporting, and analysis. All these stages require a high and complex degree of technical skill and judgment to ensure that accurate conclusions and right decisions are made during the establishment of benefit-risk profile for a product. A poor pharmacovigilance data management not only jeopardizes patient safety; it also increases the risk of investing in the development of wrong product which causes a huge loss to a pharmaceutical company. Therefore, it is very important to establish a robust pharmacovigilance data management system which complies with the stringent regulatory guidelines, global pharmaceutical norms and ultimately safeguard the pharmacovigilance end users, the patient.

NPVU will engage stakeholders and MOH partners to combat these and other related challenges through linking active surveillance activities of PHPs to NPVU by connecting the databases of the NPVU and Programs. NPVU in collaboration with NTCP, ENAP and Chemonics will review and update the active surveillance and passive PV forms print it in a booklet, duplicate and distribute to health facilities. Provide training to clinicians for reviewed active surveillance PV forms

In the mission to have strong ADR reporting and data management system, NPVU will engage the Health Management Information Systems (HMIS) department at MoH to integrate PV module into CMIS. This is with an intention of identifying of PV indicators and development of PV reports within CMIS. Creating a pharmacovigilance dashboard centrally and at facility level is another sub activity planned to be done under this strategic objective.
Prepare an ADR report receipt acknowledgement letter template, engaging two data clerks for capturing PV reports into electronic systems at NPVU using Vigiflow®, Provide training for data clerks to enter data into global reporting systems (UMC, aDSM, GDF), Ensure regular PV feedback sessions

at existing platforms (REHSAR, NAHSAR, TB QRMs, RHMTs, DR-TB Expert meetings, news bulletins etc.)

To increase global visibility of a country's pharmacovigilance system it was also planned to identify and write a project proposal in year 1 of the project and complete the project in year II. Preparing at least two Abstracts and presenting it on a different international workshop are also planned under this strategic objective.

4.6. Strategic Area 6. Pharmacovigilance Awareness

Disseminating newsletters, medicine bulletins are some of activities that planned to improve awareness on PV in the country. The most recent medicine safety information from reputed medical or pharmaceutical journals will be used as routes of effective propagation of latest developments in medicine research and therapy to the healthcare professionals. Public awareness creation on PV through a MOH radio program is also another activity area included under this strategic objective. Advocating for the creation of a PV section under the MoH webpage on the government website is another way of creating awareness as it will assist to regularly update Physicians, Pharmacists, Programs and public on safety issues of medicines. Information through the webpage can also be an alternative platform to provide informal education and trainings. Training material can be adapted from WHO-UMC open access platforms. Additionally, the unit requires a permanent secretariat to handle phone calls, database, and documentation of literature and coordination of activities like interfacing with related departments to maintain secretariat continuity for successful functioning of the center.

PV Sensitization Meetings for MOH & Partner Senior Staff (MOH Senior Staff, Country Program Directors, Technical Directors, and Program Managers) as well as senior Management in the Regions (RHMTs) through appropriate platforms will be done to strengthen PV.

5. Action plan

The implementation plan of the National Action Plan will include M&E. The M&E framework of the implementation plan will include output/deliverables for the activities/sub activities in the plan. The monitoring of the strategic plan will conduct by tracking each activity and sub-activity using the time line indicated for each activity. The detailed description of the Action plan is given under Annex 1.

6. Conclusions

The six strategic objectives outlined will be implemented by the NPVU in collaboration with key PV stakeholders in the course of three years. The established roles and responsibilities for all major stakeholders and participants in in this roadmap will be followed on by identifying challenges and gaps during the implementation of the roadmap. This roadmap will strengthen pharmacovigilance though education, training, supervision, clinical monitoring as well as provision of policy and regulation.

Annex 1. Eswatini Pharmacovigilance work-plan

Objective	Activity	Sub-Activity	Responsible	Timeline	Resource Required	Source of Funds	Measure of Success
***Eswatini PAVIA Project Core Team = PAVIA Coordinator, NPVU, TB Program, MRU and HIV Program(ad hoc basis)**							
Strategic Area 1: Coordination, Policy and Implementation Development System							
1.1. To Strengthen Coordination of PV Activities in Eswatini	**Activity 1.1.1.** Finalize PAVIA Annual Work Plan	Meeting (Eswatini PAVIA Project Core Team	PAVIA Coordinator, Eswatini PAVIA Project Core Team	Apr 19	Staff Time, Meeting Resources-(600 USD)	Chemonics	Finalized Work Plan
	Activity 1.1.2. Establish National PV Centre within MRU	Procurement of Office Equipment and IT Accessories	PAVIA/BAYLOR	Aug 19	Financial Resources (Procurement of Office Equipment, Hardware & Software Accessories-17,000USD)	PAVIA Baylor	Infrastructure in place (Procured Desktops(x2), 5 Laptops, 1 projector , 5 office desks, 1 server software accessories for NPVU (antivirus, windows package)
	Activity 1.1.3. Conduct quarterly PV work plan meetings		NPVU,PAVIA Coordinator	quarterly	Staff Time, Meeting Resources- (500 USD)	PAVIA Baylor	Meeting minutes, Updated Work Plan
	Activity 1.1.4. Establish aDSM Task Team and TOR		ODDPS, NPVU, NTCP ,SNAP, PAVIA	May 19	Staff Time	N/A	aDSM specific Coordinating Task Team established with TORs
	Activity 1.1.5. Conduct aDSM Task Team Quarterly Meeting		NPVU, NTCP	Quarterly	Staff Time, Meeting Resources-(500 USD)	PAVIA Baylor	Meeting Minutes
	Activity 1.1.6.Conduct NPSMC quarterly meetings		NPVU/NPSMC	Quarterly	staff time and Financial resource for meetings (600 USD	Chemonics	Meeting Minutes
	Activity 1.1.7. Disseminate situational analysis results and PV road map		NPVU/PAVIA coordinator	Mar 19	staff time	NA	Workshop report
	Activity 1.1.8. External for travel to PAVIA Annual Meetings and face to face trainings		NPVU, NTP, KNCV, Baylor	Apr 19	Financial Resources for travel: Air ticket, accommodation, per diem(8000USD)	PAVIA MO and PAVIA Baylor	Mission reports

1.2. To Strengthen Legislative, Policy and Operational Environment for Pharmacovigilance in Eswatini	**Activity 1.2.1**.Develop PV Policy, Guideline and Standard Operation Procedure(s)	Advocacy with ODDPS	NPVU(Siphesihle)	May 19	Staff time	N/A	Meeting minutes
		Inventory of all policy related docs	NPVU, PAVIA Coordinator	Sep 19	Staff Time	N/A	List of supporting Documents for the development of the PV policy
		Key Stake holder identification	NPVU, PAVIA Coordinator	Sep 19	Staff Time	N/A	List of Key stakeholder
		Outline the framework of PV policy and Guideline (zero draft)	PAVIA coordination office/Prof. Ambrose	Sep 19	Transport/visa/accommodation and other travel expenses???	PAVIA MOH	PV policy, guideline and SOP frame work
		Stakeholder meeting 1(email)	NPVU/PAVIA coordinator	Oct 19	staff Time	PAVIA MOH	Inputs from the participants
		Stakeholder meeting 2(workshop)	NPVU, Baylor	Nov 19	Financial Resource (Breakfast Meeting x 25pple- 1000USD) (Day Meeting x 50pple- 2000USD)	PAVIA MOH	Workshop report and inputs from the participants
		Review of the document(PV policy/Guideline /SOP	NPVU	Jan 20	Financial Resource (Breakfast Meeting x 50 people- 2000 USD)	PAVIA MOH	Workshop report and prepare the final draft documents
		Approval/endorsement	ODDPS/NPVU/PAVIA coordinator	Feb 20	Staff Time	N/A	Approved Stand-alone PV policy, PV guideline and SOP
		Printing and dissemination	NPVU/PAVIA coordinator	Mar 20	Financial resource for printing (10,000 USD)	PAVIA MOH	Printed and distributed PV policy/Guideline/SOP : 500 copies of PV policy and 1000 copies PV GL and SOP each

	Activity 1.2.2. Provide for Pharmacovigilance in Eswatini Legislative Framework	Drafting Regulations for Medicines and Related Substances Control Act No. 9 of 2016	MRU, NPVU, PAVIA Coordinator, ODDPS	Jun 19	Financial Resource (5-day Meeting x 10 people - 3000USD	MOH PAVIA	Draft Regulations of Medicines and Related Substances Control Act No. 9 of 2016
1.3 Financing PV	**Activity 1.3.1.** Resource mobilization for NPVU funds		DDPS/Quality control Pharmacist	ongoing	Staff Time	N/A	Meeting Minutes
	Activity 1.3.2. Advocate for inclusion of clear policy statements on PV in all national health policy and strategic health documents in Eswatini		DDPS	ongoing	Staff time	N/A	Meeting minutes
	Activity 1.3.3. Recruit staff for NPVU		DDPS	ongoing	Staff time	N/A	Meeting minutes
	Activity 1.3.4 Develop MRA regulation		MRU, NPVU, PAVIA Coordinator, ODDPS	ongoing	Staff time	N/A	Meeting minutes
	Activity 1.3.5. Advocate for the establishment of NMRA		MRU, NPVU, ODDPS	ongoing	Staff time	N/A	Meetings Minutes
Strategic Area 2: Adverse Events/Serious Adverse Events Recording and Reporting							
2.2. To Strengthen PV Reporting in Eswatini	**Activity 2.2.1.**Develop SOP(s) for data clerks on handling and capturing reports into Vigiflow		PAVIA coordinator	Jun 19	Staff Time	N/A	SOP(s) Developed
	Activity 2.2.2. Review and Develop PV Job Aids	Review Current PV Job Aids	PAVIA coordinator	Jun 19	Staff Time, Meeting Resources (60 USD)	PAVIA Baylor	PV Job Aids in place (5 x 1000 copies)
		Develop new PV Job Aids	PAVIA coordinator	Jun 19	Staff Time, Meeting Resources (60 USD)	PAVIA Baylor	
		Print new and reviewed PV Job Aids	PAVIA coordinator	Jun 19	Financial Resource (Printing of Job Aids-1000 USD)	PAVIA Baylor	
	Activity 2.2.3. Define aDSM intermediate Package		PAVIA coordinator/NTCP	May 19	Staff Time	N/A	Defined intermediate Package and printed (20 copies)

	Activity 2.2.4. Explore on WEB-RADR mob app and use		PAVIA coordinator	Feb 20	staff time and Financial Resource to Adapt the mobile app (500 USD??)	PAVIA	Adapted WEB-RADR app
	Activity 2.2.5. Renew subscription of Vigiflow® with UMC		MOH PAVIA	May 19	Financial Resources for subscription fees (1500USD)	PAVIA MOH	Renewed UMC Subscription
	Activity 2.2.6. Establish global aDSM (GDF and aDSM global database) reporting for the country		NPVU/PV coordinator	Jul 19	Staff time	N/A	Number of ADR reports submitted to global aDSM database
Strategic Area 3. Health Care Workers Capacity Development							
3.1. To Improve the Capacity of Health Care Workers on PV knowledge, reporting and data analysis	**Activity 3.1.1.**training for clinical and lab mentors		NPVU/Chemonics/PV Coordinator	Jul 19	Financial resource for training venue and refreshment (500 USD)	Chemonics Eswatini	Training report
	Activity 3.1.2. Establish PV training needs (use PAVIA baseline assessment report)		NPVU/Programs/BAYLOR/PAVIA	May 19	Staff time, PAVIA baseline assessment Report	N/A	PV training needs report
	Activity 3.1.3. Develop a National PV (including aDSM) training curriculum		TA (Technical Assistance TB Cares II Global Team),	Jun 19	Financial Resources: Meetings and Printing of Training Manuals- (500 USD)	PAVIA Baylor	Printed training manuals
	Activity 3.1.4. Conduct Training of Trainers on Causality Assessment, Signal Detection and Risk Identification (for NPVU)		TB Care II Global Team, WHO, PAVIA	Jun 19	Financial Resource: Venue, Accommodation and Transport Allowance- (10000 USD)	PAVIA Baylor	Training report
	Activity 3.1.5. Develop PV Support Supervision (SS) and Mentoring Tools		NPVU/NTCP/ENAP/Baylor/PAVIA	Jul 19	Staff time	N/A	Final SS visit and Mentoring tool
	Activity 3.1.6. Sensitization and onsite support supervision of Active PV		NPVU, NTCP, PAVIA Coordinator	Monthly	Staff time and Transport	N/A	Sensitization and onsite support supervision of Active PV Reports

	Activity 3.1.7. Conduct PV (NTCP, SNAP and NPVU) Quarterly SS and Mentoring Visits		NPVU/Programs/PAVIA	Oct-2018 (Ongoing)	Staff Time, Financial Resource: Transport and lunch (6000 USD)	PAVIA Baylor	SS visits and mentoring reports
Strategic Area 4: Clinical Management							
Objective 4.1. To improve the clinical management of AEs	**Activity 4.1.1**.Follow up of adverse events for patients on new drugs		NTCP, DR TB Health Facilities	Aug-2018(ongoing)	Staff Time	N/A	Report
	Activity 4.1.2.Advocate for common ancillary drugs(for management of adverse effects) to be in Essential drug list		NTCP, DR TB Health Facilities	Jun 19	Staff Time	N/A	Meeting minutes
	Activity 4.1.3. Advocate for procurement of visual monitoring tools (Ishihara chart, Snellen chart and ophthalmoscopes) in DR-TB sites, hospitals and health centers		NTCP	ongoing	Staff time	NA	Meeting minutes
	Activity 4.1.4. Routine monitoring using ECG machine and Visual monitoring tools for patients on QTc prolonging drugs or visual impairing drugs as defined by DR-TB guidelines	A. Annual refresher offsite training and ongoing onsite training	NTCP, DR TB Health Facilities	ongoing	Staff time/Global Fund	Global Fund	Meeting minutes
		B. Monthly collection of data on ECG and visual screening tools for patients on QTc prolonging drugs or visual impairing drugs	NTCP		NTCP	NTCP/PAVIA MOH	Collected and compiled data
	Activity 4.1.5.Routine monitoring of ototoxicity using audio equipment for patients on injectable drugs b) Annual refresher offsite training and ongoing onsite training's) Monthly collection of data on		NTCP, DR TB Health Facilities, NPVU, Baylor, Chemonics	ongoing	Staff time, transport, lunch	Na	Meeting minutes

	ototoxicity for patients on injectable drugs						
Strategic Area 5: Data Management and Analysis (Data Management Systems, Electronic System, and Causality Assessment)							
Objective 5.1. To harmonize and Develop PV tools	**Activity 5.1.1.** Identify indicators and development of PV reports within CMIS,		**NPVU**	**Done**	**staff time**	**N/A**	**Identified indicators**
	Activity 5.1.2. Integration of PV modules into CMIS (including ensuring compatibility with Vigiflow)		NPVU, MOH-SID, IHM, Baylor	19 Jul	Staff Time, Financial Resources: Consultancy Fee-(7000 USD)	PAVIA MOH	PV Module available in CMIS, Consultant Report on...
	Activity 5.1. 3. review and print Passive PV forms		NPVU/PAVIA coordinator	19 Jul	Financial resource for printing(1000 USD)	Chemonics	Printed Passive PV forms
	Activity 5.1.4. Prepare a receipt of ADR report acknowledgement letter template		PAVIA Coordinator	19 Jun	Staff time	NA	Finalized Template
	Activity 5.1.5. Review and Print Active ADR Forms		NPVU/NTCP/Chemonics	Quarterly (Printing)	Staff Time, Financial Resources: Printing of Forms-(2000 USD)	PAVIA Baylor	Printed and distributed ADR forms
Objective 5.2.To Strengthen PV Data Management and Analysis	Activity 5.2.1. Conduct training on general PV for all health care workers (IMAI, NARTIS, TB/HIV training , RHMTs)		NPVU, PAVIA Coordinator	As scheduled by programs and regions	Staff Time	N/A	Number of health facility staff trained on PV
	Activity 5.2.2.Conduct training to conduct Causality Assessment for facility PTCs, PV Committee(s), RHMTs		NPVU, PAVIA Coordinator	19 Jun	Training Venue, accommodation and transport allowance (5000 USD)	PAVIA MOH	Training Report
	Activity 5.2.3.Engage two data clerks for capturing PV reports into electronic systems at NPVU (Vigiflow)		Chemonics	19 Apr	Staff Salary-(15,000USD annually	Chemonics	Data Clerks Engaged

	Activity 5.2.4. Provide training for data clerks to enter data into global reporting systems (UMC, aDSM, GDF)		NPVU	19 May	Staff time	NA	Training Report
	Activity 5.2.5. Conduct a quarterly Causality assessment		NPVU/PROGRAMMES /PAVIA-BAYLOR	Quarterly	Financial resource for a one week Meeting venue, accommodation (20,000USD)	PAVIA Baylor/EGPAF/Chemonics	Compiled Assessment report
	Activity 5.2.6. Ensure regular PV feedback sessions at existing platforms (REHSAR, NAHSAR, TB QRMs, RHMTs, DR-TB Expert meetings, news bulletins etc.)		NPVU/PROGRAMMES /PAVIA-BAYLOR	As scheduled by programs and regions starting July 2019	Staff time	N/A	Number of PV feedback sessions conducted
	Activity 5.2.7. Identification and Proposal writing		MOH	19 Jan	Staff time	N/A	Completed proposal(s)
	Activity 5.2.8. Ethical consideration		MOH	19 Nov	Staff time	N/A	Approved research proposal(s)
	Activity 5.2.9. Abstract for conferences attending workshop(x2)		PAVIA	June – Dec 19	Staff time, Financial resources to attend workshops (5000USD)	PAVIA MOH	Prepared abstract and trip report
Strategic Area 6. Pharmacovigilance Awareness							
Sub-Objective 6.1. To Improve Awareness on PV	**Activity 6.1.1.**Create Public Awareness on PV through MOH Radio Program		NPVU focal person	Quarterly	Staff Time	N/A	Number of public awareness activities conducted
	Activity 6.1.2. Advocate for incorporation of PV MOH Webpage		Quality Control Pharmacist	Jun 19	Staff Time	N/A	Information on PV available on MOH webpage
	Activity 6.1.3. Produce PV Newsletter		NPVU, PAVIA Coordinator Eswatini PAVIA Project Core Team	Quarterly	Staff Time, Financial Resources (Print of Quarterly Newsletter-2000USD)	Chemonics	Printed and distributed Quarterly News letter

	Activity 6.1.4. Conduct PV Sensitization Meeting for MOH & Partner Senior Staff (MOH Senior Staff, Country Program Directors, Technical Directors, Program Managers)		Quality Control Pharmacist. PAVIA Coordinator and STTA (TB Care II Global Team)	Jun 19	Staff Time, Financial Resources (Breakfast Meeting x 25 pple-1000 USD)	WHO	Sensitization Meeting Report
	Activity 6.1.5. Conduct PV Sensitization Meeting of Senior Management in the Region (RHMTs) through appropriate platforms		Quality Control Pharmacist. PAVIA Coordinator	Jun 19	Staff Time, Financial Resources (Meeting x 25 people x 4regions 1500 USD)	PAVIA MOH	Sensitization Meeting Report
YEAR II							
Strategic Area 1: Coordination, Policy and Implementation Development System							
Objective 1.1. To Strengthen Coordination of PV Activities in Eswatini	**Activity 1.1.1. R**eview Annual Work Plan		NPVU/ENAP/NTCP/Baylor/Chemonics	Mar 20	Financial resources for a meeting (500USD)	Chemonics	Reviewed Annual Work plan
	Activity 1.1.3. Conduct quarterly PV work plan meetings		NPVU/NTCP/ENAP/Baylor/PAVIA	Quarterly	Financial resources for a meeting (500USD)	PAVIA MOH	Meeting minutes
	Activity 1.1.4. Conduct aDSM Task Team Quarterly Meeting		NPVU/NTCP/ENAP/Baylor/PAVIA	Quarterly	Financial resources for a meeting (500USD)	PAVIA MOH	Meeting minutes
	Activity 1.1.5. Conduct PAVIA Project Annual Meeting(Eswatini Annual Consortium Meeting)		NPVU	Mar 20	Financial resource for the meeting	PAVIA MOH	Meeting Minutes
	Activity 1.1.6.Conduct NPSMC quarterly meetings		NPVU	Quarterly	Financial resources for a meeting (500USD)	Chemonics	Meeting minutes
Strategic Area 2: Adverse Events/Serious Adverse Events Recording and Reporting							
Sub-Objective 2.1. To improve the	Activity 2.1.1. Provide a refresher training to clinicians on active surveillance PV forms		NPVU	Jun 20	Financial Resources for the training (5000USD)	PAVIA MOH	Training report

recording and reporting of AEs and SAEs	**Activity 2.1.2.** Introduce WEB-RADR mob app and use		PAVIA/NPVU/WHO	Jul 20	Financial Resources to develop the app and roll out (?????? USD	PAVIA/WHO???	Mobile app available
	Activity 2.1.3. Renew subscription of Vigiflow® with UMC		NPVU	May 20	financial Resources for UMC subscription (1500USD)	PAVIA MOH	Proof of Subscription
	Activity 2.1.4. Update global aDSM (GDF and aDSM global database) reporting for the country		NPVU/NTCP	quarterly	Financial resources for transportation and Lunch allowances (1000 USD)	PAVIA Baylor??	Filed database
Strategic Area 3. Health Care Workers Capacity Development							
Sub-Objective 3.1. To incorporate PV curriculum in pre-service training	**Activity 3.1.1.** incorporate PV curriculum in pre-service training(nursing and Pharmacy)	Engage TA to develop the curriculum	NPVU	Mar 20	Financial resource to hire a consultant (1000USD)	Chemonics Eswatini	Draft PV curriculum for pre-service trainings
		Engage tertiary institutions (both in country and in the region), Education Partners (UN??	NPVU/SANU/SCU/UNISA/UNICEF/WHO	Apr 20	Financial Resource for the meeting (2000 USD???	Chemonics	Meeting Minutes
		Prepare first draft	PAVIA/NPVU	May 20	Staff time	NA	First draft of the curriculum
		conduct stakeholder meetings and review the curriculum	PAVIA/NPVU	May 20	Financial Resource for the meeting (1000 USD???	WHO/PAVIA MOH/PAVIA Baylor	Meeting Minutes
		Develop the final draft and roll out	NPVU	Jun 20	Staff time	NA	Final document incorporated into the institution's curriculum

Sub-Objective 3.2. To build the capacity of health care workers on pharmacovigilance	Activity 3.2.1. Conduct a refresher training for clinical and lab mentors		NPVU	May 20	Financial resource for the training venue and accommodation(10,000USD)	PAVIA Baylor??	Training report
	Activity 3.2.2. Conduct a refresher Training of Trainers on Causality Assessment, Signal Detection and Risk Identification for PTCs		NPVU	Jul 20	staff time	NA	Training Report
	Activity 3.2.3. Review PV Support Supervision (SS) and Mentoring Tools		NPVU/ENAP/NTCP	Aug 20	staff time	NA	Final SS visit Tool
	Activity 3.2.4.Sensitization and onsite support supervision of Active PV		NPVU/ENAP/NTCP	Monthly	Financial resource to conduct the SS visit (????)	NTCP/PAVIA MOH	SS visit report
	Activity 3.2.5.Conduct PV (NTCP, SNAP and NPVU) Quarterly SS and Mentoring Visits		NPVU/ENAP/NTCP	Quarterly	Financial resource to conduct the SS visit (10,000USD)	NTCP/PAVIA MOH	SS visit report
	Activity 3.2.6. Conduct General PV training for health care workers		University of Verona	Apr 20	Financial resource for the training venue and accommodation (10,000USD)	PAVIA Baylor??	Training Report
	Activity 3.2.7. Conduct training on general PV for all health care workers (IMAI, NARTIS, TB/HIV training , RHMTs)		NPVU	As scheduled by programs and regions	Staff time	NA	Training report
Strategic Area 4: Clinical Management							
	Activity 4.1.1.Follow up of adverse events for patients on new drugs		NPVU/NTCP	Monthly	staff time	NA	Report
	Activity 4.1.2.Advocate for common ancillary drugs(for management of adverse effects) to be in Essential drug list		NPVU/NTCP		Staff time	NA	Report

Strategic Area 5: Data Management and Analysis (Data Management Systems, Electronic System, and Causality Assessment)							
	Activity 5.1. 1. Review and print Passive PV forms		NPVU/PAVIA coordinator	Mar 20	Financial resource for printing(1000 USD)	Chemonics	Printed Passive PV form
	Activity 5.1.2. Review and Print Active ADR Forms		NPVU/NTCP/Chemonics	Quarterly (Printing)	Financial resource for printing(1000 USD)	Chemonics	Printed Active PV form
	Activity 5.1.3. Ensure regular PV feedback sessions at existing platforms (REHSAR, NAHSAR, TB QRMs, RHMTs, DR-TB Expert meetings, news bulletins etc.)		NPVU/PROGRAMMES /PAVIA-BAYLOR	As scheduled by programs and regions	staff time	NA	Report
	Activity 5.1.4. Conduct a quarterly Causality assessment		NPVU/PROGRAMMES /PAVIA-BAYLOR	Quarterly	Financial resource for a one week Meeting venue, accommodation (20,000USD)	PAVIA Baylor/EGPAF/Chemonics	Compiled Assessment report
	Activity 5.1.5. Abstract for conferences attending workshop(x2)		PAVIA	Twice a year	Staff time, Financial resources to attend workshops (5000USD)	PAVIA MOH	Trip report
Strategic Area 6. Pharmacovigilance Awareness							
	Activity 6.1.1. Create Public Awareness on PV through MOH Radio Program		NPVU	Quarterly	staff time	NA	
	Activity 6.1.3. Produce PV Newsletter		NPVU	Quarterly	Staff Time, Financial Resources (Print of Quarterly Newsletter-1000USD)	Chemonics	Printed and disseminated Newsletter
YEAR III							
Strategic Area 1: Coordination, Policy and Implementation Development System							
	Activity 1.1.1. Review Annual Work Plan		NPVU	Mar 21	Financial resources for a meeting (500USD)	Chemonics	Reviewed Annual Workplan
	Activity 1.1.2. Conduct quarterly PV work plan meetings		NPVU/NTCP/ENAP/Baylor/PAVIA	Quarterly	Financial resources for a meeting (500USD)	PAVIA MOH	Meeting minutes

	Activity 1.1.3. Conduct aDSM Task Team Quarterly Meeting		NPVU/NTCP/ENAP/Baylor/PAVIA	Quarterly	Financial resources for a meeting (500USD)	PAVIA MOH	Meeting minutes
	Activity 1.1.4. Conduct PAVIA Project Annual Meeting (Eswatini Annual Consortium Meeting)		NPVU	Mar 21	Financial resource for the meeting	PAVIA MOH	Meeting Minutes
	Activity 1.1.5.Conduct NPSMC quarterly meetings		NPVU	Quarterly	Financial resources for a meeting (500USD)	Chemonics	Meeting Minutes
	Activity 1.1.6. External for travel to PAVIA Annual Meetings and face to face trainings		NPVU, NTP, KNCV, Baylor	Apr 21	Financial Resources for travel: Air ticket, accommodation, per diem(8000USD)	PAVIA MO and PAVIA Baylor	Mission reports
Strategic Area 2: Adverse Events/Serious Adverse Events Recording and Reporting							
	Activity 2.1.1. Provide a refresher training to clinicians on active surveillance PV forms		NPVU/PAVIA	Jun 21	staff time	NA	Training report
	Activity 2.1.2. Update global aDSM (GDF and aDSM global database) reporting for the country		NPVU/PAVIA	quarterly	Financial resources for transportation (1000 USD)	PAVIA Baylor	Global data available
	Activity 2.1.3: Update Vigiflow		NPVU/PAVIA	Monthly	staff time		
Strategic Area 3. Health Care Workers Capacity Development							
Sub-Objective 3.1. To build the capacity of health care workers on pharmacovigilance	Activity 3.1.1. Conduct a refresher training for clinical and lab mentors		NPVU	May 21	Financial resource for the training venue and accommodation (10,000USD)	PAVIA Baylor??	Training report
	Activity 3.1.2. Conduct a refresher Training of Trainers on Causality Assessment, Signal Detection and Risk Identification for PTCs		NPVU	Jul 21	staff time	NA	Training Report
	Activity 3.1.3. Review PV Support Supervision (SS) and Mentoring Tools		NPVU/ENAP/NTCP	Aug 21	staff time	NA	Final SS visit Tool

	Activity 3.1.4.Sensitization and onsite support supervision of Active PV		NPVU/ENAP/NTCP	Monthly	Financial resource to conduct the SS visit (????)	NTCP/PAVIA MOH	SS visit report
	Activity 3.1.5.Conduct PV (NTCP, SNAP and NPVU) Quarterly SS and Mentoring Visits		NPVU/ENAP/NTCP	Quarterly	Financial resource to conduct the SS visit (10,000USD)	NTCP/PAVIA MOH	SS visit report
	Activity 3.1.6. Conduct training on general PV for all health care workers (IMAI, NARTIS, TB/HIV training , RHMTs)		NPVU	As scheduled by programs and regions	Staff time	NA	Training report
Strategic Area 4: Clinical Management							
	Activity 4.1.1.Follow up of adverse events for patients on new drugs		NPVU/NTCP	Monthly	staff time	NA	Report
Strategic Area 5: Data Management and Analysis (Data Management Systems, Electronic System, and Causality Assessment)							
5.1. Review PV Tools	Activity 5.1. 1. Review and print Passive PV forms		NPVU/PAVIA coordinator	Mar 21	Financial resource for printing(1000 USD)	Chemonics	Printed Passive PV form
	Activity 5.1.2. Review and Print Active ADR Forms		NPVU/NTCP/Chemonics	Quarterly (Printing)	Financial resource for printing(1000 USD)	Chemonics	Printed Active PV form
5.2. PV data analysis and Dissemination	**Activity 5.2.1.** Ensure regular PV feedback sessions at existing platforms (REHSAR, NAHSAR, TB QRMs, RHMTs, DR-TB Expert meetings, news bulletins etc.)		NPVU/PROGRAMMES /PAVIA-BAYLOR	As scheduled by programs and regions starting July 2019	Staff time	NA	
	Activity 5.2.2. Conduct a quarterly Causality assessment		NPVU/PROGRAMMES /PAVIA-BAYLOR	Quarterly	Financial resource for a one week Meeting venue, accommodation (20,000USD)	PAVIA Baylor/EGPAF/Chemonics	Compiled Assessment report

5.3. Abstract writing and attending workshops	**Activity 5.3.1.** Abstract for conferences attending workshop(x2)		PAVIA	Twice a year	Staff time, Financial resources to attend workshops (5000USD)	PAVIA MOH	Trip report
Strategic objective 6:							
	Activity 6.1.1.Create Public Awareness on PV through MOH Radio Program		NPVU	Quarterly	staff time	NA	
	Activity 6.1.2. Produce PV Newsletter		NPVU	Quarterly	Staff Time, Financial Resources (Print of Quarterly Newsletter-1000USD)	Chemonics	Printed and disseminated Newsletter