

**NATIONAL TUBERCULOSIS & LEPROSY
CONTROL PROGRAMME (NTBLCP)**
Federal Ministry of Health



ROADMAP TOWARDS A STRENGTHENED NATIONAL PHARMACOVIGILANCE SYSTEM IN NIGERIA 2019 -2022

Preface

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.” The aim of the PV system is to protect the public from medicines-related harm.

The National Pharmacovigilance Centre (NPC) in Nigeria became the 74th member of the WHO international drug monitoring program on 9th September, 2004. PV activities in Nigeria have evolved from spontaneous reporting to active surveillance systems in the form of CEM in 2009. Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as a complement to spontaneous reporting commonly used in pharmacovigilance systems.

NAFDAC, in collaboration with relevant stakeholders, in 2012 developed the Nigeria National PV Policy and Implementation Framework; NAFDAC Good Vigilance Practice Guideline 2016 and the Guideline for Reporting ADR by MAHs and health care professionals.

The Nigerian pharmacovigilance system has grown since its conceptualization and entry into the WHO Program for International Drug Monitoring in the last two to three decades.

The strengths of this system include its visibility with basic infrastructure distributed around the country by regionalization/zonalization and growing availability of resource persons.

The weakness of the PV System is the inadequate awareness amongst health care professionals and the public as is reflected by the low reporting rate of adverse drug reactions to NAFDAC. The major threats to the strengthening of the pharmacovigilance system remain those of funding and the mobility of staff to other sectors of the economy.

This roadmap was developed based on a baseline situational analysis that assessed the situation of the various aspects and needs of the PV systems in Nigeria at the start of the PAVIA project, including its strengths and gaps.

Based on the gaps and challenges identified during the baseline situational analysis, a workshop with all key stakeholders in the country was held to discuss the findings and define the desired ‘end state’ for the PV situation. This roadmap has been developed through a stakeholder engagement process involving the baseline assessment, the subsequent stakeholder workshop and consultations.

This roadmap outlines the areas for PV strengthening, with key activities. Detailed activities specific for the PAVIA project will be laid down in annual work plans, which will cover year 2 (April 2019-March 2020) to year 4 (April 2021-March 2022) of the PAVIA project.

The management of NAFDAC is committed to the implementation of these road-map using available resources

I urge relevant Stakeholders in Pharmacovigilance to provide adequate support to NAFDAC and other PAVIA partners to enhance implementation of this road map to enable the Agency improve safety monitoring of medicines in Nigeria.

Prof. Christianah Mojisola Adeyeye, FAS.
Director-General.

This roadmap was developed as a product of the PAVIA project¹, which is part of the EDCTP2 programme supported by the European Union (grant number CSA2016S-1627-PAVIA).



EDCTP



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 Drug Reaction
ACRO	Assistant Chief Regulatory officer.
aDSM	active Drug Safety Management And Monitoring
AE	adverse event
CAP	chapter (Latin); used in legal documents
CEM	Cohort Event Monitoring
DOT	Directly Observed Treatment
EAC	East African Community
FMOH	Federal Ministry of Health
GOPD	General outpatient department
HCP	Health Care Professional
HIV	Human Immunodeficiency Virus
ICSR	Individual Case Safety Report
IHVN	Institute of Human Virology, Nigeria
IPAT	Indicator-based Pharmacovigilance Assessment Tool
LGTBLS	Local Government Tuberculosis and Leprosy Supervisor
MDR	multidrug resistant
M&E	Monitoring and Evaluation
NACA	National Agency for Control of Aids.
NAFDAC	National Agency for Food and Drug Administration and Control
NASCAP	National Aids/STI Control Programme
NETIMS	National Electronic TB Information Management System
NMRA	National Medicines Regulatory Authority
NPC	National Pharmacovigilance Centre
NTBLCP	National Tuberculosis and Leprosy Control Program
OPD	outpatient department
PHP	Public Health Program
PMDT	Programmatic Management of Drug-resistant Tuberculosis
PMS	Post-marketing surveillance
PRASCOR	Pharmacovigilance rapid Alert System for Consumer Reporting
PSUR	Period Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person responsible for Pharmacovigilance
SAE	Serious Adverse Event

SOP	Standard Operating Procedures
SPHAR-TI	Structured Pharmacovigilance and Training Initiative
SSA	Sub-Saharan Africa
STR	Shorter Treatment Regimen
TB	tuberculosis
WHO	World Health Organization
XDR	extensively drug-resistant

Table of contents

ROADMAP TOWARDS A STRENGTHENED NATIONAL PHARMACOVIGILANCE SYSTEMS IN NIGERIA 2019 -2022	1
Table of contents	6
1. Background and justification	7
1.1. Pharmacovigilance in Nigeria.	7
1.2. Why a roadmap?	8
1.2.1. Brief description of the roadmap development process	8
1.2.2. Overview of key gaps identified from the baseline situational analysis	8
1.3 Alignment of this roadmap with existing national strategic plans	8
2. Goals and strategic objectives of this roadmap	9
3. Methodology and team	9
3.1. Stakeholder workshop	9
3.2. Developing the roadmap	10
3.3. Relationship between this roadmap and the annual workplan	10
4. Key milestones and activities per strategic area	11
4.1. Improving the efficiency and functioning of regulatory and organisational structures	20
4.2. Improving the financial sustainability of PV activities in the country	20
4.3. Clarifying the roles and responsibilities for all stakeholders towards ensuring the safety of medicines	21
4.4. Increasing the effectiveness of active (sentinel) surveillance of ADRs	21
4.5. Improving connectivity of databases and (use of) tooling for event detection, reporting, analysis and dissemination to relevant stakeholders	22
4.6. Increasing human resources to sufficiently exercise safety-monitoring activities throughout the country	22
4.8. Gaining experience in monitoring and steering the performance of the PV system	23
4.9. Better align with regional and international initiatives to avoid fragmentation of resources & investments	23
5. Action plan	24
6. Conclusions	24

1. Background and justification

1.1. Pharmacovigilance in Nigeria.

The World Health Organization (WHO) has defined 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 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.

Pharmacovigilance activities in Nigeria date back to the 1980s with initial attempts of training of Ministry of Health officials, facilitated by the University of Benin where preliminary collection of adverse drug reactions (ADR) had started and an ADR Registry/Drug Poisons Information Unit was established.

The National Pharmacovigilance Centre (NPC) in Nigeria is part of the National Agency for Food and Drug Administration and Control (NAFDAC). The scope of PV activities in Nigeria includes the monitoring of adverse drug reactions (ADR), medication errors, interactions of medication, abuse/misuse of medicines and lack of effectiveness. NPC collects ADR reports on pharmaceutical products such as drugs, vaccines and biologicals as well as medical devices and cosmetics. There is a National Drug Safety Advisory Committee which provides expert advice on the safety of medicines. There are six Zonal PV centers, one in each of the six geopolitical zones of the country.

The NPC in Nigeria became the 74th member of the WHO international drug monitoring program on the 9th of September 2004. PV activities in Nigeria have evolved from spontaneous reporting to active surveillance systems in the form of CEM in 2009. Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as a complement to spontaneous reporting commonly used in pharmacovigilance systems. NAFDAC, in collaboration with relevant stakeholders, in 2012 developed the Nigeria National PV Policy; NAFDAC Good Vigilance Practice Guideline 2016 and the Guideline for Reporting ADR by MAHs and health care professionals.

The Nigerian pharmacovigilance system has grown since its conceptualization and entry into the WHO Programme for International Drug Monitoring in the last two to three decades.

The strengths of this system include its visibility with basic infrastructure distributed around the country by regionalization/zonalisation and growing availability of resource persons

The presence of a standing National Drug Safety Advisory Committee and a legal/policy framework. This is enhanced by the standalone National Pharmacovigilance Policy approved by the country’s President in Council which to a significant extent demonstrates government’s support and goodwill.

The weakness of the PV System is the lack of awareness amongst health care professionals and the public as is reflected by the low reporting rate of adverse drug reactions to NAFDAC

Failure to address the numerous factors hindering reporting of adverse events such as reporting process and fears of litigation are of importance.

The major threats to the strengthening of the pharmacovigilance system remain those of funding and the mobility of staff to other sectors of the economy.

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

1.2. Why a roadmap?

1.2.1. Brief description of the roadmap development process

This roadmap was developed based on a baseline situational analysis that assessed the situational analysis of the various aspects and needs of the PV systems in Nigeria at the start of the PAVIA project, including its strengths and gaps.

Based on the gaps and challenges identified during the baseline situational analysis a workshop with all key stakeholders in the country was held to discuss the findings and define the desired 'end state' for the PV situation per country. This roadmap has been developed through a stakeholder engagement process involving the baseline assessment, the subsequent stakeholder workshop and consultations.

This roadmap outlines the areas for PV strengthening, with key activities. Detailed activities specific for the PAVIA project will be laid down in annual work plans, which will cover year 2 (April 2019-March 2020) to year 4 (April 2021-March 2022) of the PAVIA project.

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

Policy, Law and Regulations

- Nigeria National Standalone Pharmacovigilance Policy document (2012) with implementation strategies approved by the President in Council but yet to be revised
- Existing legal provision for MAH but poor compliance by local manufacturers

Systems, Structure and Stakeholder coordination

- National Pharmacovigilance Center: Pharmacovigilance (PV) and Post marketing Surveillance (PMS) directorate coordinates the NPC however with low staff strength.
- There are 6 Zonal Pharmacovigilance Centers located in tertiary institutions but they are inadequately funded and lack of regular communication with NPC
- Funding for budgetary allocation to NAFDAC: No independent budget line for Pharmacovigilance activity.
- Different stakeholder's engagement: IHVN (Nigeria) is the most important partner for NAFDAC when it comes to provision of PV trainings.

Signal detection and Data Management

- Low ADR reporting rate in Nigeria: 2,173 ADR reports received by NPC in 2017 (14 reports per 100,000 population).
- Vigiflow in use but incomplete data in ICSRs limits uploading.

Risk Assessment and Evaluation

- Insufficient feedback given to HCPs and PHPs on the contents of the ADR reports submitted
- Causality assessment being carried out but inadequate expertise and low staff strength in NPC.

1.3 Alignment of this roadmap with existing national strategic plans

1.3.1 In the NAFDAC Strategic Plan for 2016-2020, Strategic Objective 7 highlights; Awareness of safety in the use of medicines created through advocacy of pharmacovigilance activities in the healthcare system in Nigeria with the following proposed activities:

- Hold 4 annual consultative meetings with relevant stakeholders in the health sector.

- Advocate for Institutional heads to set up PV infrastructure in their institutions.
- Advocate for Professional Associations of health care practitioners to integrate private practitioners into the PV system.
- Increase the number of PRASCOR/PV Jingles by 3 to improve on behavioral change communication and increased reporting of ADR.

Most of the above proposed activities are also captured in the PAVIA roadmap.

1.3.2 In the National Strategic plan for tuberculosis, towards universal access to prevention, diagnosis and treatment 2015 – 2020

Strategic objective 9 highlights: Strengthening the NTBLCP systems and capacity to support full implementation of the National Strategic Plan at all levels. These are in alignment with the proposed activities captured in the PAVIA roadmap.

The activities proposed under this area of strengthening include:

- Conducting training of one DOTS center provider for each of the remaining 5184 DOTS centers in the country, 774 LGTBLS on basic LMIS and pharmacovigilance
- Conducting 2 day bi-annual supply review meetings
- Instituting efficient drug management and pharmacovigilance practices in all DOTS sites
- Conduct a meeting to review and revise the existing training curriculum and trainers guide on drug management and pharmacovigilance to meet contemporary needs.

2. Goals and strategic objectives of this roadmap

Overall goal: to strengthen the Pharmacovigilance system to ensure the rational and safe use of medicines.

Objective:

- To ensure that PHPs and MAHs have an effective PV system to monitor, detect and report ADRs associated with Medicine to the National Pharmacovigilance Centre.
- To engage in Active monitoring of Poverty related diseases(MDR-TB) drugs and other medicines used in management of TB
- To build capacity of staff of NPC and Healthcare providers to effectively monitor, detect and report ADRs associated with use of Medicines.

3. Methodology and team

3.1. Stakeholder workshop

The Roadmap Stakeholders workshop was organized by NAFDAC in collaboration NTBLCP, UniBen, IHVN and KNCV Tuberculosis foundation Nigeria. The workshop was held at the KNCV Conference Hall, Abuja from 20th – 21st March 2019.

The Objectives of the Road-map workshop were:

- To share the gaps on the Nigerian national pharmacovigilance system identified through the situational baseline analysis conducted by PAVIA project in September 2018
- To enrich the draft road map proposed to address the gaps identified in the baseline situational analysis and provide a country specific solution with stakeholders input.

A total of 26 participants, including the PAVIA Nigeria Partners were in attendance at the stakeholder's workshop. Participants included: Federal Ministry of Health, SANOFI Pharmaceuticals, SWIPHA Pharmaceuticals, NAFDAC, UniBen, IHVN, KNCV, and National Agency for Control of Aids (NACA), National AIDS/STI Control Programme (NASCAP) and NTBLCP Zaria, Jos University Teaching Hospital, World Health Organization. The chairperson of the workshop was the DG NAFDAC, Prof Mojisola C. Adeyeye

3.2. Developing the roadmap

As part of the PAVIA projects planned activities, a baseline situational assessment was conducted in September 2018 with the aim of identifying the gaps in the PV system of the Nigeria Healthcare sector. The identified gaps were used as a basis to draft the countries road-map activities.

The PAVIA Nigeria Partners (NAFDAC, UniBen, IHVN, KNCV and NTBLCP) held series of meeting to enrich the strategic objectives of the Road-map. A Zero draft of the Road Map was developed by NAFDAC and forwarded submitted to other partners for the input.

A stakeholder's workshop was held (as seen above) and a joint review of the Road-Map was carried out during the Stakeholders meeting and the draft Road-Map was finalized.

Partners involved in the Development:

NAFDAC:

- Mr. Ali Ibrahim, Pharmacist, Director PV/PMS, NAFDAC
- Mrs. Helga Nosiri, Pharmacist, Deputy Director PV/PMS, NAFDAC
- Dr. Abiodun Abiola, Medical Doctor, ACRO (PV/PMS), NAFDAC

UniBen:

- Prof. Ambrose Isah, Consultant Physician/Clinical Pharmacologist, Departments of Medicine and Clinical Pharmacology and Therapeutics, University of Benin, PAVIA WP2 lead
- Dr. Abimbola Opadeyi, Departments of Medicine and Clinical Pharmacology and Therapeutics, University of Benin

IHVN:

- Mr. Yohanna Avong, Pharmacist, IHVN

NTBLCP:

- Mr. Alhassan Shuaibu, Pharmacist Deputy Director NTBLCP

KNCV:

- Ms. Cassandra Aishatu Elagbaje, Pharmacist, PV coordinator for PAVIA in Nigeria

3.3. Relationship between this roadmap and the annual work plan

This roadmap will be accompanied by annual workplan, detailing the activities to be implemented in the first following 12 months. These annual workplans 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 for every 12 months, referring to this roadmap that outlines the overall strategy for PV strengthening and the links with other existing strategic plans.

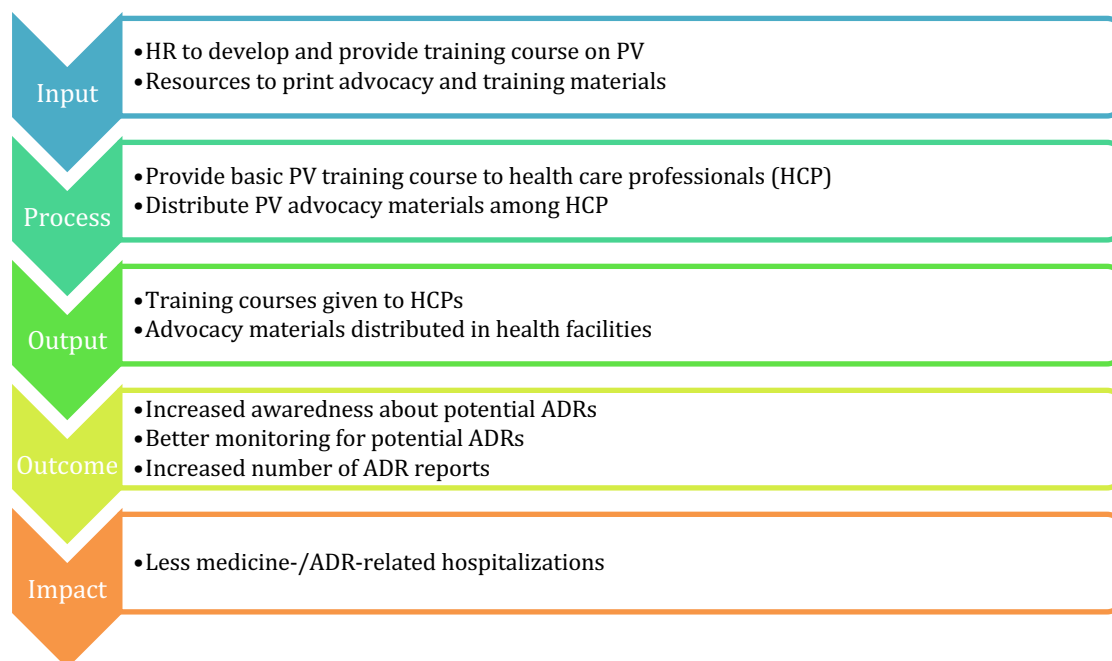


Figure 1. Monitoring and evaluation framework.

4. Key milestones and activities per strategic areas

Strategic objective 1: Improving the efficiency and functioning of regulatory and organizational structure. Full operationalization of PV standalone Policy					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
A Nigerian National Pharmacovigilance Policy (2012) is in place.	Lack of revision of PV Policy in 2017 (five (5) years after its development.)	Joint revision of PV Policy	2021	FMOH, UNIBEN, NAFDAC & PV stakeholders	No available direct funding source. Resources to be mobilized through Donor Agencies

					interested in PV. FMOH & NAFDAC to lead.
	Inadequate implementation of the policy.	- Periodic Stakeholders meeting to reinforce the concept of PV. - Training to improve implementation of Policy. - Training, advocacy, awareness creation and sensitization on PV. - Wider dissemination of the Policy	2021	FMOH, UNIBEN, NAFDAC, MAH.	No available direct funding source. Budgetary allocation.
	Inadequate communication with the relevant stakeholders	NAFDAC should have a clear SOP for communicating with stakeholders. Regular Forum/meeting with stakeholders.	09/2019	NAFDAC NAFDAC, FMOH, MAH, HCP, WHO, NC OF PHPs AND OTHER PV STAKEHOLDERS.	Budgetary allocation Budgetary allocation Support from PV stakeholders, especially donor agencies.
Strategic objective 2: Improving the financial sustainability of PV activities in the Country					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)

No direct funding for PV, NAFDAC as an agency receives funding from the government.	- Lack of direct fund for PV - Problems with the budget release from the government. - Receiving funding for PV capacity building is difficult.	- Develop a financial Model for PV activities. - Integrate PV into the normal Hospital care- have a PV center in Hospital to be funded by Hospital - NPC also search for donor funding,/grant from NGOs - Include PV activities in NAFDAC registration and renewal of product fees - Advocate to Federal Ministry of Budget & National planning on how to attract funds.	01/2022	FMOH, NAFDAC, KNCV, HEALTH INSTITUTION, PHPS, NGOS and Other relevant stakeholders	No available direct funding source. Budgetary allocation.
---	---	--	---------	--	---

Strategic objective 3: Clarifying the roles and responsibilities for all stakeholders towards ensuring the safety of Medicine

Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
No direct link between the NPC and Public Health Programs	- Lack of structural link between the NPC and Public Health Programs. - Inadequate implementation of National PV Policy - Non-adherence to the National PV policy.	Identify all PHPs including but not limited to poverty-related diseases(PRD< such as tuberculosis, HIV, malaria), childhood vaccination and neglected tropical disease	08/2020	NAFDAC NAFDAC	Budgetary allocation. Budgetary allocation

	Lack of proper communication channel between the NPC and PHPs	- Have a PHPs register that is updated regularly. - Strict Regulatory action on non-adherence to the Policy. - NAFDAC develop an SOP on communication and collaboration with PHPs.		NAFDAC/PAVIA TRIANGLE	Support from Donor agencies and NGOs interested in PV.
Reporting of ADRs is voluntary in Nigeria and low compared to the population of Nigeria.	- No on-line procedures for collecting ADRs information from PHPs on ADRs - No Mobile App channel of reporting ADRs.	- Develop an online platform for direct ADRs reporting from PHPs - Create a mobile Application for ADRs reporting. - If there is an existing Online platform (e.g. the WEB-RADR powered by the WHO WHO UPSALA), integrate into this platform.	02/2020 11/2020	PAVIA Triangle	No available direct funding source. Is it possible for PAVIA to apply for additional funds to acquire the WEB-RADR application
Causality assessment carried out by NAFDAC staff, but rate of Signal detection is low	- Inadequate training for NAFDAC staff carrying out causality assessment - Inadequate training on signal detection. - Lack of feedback to PHPs from NAFDAC - Incomplete data limits the	- Capacity building on causality assessment and signal detection. - Training for stakeholders on filling ADR form. - Develop a blended learning module on safety of medicines (TB drugs) for healthcare professionals	02/2020	PAVIA partners, PV stakeholders (PHPs, health institution and NGOs) NIROPHARM, PMG-MAN, APIN INDIAN.....	Budgetary allocation. Support from Donor agencies and NGOs interested in PV.

	understanding of the magnitude and nature of ADR.	NAFDAC develop an SOP on communication and collaboration with PHPs and Health Institution			
Strategic objective 4: Strengthen existing capacity for causality assessment and signal detection Increasing the effectiveness of active (sentinel) surveillance of ADRs					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
In-adequate monitoring of aDSM in TB programme in Nigeria.	Lack of financial and material resources to carry out adequate monitoring as related to aDSM of new medications in NTBLCP.	Review of programmatic aDSM Policy and Guidelines and review of PV policy as to include compulsory active PV (e.g. CEM, Targeted spontaneous reporting, Registry) of new and repurposed drugs and regimens.	2020 2020	FMOH/NTBLCP/NAFDAC/UNIBEN/IHVN/Other PHP	Sponsorship of active PV by NTBLCP and other TB supporting partners Sponsorship of active PV by National programme
Linkages and collaboration between NAFDAC, NTBLCP other Health program	Poor collaboration between NAFDAC, NTBLCP and other health programme	There must be a scheduled meetings for improved collaborations and discussions on strengthening of Pharmacovigilance and aDSM policies in the country.	Q2 2020	NAFDAC/NTBLCP/ and other partner	NAFDAC Contribution.
No Electronic transmission of data to NPC IN NAFDAC	No information technology available to allow the transmission of Data to NAFDAC	Introduction of information technology tools. e.g. mobile Apps	Q1 2021	NAFCAC/NTBLCP/USAID	PAVIA

Inadequate capacity for causality assessment of SAEs, of DRTB medicines	Lack of formal causality assessment of ADR Data from the use of DRTB medicines on monthly basis by the aDSM expert committee (The committee should comprise of experts from NAFDAC (NPC), NTBLCP as well as other PV/TB stakeholders.	Finalization of the zero draft aDSM guidelines to include a well-structured strategy on the conduct of causal evaluation of ADR due to the use of TB medicines	2020	NTBLCP/NAFDAC/USAID	Partners Support
Strategic objective 5: Improving connectivity of databases and (use of) tooling for event detection, reporting analysis and dissemination to relevant stakeholders					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)

There is a Local database but the data captured are minimal	Loss of Data from the Local database due to absence of back-up. •Lack of efficient internet service for PV activities.	Local database should be backed up on a regular basis to prevent loss of data.	2020	NAFDAC	Budgetary allocation.
		Introducing the new E2B-R3 compatible VigiFlow should be considered as this version of VigiFlow does have any validation rules. VigiFlow could then act as the local database which would make double data entry redundant.	2020	NAFDAC/WHO UPSALA	
		There is urgent need to provide an efficient internet service for PV function.	2019	NAFDAC	
Data collection tools are mainly manual	Lack of tool for Electronic data collection.	Electronic data collection tools should be considered and developed.	2020	PAVIA TEAM, WHO-UMC	Budgetary allocation, support from NGOs interested in PV.
		The logistics and processes around distributing and collecting reports could be	2020	NAFDAC	

		streamlines to ensure quality and efficiency. Develop an online reporting tool/mobile application.		PAVIA	
Strategic objective 6: Increase human resources to sufficiently exercise safety-monitoring activities throughout the country.					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
There is NPC (National Pharmacovigilance Centre) situated in NAFDAC. There are ZPCs (Zonal PV Centre) located in six institution in the six geopolitical zones.	- NPC requires more human capacity - Lack of fund to run the ZPCs - No focal PV designated staff in PHPs and health facilities.	- Request for employment of new staff to work in the National PV centers - Trainings to strengthen staff capacity. This can start with initial trainings (TOT) for staff of NAFDAC and health facilities focal PV staff then cascade of trainings throughout health facilities in Nigeria. - A focal person in the PV Centre to jointly coordinate PV activities within the PHP	2020	NAFDAC PAVIA TEAM NAFDAC/PHP/Health Institution/FMOH	Budgetary allocation. Support from Donor Agencies and NGO's interested in PV. Budgetary allocation. Support from Donor Agencies and NGO's interested in PV.
STRATEGIC OBJECTIVE 7: Improving PV-relevant skills and competencies at various levels					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)

Competent Staff in NPC, ZPC	- No adequate training and retraining. - No adequate training for Healthcare professional	Training plan for existing PV staff, including short course, MSc and PhD training	2019	PAVIA TEAM	Budgetary allocation.
		Training Plan for healthcare professionals to improve their knowledge and expertise on the principle of PV and on the safety of new drugs	2019	PAVIA TEAM	Support from Donor Agencies and NGO's interested in PV.
		Develop and introduce PV modules in the medical curricula at universities and medical schools, Nursing schools, Pharmacist schools, Lab technicians	2020	PAVIA TEAM /health institution/FMOH/ NUC/FMOE/PCN/MDCN/ Professional Councils	TET-FUND

Strategic objective 8: Gaining experience in monitoring and steering the performance of the PV system.

Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
Inadequate monitoring of PV system in the country	Inadequate monitoring or evaluation done in the country	- Strengthening the monitoring and evaluating country progress on PV - Further promote the use of WHO indicators to monitor	2020	PAVIA TEAM	Budgetary allocation.
			2019	PAVIA TEAM	

		PV activities. (Number of reports submitted by health facilities, MAHs, PHPs) to NPC •Put in place a process to conduct a survey to monitor the impact of PV in Nigeria.	2021	NAFDAC/FMOH/MAH NGOs/	Budgetary allocation/ NGOs interested in PV.
Strategic objective 9: better align with regional and international initiatives to avoid fragmentation of resources and investments					
Present Situation	Identified Gaps	Recommended Activities	Timelines	Responsible Stakeholders	Resources (available & needed)
NPC presently collaborate with WHO, ISOP and Uppsala Monitoring Centre.	Inadequate collaboration with regional and international initiatives on PV.	Engage with regional Economic communities (WAHO)and regional centers of excellence PV, NEPAD, WHO, ISoP, Uppsala Monitoring Centre etc.	2019	PAVIA TEAM/WHO/WAHO ISOP	Budgetary allocation and support from donor Agencies and NGOs

4.1. Improving the efficiency and functioning of regulatory and organizational structures

- Develop and introduce a communication and dissemination strategy for routine- and crisis communication.
- Full operationalization of PV standalone Policy- Joint revision of PV Policy
- Periodic Stakeholders meeting to reinforce the concept of PV.
- Training to improve implementation of Policy.
- Training, advocacy, awareness creation and sensitization on PV.
- Wider dissemination of the Policy

4.2. Improving the financial sustainability of PV activities in the country

- Develop a financial Model for PV activities.
- Integrate PV into the normal Hospital care-have a PV center in Hospital to be funded by Hospital

- NPC should search for donor funding, /grant from NGOs
- Include PV activities in NAFDAC registration and renewal of product fees
- Advocate to Federal Ministry of Budget & National planning on how to attract funds.

4.3. Clarifying the roles and responsibilities for all stakeholders towards ensuring the safety of medicines

- Establish a structural link between the PV Center and public health programs (PHPs) – including but not limited to poverty-related diseases (PRD, such as tuberculosis, HIV, malaria), childhood vaccination and neglected tropical diseases. For the National TB Programme and potentially other PHPs this would include the PAVIA Triangle as a collaborative approach in which healthcare professionals, PHPs and national PV Centers join efforts in collecting, analyzing and exchanging information and sharing expertise.
- Establish standardized procedures for collecting information from PHPs on adverse drug reactions (ADRs) and sharing this information with the national PV Centre.
- Establish standardized procedure for signal detection and signal communication between PHPs and PV Centers.
- Make healthcare professionals working in/with these PHPs aware of, and involve them in, PV to improve reporting of potential ADRs. For example, PAVIA will develop a blended learning module on safety of TB drugs for healthcare professionals treating TB and provide a train-the-trainer course to further apply this blended learning module.
- Establish collaborative approach in which healthcare professionals, PHPs and national PV Centers join efforts in collecting, analyzing and exchanging information and sharing expertise.
- Strict Regulatory action on non-adherence to the Policy.
- NAFDAC develop an SOP on communication and collaboration with PHPs.
- Develop an online platform for direct ADRs reporting from PHPs

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

- 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.
- Establish a process for how aDSM data will be analyzed and interpreted.
- Engage in active surveillance for drugs to treat (MDR-)TB in collaboration with the National TB program.
- Engage in active surveillance for drugs used in treatment of at least one other poverty-related disease in collaboration with the relevant PHP.
- Review of National PV Policy to include Compulsory CEM of new drugs
- Attach compulsory CEM to authorization/waivers granted for new drugs used in PHPs
- Develop a functional flow chat on data collation by PHPs and collection by NAFDAC with Time-line.
- Training and Re-training personnel on data analysis and interpretation

4.5. Improving connectivity of databases and (use of) tooling for event detection, reporting, analysis and dissemination to relevant stakeholders

- Develop and introduce a strategy for increasing the number of reports from the country to international databases by more efficient use of the VigiFlow data management system
- Simplify and adapt currently used tools for AE/ADR reporting (e.g. paper forms or electronic reporting systems for AE reporting by health facilities and patients; additional reporting options through email, toll-free phone calls, SMS code system and walk-ins) with more user-friendly interfaces
- Harmonize these mechanisms with current health management information systems and electronic reporting systems for the PHPs.
- Optimize the efficiency of the processing of reports in the PV Centre.
- There is urgent need to provide an efficient internet service for PV function.

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

- Establish focal persons in PHP health facilities with high patient loads, and a focal person in the PV Centre to jointly coordinate PV activities within the PHP.
- Trainings to strengthen capacity. This can start with initial trainings (TOT) then cascade of trainings throughout health facilities in Nigeria.
- Training plan for existing PV staff, including short course, MSc and PhD training. For example, hands-on training of selected PV staff is included in the PAVIA plan (linked to the annual consortium meeting).
- Training plan for healthcare professionals to improve their knowledge and expertise on the principles of PV and on the safety of new drugs, and become aware of their role in documenting, reporting and learning from experience of medicine-related harm. For example, PAVIA will develop a blended learning module on PV for healthcare professionals and provide a train-the-trainer course to further apply this blended learning module.
- Develop and introduce PV modules in the medical curricula at universities and medical schools.

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

- Training plan for existing PV staff, including short course, MSc and PhD training.

- Training Plan for healthcare professionals to improve their knowledge and expertise on the principle of PV and on the safety of new drugs
- Develop and introduce PV modules in the medical curricula at universities and medical schools, Nursing schools, Pharmacist schools, Lab technicians

4.8. Gaining experience in monitoring and steering the performance of the PV system

- Establish a process for monitoring and evaluating country 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); analyze barriers (national as well as overarching); and adapt roadmaps where needed. For example, PAVIA includes mid-project in-country stakeholder workshop to evaluate country progress (including breakouts with specific target groups) as well as discussions of the country progress reports during its annual meetings.
- Further promote the use of WHO indicators to monitor PV activities. (Number of reports submitted by health facilities, MAHs, PHPs) to NPC.
- Put in place a process to conduct a survey to monitor the impact of PV in Nigeria.
- Hold subsequent PV assessments (e.g. the PAVIA end-line assessment) improving the methodology based on the experiences with the baseline assessment.

4.9. Better align with regional and international initiatives to avoid fragmentation of resources & investments

- Engage with e.g. Regional Economic Communities and regional centers of excellence in PV, NEPAD, the African Medicines Agency, WHO, ISOP and the Uppsala Monitoring Center. For example, PAVIA will hold sessions with representatives of these stakeholders and initiatives (who are member of PAVIA's Advisory Board) during its annual consortium meetings.
- Complement/strengthen the supranational capacity for PV and comprehensive risk management of the regional centers of excellence for PV.

5. Action plan

The resource requirement and where to find these resources is captured in Section 4 above. It is necessary to emphasize that most of these activities requires fund for implementation. Budgetary Allocation from NAFDAC, and Support from Donor Agencies and NGO's interested in PV are the two main identified source of fund.

The Monitoring and Evaluation will be conducted on an Annual basis with the indicators identified in the Annual Work plan.

6. Conclusions

This roadmap was developed taking into consideration the Baseline situational analysis that assessed the situational analysis of the various aspects and needs of the PV systems in Nigeria at the start of the PAVIA project, including its strengths and gaps. These roadmap outlines the areas for PV strengthening, with key activities.

The implementation of the activities in the roadmap will be carried out on annual basis using the detailed activities specific for the PAVIA project identified in the Annual Work plan.

We are determined to galvanize the stakeholders to provide resources for the implementation to enable us achieve the objective of PAVIA. We appreciate the support of DG NAFDAC, Officials of PAVIA, and all PV stakeholders for their support towards strengthening PV through PAVIA project.