Roadmap toward a strengthened national Pharmacovigilance system in Ethiopia, for a Period of Five Years

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A.A, Ethiopia

Preface

Worldwide, numerous numbers of drugs are released into the market every day with incomplete information about their safety on larger and diversified populations raising concern on their safety. This calls upon strengthening pharmacovigilance system. It is also a common practice of public health programs to make use of Mass drug and vaccine administration. The large number of populations receiving these drugs may come up with harm if not monitored properly. This has given an opportunity to develop systems for generating valid data that will contribute to informed decision making.

The development of this national roadmap is a reflection of implementation of the core initiatives within the county's health sector transformation plan that strategizes to improve the Regulatory system through pharmacovigilance. It has also comprehended the links with the drug safety monitoring strategies of public health programs.
This national pharmacovigilance road map of Ethiopia for 2019-2023; expresses the continued commitment of the national drug regulatory Authority and the Federal Ministry of Health towards the attainment of the overarching goal of having a matured Pharmacovigilance system.

Finally, the National Regulatory Authority calls upon all stakeholders working in the area of Pharmacovigilance to use this national roadmap as our common guiding reference for our operations, to take improved actions and commitment to bring prompt change in reducing medicines related harm.

HeranGerba
Director General,
Ethiopian Food and Drug Authority,

List of abbreviations/Acronyms

ADR	Adverse drug reaction
ADE	Adverse drug event
AEFI	Adverse Event Following Immunization
AHRI	Armauer Hansen Research Institute
aDSM	Active Drug Safety Monitoring
CDT-Africa	Center for Innovative Drug Development and Therapeutics trials for Africa
DAC	Drug Advisory Committee
DIC	Drug Information Center
DTC	Drug and Therapeutics Committee
EAC	East African Community
EFDA	Ethiopian Food and Medicine Authority
EPI	Expanded Programme on Immunization
HCP	Health-Care Professionals
HSTP	Health Sector Transformation Plan
ICSR	Individual Case Safety Report
MAH	Marketing Authorization Holder
MOH	Ministry Of Health
NEPAD	New Partnership for Africa's Development - agency
NTD	Neglected Tropical Diseases
NTP	National TB Program
PASS	Post Authorization Safety Study
PAVIA	Pharmacovigilance Africa
PHP	Public Health Programme
PROFORMA	Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional regulatory harmonization in East Africa
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance

QPPV	Qualified Person for Pharmacovigilance
RMP	Risk Management Plan
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TB	Tuberculosis
ToR	Terms of Reference
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

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1. Background and justification

1.1. Pharmacovigilance in Ethiopia

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

Ethiopia established its national PV system under Food, Medicines and Healthcare Administration and Control Authority (FMHACA) in 2002. In 2009 Ethiopia became a full member of the WHO Program for International Drug Monitoring. The number of adverse drug reaction (ADR) reports received from healthcare providers to the national centre have been limited.

Voluntary reporting has come into effect as of 2002 through the activities performed by the Adverse Drug Reaction Monitoring Division of the Drug Administration and Control Authority. A simple reporting form was developed and made available throughout all the health facilities. Various trainings were given, and face-to-face discussions about adverse drug reaction/events monitoring were also performed. In spite of these activities, still there remain important interventions to be implemented to strengthen the existing system and infrastructure, in monitoring ADR and reduce related harms in the public.

1.2. Significance of the Road Map

1.2.1. Brief description of the roadmap development process

This roadmap was developed based on a baseline situational analysis on the strength and gaps of pharmacovigilance system of Ethiopia performed by PAVIA and PROFORMA projects.

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 of the country. This roadmap has been developed

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

through stakeholders' engagement involving baseline assessment, subsequent stakeholders' workshop and consultations.

This roadmap outlines the areas for PV strengthening, with key activities. Detailed activities are laid down in the subsequent annual work plans.

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

- Resources at the PV centre are inadequate for the full implementation of provisions in the 2014 Guidelines for Adverse Events Monitoring. The annual budget of EFDA has no earmarked budget for the PV function which hinders, its management to plan properly for sustainability and long-term development.

- EFDA would need to establish a PV inspectorate to ensure that stakeholders e.g. MAH are following the reporting requirements mentioned in the guidelines.

- Although the staff members of the PV centre are experienced and well trained, given the large population size of Ethiopia, they are too few to promote PV and engage all stakeholders such as healthcare organizations, healthcare professionals, Marketing Authorization Holders, Academia, Public Health Programmes, media and the public at large. The input of reports of suspected medicine related harm received from these stakeholders is far too low, leading to very limited output and results from the system.

- Currently, there is no specific PV advisory committee. The Drug Advisory Committee (DAC) / AEFI committee is used to serve as such but may not consider all PV issues. Thus, there is a need to establish a formal PV Advisory Committee and provide the required training to members of the committee.

- The inadequate input of observations of suspected harm to the system leads to an under-utilization of the Adverse Reactions Advisory Committee. Members of this committee should be engaged in the promotion of the system nationwide. The fact that only 10% of the ICSRs were subjected to causality assessment is an indication that the available expertise is not fully utilized.

- Self-medication of both conventional and traditional medicines is widely practiced in Ethiopia. The level of harm in the community is not known to authorities unless direct patient reporting is facilitated and encouraged.

- The PV centre is poorly supported by technical facilities. Data management is fragmented. Relevant information is stored in different systems and moved between systems. This invites mistakes and is resource demanding and complicates signal detection. There are no library facilities easy at hand which makes data analysis tedious if not impossible.

- There are questions around the internal quality management; the reliability of keeping data in different IT-systems, absence of relevant SOPs, the long-term planning of competence development for staff etc.

- Identified signals leading to regulatory actions have mainly concerned product quality related issues, which probably reflects the inadequate input of clinically serious consequences of pharmacotherapy reported from the healthcare system, MAH and Public Health Programmes.

- Although plans for communication of patient safety issues developed by EFDA and communication channels are available, they are not optimally used because of inadequate resources, both financial and human. Low visibility leads to a poor understanding in the community of the importance of the system.

- Currently, aDSM activities are not supported by supportive supervision visits organized jointly by EFDA and NTP.

- Not all facilities are familiarized with aDSM recording and reporting systems, besides; there is no clear understanding among reporters regarding which adverse events to report.

- No copies of submitted forms are kept at the health facilities, tracking of adverse event reports is difficult and acknowledgement of receipt is not commonly received by reporting facility.

- For DR-TB treatment, there is no local database. The ADR reports (yellow forms and/or line listings, this depends on the availability of internet) are sent to FMHACA through e-mail and are recorded in an Excel spread sheet used by the PV centre to record all ADR reports received.

1.3 Alignment of this roadmap with existing national strategic plans

There are existing national plans formulated to strengthen the national Pharmacovigilance system, some of which are mentioned below.

The national health sector transformation plan (HSTP), which is the current five-years national health sector strategic plan of the government of Ethiopia, covers the period from 2008-2012 EC (i.e. July 2015–June 2020). One of the strategic objectives of this plan is to 'Improve the Regulatory System". Among the many listed, this objective will be achieved through Pharmacovigilance & post marketing surveillance of products. As part of the HSTP EFDA has developed health regulatory sector transformation plan (HRSTP) which covers the year 2015/16-2019/20. The HRSTP has considered an initiative of excelling Pharmacovigilance system and post market surveillance under the strategic objective of improving efficiency of health products regulation

In the WHO Global Benchmarking Tool (GBT) for evaluation of National Regulatory System of medical products, pharmacovigilance is one of the main tools which is incorporated as institutional development plan (IDP) of the Authority. All the six core indicators namely Legal provisions, regulations and guidelines required to define regulatory framework of vigilance, Arrangement for effective organization and good governance, Human resources to perform vigilance activities, Procedures established and implemented to perform vigilance activities, Mechanism in place to monitor regulatory performance and output and Mechanism exists to promote transparency, accountability and communication are in line with and compatible to this Pharmacovigilance road map.

During the pharmacovigilance roadmap development process, the existing strategic plan documents were reviewed. The execution period for the activities was discussed with the respective implementing bodies in order to align the activities with the institutional annual plans.

So far, a number of efforts have been made to improve coordination and improve alignment of strategies to address the health issues in the country. One such intervention is the formation of a joint steering committee in which managers of all sectors under the MOH meet for a consultative forum where policies and strategies are debated and consensus built in leading the health sector. Annual operational plans are set jointly, performances reviewed and follow-up actions streamlined accordingly in these meetings.

2. Goals and strategic objectives of this roadmap

The over-arching goal of this road map is to achieve the higher level of PV maturity that is WHO maturity level three. The strategic objectives are:

1) Ensure strong PV Policy, law and regulations
2) Strengthen PV's systems, structure and stakeholder coordination.
3) Improve Signal generation and data management
4) Improve Risk Assessment and Evaluation
5) Improve risk management and communication practice

3. Methodology and team

3.1. Developing the roadmap

The Ethiopian Food, and drug Authority in collaboration with stakeholders and partners including AHRI, NTP, KNCV (PAVIA), PROFORMA and AAU developed this road map towards a strengthened national pharmacovigilance system to be implemented from 2019 –

2023. It is prepared based on the findings of a baseline assessment (a situational analysis) of the various aspects and needs of the PV system in Ethiopia. The findings of the assessment were discussed with broader stakeholder involvement and the desired development goals of and interventions for strengthening the PV system were agreed up on which later were used for development of this road map.

During the pharmacovigilance roadmap development process, the existing strategic plan documents were reviewed. The document was organized in two major sections. The first section described the intervention points to address the gaps identified at the national PV

center and marketing Authorization Holders, while the second section was dedicated for intervention points on the assessed PHPs (TB, EPI and NTD).

The draft roadmap document was further supplemented by inputs from a wider group of stakeholders and partners working on Pharmacovigilance. This was obtained through a two day consultative workshop organized by EFMHACA on March 14 and 15, 2019. The workshop was attended by 42 participants who were representatives from the national Pharmacovigilance Center, research Institutes, neglected tropical drugs program, the National TB Program, WHO- Ethiopia, Regional Health Bureau, Market Authorization Holders, Professional Association, Healthcare facilities, Non- governmental Partners working on TB, University/academia, PAVIA project and PROFORMA Project representatives. The stakeholders were divided into groups as per their expertise and discussed the road map document. Each group then presented to the plenary the comments and inputs on the respective sections of the document. After a comprehensive discussion by the plenary on the forwarded inputs; they were then incorporated in the final roadmap document.

The final roadmap document was presented to the management members of EFDA for discussions and input was captured and incorporated and finally endorsed by the Director General of the Ethiopian Food and Drug Authority.

3.2. Relationship between this roadmap and the annual work plans

This roadmap will be accompanied by annual work plans which will be published as separate documents for every 12 months, detailing the activities to be implemented in the consecutive periods until the end of the road map implementation. These annual work plans will provide information about the main organization and focal department responsible for each activity, contributing partners, detailed timelines, budget needed and funding source, output and outcome indicators.

Monitoring and Evaluation Tools will be developed by the Authority on how to measure the established indicators and Final evaluation of the implementation status of this road map will be carried out accordingly. (Figure 1).

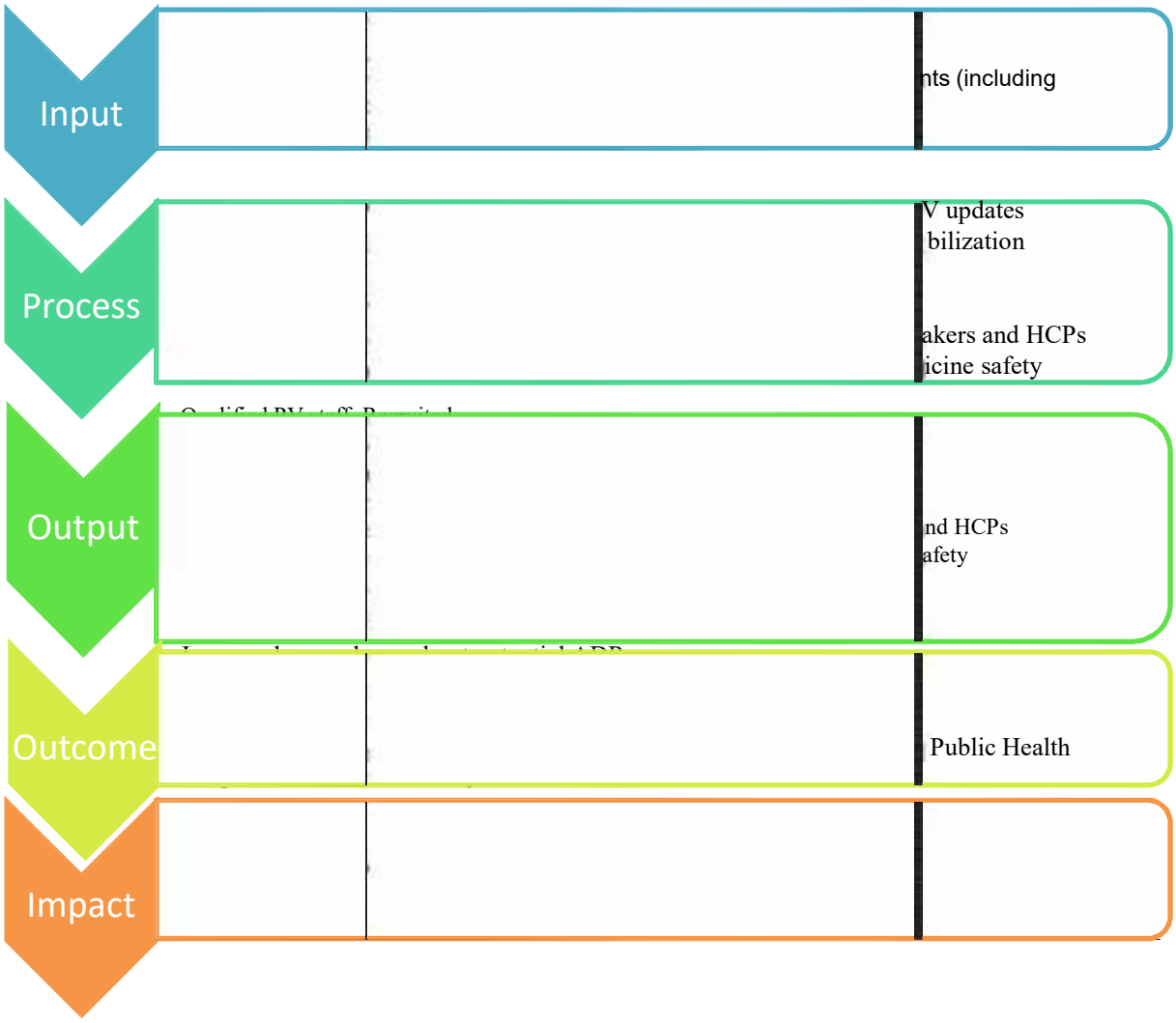

Figure 1. Monitoring and evaluation framework.

4. Key milestones and activities per strategic area

Activities are listed under the respective strategic areas. The detailed activity plans are further outlined in table 1.

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

- Incorporate PV contents into the existing National Drug policy
- Re- define the scope and re-structure the PV Unit
- Develop a guideline for patient reporting
- Develop and introduce a communication and dissemination strategy for routine- and crisis communication.

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

- Develop and introduce a strategy for improving the longer-term funding base for PV activities.
- Conduct financial resource mobilization for PV activities
- Sustainability/exploitation model for PV activities to facilitate mobilization of financial resources to strengthen capacity and provide better working conditions

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 programmes (PHPs) – including but not limited to poverty-related diseases (PRD, such as tuberculosis, HIV, malaria), childhood vaccination and neglected tropical diseases.
- 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 Centres.
- Establish collaborative approach in which healthcare professionals, PHPs and national PV Centres join efforts in collecting, analyzing and exchanging information and sharing expertise.

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.
- Perform active surveillance on safety and quality of selected medicines of public health importance in collaboration with the relevant PHPs (TB , Malaria, HIV, NTD, NCD ,EPI) and take the necessary regulatory measures
- Conduct a quarterly joint supportive Supervision by NTP and National Regulatory Authority on TICs.
- Plan and conduct a refresher /gap filling training for health professionals on selected medicines of public health importance (TB aDSM, AEFI and NTD) in collaboration with the relevant PHP drugs

- Provide training for PV/aDSM advisory committee to systematically undertake causality assessment.
- Conduct face to face discussions with health care professionals

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

- 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/AEFI/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-in) with more user-friendly interfaces
- Harmonize these mechanisms with electronic reporting systems for the PHPs.
- Optimize the efficiency of the processing of reports in the PV Centre

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.
- Create network of healthcare professionals, PV focal persons, DTCs, DICs as means of alert to safety reporting (e.g., social media group,)
- Conduct regular supportive supervision and Progress review workshops regularly.
- Community sensitization and promotion using different media outlets (public campaign, TV/Radio coverage, IEC materials)
- Recognizing healthcare facilities and professionals based on their safety reporting performance

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

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

- Develop training curriculum for various actors in PV (PV Experts, PV Advisory committee members, HCP, PHPs, MAH, consumers, Media, community health workers, etc.); includes web-based training tool development
- Provide training on PV to the different stakeholders. (Detailed training plan to be prepared for different stakeholders)
- Avail resources (Library services, Micromedex, Drug reference materials) for PV Centers.

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.
- Conduct subsequent PV assessments
- Prepare and implement PV quality manual (assign PV Quality assurance officer, monitor for adherence and performance such as feedback)

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

Table. 1. Activity Plan

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
Ensure strong PV Policy, law and regulations	Ensure that PV issues (strengthening the requirements for MAH and Healthcare facilities) are well addressed in relevant policies	No PV policy either as standalone or subset to other	Incorporate PV contents into the existing national Drug policy	Q4,2020	PV Center	Policy Document prepared	PV Policy and guidelines utilized by respective bodies	PAVIA/PROFORMA
			Revise the national PV guideline	Q4,2019	PV Center	Updated guideline		
		Patient reporting requirements are not well addressed	Develop a guideline for patient reporting,	Q4,2020	PV center	Patient reporting guideline developed and familiarized		
		MAHs are not required to	Establish a mandatory	Q4,2019	PV Center			

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		keep a position for Pharmacovigilance (QPPV), carry out investigations, so called Post Authorization Safety Studies (PASS), if signals have been received about possible problems.	requirement of QPPV for MAHs			MAH requirements stated in the Regulation document	MAH with QPPV and post Authorization Safety Study evidence undertaken	
			set out timelines for submission of PSUR, ISCRs, RMP in line with International Standards,	Q4,2019	PV Center			
			Incorporate Mandatory performance and funding of Post Authorization Safety Studies (PASS)	Q2,2019	PV Center			
		There are no specific	Ensure that PV is a requirement for licensing of HC	Q2,2020	PV center	PV incorporated	certified HC	WHO

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		requirements for pharmacovigilance systems in the licensing of private healthcare facilities.	facilities			in Licensing guidelines	facilities with well-established PV system	
	Ensure the establishment of Branch offices with relevant legal perspectives	No legal requirements for establishment and functioning of branch offices	Incorporate legal requirements for establishment and functioning of branch and university Hospitals in the regulation	Q4,2019	PV center	Regulation indicating legal mandates for branch offices	Branch offices with written legal mandates	PAVIA/PRoFORMA

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
Strengthen PV's systems, structure and stakeholder coordination.	Establish independent organizational structure and PV System	There are no detailed Terms of Reference (ToR) for the staff members employed.	Re- define the scope and re-structure the PV Unit	Q2,2020	EFMHA CA Management	Visibility of the PV unit on the organogram	PV center with qualified and adequate staff members	
		Staff members of the PV centre are too few to be able to interact with, promote and engage stakeholders needed to ensure input to	Recruit adequate and qualified manpower for executing PS, AS, AEFI, PHP, PMS,SFFS, MAH, drug consumption data compilation, Inspection activities	Q2,2020	EFMHA CA Management	Adequate staff for the PV Unit.		

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		the PV system.	Training plan for existing PV staff, including short course, MSc and PhD training.	End of project	PV Center	Training plan prepared; PV staff trained as per plan.		PROFORMA and PAVIA (for short courses
	Ensure Adequate and sustainable resource base	The ADE reporting form is not available electronically	Develop user friendly reporting tool.	Q4,2019	PV Center	Electronic reporting tool developed	National & Regional PV centers utilizing e-reporting and Vigiflow	WHO
			Decentralize vigiflow to PHP and Regional Centers	Q3,2019	PV Center	Vigiflow access given to regional PV Centers		WHO

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		There is no separate safety Advisory committee.	Strengthen and redefine the scope of the existing AEFI committee as a national PV Advisory Committee	Q4,2019	PV Center	TOR for the national PV Advisory committee.	Number of causalities established with the support of the Committee	PAVIA/PRPFORMA
			Provide training on causality Assessment to the PV Advisory committee	Q1,2020	PV Center	Trained committee members		PROFORMA, WHO, PAVIA
		The pharmacovigilance function does not benefit from a	Develop and introduce a strategy for improving the longer-term	Q4,2022	PV Center	Strategy developed	Budget ear marked for PV	

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		designated annual budget, which doesn't allow it to plan properly for sustainability and long-term development.	funding base for PV activities.				activities	
			Have a specific budget line for Pharmacovigilance on the Authority's financial scheme	Q3,2021	EFMHACA Management	PV indicated as a specific budget line.		
	Establish internal quality management for the PV system	A draft Standard Operating Procedures	Develop, familiarize and avail PV SOPs for the center	Q4,2019	PV Center	Narrated list of relevant SOPs, developed SOPs		PAVIA, PROFORMA and WHO

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		(SOP) for PV is available but not officially endorsed.	Prepare and implement PV quality manual (assign PV Quality assurance officer, monitor for adherence and performance such as feedback…)	Q2,2020	EFMHA CA Management	Quality manual developed.	PV system with IQM	WHO, World Bank
		There is a very high turn-over rate of personnel at the healthcare facilities hence	Develop training curriculum for various actors in PV (PV Experts, PV Advisory committee	Q4,2019 to Q4, 2020	PV Center	Training Curriculum developed; Web bases tool developed		PAVIA, PROFORMA

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
	Build the Capacity of the national PV system	trained HPs are not available. Healthcare providers at health facilities	members, HCP, PHPs, MAH, consumers, Media, community health workers) ; includes web based training tool development				Pool of trained professionals on PV	
		Trainings are not given to community health workers.	Provide training to the different stakeholders. (detailed training plan to be prepared for different stakeholders)	Q3,2019-2023	PV Center	Training Plan developed		PAVIA/PROFORMA

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
		EFDA does not have access to any library service	Avail resources (Library services, Micromedex, Drug reference materials) for PV Centers	Q4,2019	PV Center	Reference materials availed at the centers	Utilization rate of Library and quality of reference materials	PAVIA
	Create effective stakeholder coordination system	Poor coordination between EFMHACA and PHP in harmonization of implementation of PV	Establish a national platform for coordination of PV Activities among stakeholders and ensure the functionality (MOU, TOR)	Q1,2020	PV Center	National Platform established by TOR/MOU	Number of coordination events conducted	PAVIA/PROFORMA

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
			Mark annual PV day	Q1,2020	PV Center	PV day celebrated		PAVIA/PROFORMA
		There are minimal number, type and quality of safety reports	Create network of healthcare professionals, PV focal persons, DTCs, DICs as means of alert to safety reporting (e.g socialmedia group,…)	Q3,2019	PV Center	Network created	Increased	
			Establish regional Pharmacovigilance centers	Q4,2019	PV Center	Established six Regional PV Centers		WHO
			Conduct regular supportive supervision and	Q4,2019	PV Center	Supervision conducted; review		EFDA

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
Improve Signal generation & data management	Optimize ADE reporting and signal generation efforts	received by the PV center	Progress review workshops bi-annually.			workshop conducted	number of reports to 5,000 and reports per year	
			Community sensitization and promotion using different media outlets (public campaign, TV/Radio coverage, IEC materials)	Q3,2019 (four sensitization events per year)	PV Center	Four community sensitization events conducted per year		
			Recognizing healthcare facilities and professionals based on their safety reporting	Annually	PV Center	Appreciation Certificates awarded to reporters		

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
			performance			based on performance		
Improve Risk Assessment and Evaluation	Perform risk assessment and evaluate risk/benefit ratio based on investigations of available national/international	Limited records on causality Assessment (Only 10 reports were subjected to a formal causality assessment during the past calendar year,2010EC)	Carry out analysis on safety data obtained from passive surveillance/spontaneous reporting and take the necessary regulatory measures	Starting Q2,2019, Continuous	PV Center	Reports analyzed; regulatory measures taken	*Improve the number of* causality Assessments conducted *and signals detected*	
	Conduct Post-Marketing	Limited number of	Perform active surveillance on	Starting from	PV Center,	Ongoing active		PROFORM, PAVIA, Global

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
	Active Surveillance of medicines	active cohort study initiated by the regulatory	safety and quality of selected medicines and vaccines of public health importance (TB, Malaria, HIV, NTD, NCD, HPV) and take the necessary regulatory measures	Q4,2019	AHRI	surveillances		fund, WHO
	Ensure the availability and implementation of Risk Management and	There is no record of PV plan by MAH as required by FMHACA	Archive records of RMP and communication plan for all marketed products by MAH	Q2,2020	PV Center	Archived RMPs and communication plan		

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
Improve risk managemen	communication plan	Public Questions received by the toll-free line are neither forwarded to nor recorded by the PV Center.	Develop risk communication strategy for the national PV center to communicate with key stakeholders in the PV network nationally and internationally	Q4,2019		Risk communication strategy developed	The number of risks communicated	PAVIA, WHO

Strategic objective	***Strategic initiative***	**Gap addressed**	**Activities**	**Timeline**	**Responsible partner& person**	**Output indicator**	**Outcome indicator**	**Funding**
t and communication practice		Thereis no communication records related to medicine safety that have been targeted towards the general public	Develop/ adopt communication plan for PV activities	Q1,2020	PV Center	Communication plan developed		PAVIA

Activities regarding aDSM

Specific objective	Gap addressed	Activities	Timelines	Responsible partner & person	Output indicator	Outcome indicator	Funding
Establish / strengthen TB aDSM coordination mechanism	There is no functional TB aDSM coordinating committee.	Establish/revitalize a national TB aDSM coordinating team (NTP, FMHACA, Other stakeholders) with defined TOR	Q3,2019	PV Center, NTP	Signed TOR	Functional TB aDSM coordination mechanisms	PAVIA
	No coordination between the national PV advisory committee and the TB Clinical Review Committee.	Update the respective TORs and indicate clear responsibilities of the CRC and National PV Advisory Committee	Q3,2019	PV Center, NTP	Signed TORs		
	There is no clear understanding among reporters regarding which adverse events to report.	Develop SOP to indicate the reporting flow and which adverse events to report for TB aDSM	Q4,2019	PV Center, NTP	SOP/ guide developed	Improved number of safety reports and TB aDSM data	

Specific objective	Gap addressed	Activities	Timelines	Responsible partner & person	Output indicator	Outcome indicator	Funding
Promote existing ADE reporting tools for capturing aDSM data	No copies of submitted forms are kept at the health facilities, tracking of adverse event reports is difficult and acknowledgement of receipt is not commonly received at by reporting facility	Promote electronic and Medsafety app ADE reporting systemfor recording and reporting aDSM data	Q4/2019	NTP	Number of aDSM data captured with Medsafety app &Electronic reporting tool		WHO
Strengthen the capacity of health care providers on safety reporting and TB aDSM	Supportive supervisions are not conducted by NTP and EFDA.	Conduct a quarterly joint supportive Supervision by NTP and EFMHACA on TICs.	Starting Q2,2019	PV center, NTP, AHRI	Supportive Supervision checklist developed, conducted, Action plan developed	Improved number of safety reports and TB aDSM data	PAVIA
	Not all facilities are familiarized with aDSMrecording and reporting systems	Plan and conduct a refresher /gap filling training for health professionals on TB aDSM	Starting Q4,2019	PV center, NTP	Training plan developed; training provided		
Assure that	PV/aDSM advisory	Provide training for	Q1, 2020	NTP, PV	Trained		PAVIA,

Specific objective	Gap addressed	Activities	Timelines	Responsible partner & person	Output indicator	Outcome indicator	Funding
causality assessment is conducted as per the required standards	committee is not formally trained on causality assessment	PV/aDSM advisory committee to systematically undertake causality assessment		center	committee members	Improved number of Causalities established	WHO PAVIA, WHO
Ensure that safety information is timely communicated to the public and healthcare providers.	Safety issue is not incorporated in routine clinical mentoring and cohort analysis.	Incorporate safety issues in routine clinical mentoring and cohort analysis.	Starting Q4,2019	NTP	Safety issues addressed in routine practices	Number of safey communications related to MDR TB drugs	
	AE information is not routinely featured in any form available at the NTP	Incorporate special issue of TB aDSM on quarterly PV newsletter	Starting Q3,2019	NTP, PV Center	aDSM section included in the newsletter		
		Organize a session on a regular basis and present summaries on TB aDSM at DTCs of TICs	Starting Q3,2019	NTP, PV Center	aDSM summaries presented to TICs		

Activities Regarding EPI and NTD Program

Strategic Objectives	Strategic Initiatives	Gap Addressed	Activities	Timeline	Responsible Partner	Output Indicator	Outcome Indicator	Funding
Creating a national PV/EPI/NTD coordination plat form	Establish an Independent and functional national PV coordinating body	The AEFI guideline and the 2016 – 2020EPI comprehensive plans are not being implemented properly.	Establish a national PV platform for coordination of PV Activities among stakeholders (Develop MOU/TOR,and SOP)	2020	EFDA/MoH/ Developing partners	Platform created and supportive documents developed	Functional National PV platform	EFDA/PROFORMA
	Strengthen monitoring mechanism and tool for PV activities at EPI and NTD programs	Poor coordination between EFDA and PHP in harmonization of planning, implementation and monitoring and evaluation of PV activities	Implementing regularPV-program review meetings & supportive supervision at national & regional level in	Continuous	EFDA/MoH/ Developing partners	Assigned review meeting for PV PV indicated in SS checklist	Number of Review meeting and supportive supervision	

Strategic Objectives	Strategic Initiatives	Gap Addressed	Activities	Timeline	Responsible Partner	Output Indicator	Outcome Indicator	Funding
			collaboration					
Strengthening PV activities at EPI and NTD program	Establish separate PV-TWG for coordinating PV activities	The NTD master plan and the EPI-comprehensive plan lack details on PV	Establish separate PV-TWG at national and regional level with clear roles and responsibility	2020	EFDA/MoH/ Developing partners	Established TWG	PV activities implemented at EPI and NTD program	
Build the Capacity of Healthcare workers working at EPI and NTD program at all level	Develop national standard training packages for PV	PV trainings given toHCPs and the community workers lacks details on AEFI/ADE	Develop training curriculum for healthcare workers	2020	EFDA/MoH/ Developing partners	Training Curriculum developed	Pool of trained HCP	EFDA/PROFORMA
		No national standard-PV training packages	*Prepare national PV standard "Trainer guide and Participant manual" HCP working*	2020	EFDA/MoH/ Developing partners	Training Package developed	Pool of trained HCP	EFDA/PROFORMA

Strategic Objectives	Strategic Initiatives	Gap Addressed	Activities	Timeline	Responsible Partner	Output Indicator	Outcome Indicator	Funding
			on EPI and NTD program					
Improve Risk Assessment and Evaluation	Conduct Post-Marketing Active Surveillance of EPI/NTD medicines	No active surveillance studies have been carried out on EPI and NTD medicines	Perform Post marketing active surveillance on the safety and efficacy of selected medicines	2021-2023	EFDA/MoH/ Developing partners	Ongoing active surveillance	Surveillance result	EFDA/PROFORMA
Improve Risk management and Communication	Ensure that safety information related to EPI and NTDs are timely communicated to the public and healthcare providers	The existing information communications to the public and healthcare professionals doesn't target PV	Develop PV communication strategy and materials Incorporate special issue EPI and NTD on quarterly PV newsletter.	Starting from 2020	EFDA/MoH/ Developing partners	Developed PV communication strategy and material EPI and NTD section included in the newsletter	Number of risks communicated	EFDA

5. Conclusion

Guided by this roadmap, the national pharmacovigilance center will strive for establishing PV quality management systems and improvement in the number of reports collected to 5,000 reports per year with the aim of making the PV Center regional center of excellence and finally achieve the higher level of PV maturity that is WHO maturity level three.

The roadmap is not intended to cover every possible area, nor can it accurately predict the changes that will occur in the Pharmacovigilance theme. The roadmap is set out for a period of five years in order to fill the gaps identified through the baseline situational analysis on the national Pharmacovigilance system. During this time period, additional activities may be identified as part of the Authority's ongoing strategic thinking especially in the process of performance reviews and developing annual plan.

This roadmap was developed as a product of the PAVIA project [2] and PROFORMA[3], which is part of the EDCTP2 programme supported by the European Union (grant number CSA2016S-1627-PAVIA) and CSA2016S-1618 -PROFORMA.

[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:

1. To strengthen governance of Pharmacovigilance (PV) systems, by strengthening regulatory and organizational structures and defining clear roles and responsibilities for all stakeholders
2. 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
3. To build capacity and skills to sufficiently conduct safety-monitoring activities throughout the country
4. 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.

[2]**PROFORMA_PhaRmacOvigilance infrastructure and post-marketing surveillance system capacity building FOR regional Medicine regulatory harmonization in East Africa. PROFORMA aim is to strengthen the national pharmacovigilance infrastructure and post-marketing surveillance system in four east African countries Ethiopia, Kenya, Tanzania, and Rwanda.** The goal of PROFORMA is to establish/strengthen sustainable pharmacovigilance system in East Africa that is aligned with the large-scale African medicine regulatory harmonization and WHO's Pharmacovigilance programme. The objectives of PROFORMA are

1. To strengthen the national **pharmacovigilance infrastructure and post-marketing surveillance systems, and regulatory capacity,**
2. To strengthen Pharmacovigilance/monitoring of medicines safety **in mass drug administration and immunization programs** to monitor the public safety
3. To establish a triangular collaboration between **Academia, national medicine regulatory Authorities and public health programs to strength the capacity of safety monitoring through collaboration in capacity building traning and research for evidence based decision.**

Based on the baseline assessment the main regulatory functions that need capacity building will be identified and prioritized. PROFORMA aims to generate a cohort of pharmacovigilance trained human resources from all stockholders including patients, healthcare providers, regulatory staffs that are engaged in pharmacovigilance data collection, analysis, interpretation and data sharing. Emphasis will be given to implement active drug safety surveillance in clinical trials regulation and post-marketing surveillance in public health programmes involving mass drug administration and immunization programmes. A total of 12 postgraduates (4 PhDs + 8 MSc) will be trained to serves as part of the future PV expert regional task force.