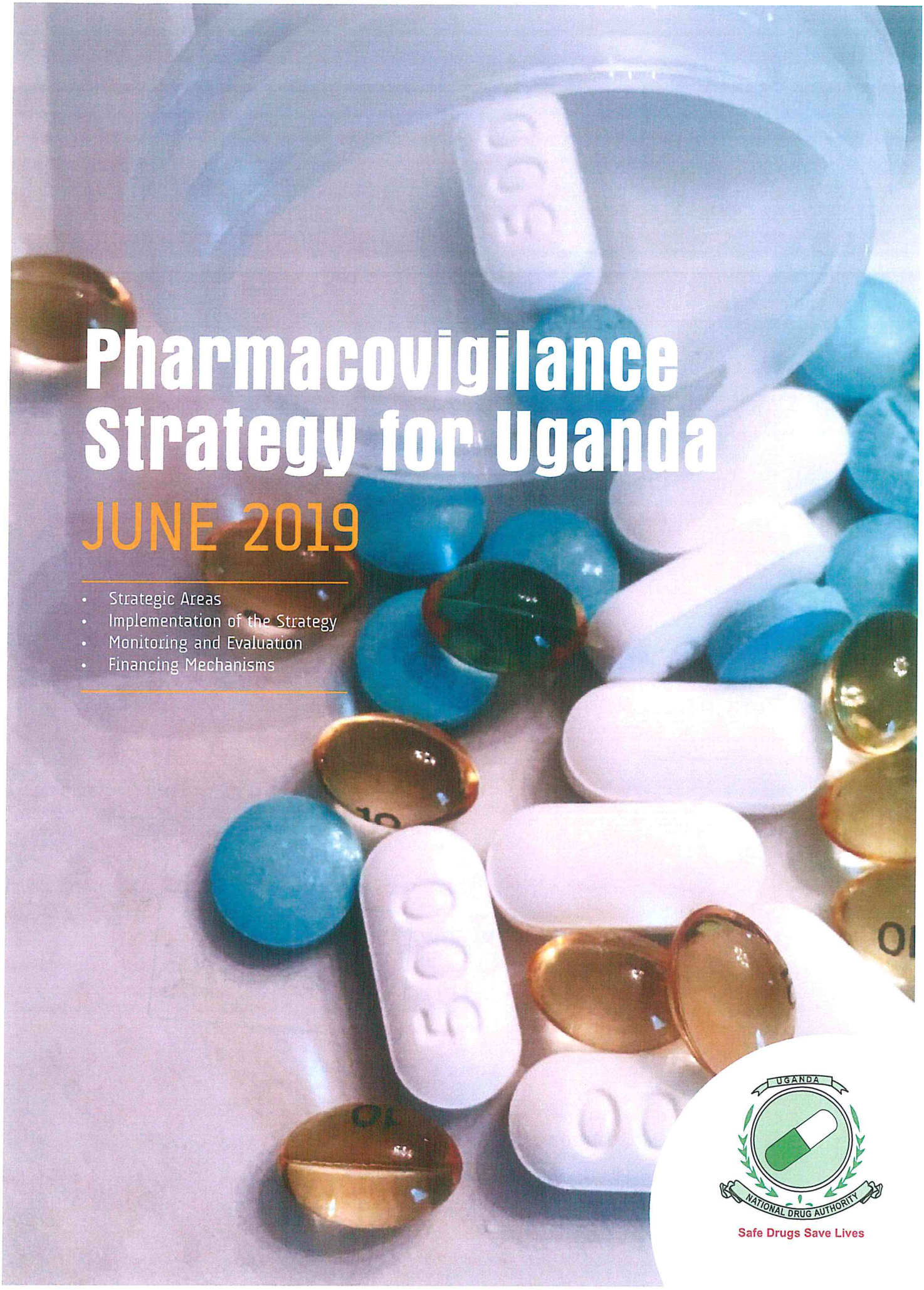

Pharmacovigilance Strategy for Uganda

JUNE 2019

- Strategic Areas
- Implementation of the Strategy
- Monitoring and Evaluation
- Financing Mechanisms

UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

FOREWORD

Established in 1993, the National Drug Authority (NDA) is mandated to ensure the availability, at all times, of essential, efficacious and cost effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

Over the years, the NDA has worked tirelessly to improve the health of the people of Uganda through strengthening of the pharmacovigilance system and infrastructure in the Country. In spite of that, numerous gaps have been identified, that necessitate immediate response from all concerned stakeholders. We are focused on ensuring improvements in the field of pharmacovigilance, with the overall goal of improving patient safety.

The strategies described in the subsequent pages have been designed to be a roadmap for the next five years. They are intended to mend the gaps that have been identified from previous strategies, through focusing on the four key areas of interest, namely: Pharmaco-vigilance technical capacity and infrastructure, Policy enhancement, Collaborations and information exchange, and Visibility and awareness.

We would like to offer our sincere appreciation to all the departments and persons that contributed to the development of this document.

For God and My Country

Dr. Medard Bitekyerezo
Chairman
National Drug Authority

PREFACE

The National Drug Authority (NDA) is a statutory body established by an Act of Parliament, The mandate of the NDA is to protect public and animal health by ensuring that accessible medicines, vaccines and medical devices are safe, effective and of good quality through enforcement of adherence to standards by manufacturers and distributors.

In this strategy, National Drug Authority sets out the course for the next five years to respond to national and international developments in medicine regulation, assuring improved safety and quality of medicines and healthcare products on the market and improving public confidence in the work that we do.

In line with the NDA Strategic priority # 1 (SEQ) and specifically strategic objective 1.4, NDA commits itself to monitor safety of drugs post market authorization. To achieve this objective, we have to work with several stakeholders (including Ministry, Public Health Programs, the public, Implementing Partners, among others) to ensure timely detection and mitigation of drug related risks.

The strategy is made to harmonize activities of all partners to reduce duplication, maximize utilization of available resources, and adequately leverage on existing structures while focusing on identified common goals.

The NDA will provide leadership in the implementation of the strategy. The other stakeholders will use the strategy to inform their work plans and initiatives in implementation of pharmacovigilance in their jurisdictions. Partners are encouraged to direct funding and other resources towards these key priority areas identified in this strategy.

I urge both private and public health programs to set up sustainable pharmacovigilance systems in collaboration with NDA, and promote medicines safety data sharing and communication in a way that promotes patient safety and rational drug use. We would like to take this opportunity to offer our sincere gratitude to all those who have contributed to the various stages of the formulation of this strategy. We call on the continued support of the stakeholders to make it a success. We hope that this plan will be a source of inspiration for the entire country. With a joint effort, we will be able to contribute to a better, healthier future for Ugandans.

David Nahamya
Secretary to the Authority

Acknowledgements

This Pharmacovigilance strategy was developed by National Drug Authority, with contribution from various stakeholders. We would like extend our gratitude to Authority members, staff and external stakeholder who contributed to the development of this strategy.

Special recognition goes to the Pharmacovigilance team lead by Victoria Nambasa for spearheading the development process. Other members include;

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- David Walusimbi
- Ian Mugisa
- Elijah Kibira
- Dr. Racheal kyeyune

Special acknowledgement to the following authority members for their advisory role

- Dr. Hanifah Naamala Sengendo
- Dr. Grace Nambatya Kyeyune
- Dr. Daniel Obua
- Dr. Sekagya Yahaya Hills

Helen Byomire Ndagije
Director, Product Safety

Definitions

For the purpose of this document, these definitions are used.

Pharmacovigilance (PV): The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems.

"Smart safety surveillance".
A strategy that embraces a risk-based prioritization of investments, work-sharing, joint activities and reliance for maximum return on investment for all medical products.

Marketing Authorization Holder (MAH)
An individual or a corporate entity responsible for placing a pharmaceutical product in the market.

National Medicines Regulatory Authority
Entities that exercises a legal right to control the use or sale of medical products within its jurisdiction, and that may take enforcement actions to ensure that medical products marketed within its jurisdiction comply with legal requirements.

National Pharmacovigilance Centre
A single, government recognized center (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advice on all information related to drug safety.

Abbreviations and Acronyms

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Following Immunization
AMRH	African Medicines Regulatory Harmonisation
ART	Anti-retroviral therapy
CRO	Contract Research Organization
EAC	East African Community
IP	Implementing Partners
MAH	Market Authorization Holder
MOH	Ministry of Health
NDA	National Drug Authority
NMRA	National Medicines Regulatory Authority
NPC	National Pharmacovigilance Center
PIDM	Programme for International Drug Monitoring
PHP	Public Health Programs
PV	Pharmacovigilance
TB	Tuberculosis
WHO	World Health Organization
WHO-UMC	World Health Organization-Uppsala Monitoring Centre

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1.0 Introduction

1.1 Background

Evidence of the risks and benefits of drugs and vaccines continue to emerge over the lifecycle of the product. The post-market uncertainties concerning the benefits and risks of a drug or vaccine extend beyond its inherent properties. The incidence, risk factors, and severity of reactions to a drug or vaccine in one population may differ significantly from another based on environmental and genetic reasons that can be difficult to predict. Programmatic errors occur in prescribing, preparing, administering, or taking medicines.

Pharmacovigilance aims at early detection and minimization of risks that may be associated with pharmaceutical products in their product lifecycles. Pharmacovigilance activities in Uganda are carried out by various stakeholders at different levels with NDA undertaking the coordination role.

The strategies listed respond to the gaps in the current system and and leverage on existing opportunities for effective pharmacovigilance in the country.

This strategy presents four key minimum requisite pharmacovigilance elements that will be the focus for the vibrant system over the next 5 years.

- Pharmacovigilance technical capacity & infrastructure
- Policy and regulatory enhancement
- Collaborations & information exchange
- Visibility & awareness

The strategy has been developed through a consultative process with a wide range of stakeholders that are part of the pharmacovigilance framework.

The overall basis of the strategy was hinged on the WHO pharmacovigilance indicators that define a functional pharmacovigilance system and findings from several pharmacovigilance assessments undertaken in the country. In addition, the strategy has been aligned with the EAC pharmacovigilance policy under the Chapter 21 (Article 118) of the EAC Treaty, the National Drug Authority strategic plan 2016-2021 plan, Health Sector Development Plan 2015- 16_2019-20 and National Pharmaceutical Sector Strategic Plan 2015-2020

This plan is divided into 4 parts. Part one provides the background and introduction. Part two provides a situational analysis outlining the pharmacovigilance framework and a summary of the critical gaps that need to be addressed. Part three gives the strategic priorities for Pharmacovigilance in the country. Part four addresses the implementation, monitoring and evaluation mechanisms.

1.2 Policy and Legal provision for Pharmacovigilance

The legal provisions for pharmacovigilance in Uganda are;

- National Drug Policy 2012 provides for Pharmacovigilance frame work in Uganda, whereas the National Drug Authority Act, CAP 206 establishes the NDA, which is responsible for safety, quality and efficacy of medicines in the country.
- The Pharmacovigilance regulations (Statutory Instrument no. 37) of 2014 provides for details on the specific regulatory provisions on pharmacovigilance in Uganda.

2.0 Situational Analysis and Context

Access to medicines and vaccines in low- and middle-income countries (LMICs) like Uganda has improved in the past two decades. However there has not been a proportionate improvement in pharmacovigilance infrastructure and activities to monitor adverse events and address safety issues.

Uganda, through the National Drug Authority which doubles as the National Pharmacovigilance Centre became the 83rd member of the WHO Programme of International Drug Monitoring (PIDM). the role of the national drug authority as a pharmacovigilance centre is to collect, collate and evaluate information relevant to the benefit -risk balance of medicinal products on the market .

NDA has over the years worked to strengthen Pharmacovigilance systems in the country in healthcare facilities, public health programs, and market authorization holders as well as engaging in active Pharmacovigilance activities.

The national policy on drug use as stated in the National Health Sector Development (HSDP) 2015-20, National Medicines Policy 2015, and National Pharmaceutical Sector Strategic Plan (NPSSP) 2015-20 has as its core strategy "to strengthen the national pharmacovigilance system for both the public and private Sector."

Previous pharmacovigilance assessments undertaken in Uganda identified gaps in the current PV system as highlighted below;
Inadequate coordination of pharmacovigilance in the country

Lack of documented procedures to carry out risk assessment, risk management and communication.
Staffing gaps that do not match the wide scope of coordinating PV activities in the country.

Limited engagement of all other health care cadres in all universities to improve PV competencies and awareness.
Minimal PV structures and function at health facilities and in public health programs for better risk detection and communication.
Limited efforts to ensure MAHs meet the legal obligations to monitor and report the safety issues relating to all drugs for which they have authorization to market.

The strategy therefore aims at addressing issues related to the systems and structures required for pre- and post-authorization monitoring of safety and effectiveness of medicines in Uganda.

2.2. SWOT analysis

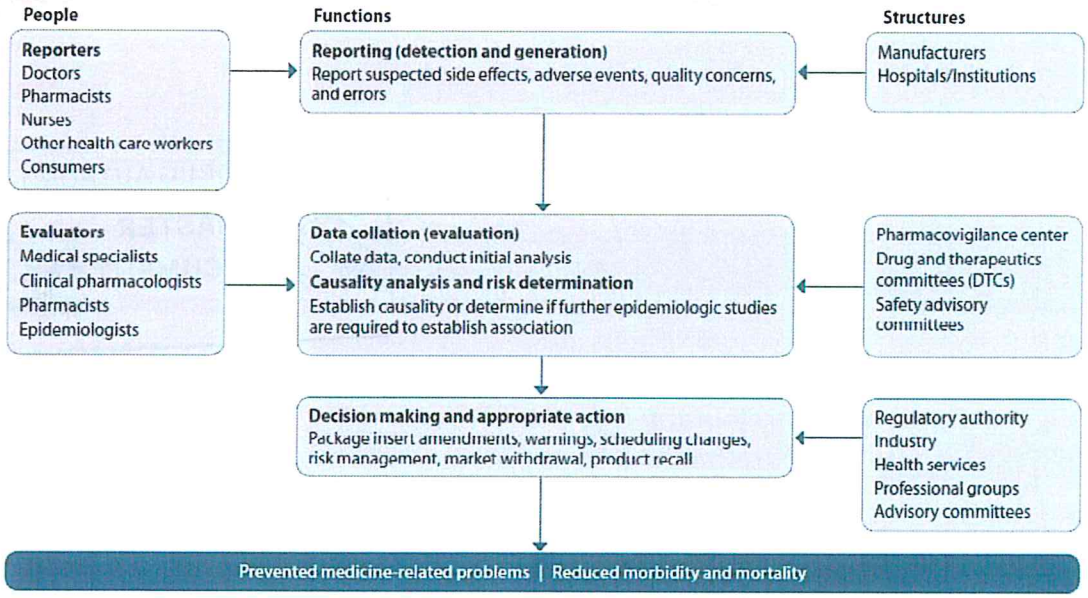
The SWOT covers the strengths, weaknesses, opportunities and threats that need to be recognized to strengthen pharmacovigilance activities in the country.

Strengths	Weaknesses
• Set up by statute with a defined mandate, regulations and guidelines. • Committed leadership • Competent and knowledgeable staff. • Dedicated funds and structure at the NPC to coordinate PV activities. • Member of the WHO drug monitoring program.	• Limited awareness of PV by health workers and the public. • Weaknesses in enforcement due to inadequate laws. • Reliance on passive means of collecting safety data. • Poor ADR reporting culture.

	• Poor documentation at health facility level thus compromising evidence and root cause analysis. • Lack of timely feedback to reporters. • PV Capacity gaps at all levels. • Limited resources allocated to PV at all levels of health care. • Inadequate stakeholder coordination.
Opportunities	Threats
• Supportive regional and International collaborative mechanisms with EAC, AMRH, WHO. • Increased public concern about drug quality and safety • Collaboration with Ministries, Departments and Agencies (MDAs) and other relevant organizations to execute NDA functions • Development partners interest in increased quality and safety of Medicines • Global shift towards self-financing mechanisms to support regulatory activities	• Gaps in the existing laws (NDA & P Act) • Porous borders that allow inflow of unregulated products • Limited access to health services • Non-disclosure of information due to factors such as fear of litigation. • Interference of information flow by drug suppliers • Aggressive marketing practices by some MAHs leading to intimidation of HCWs from reporting drug-related concerns

2.3 Key stakeholders and Pharmacovigilance frame work

The Pharmacovigilance system is composed of structures, processes, resources, documentation and outcomes of pharmacovigilance activities and is designed to monitor the safety of medical products and health technologies. The aim is to promote safe and effective use of the products and timely provision of safety information to ensure that consumers of medical products are prevented from any harm that may arise from their use. Pharmacovigilance system is used by NMRAs, Manufacturers, Market Authorization Holders, health facilities, Public Health Programs, suppliers, MoH, CROs, professional bodies/councils, academia, distributors and several other stakeholders of regulated products to fulfill their obligations towards patient and public safety.



Source: CPM/MSH 2011.

Figure 1: The Pharmacovigilance Framework

2.4 Rationale for the pharmacovigilance strategy

In line with the NDA Strategic priority # 1 (SEQ) and specifically strategic objective 1.4, NDA commits to itself to monitor safety of drugs post market authorization. To achieve this objective, we have to work with several stakeholders to ensure timely detection and mitigation drug related risks. The strategy is made to harmonize activities of all stakeholders to reduce duplication, maximize available resources, and adequately leverage on existing structures while focusing on identified common goals.

Harmonization and direction of the activities/initiatives of all the parties involved in PV in Uganda will be guided by the four (4) strategic areas as laid out herein, as a means of achieving the health sector goals on pharmacovigilance, and the WHO requirements for a functional PV system. Additionally, as the 83rd member of the WHO International Drug Monitoring programme, the NDA will embrace the "Smart safety surveillance" approach throughout the implementation of the strategy.

3.0 Strategic Areas

NDA has highlighted four (4) focus areas to guide pharmacovigilance activities for the period 2018 to 2022.

These key focus areas strive to implement the national drug policy, NDA strategies, respond to emerging drug safety issues so that the Ugandan population accesses safe, effective and quality medicines and healthcare products.

3.1 Strategic areas

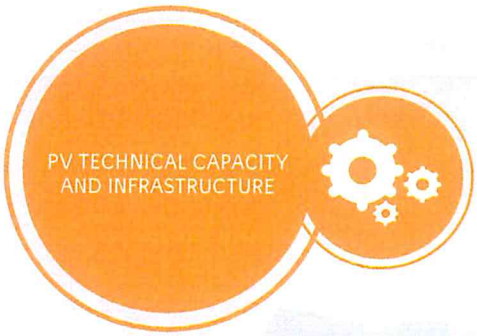
1. Pharmacovigilance is a science that leverages on other technical knowledge areas such as clinical, research, and statistics to collect safety information, analyze, understand, and mitigate drug related risk of harm. These processes are greatly dependent on the technical capacity of the individuals manning the system. This strategic area is vital for the gathering of evidence-based facts through the application of scientific methodologies and techniques to facilitate informed decisions regarding the risk-benefit balance of drugs through improved reporting structure, health workers' and NDA staff training in the technical areas.

2. Pharmacovigilance policy instruments are necessary to empower the NDA and other stakeholders to carry out their different pharmacovigilance activities and implement the necessary regulatory actions. The NDA and stakeholders will ensure that the existing laws, regulations and guidelines are comprehensive to Cover all areas of the drug supply chain.

3. Drug safety monitoring involves several stakeholders who carry out some PV activities, sometimes duplicating roles in the process. The NPC and stakeholders will harmonise their activities through establishing collaborative and information exchange structures across the board and harnessing both National and International synergies.

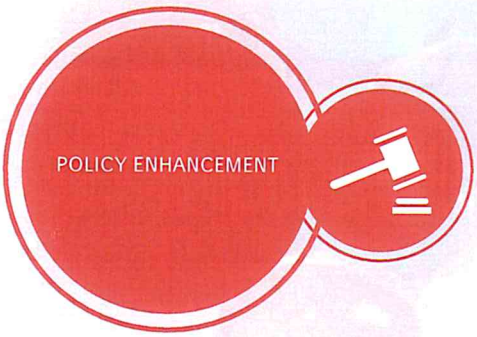
4. Previous surveys carried out by the NDA have indicated a limited awareness about PV among health workers, market authorization holders, and the general public. Focusing on improving PV awareness and providing current drug safety information is expected to ensure that patients and their health care providers have adequate information to inform their decisions on treatment optimisation.

3.2 Strategic Areas & Strategic Objectives



Objectives:

1. Enhance technical capacity at all levels involved in pharmacovigilance to improve safety data management and signal detection.
2. To strengthen existing reporting systems through implementation of smart safety surveillance initiatives.



Objectives:

1. Ensure existing laws comprehensively cover all areas of drug regulation including the responsibilities of MAH
2. Offer adequate guidance to stakeholders on the implementation of the legal provisions

Objectives:

1. Enhance safety information exchange at national, regional, and international level
2. Facilitate collaborations between the different PV stakeholders through harmonization of activities

Objectives:

1. Enhance dissemination of safety information, increase transparency and feedback to the relevant stakeholders
2. Establish systems of enhancing public awareness about the importance of pharmacovigilance and the roles of the different partners through educational and behavior change activities
3. Establish a mechanism to communicate and manage risks identified through ADR reporting to the public

3.3 Strategic Interventions and Targets

Strategic area 1: Pharmacovigilance technical capacity and infrastructure				
Objective	Intervention	Key Outputs	Responsibility	Timeframe
Enhance technical capacity of PV personnel at all levels	Support training and capacity building of NDA staff involved in PV.	Trained NDA staff.	NDA	Y on Y
	Training and skilling of PV staff at all levels.	Staff involved in pharmacovigilance in the stakeholder organisations at the different levels are trained in PV.	All Stakeholders	Y on Y
	Develop the National training curricula for health workers on PV.	Pre-service and in-service training curricula and tools developed.	NDA, MOH	Y2
	Incorporation of pharmacovigilance in the pre and in-service national training curricula for health workers.	Pharmacovigilance incorporated in the national training curricula for health workers. CPD accreditation by professional councils to provide PV courses.	Academia, MOH,NDA	Y4
	Utilization of experts for evaluation of risk management plans and safety data to aid decisions on the safety of medicines in the country.	A pharmacovigilance and risk assessment committee (PRAC) established that provides scientific opinion to MPM-TWG/NDA.	NDA	Y on Y
To strengthen effectiveness of existing reporting, through implementation of smart safety surveillance initiatives.	Use of innovative reporting platforms, and database for collation and coordination of ADE data	Electronic online ADR reporting platforms and database in place for health workers and patients.	NDA, All Stakeholders	Y1

	Implement active drug surveillance methods through Sentinel sites.	Established sentinel sites for active monitoring	MOH, NDA	Y on Y
	Utilization of existing healthcare databases for active surveillance	Healthcare database data mining established.	NDA	Y2-Y5
	Utilization of targeted reporting in public health programs	PV included in public health programs	MOH, NDA	Y on Y
	Recognition of out-standing performance in pharmacovigilance	Recognition to outstanding performers involved in pharmacovigilance	NDA, *IPs, MOH	Y on Y
	Facilitate Medicine Therapeutic Committees (MTC) to utilize facility level safety data to address medicine safety issues	Hospital pharmacovigilance teams transformed into sub-committees of the MTC to facilitate MTC led facility level risk mitigation	MOH, NDA	Y on Y

* IP stands for Implementing Partners

Strategic area 2: Legal Environment				
Objective	Intervention	Key Outputs	Responsibility	Timeframe
Increase compliance to existing laws and regulations for pharmacovigilance	Review of relevant pharmacovigilance regulations to ensure effective implementation of PV in the country	Laws in place to support implementation of Pharmacovigilance	NDA	Y1
	Develop and disseminate guidelines regarding implementation of all pharmacovigilance legal provisions	Pharmacovigilance guidelines for MAH, public health programs, health workers developed	NDA	Y1
	Develop guidelines to public health and other stakeholders on the establishment of program level pharmacovigilance systems for reporting of ADRs		NDA, MOH	Y2

Strategic area 3: Collaborations and information exchange				
Objective	Intervention	Key Outputs	Responsibility	Timeframe
Enhance safety information exchange at national, regional, and international level	Develop a procedure for monitoring and utilization of safety information from external sources	Procedure for monitoring and utilization of extraneous safety data developed	NDA	Y1
		Regular sharing of local safety data with regional and international agencies.		
Facilitate collaborations between the different PV stake holders.	Establishment of a formal pharmacovigilance stakeholder platform for coordination of pharmacovigilance activities locally	Functional PV platform for stakeholders established.	NDA	Y1
	Contribute to international fora for medicines to address global challenges, promote Convergence of regulatory standards in PV , and sharing of information at regional and international level. Participate in specific working groups to support sharing of information and sharing of resources	Expert working group activities undertaken at all levels.	NDA, IPs	Y on Y
		International pharmacovigilance meetings and conferences attended		Y on Y

Strategic area 4: Feedback, health worker engagement and community participation				
Objective	Intervention	Key Outputs	Responsibility	Timeframe
Enhance dissemination of safety information, increase transparency and feedback to the relevant stakeholders	Regular publication of safety information through bulletins, ADR summary reports, notices, and other means	Published bulletins, ADR summary reports, notices	NDA	Y on Y
	Develop a procedure to guide issuance of safety alerts/ dear healthcare provider letter (DHCP), and feedback to health facilities on ADRs received	Written procedure, communication templates		
Establish systems of enhancing public awareness about the importance of pharmacovigilance and the roles of the different partners	Utilize media engagements (talk shows, adverts/jingles, social media etc) to sensitize the public on pharmacovigilance	Information disseminated to the public through Talk shows, adverts, posters, publications and people-centered dialogues and other platforms	NDA	Y on Y
	Utilize community dialogues to increase awareness on pharmacovigilance			
	Development and dissemination of educational programs and IEC materials			

4.0 Implementation of the Strategy

The strategic areas identified in this strategic plan will be translated into local action plans annually to be implemented by NDA through the National Pharmacovigilance Center and other relevant stakeholders. Resources necessary for the implementation of this strategy will be acquired from the NDA budget, support of implementing partners, and other funders.

5.0 Monitoring and Evaluation

The implementation of this strategy shall be monitored and measured annually, quarterly, and monthly to review the trend in performance of Pharmacovigilance.

Annual implementation plans will be prepared by different stakeholders to guide the operationalization of the Pharmacovigilance strategy. The plan will outline how strategic objectives and strategic priorities will be realized by indicating what will be done, by who, when, and how and this will serve as a checklist that will be regularly updated, monitored, and shared among stakeholders.

The core WHO structural indicators that assess the existence of key Pharmacovigilance structures, systems and mechanisms that give visibility to a functional Pharmacovigilance system in a country will be used. The WHO link for all the structural indicators is http://apps.who.int/medicinedocs/documents/s21970en/s21970en.pdf.

Strategic Area 1: Pharmacovigilance technical capacity and infrastructure										
Objective	Intervention	Key Outputs	Indicator	Indicator Definition	Target	Formula (How the Indicator is Calculated)	Reporting Interval	Means of Verification	Responsibility	Time Frame
1.1 Enhance technical capacity of PV personnel at all levels	**1.1.1** Support training and capacity building of NPC staff.	Trained NPC staff	Number of NPC staff trained	This indicator measures the total of NPC staff trained	10	Count of all the NPC trained staff in the reporting period	Annually	Training Reports	NDA	Y on Y
	1.1.2 Training and skilling of PV staff at all levels	Trained PV staff at all levels	Number of PV staff trained at all national and facility levels	This indicator measures the total of PV staff trained at all national and facility levels	All eligible staff at national and facility levels	This is got by counting of all the PV staff trained in reporting period	Annually	Training Reports	All Stakeholders	Y on Y
	1.1.3 Develop the National training curricula for health workers for PV	Pre-service and in-service training curricula and tools developed	Number of pre-service training curricula's developed	This indicator measures the number of pre-service curricula's developed	1 PV training curricula in higher institutions developed	Count of all training curricula's developed	Once in the strategic period	Training Curricula's developed	NDA, MOH	Y5
			Number of in-service training curricula's developed	This indicator measures the number of in-service training curricula's developed	1 national training for in-service	Count of all training curricula's developed	Once in the strategic period	Training Curricula's developed	NDA	Y5
	1.1.4 Incorporation of Pharmacovigilance in the pre and in-service national training curricula for health workers	Pharmacovigilance incorporated in the national training curricula for health workers	Percentage of training curricula for health workers with Pharmacovigilance information incorporated	This indicator measure the % of training curricula's with Pharmacovigilance information incorporated	100%	(Number of training curricula's with Pharmacovigilance information incorporated/ Total number of training curricula's for health workers) * 100	Annually	Training Manuals	Academia, MOH	Y4
	1.1.5 Utilization of experts for evaluation of risk management plans and safety data to aid decisions on the safety of medicines in the country	Pharmacovigilance and risk assessment committee (PRAC) established that provides scientific opinion to MPM-TWG/NDA	Pharmacovigilance and risk assessment committee (PRAC) established to provide scientific opinion to MPM-TWG/NDA	This indicator measures the utilization of experts for evaluation of risk management and safety of medicines in the country	1 Committee Established	Evidence of Pharmacovigilance and risk assessment committee (PRAC) established to provide scientific opinion to MPM-TWG/NDA	Once in a year	NDA Annual Report	NDA	Y on Y
1.2 To strengthen effectiveness of existing reporting, through implementation of smart safety surveillance initiatives.	**1.2.1** Use of innovative reporting platforms, and database for collation and coordination of ADE data	Electronic online ADR reporting platforms and database in place for health workers and patients.	Percentage increase in the number of ADR reports received annually.	This indicator measures the effectiveness of the effort put in the system for reporting drug related problems in order to detect medicine risks during use on the market.	50%	(Number of ADR reports received in the current year - Number of ADR reports received in preceding year/ Number of ADR reports received in preceding year)r × 100	Annually	PV Report	NDA, All Stakeholders	Y1

	1.2.2 Implement active drug surveillance methods through Sentinel sites	Established sentinel sites for active monitoring	Number of sentinel sites established for active monitoring of drugs	This indicator measures the active drug surveillance methods through Sentinel sites established	10	Count of all sentinel sites established for active monitoring of drugs	Annually	ADR Reports	MOH, NDA	Y on Y
	1.2.3 Utilizing of targeted reporting in public programs	PV included in public health programs	Percentage of public health programs reporting Pharmacovigilance	This indicator measures the percentage in Pharmacovigilance reporting by public health programs from 60% to 100%	100%	(Number of public health programs reporting on Pharmacovigilance in the reporting period/ Total number of public health programs in the country) × 100	Annually	PV Report	MOH, NDA	Y on Y
	1.2.4 Recognition of out-standing performance in Pharmacovigilance	Recognition to out-standing performers involved in Pharmacovigilance	Number of recognition messages/ awards sent to the outstanding Pharmacovigilance performers in safety surveillance	This indicator measures the number of messages/ awards given to the outstanding Pharmacovigilance performers in safety surveillance	All Best performers sent messages and awarded annually	Count of all messages/ awards given to the outstanding Pharmacovigilance performers in safety surveillance	Annually	PV Report	NDA, *IPs, MOH	Y on Y
	1.2.5 Facilitate Medicine Therapeutic Committees (MTC) to utilize facility level safety data to address medicine safety issues	Hospital Pharmacovigilance teams transformed into sub-committees of the MTC to facilitate MTC led facility level risk mitigation	All Regional Hospitals added to Medicine Therapeutic Committees (MTC) to utilize facility level safety data to address medicine safety issues	This indicator measures all Regional Hospitals added to MTC to utilize facility level data to address medicine safety issues	100%	(Total number of Regional Hospitals added to Medicine Therapeutic Committees (MTC) to utilize facility level safety data to address medicine safety issues / Total number of Regional Hospitals in the country)*100	Annually	PMS Report	MOH, NDA	Y on Y

Strategic Area 2: Legal Environment										
Objective	Intervention	Key Outputs	Indicator	Indicator Definition	Target	Formula (How the Indicator is Calculated)	Reporting Interval	Means of Verification	Responsibility	Time Frame
2.1 Increase compliance to existing laws and regulations for Pharmacovigilance	**2.1.1** Review of relevant Pharmacovigilance regulations to ensure effective implementation of PV in the country	Laws in place to support implementation of Pharmacovigilance	Review the Pharmacovigilance approved law	This indicator measures the availability of laws in place for implementation of Pharmacovigilance in country	1 PV Law	Evidence of Pharmacovigilance approved law reviewed	Once in the strategic period	Hard copies of the regulations and law	NDA	Y1
	2.1.2 Develop and disseminate guidelines regarding implementation of all Pharmacovigilance legal provisions	Pharmacovigilance guidelines for MAH, public health programs, health workers developed	Proportion of guidelines disseminated regarding implementation of all Pharmacovigilance legal provisions	This indicator measures the dissemination rate of guidelines regarding implementation of all Pharmacovigilance legal provisions	100%	(Total number of guidelines disseminated regarding implementation of all Pharmacovigilance /Total number of guidelines developed regarding implementation of all Pharmacovigilance legal provisions)*100	Annually	PV Report	NDA	Y1
	2.1.3 Develop guidelines to public health programs and other stakeholders on the establishment of program level Pharmacovigilance systems for reporting of ADRs									

Strategic Area 3: Collaborations and information exchange										
Objective	Intervention	Key Outputs	Indicator	Indicator Definition	Target	Formula (How the Indicator is Calculated)	Reporting Interval	Means of Verification	Responsibility	Time Frame
3.1 Enhance safety information exchange at national, regional, and international level	**3.1.1** Develop a procedure for monitoring and utilization of safety information from external sources	Procedure for monitoring and utilization of extraneous safety data developed	Number of Procedures for monitoring and utilization of extraneous safety data developed	This indicator measures the procedures developed for monitoring and utilization of extraneous safety data	1	Count of all procedures developed for monitoring and utilization of extraneous safety data	Annually	Pharmacovigilance report	NDA	Y1
		Regular sharing of local safety data with regional and international agencies.	Proportion of local safety data reports disseminated with regional and international agencies	This indicator measures the sharing rate of safety information reports at different levels	100%	(Number of local safety data reports disseminated at different levels/Total number of safety data reports compiled in the reporting period)*100	Annually	Pharmacovigilance report	NDA	
3.2 Facilitate collaborations between the different PV stake holders.	**3.2.1** Establishment of a formal Pharmacovigilance stakeholder platform for coordination of Pharmacovigilance activities	Functional PV platform for stakeholders established.	Functional Pharmacovigilance stakeholder platform for coordination of Pharmacovigilance activities established	This indicator measures the Pharmacovigilance stakeholder platform for coordination of Pharmacovigilance activities established and functional	1 stakeholder meeting annually	Count of all Pharmacovigilance stakeholder platform for coordination of pharmaco-vigilance activities established	Annually	Pharmacovigilance report	NDA	Y1
	3.2.2 Participate in joint activities at local, regional and international level	Expert working group activities undertaken at all levels.	Number of joint activities undertaken at different levels by Expert working group	This indicator measures the number of joint activities undertaken by Expert working group	Pre-Qualified experts	Count of all joint activities undertaken by expert working group in the reporting period	Annually	Pharmacovigilance report	NDA, IPs	Y on Y
		Local and international Pharmacovigilance meetings and conferences attended	Number of Local and international Pharmacovigilance meetings and conferences attended	This indicator measures the NDA's participation in joint activities at local, regional and international level in the reporting period	2 (WHO and ASOP Meeting)	Count of all local and international meetings and conferences held in the reporting period	Annually	Pharmacovigilance report	Y on Y	

Strategic Area 4: Feedback, health worker engagement and community participation										
Objective	Intervention	Key Outputs	Indicator	Indicator Definition	Target	Formula (How the Indicator is Calculated)	Reporting Interval	Means of Verification	Responsibility	Time Frame
4.1 Enhance dissemination of safety information, increase transparency and feedback to the relevant stakeholders	**4.1.1** Regular publication of safety information through bulletins, ADR summary reports, notices, and other means	Published bulletins, ADR summary reports, notices	Number of bulletins disseminated to increase transparency and feedback to stakeholders	This indicator measures the total number of bulletins published	4 Bulletins	Count of all the bulletins published as a way of increasing transparency and feedback to stakeholders	Annually	Pharmacovigilance report	NDA	Y on Y
			Number of ADR summary reports disseminated	This indicator measures the ADR summary reports disseminated	4 ADR Summary Reports	Count of all the ADR summary reports analyzed and disseminated to increase transparency and feedback to stakeholders	Annually	ADR Reports	NDA	Y on Y
	4.1.2 Develop a procedure to guide issuance of safety alerts/ dear healthcare provider letter (DHCP), and feedback to health facilities on ADRs received	Written procedure, communication templates	Procedure and communication template disseminated	This indicator measures the evidence of one procedure and communication template shared	1 Procedure shared	Evidence of one procedure shared	Annually	Pharmacovigilance report	NDA	Y on Y
4.2 Establish systems of enhancing public awareness about the importance of Pharmacovigilance and the roles of the different partners	**4.2.1** Utilize media engagements (talk shows, adverts/ jingles, social media) to sensitize the public on Pharmacovigilance	Talk shows, adverts, posters, publications and people-centered dialogues and other means of disseminated to the public	Number of media engagements used to sensitize the public on Pharmacovigilance importance	This indicator measures the number of talks shows, adverts, posters, people centered dialogues and other means done to create awareness in the public about the importance of Pharmacovigilance	4 Engagements (1 per quarter)	Count of all media engagements done to create awareness in the public about the importance of Pharmacovigilance	Annually	Pharmacovigilance report	NDA	Y on Y
	4.2.2 Development and dissemination of educational programs and IEC materials		IEC/Educational materials on Pharmcovillance targeting the public and health professionals developed and accessed	This indicator proves the availability Educational and IEC materials on the role of Pharmacovigilance	Evidence of IEC materials for public and professionals	Evidence of developed IEC materials and accessibility	Annually		NDA	Y on Y
		ADR reporting platforms availed for public and health professionals	Availing ADR reporting platforms to public and health professionals	This indicator measure the availability of ADR reporting platforms for public and health professions	Evidence of ADR reporting platforms for public and health professionals	Evidence of ADR reporting platforms for public and health professionals		Summary ADR report	NDA	Y on Y

6.0 Financing Mechanisms

Delivering this strategy will require financial, human and other forms of technical resources. Therefore individual stakeholders will be required to solicit for the relevant resources for effective implementation of this strategy.

7.0 References

1. WHO: Pharmacovigilance indicators: a practical manual for the assessment of Pharmacovigilance systems; World Health Organization 2015
2. The National Drug Authority strategic plan 2016-2021 plan
3. National Pharmaceutical Sector Strategic Plan 2015-2020
4. Health Sector Development Plan 2015-16_2019-20

Appendix

Appendix 1: List Of Stakeholders Who Contributed to the Strategy

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2. Joseph Mwoga	World Health Organization
3. Robert Offiti	HEPS Uganda
4. Shamim Nakade	Infectious Diseases Institute
5. Rogers Sekabira	Baylor Uganda
6. Victoria Nyombi	Mulago National Referral Hospital
7. Martha Ajulong	Mulago National Referral Hospital
8. Dan Kajungu	Makerere University
9. Joan Kilande	HEPS Uganda
10. Michael Isabirye	MOH/ACP
11. Mark Agaara	MOH/ACP
12. Gladys Nalukenge	CHAIN
13. Francis Kidega	USAID GHSC-PSM Chemonics
14. Kevin Otieno..	Joint Medical Stores
15. Thomas Ocwa Obua	Ministry of Heath
16. Joseph Mwoga	World Health Organization
17. Shahidah Nalumansi	USAID GHSC-PSM Chemonics
18. Martha Ajulong	Mulago National Referral Hospital
19. Ester Nabeeta	Private Sector Foundation Uganda
20. Allen Kagoya	Anti-Counterfeiting Network (ACN) Africa
21. Denis Mugabi	Uganda Health Federation
22. Suubi Lubega	Medical Access Uganda Ltd
23. Thomas Obua	Ministry of Health
24. Brian Sekayombya	Uganda Health Supply Chain
25. Pamela Nawaggi	Clinton Health Access Initiative
26. Regina Kamoga	Community Health and Information Network (CHAIN)
27. Lawrence Otim	Infectious Disease Institute
28. Robinah Keitirimba	Uganda National Health Consumers Organization

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