Treatment action action	Indicator description	Baseline	Indicator value		Status of Implementation	Residual Risk			Data collection instrument and methods
			Cumulative Target Value	Action undertaken		Likelihood	Impact	Rating	
Existence of falsified, substandard and unauthorized products on the market-NDA/OPR/DIE-PMS/R001									
1. Contribute to the development of a National supply chain transition road map		0			Partially Implemented				Review of staff records
2. Introduce an automated track and trace system	A functioning Trace &Track system	0	1						Review of documents/system
3. (a) Conduct inspection to monitor medicines and biocidal imported under special conditions	Percentage of consignments imported under special conditions monitored	0	60%						Review of progress reports
. (b) Conduct inspection to monitor medical devices and diagnostics imported under special conditions	Percentage of consignments imported under special conditions monitored	0	100						Review of progress reports
4. Monitor implementation of action plan to promote/support local drug manufacturing and domestic medical products manufacturing facilities 2023/24	Number of monitoring reports (NO of local manufacturers inspected)	0	4						Review of performance evaluation records
5. Review and implement routine inspection checklist	Revised checklist in place	0							Review of Documents
	% of routine inspections conducted using revised checklist	0							Review Inspection reports
6. Conduct inspectors training on intelligence techniques	Number of inspectors trained								Review of progress reports
7. Conduct sensitization of Whistleblowing Policy to NDA staff	% of staff sensitized	0							Review of progress reports
8. Review and widen scope of PMS	Number of products increased in PMS								Review of PMS program
10. Collaboration with MDA on actions to deter unauthorized products reaching the market (Establish and implement plan for the signed MoUs between NDA and other MDAs and traditional institutions.	Plan in place	0	1						Review of documents
	% implementation of the plan	0							Review of progress reports
13. Establish and implement procedures for internal coordination for planning and sensitization of different categories of stakeholders.	Procedure for internal coordination in place	0	1			1	4	4	Review of documents
	%of stakeholders sensitized disaggregated by categories	0							Review of progress reports

14. (a) Review procedure for conducting inspection of medicines and biocidal to include risk based criteria for planning inspection activities including format for planning such inspection	Revised procedure in place	0	1						Review of MCIE documents
14. (b) Conduct sensitization on pharmacovigilance vigilance to stakeholders including village leaders, celebrities, religious, political, and other influential figures in the community to sensitize reporting	%of stakeholders sensitized disaggregated by categories	0							Review of progress reports
15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print		0							
16. Regional offices to regularly disseminate drug safety information to the public.		0							
2. Train inspectors and assessors on enforcement of pharmacovigilance regulations and Good Vigilance Practice (GVP)	% of inspectors and assessors trained	0							Review of progress reports
3. Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap	Number of monitoring reports	0	4						Review of performance evaluation records
4. (a) Conduct regular sensitization to healthcare providers and focal person/zones on reporting of ADRs	%of health care providers sensitized disaggregated by categories	0							Review of progress reports
5. Integrate ADR reporting forms into Ministry Health Management Information System (HMIS)	Functional integrated HMIS in place	0	1						Physical verification of HMIS
8. Establish database for processing field safety reports for medical devices	Functional database in place	0	1						Review of records
9. Provide feedback to reporters after receiving ADRs	% of feedback to reporters	0							Review of progress reports
9 (b). Provide feedback to reporters after receiving and AEs	% of feedback to reporters	0	100						Review of progress reports
Failure to manage Authority's assets effectively;									
1. Review frequency of asset verification procedure for asset management									

2. Revise and disseminate NDA accounting manual	Revised accounting manual in place	0	1						Review of progress reports
5. Approve and disseminate estate management guideline	Approved estate management guideline in place	0	1						Review of progress reports
	% of staff with approved estate management guideline	0							Review of HRA documents
7. Inspect availability of performance reporting of contracts given to service providers	% of contracts with performance reports	0				4	4	16	Review of procurement records
8. Hire highly skilled guards		0							
9. Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management	Number of sanitization conducted	0	4						Review of progress reports
	% of staff sensitized	0	100						Review of progress reports
Lack of sufficient revenues to sustain NDA activities (Revenue losses)									
1. Review fees and charges regulations	Reviewed fees and charges regulations in place	0	1						Review of progress reports
2. Prepare annual risk-based inspection plan at regional offices	Annual risk-based inspection plans in place	0	9						Review of inspection records
3. Institute system alert to cover all service associated with revenues collection	% of service associated with revenues collection with system alert	0							Review of progress reports
4. Designate person to make follow-up of outstanding invoices and debts	Engage MoH to clear the outstanding debt	0	1						Review of progress reports
5.Prepare and implement Laboratory business plan	Laboratory Business Plan in place	0	1						Review of progress reports
6. Staff sensitization on code of ethics	% of staff sensitized	0	100						Review of progress reports
7. Develop and implement a stringent fraud policy	A Fraud Policy approved	0	1						Progress report
8. Strengthen resource mobilization and exercising priority spending	Meticulous cash flow management	0							Progress report
9. Engage Ministry of Finance to clear MoH arrears		0							
10. a) Regular training of staff on matters of accountability and budget expenditure. b) Finance should not advance funds to the whole department until the members in default account for the funds, additionally, The newly upgraded Finance system(BC 360) is now able to execute budget checks	a) Number of staff trained b) Budget checks execution								
11. To do a remapping of the Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry physical address.	Mapping of the system								
12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry									
13. Review the entire approval process. Develop Internal Service Level Agreement with other departments.	Internal service development					4	4	16	
Unavailability of ICT services (Cyber risk)									
1. Develop and implement a BCP & DRP	An approved BCP & DRP	0	2						Document review
2. Conduct periodic testing of ICT disaster recovery plans.	ICT disaster recovery plan tested	0	1						Review of progress reports
3. Conduct periodic testing of BCP	BCP testing conducted	0	1						Review of progress reports
4. Prepare schedule for preventive maintenance of power backup system	Schedule for power backup system in place	0	1						Review of progress reports
5. Prepare schedule for preventive maintenance of generators	Schedule for preventive maintenance of generators in place	0	1						Review of progress reports
6. Upgrade power back up system at NDA offices	Number of hours for power backup	3	9						Review of progress reports
7. Report on adherence to Service Level Agreement	% of adherence to Service Level Agreement	0							Review of progress reports
8. continuous update of the clinical trials databases	% of the clinical trial database updated	0							

9. automate the clinical trial application system	% of the system automated	0							
10. Develop an electronic system to facilitate signal detection		0							
11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data	No. of NDAs signed	0							
12. Setup of Hot site for redundancy, systems upgrades	No of upgrades	0							
13. infrastructure upgrade, Repair of faulty equipment		0							
14. Update security policies, Sensitize users to be aware of social engineering,	No of staff sensitized	0							
15. Turn on multifactor authentication for your online accounts.		0							
16. Increased Monitoring network and systems with advanced tools		0							
17. Improve on surveillance and physical security		0							
18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance.		0							
Fire outbreak									
1. Conduct firefighting and rescue training to at least 50% of staff annually	% of trained staff	0	50						Review of progress reports
2. Install automatic fire suppression and fighting devices in ICT server room at NDA buildings	Automatic fire suppression and fighting devices in place	0	2						Review of progress reports
3. Conduct awareness training on emergency exit plan to staff	% of trained staff	0	100						Review of progress reports
4. Designate firefighting champions	Number of designated fire fighting champions	0							Review of progress reports
5. Conduct regular firefighting drill exercises at all offices	Number of offices conducted firefighting drill exercise	0	9						Review of progress reports
6. Inspection of NDA new tower building	Inspection conducted at NDA tower	0	1						Review of progress reports
7. Communicate emergency number for fire rescue department of Police to all NDA offices	Number of TMDA offices communicated with emergence numbers	0	9			4	4	16	Review of progress reports
8. Procure designated cabinets for storage of volatile and flammable for the laboratory	Number of laboratories installed with designated cabinets for storage of volatile and flammable	1	2						Review of progress reports
9. Conduct periodic inspection of electrical systems at NDA buildings	Number of buildings conducted Electrical system Inspection	0	3						Review of progress reports
10. Conduct periodic maintenance services for fire detection, suppression and fighting systems	Number of maintenance services performed for fire detection, suppression and fighting systems	0	4						Review of progress reports
Approval of non-existing or non GMP/quality audit compliant oversees manufacturing facilities									
1. Develop guidelines on submission of applications of quality audit for medical devices manufacturing facilities	Guidelines on submission of applications of quality audit for medical devices manufacturing facilities in place	0	1						Review of progress reports
2. Develop and disseminate guidelines for conducting desk review of medical devices	Guidelines for conducting desk review of medical devices in place	0	1						Review of progress reports
	% of assessors involved in dissemination workshops	0	100			4	4	16	Review of progress report
3. (a) Conduct PMS of medicines and biocidal approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100						Review of PMS records
3. (b) Conduct PMS of products approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100						Review of PMS records
4. Identify countries to sign mutual agreement for recognition and reliance	Number of countries identified	0	10						Review of progress report
Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification									

1. To appoint QMS focal person to each section/unit to enhance implementation of documented procedures	Number of sections with QMS focal person								Review of Progress Reports
2. Sensitization to process owners on the acceptance and positive attitude towards non conformances	Number of process owners (Managers& head of unit sensitized	0							Review of progress report
3. Develop and implement schedule for regular follow-up on QMS review meetings deliberations	Schedule for regular follow-up on QMS review meetings deliberations in place	0	1						Review of progress reports
	% implementation of scheduled follow-ups	0							Review of progress reports
4. Conduct training on auditing techniques to QMS auditors	% of auditors trained	0				4	4	16	Review of progress report
5. Establish and implement schedule for institutional self-assessment on WHO-GBT and GPQCL requirements	Schedule for institutional self-assessment on WHO-GBT and GPQCL requirements in place	0	1						Review of progress reports
	% implementation of scheduled follow-ups	0	100						Review of progress reports
6. Conduct awareness training on QMS and Risk Management	% of staff trained on QMS and risk Management								Review of progress reports
7. Invest in strengthening the Quality Management Systems across the organization.		0							
8									
Underperformance, delays or failure of NDA projects									
1. Develop and implement SOP for developing, approval, implementation and reporting of projects.	Developed SOP in place	0	1						Review of PME document
2. Conduct project risk analysis for each project at NDA.	% of project conducted risk analysis	0	100						Review of progress reports
3. Conduct stakeholders' analysis associated with each project to determine their need and expectations	% of stakeholders analyzed for their needs and expectations	0	100						Review of progress reports
4. Institute use of project management software	Project management software instituted	0	1						Review of progress reports
5. Appoint and train project focal persons on project management	Focal persons on project management appointed and trained	0	1						Review of progress reports
6. Establish a prequalified list of expert reviewers. Conduct individual and group training on selected, problematic CT processes with intention of co-opting more internal reviewers.		0							
7. Propose to management to carryout consultation with the directorate before approval of the training plan		0				4	4	16	
8. a) An ICT steering committee needs to be setup to guide the process for all changes. b) A clear implementation plan should be in place that supports parallel change over ,		0							
9. Collaboration and strategic alliances with other Government Agencies and international drug regulatory authorities to work on price capping		0							
10. Developing guidelines in line with the law to avoid complaints		0							
11. Publish more frequent reports on the activity of NDA and respond timely to all media issues.		0							
12. Involving management (Directors) to avail internal Auditors.		0							
13. Strengthen third party due diligence review processes.		0							
14. Reevaluate the reorder levels.		0							
Loss of product samples or exhibits									
1. Install biometric access control systems to all storage rooms	number of storage rooms with biometric access control systems								Review of progress records

2. Provide secured rooms including cabinets/shelves for storage of samples and exhibits	Number of rooms provided								Review of progress reports
	Number of cabinets/shells provided								Review of progress reports
3. Procure special labelled samples collection bags	Number of special labelled samples collection bags	0							Review of progress reports
4. Regular staff training on procedures for handling of product samples, exhibits and dossiers	% of staff trained on procedures for handling of product samples, exhibits and dossiers	0	95						Review of progress records
Non-compliance to Legal requirements									
1. Conduct regular staff trainings and dissemination on relevant laws, regulations and guidelines.	% of staff trained on relevant laws, regulations and guidelines.	0	95						Review of progress records
2. Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders.	% of stakeholders attending workshops on Laws, Regulations and Guidelines	0							
3. Routine document screening before receipt by registry.		0							
4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting	Number of revised regulation	0				4	4	16	
5. Expand the scope of the existing law and regulations to address the legal gaps.		0							
6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness	Number of stakeholders meeting conducted in a year	0							
7. Consider actions to streamline the legal and regulatory framework for operational effectiveness.		0							
8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions.									
9. Training management and the Drug Authority on judicial review.									
10 a) Conduct regular staff training and dissemination on relevant laws,									
b) regulations and guidelines									
c) Conduct dissemination workshops on Laws,									
d) Regulations and Guidelines to stakeholders.									
11. Improved liaison with the Legal Department to ensure compliance		0							
Staff safety, security and occupational health hazards									
1. Sensitize staff on workers Compensation	% of staff sensitized on benefits of workers Compensation Fund		95						Review of progress report
2. Provide sufficient number of ergonomic chairs to cover all staff	% of staff provided with ergonomic chairs to cover all staff		50						Review of progress report
3. Sensitize staff on wellness programme including regular check up	% of staff sensitized on wellness programme including regular check up		95			4	4	16	Review of progress report
4. Secure sport ground for staff at NDA for regular exercise and training	Number of sport grounds secured		95						Review of progress report
5. Install Security Devices like CCT Cameras	Number of cameras installed								
6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually	% of staff trained								
7. vehicle tracking system should be prioritized	Number of vehicle tracking systems installed								
Staff turn over									
2. Develop and implement incentive schemes	incentive schemes in place								Review of progress report
4. Sensitize and train staff on conducting Training Need Assessments (TNA)	% of staff sanitized Training Need Assessments(TNA)					4	4	16	Review of progress report

5. Recruit more procurement staff	Number of staff recruited	0							
6. Continuous training of Board of Survey members	Number of staff trained	0							
Inappropriate exposure of samples leading to possible damage or compromise of results.									
1. Avail HVAC system		0	1			4	4	16	Review of progress report
Delayed coding and analysis of samples									
1.Enhanced sensitization of the inspectors to forward samples with full documentation.	Number of inspectors sensitized	0				4	4	16	Review of progress report
2. Reject samples with incomplete documentation	Number of samples rejected.	0							Review of progress report
3. Automation of the process (sample receipt, analysis and coding)	% of the process automated	0							Review of progress report
4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures.		0							
Use of Invalid reference standards since validity is not indicated on the bottle.									
1. Analysts required to attach a copy of the certificate of analysis for reference standards used during analysis.	Copies attached	0				4	4	16	Review of progress report
contamination of samples being tested due to the use of un clean glassware.									
1. Procure glassware washing machine.	Number of machines procured	0				4	4	16	
Laboratory Accidents occur									
1. Enhance PPEs		0				4	4	16	
Litigation arising out of the legally challenged appointment of non-pharmacists as drug inspectors.									
1. Application to court to set aside the out of court settlement		0				4	4	16	
2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law		0							
Antimicrobial resistance occurs in both human and animals due to toxicities in veterinary drugs.									
1. Develop a module in NDAMIS to capture Import quantities of Vet drugs to monitor the antimicrobial use in the country		0				4	4	16	
Scope of available regulation is narrow, only for ectoparasiticides									
1. Recruitment of other cadre of staff and function-specific training of assessors.	Number of cadre staff recruited					4	4	16	
2. Expedite formulation of new regulations for general applications to all veterinary trials.	Development of new regulations	0							
Entry errors on the CNF list, register and certificate of registration.									
1. Revised assessment template to improve the vigilance.		0				4	4	16	
2. Continuous training of the assessors.	Number of assessors trained	0							
3. Errors routed to the resource that does drafting	% of errors routed	0							
4. Maker-checker process implemented. (QA process)		0							
5. Full automation of the register.		0							
Disclosure of confidential information in an application to an unauthorized person.									
1. Strengthening controls by restricting access to dossiers to person with signed confidentiality undertaking.		0				4	4	16	
2. DPAR has further restricted distribution of information to senior assessors within the Directorate.		0							
Shortage of Infrastructure and facilities to meet the NDA's needs.									
1. Monitoring the time a client parks to create space for the upcoming clients		0				4	4	16	
Under staffing									
1. Recruiting new staff to fill the positions in the organogram	Number of new staff recruited	0				4	4	16	
Delay in implementing research									
1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research		0			Fully Implemented	4	4	16	
2. use temporary staff and hire research assistants to support the research activities		0							
chain of evidence for impounded drugs compromised.									
1. Procure bigger office space to address the poor storage challenge.	Procurement of bigger office space	0							

2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances.		0				4	4	16	
Failure to facilitate the process of improving the legal mandate of NDA and the proposed extended mandate on food and cosmetics safety									
1. NDA Authority to engage and support MOH in undertaking high level lobbying with key stakeholders and have the Bill fast tracked in Parliament		0				4	4	16	
Confidential information is publicly released/Leakage of sensitive information									
1. Awareness on the Internal and External communication and relationship management.		0				4	4	16	
2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms		0							
3. Stringent security checks both before staff are hired and after they've left.		0							
REGIONS									
Forged academic documents submitted for persons to be incharges.									
1.Give DDIs tools enabling them verify academic documents submitted to them	%ge of DDIs supported with tools	0	100			4	4	16	
2.NDA to liaise with various professional councils to have in place a shared data base of all qualified/registered health personnel		1	1						
Absentee incharges									
Close outlets with absentee in charges (manned by unqualified attendants)	No. of outlets with absentee in charges closed	0				4	4	16	
Smuggling of drugs across the boarders -Uganda - south Sudan & DRC boarders									
Establish port of entry in tguhe region. E.g. in Eleju						4	4	16	
Increase boarder routine inspection and vigilance	No. of boarder surveillance visits	4	4	1					
Delayed basic testing of suspected substandard, falsified and counterfeit products									
Establish well equipped mini labs in the regions	One mini lab equipped	1	1			4	4	16	
illegal, unlicensed drug outlets operating (and Hawkers)									
Have more severe penalties given to offenders						2	2	4	
Impound and close the outlet until compliance	%ge of illegal outlets impounded								
Impound and arrest all hawkers and charge them	No. of Hawkers charged								

Frequency of reporting	Means of verification	Responsible person(s)
Quarterly		DIE
Quarterly	System installation	DIE
Quarterly	Approved reports	DIE (Control of imports)
Quarterly	Approved reports	Medical Devices
Quarterly	Monitoring reports	Manager Herbal Medicines
Once	Approved revised checklist	DIE /GMP
Quarterly	Inspection reports	
Annually	Training records	DIE/Inspectorate
Quarterly	Sensitization records	SA
Quarterly	Approved PMS Program and reports	DPMS
Once	Approved Plan	SA /PRO
Quarterly	Implementation reports	SA / PRO
Once	Approved procedure	SA/PRO
Quarterly	Sensitization records	SA/PRO

Once	Approved procedure	DIE/QMS
Quarterly	Sensitization records	DPS/MPV
		DPS/MDP
		DIE/Head Regions
Quarterly	Training records	DPS/MPV
Quarterly	Monitoring reports	DPS/MPV
Quarterly	Sensitization records	DPS/MPV
Once	ADR Forms in HMIS	DPSMPV/HICT
Once	Physical verification of the database	MMDV
Quarterly	Copy of feedback	MPV
Quarterly	Copy of feedback	MMDV

Once	Approved accounting manual	SA/IA/DHRMA
Once	Approved guideline	DHRMA
Once	Distribution List and sensitization records	DHRMA
Quarterly	Performance Reports	HPDU
		DHRA
Quarterly	Sensitization records	HPDU/DHRMA
Quarterly	Sensitization records	DHRMA
Once	Approved reviewed the regulations	HBPD/DCS/SA
Once	Approved inspection plans	Head regions/ Managers
Quarterly	Installation reports	HICT/DCS
Once		DCS
Once	Approved Business plan	DLS
Quarterly	Sensitization records	DHRMA
Quarterly	Approved Fraud policy	BPD
Quarterly		NDA
		FIN
		DCS/FIN
		DHRA
		HICT
		DCS/FIN
Once	Report	HICT/RMO/HBPD
Once	Report of testing of ICT disaster recovery plan	HICT/RMO
Once	BCPTesting report	RMO/HICT/HBPD
Once	Approved Schedule	HICT
Once	Approved Schedule	DHARMA
Quarterly	Installation/Upgrading reports	HICT
Quarterly	Performance reports	HICT
		DPS/CT

		DPS/CT
		DPS
		DPS/MPV
		HICT
		HICT
		HICT
		HICT
		HICT
		HICT
		DIE/HICT
Quarterly	Training records	DHRA
Quarterly	Installation reports	HICT
Quarterly	Training records	DHRA
Quarterly	Appointment letter	DHRA
Quarterly	Firefighting drill exercise report	DHRA
Quarterly	Building Inspection report	DHRA/RMO
Quarterly	Communication records	DHRA
Quarterly	Installation records	DLS
Quarterly	Inspection report	DHRA
Quarterly	Maintance services Reports	HICT/DHRA
Once	Approved	DLS/MMD
Once	Approved	DLS/MMD
Quarterly	Dissemination records	MDL
Quarterly	PMS Reports	DIE/PMS
Quarterly	PMS Reports	MMDV
Once	List of identified countries	DIE/DPAR

Once	Appointment letter	MQMS
Once	Sensitization records	MQMS
Once	Approved schedule	MQMS
Quarterly	Progress report	MQMS
Quarterly	Training records	MQMS
Once	Approved schedule	MQMS
Quarterly	Progress report	MQMS
Quarterly	Training records	MQMS/RMO
		SA/QMS
Once	Approved Procedure	HBPD/PM&EO
Quarterly	Risk analysis reports	RMO/HBPD
Quarterly	Stakeholders analysis reports	PME
Once	Software installation records	HBPD/HICT
Once	Appointment letter and training records	HBPD
		DPS/CT
		DPS/CT
		SA/HICT
		SA/QMS
		PRO
		SA/IA
		DHRA
		PDU
Once	Physical verification of installed biometric access control system	HICT

Once	Asset inventory	DHRA
Once	Asset inventory	DHRA
Once	Delivery note	HPDU
Quarterly	Training records	DLS/DIE/IC
Quarterly	Training records	HLS
		HLS
		DPS/CT
		DPS/MPV
		DIE/LEGAL
		SA/LEGAL
		SA/LEGAL
		HLS
		HLS
		HLS
		HLS
		HLS
Quarterly	Progress reports	DHRA
Quarterly	Progress reports	DHRA
Quarterly	Progress reports	DHRA
Once	Progress reports	DHRA
		DHRA
		DHRA
		DHRA
Once	Progress reports	DHRA
Once	Progress reports	DHRA

		DHRA
		DHRA
Quarterly		DLS
Quarterly	Progress reports	DLS
		DLS
		DLS
		DIE/HICT
		DLS
		DLS
		DLS
		DVS
		DVS
		DVS
		DVS
		DPAR
		DPAR
		DPAR
		DPAR
		DPAR
		DPAR
		DPAR
		DHRA
		DHRA
		DPS
		DPS
		DIE

		DIE
		SA
		PRO
		PRO
		PRO
		DIE
		DIE

Treatment action action	Indicator description	Baseline	Indicator value		Status of Implementation	Residual Risk		
			Cumulative Target Value	Action undertaken		Likelihood	Impact	Rating
Existence of falsified, substandard and unauthorized products on the market-NDA/OPR/DIE-PMS/R001								
1. Contribute to the development of a National supply chain transition road map		0			Partially Implemented			
2. Introduce an automated track and trace system	A functioning Trace &Track system	0	1					
3. (a) Conduct inspection to monitor medicines and biocidal imported under special conditions	Percentage of consignments imported under special conditions monitored	0	60%					
. (b) Conduct inspection to monitor medical devices and diagnostics imported under special conditions	Percentage of consignments imported under special conditions monitored	0	100					
4. Monitor implementation of action plan to promote/support local drug manufacturing and domestic medical products manufacturing facilities 2023/24	Number of monitoring reports (NO of local manufacturers inspected)	0	4					
5. Review and implement routine inspection checklist	Revised checklist in place	0						
	% of routine inspections conducted using revised checklist	0						
6. Conduct inspectors training on intelligence techniques	Number of inspectors trained							
7. Conduct sensitization of Whistleblowing Policy to NDA staff	% of staff sensitized	0						
8. Review and widen scope of PMS	Number of products increased in PMS							
10. Collaboration with MDA on actions to deter unauthorized products reaching the market (Establish and implement plan for the signed MoUs between NDA and other MDAs and traditional institutions.	Plan in place	0	1					
	% implementation of the plan	0						
13. Establish and implement procedures for internal coordination for planning and sensitization of different categories of stakeholders.	Procedure for internal coordination in place	0	1					
	%of stakeholders sensitized disaggregated by categories	0				1	4	4
14. (a) Review procedure for conducting inspection of medicines and biocidal to include risk based criteria for planning inspection activities including format for planning such inspection	Revised procedure in place	0	1					

14. (b) Conduct sensitization on pharmacovigilance vigilance to stakeholders including village leaders, celebrities, religious, political, and other influential figures in the community to sensitize reporting	%of stakeholders sensitized disaggregated by categories	0						
15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print		0						
16. Regional offices to regularly disseminate drug safety information to the public.		0						
2. Train inspectors and assessors on enforcement of pharmacovigilance regulations and Good Vigilance Practice (GVP)	% of inspectors and assessors trained	0						
3. Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap	Number of monitoring reports	0	4					
4. (a) Conduct regular sensitization to healthcare providers and focal person/zones on reporting of ADRs	%of health care providers sensitized disaggregated by categories	0						
5. Integrate ADR reporting forms into Ministry Health Management Information System (HMIS)	Functional integrated HMIS in place	0	1					
8. Establish database for processing field safety reports for medical devices	Functional database in place	0	1					
9. Provide feedback to reporters after receiving ADRs	% of feedback to reporters	0						
9 (b). Provide feedback to reporters after receiving and AEs	% of feedback to reporters	0	100					
Failure to manage Authority's assets effectively;								
1. Review frequency of asset verification procedure for asset management								

2. Revise and disseminate NDA accounting manual	Revised accounting manual in place	0	1					
5. Approve and disseminate estate management guideline	Approved estate management guideline in place	0	1					
	% of staff with approved estate management guideline	0						
7. Inspect availability of performance reporting of contracts given to service providers	% of contracts with performance reports	0				2	4	8
8. Hire highly skilled guards		0						
9. Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management	Number of sanitization conducted	0	4					
	% of staff sensitized	0	100					
Lack of sufficient revenues to sustain NDA activities (Revenue losses)								
1. Review fees and charges regulations	Reviewed fees and charges regulations in place	0	1					
2. Prepare annual risk-based inspection plan at regional offices	Annual risk-based inspection plans in place	0	9					
3. Institute system alert to cover all service associated with revenues collection	% of service associated with revenues collection with system alert	0						
4. Designate person to make follow-up of outstanding invoices and debts	Engage MoH to clear the outstanding debt	0	1					
5.Prepare and implement Laboratory business plan	Laboratory Business Plan in place	0	1					
6. Staff sensitization on code of ethics	% of staff sensitized	0	100					
7. Develop and implement a stringent fraud policy	A Fraud Policy approved	0	1					
8. Strengthen resource mobilization and exercising priority spending	Meticulous cash flow management	0						
9. Engage Ministry of Finance to clear MoH arrears		0						
10. a) Regular training of staff on matters of accountability and budget expenditure. b) Finance should not advance funds to the whole department until the members in default account for the funds, additionally, The newly upgraded Finance system(BC 360) is now able to execute budget checks	a) Number of staff trained b) Budget checks execution							
11. To do a remapping of the Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry physical address.	Mapping of the system							
12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry								
13. Review the entire approval process. Develop Internal Service Level Agreement with other departments.	Internal service development					4	4	16
Unavailability of ICT services (Cyber risk)								
1. Develop and implement a BCP & DRP	An approved BCP & DRP	0	2					
2. Conduct periodic testing of ICT disaster recovery plans.	ICT disaster recovery plan tested	0	1					
3. Conduct periodic testing of BCP	BCP testing conducted	0	1					
4. Prepare schedule for preventive maintenance of power backup system	Schedule for power backup system in place	0	1					

5. Prepare schedule for preventive maintenance of generators	Schedule for preventive maintenance of generators in place	0	1					
6. Upgrade power back up system at NDA offices	Number of hours for power backup	3	9					
7. Report on adherence to Service Level Agreement	% of adherence to Service Level Agreement	0						
8. continuous update of the clinical trials databases	% of the clinical trial database updated	0						
9. automate the clinical trial application system	% of the system automated	0						
10. Develop an electronic system to facilitate signal detection		0						
11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data	No. of NDAs signed	0						
12. Setup of Hot site for redundancy, systems upgrades	No of upgrades	0						
13. infrastructure upgrade, Repair of faulty equipment		0						
14. Update security policies, Sensitize users to be aware of social engineering,	No of staff sensitized	0						
15. Turn on multifactor authentication for your online accounts.		0						
16. Increased Monitoring network and systems with advanced tools		0						
17. Improve on surveillance and physical security		0						
18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance.		0						
Fire outbreak								
1. Conduct firefighting and rescue training to at least 50% of staff annually	% of trained staff	0	50					
2. Install automatic fire suppression and fighting devices in ICT server room at NDA buildings	Automatic fire suppression and fighting devices in place	0	2					
3. Conduct awareness training on emergency exit plan to staff	% of trained staff	0	100					
4. Designate firefighting champions	Number of designated fire fighting champions	0						
5. Conduct regular firefighting drill exercises at all offices	Number of offices conducted firefighting drill exercise	0	9					
6. Inspection of NDA new tower building	Inspection conducted at NDA tower	0	1			4	4	16
7. Communicate emergency number for fire rescue department of Police to all NDA offices	Number of TMDA offices communicated with emergence numbers	0	9					
8. Procure designated cabinets for storage of volatile and flammable for the laboratory	Number of laboratories installed with designated cabinets for storage of volatile and flammable	1	2					
9. Conduct periodic inspection of electrical systems at NDA buildings	Number of buildings conducted Electrical system Inspection	0	3					
10. Conduct periodic maintenance services for fire detection, suppression and fighting systems	Number of maintenance services performed for fire detection, suppression and fighting systems	0	4					
Approval of non-existing or non GMP/quality audit compliant oversees manufacturing facilities								
1. Develop guidelines on submission of applications of quality audit for medical devices manufacturing facilities	Guidelines on submission of applications of quality audit for medical devices manufacturing facilities in place	0	1					
2. Develop and disseminate guidelines for conducting desk review of medical devices	Guidelines for conducting desk review of medical devices in place	0	1					
	% of assessors involved in dissemination workshops	0	100			4	4	16
3. (a) Conduct PMS of medicines and biocidal approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100					

3. (b) Conduct PMS of products approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100					
4. Identify countries to sign mutual agreement for recognition and reliance	Number of countries identified	0	10					
Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification								
1. To appoint QMS focal person to each section/unit to enhance implementation of documented procedures	Number of sections with QMS focal person							
2. Sensitization to process owners on the acceptance and positive attitude towards non conformances	Number of process owners (Managers& head of unit sensitized	0						
3. Develop and implement schedule for regular follow-up on QMS review meetings deliberations	Schedule for regular follow-up on QMS review meetings deliberations in place	0	1					
	% implementation of scheduled follow-ups	0						
4. Conduct training on auditing techniques to QMS auditors	% of auditors trained	0				4	4	16
5. Establish and implement schedule for institutional self-assessment on WHO-GBT and GPQCL requirements	Schedule for institutional self-assessment on WHO-GBT and GPQCL requirements in place	0	1					
	% implementation of scheduled follow-ups	0	100					
6. Conduct awareness training on QMS and Risk Management	% of staff trained on QMS and risk Management							
7. Invest in strengthening the Quality Management Systems across the organization.		0						
8								
Underperformance, delays or failure of NDA projects								
1. Develop and implement SOP for developing, approval, implementation and reporting of projects.	Developed SOP in place	0	1					
2. Conduct project risk analysis for each project at NDA.	% of project conducted risk analysis	0	100					
3. Conduct stakeholders' analysis associated with each project to determine their need and expectations	% of stakeholders analyzed for their needs and expectations	0	100					
4. Institute use of project management software	Project management software instituted	0	1					
5. Appoint and train project focal persons on project management	Focal persons on project management appointed and trained	0	1					
6. Establish a prequalified list of expert reviewers. Conduct individual and group training on selected, problematic CT processes with intention of co-opting more internal reviewers.		0						
7. Propose to management to carryout consultation with the directorate before approval of the training plan		0				4	4	16
8. a) An ICT steering committee needs to be setup to guide the process for all changes. b) A clear implementation plan should be in place that supports parallel change over ,		0						
9. Collaboration and strategic alliances with other Government Agencies and international drug regulatory authorities to work on price capping		0						
10. Developing guidelines in line with the law to avoid complaints		0						
11. Publish more frequent reports on the activity of NDA and respond timely to all media issues.		0						

12. Involving management (Directors) to avail internal Auditors.		0						
13. Strengthen third party due diligence review processes.		0						
14. Reevaluate the reorder levels.		0						
Loss of product samples or exhibits								
1. Install biometric access control systems to all storage rooms	number of storage rooms with biometric access control systems							
2. Provide secured rooms including cabinets/shelves for storage of samples and exhibits	Number of rooms provided							
	Number of cabinets/shells provided							
3. Procure special labelled samples collection bags	Number of special labelled samples collection bags	0						
4. Regular staff training on procedures for handling of product samples, exhibits and dossiers	% of staff trained on procedures for handling of product samples, exhibits and dossiers	0	95					
Non-compliance to Legal requirements								
1. Conduct regular staff trainings and dissemination on relevant laws, regulations and guidelines.	% of staff trained on relevant laws, regulations and guidelines.	0	95					
2. Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders.	% of stakeholders attending workshops on Laws, Regulations and Guidelines	0						
3. Routine document screening before receipt by registry.		0						
4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting	Number of revised regulation	0				4	4	16
5. Expand the scope of the existing law and regulations to address the legal gaps.		0						
6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness	Number of stakeholders meeting conducted in a year	0						
7. Consider actions to streamline the legal and regulatory framework for operational effectiveness.		0						
8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions.								
9. Training management and the Drug Authority on judicial review.								
10 a) Conduct regular staff training and dissemination on relevant laws,								
b) regulations and guidelines								
c) Conduct dissemination workshops on Laws,								
d) Regulations and Guidelines to stakeholders.								
11. Improved liaison with the Legal Department to ensure compliance		0						
Staff safety, security and occupational health hazards								
1. Sensitize staff on workers Compensation	% of staff sensitized on benefits of workers Compensation Fund		95					
2. Provide sufficient number of ergonomic chairs to cover all staff	% of staff provided with ergonomic chairs to cover all staff		50					
3. Sensitize staff on wellness programme including regular check up	% of staff sensitized on wellness programme including regular check up		95					

4. Secure sport ground for staff at NDA for regular exercise and training	Number of sport grounds secured		95			4	4	16
5. Install Security Devices like CCT Cameras	Number of cameras installed							
6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually	% of staff trained							
7. vehicle tracking system should be prioritized	Number of vehicle tracking systems installed							
Staff turn over								
2. Develop and implement incentive schemes	incentive schemes in place					4	4	16
4. Sensitize and train staff on conducting Training Need Assessments (TNA)	% of staff sanitized Training Need Assessments(TNA)							
5. Recruit more procurement staff	Number of staff recruited	0						
6. Continuous training of Board of Survey members	Number of staff trained	0						
Inappropriate exposure of samples leading to possible damage or compromise of results.								
1. Avail HVAC system		0	1			4	4	16
Delayed coding and analysis of samples								
1.Enhanced sensitization of the inspectors to forward samples with full documentation.	Number of inspectors sensitized	0				4	4	16
2. Reject samples with incomplete documentation	Number of samples rejected.	0						
3. Automation of the process (sample receipt, analysis and coding)	% of the process automated	0						
4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures.		0						
Use of Invalid reference standards since validity is not indicated on the bottle.								
1. Analysts required to attach a copy of the certificate of analysis for reference standards used during analysis.	Copies attached	0				4	4	16
contamination of samples being tested due to the use of un clean glassware.								
1. Procure glassware washing machine.	Number of machines procured	0				4	4	16
Laboratory Accidents occur								
1. Enhance PPEs		0				4	4	16
Litigation arising out of the legally challenged appointment of non-pharmacists as drug inspectors.								
1. Application to court to set aside the out of court settlement		0				4	4	16
2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law		0						
Antimicrobial resistance occurs in both human and animals due to toxicities in veterinary drugs.								
1. Develop a module in NDAMIS to capture Import quantities of Vet drugs to monitor the antimicrobial use in the country		0				4	4	16
Scope of available regulation is narrow, only for ectoparasiticides								
1. Recruitment of other cadre of staff and function-specific training of assessors.	Number of cadre staff recruited					4	4	16
2. Expedite formulation of new regulations for general applications to all veterinary trials.	Development of new regulations	0						
Entry errors on the CNF list, register and certificate of registration.								
1. Revised assessment template to improve the vigilance.		0				4	4	16
2. Continuous training of the assessors.	Number of assessors trained	0						
3. Errors routed to the resource that does drafting	% of errors routed	0						
4. Maker-checker process implemented. (QA process)		0						
5. Full automation of the register.		0						
Disclosure of confidential information in an application to an unauthorized person.								
1. Strengthening controls by restricting access to dossiers to person with signed confidentiality undertaking.		0				4	4	16

2. DPAR has further restricted distribution of information to senior assessors within the Directorate.		0						
Shortage of Infrastructure and facilities to meet the NDA's needs.								
1. Monitoring the time a client parks to create space for the upcoming clients		0				4	4	16
Under staffing								
1. Recruiting new staff to fill the positions in the organogram	Number of new staff recruited	0				4	4	16
Delay in implementing research								
1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research		0			Fully Implemented	4	4	16
2. use temporary staff and hire research assistants to support the research activities		0						
chain of evidence for impounded drugs compromised.								
1. Procure bigger office space to address the poor storage challenge.	Procurement of bigger office space	0				4	4	16
2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances.		0						
Failure to facilitate the process of improving the legal mandate of NDA and the proposed extended mandate on food and cosmetics safety								
1. NDA Authority to engage and support MOH in undertaking high level lobbying with key stakeholders and have the Bill fast tracked in Parliament		0				4	4	16
Confidential information is publicly released/Leakage of sensitive information								
1. Awareness on the Internal and External communication and relationship management.		0				4	4	16
2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms		0						
3. Stringent security checks both before staff are hired and after they've left.		0						
REGIONS								
Forged academic documents submitted for persons to be incharges.								
1.Give DDIs tools enabling them verify academic documents submitted to them	%ge of DDIs supported with tools	0	100			4	4	16
2.NDA to liaise with various professional councils to have in place a shared data base of all qualified/registered health personnel		1	1					
Absentee incharges								
Close outlets with absentee in charges (manned by unqualified attendants)	No. of outlets with absentee in charges closed	0				4	4	16
Smuggling of drugs across the boarders -Uganda - south Sudan & DRC boarders								
Establish port of entry in tguhe region. E.g. in Eleju						4	4	16
Increase boarder routine inspection and vigilance	No. of boarder surveillance visits	4	4	1				
Delayed basic testing of suspected substandard, falsified and counterfeit products								
Establish well equipped mini labs in the regions	One mini lab equipped	1	1			4	4	16
illegal, unlicensed drug outlets operating (and Hawkers)								
Have more severe penalties given to offenders						2	2	4
Impound and close the outlet until compliance	%ge of illegal outlets impounded							
Impound and arrest all hawkers and charge them	No. of Hawkers charged							

Data collection instrument and methods	Frequency of reporting	Means of verification	Responsible person(s)
Review of staff records	Quarterly		DIE
Review of documents/system	Quarterly	System installation	DIE
Review of progress reports	Quarterly	Approved reports	DIE (Control of imports)
Review of progress reports	Quarterly	Approved reports	Medical Devices
Review of performance evaluation records	Quarterly	Monitoring reports	Manager Herbal Medicines
Review of Documents	Once	Approved revised checklist	DIE /GMP
Review Inspection reports	Quarterly	Inspection reports	
Review of progress reports	Annually	Training records	DIE/Inspectorate
Review of progress reports	Quarterly	Sensitization records	SA
Review of PMS program	Quarterly	Approved PMS Program and reports	DPMS
Review of documents	Once	Approved Plan	SA /PRO
Review of progress reports	Quarterly	Implementation reports	SA / PRO
Review of documents	Once	Approved procedure	SA/PRO
Review of progress reports	Quarterly	Sensitization records	SA/PRO
Review of MCIE documents	Once	Approved procedure	DIE/QMS

Review of progress reports	Quarterly	Sensitization records	DPS/MPV
			DPS/MDP
			DIE/Head Regions
Review of progress reports	Quarterly	Training records	DPS/MPV
Review of performance evaluation records	Quarterly	Monitoring reports	DPS/MPV
Review of progress reports	Quarterly	Sensitization records	DPS/MPV
Physical verification of HMIS	Once	ADR Forms in HMIS	DPSMPV/HICT
Review of records	Once	Physical verification of the database	MMDV
Review of progress reports	Quarterly	Copy of feedback	MPV
Review of progress reports	Quarterly	Copy of feedback	MMDV

Review of progress reports	Once	Approved accounting manual	SA/IA/DHRMA
Review of progress reports	Once	Approved guideline	DHRMA
Review of HRA documents	Once	Distribution List and sensitization records	DHRMA
Review of procurement records	Quarterly	Performance Reports	HPDU
			DHRA
Review of progress reports	Quarterly	Sensitization records	HPDU/DHRMA
Review of progress reports	Quarterly	Sensitization records	DHRMA
Review of progress reports	Once	Approved reviewed the regulations	HBPD/DCS/SA
Review of inspection records	Once	Approved inspection plans	Head regions/ Managers
Review of progress reports	Quarterly	Installation reports	HICT/DCS
Review of progress reports	Once		DCS
Review of progress reports	Once	Approved Business plan	DLS
Review of progress reports	Quarterly	Sensitization records	DHRMA
Progress report	Quarterly	Approved Fraud policy	BPD
Progress report	Quarterly		NDA
			FIN
			DCS/FIN
			DHRA
			HICT
			DCS/FIN
Document review	Once	Report	HICT/RMO/HBPD
Review of progress reports	Once	Report of testing of ICT disaster recovery plan	HICT/RMO
Review of progress reports	Once	BCPTesting report	RMO/HICT/HBPD
Review of progress reports	Once	Approved Schedule	HICT

Review of progress reports	Once	Approved Schedule	DHARMA
Review of progress reports	Quarterly	Installation/Upgrading reports	HICT
Review of progress reports	Quarterly	Performance reports	HICT
			DPS/CT
			DPS/CT
			DPS
			DPS/MPV
			HICT
			HICT
			HICT
			HICT
			HICT
			HICT
			DIE/HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Installation reports	HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Appointment letter	DHRA
Review of progress reports	Quarterly	Firefighting drill exercise report	DHRA
Review of progress reports	Quarterly	Building Inspection report	DHRA/RMO
Review of progress reports	Quarterly	Communication records	DHRA
Review of progress reports	Quarterly	Installation records	DLS
Review of progress reports	Quarterly	Inspection report	DHRA
Review of progress reports	Quarterly	Maintance services Reports	HICT/DHRA
Review of progress reports	Once	Approved	DLS/MMD
Review of progress reports	Once	Approved	DLS/MMD
Review of progress report	Quarterly	Dissemination records	MDL
Review of PMS records	Quarterly	PMS Reports	DIE/PMS

Review of PMS records	Quarterly	PMS Reports	MMDV
Review of progress report	Once	List of identified countries	DIE/DPAR
Review of Progress Reports	Once	Appointment letter	MQMS
Review of progress report	Once	Sensitization records	MQMS
Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress report	Quarterly	Training records	MQMS
Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress reports	Quarterly	Training records	MQMS/RMO
			SA/QMS
Review of PME document	Once	Approved Procedure	HBPD/PM&EO
Review of progress reports	Quarterly	Risk analysis reports	RMO/HBPD
Review of progress reports	Quarterly	Stakeholders analysis reports	PME
Review of progress reports	Once	Software installation records	HBPD/HICT
Review of progress reports	Once	Appointment letter and training records	HBPD
			DPS/CT
			DPS/CT
			SA/HICT
			SA/QMS
			PRO

			SA/IA
			DHRA
			PDU
Review of progress records	Once	Physical verification of installed biometric access control system	HICT
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Delivery note	HPDU
Review of progress records	Quarterly	Training records	DLS/DIE/IC
Review of progress records	Quarterly	Training records	HLS
			HLS
			DPS/CT
			DPS/MPV
			DIE/LEGAL
			SA/LEGAL
			SA/LEGAL
			HLS
			HLS
			HLS
			HLS
			HLS
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA

Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
			DHRA
Review of progress report	Once	Progress reports	DHRA
Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
Review of progress report	Quarterly		DLS
Review of progress report	Quarterly	Progress reports	DLS
Review of progress report			DLS
Review of progress report			DLS
			DIE/HICT
Review of progress report			DLS
			DLS
			DLS
			DVS
			DVS
			DVS
			DVS
			DPAR
			DPAR
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			DPAR
			DPAR

			DPAR
			DHRA
			DHRA
			DPS
			DPS
			DIE
			DIE
			SA
			PRO
			PRO
			PRO
			DIE
			DIE

Treatment action action	Indicator description	Baseline	Indicator value		Status of Implementation	Residual Risk		
			Cumulative Target Value	Action undertaken		Likelihood	Impact	Rating
Existence of falsified, substandard and unauthorized products on the market-NDA/OPR/DIE-PMS/R001								
1. Contribute to the development of a National supply chain transition road map		0			Partially Implemented			
2. Introduce an automated track and trace system	A functioning Trace &Track system	0	1					
3. (a) Conduct inspection to monitor medicines and biocidal imported under special conditions	Percentage of consignments imported under special conditions monitored	0	60%					
. (b) Conduct inspection to monitor medical devices and diagnostics imported under special conditions	Percentage of consignments imported under special conditions monitored	0	100					
4. Monitor implementation of action plan to promote/support local drug manufacturing and domestic medical products manufacturing facilities 2023/24	Number of monitoring reports (NO of local manufacturers inspected)	0	4					
5. Review and implement routine inspection checklist	Revised checklist in place	0						
	% of routine inspections conducted using revised checklist	0						
6. Conduct inspectors training on intelligence techniques	Number of inspectors trained							
7. Conduct sensitization of Whistleblowing Policy to NDA staff	% of staff sensitized	0						
8. Review and widen scope of PMS	Number of products increased in PMS							
10. Collaboration with MDA on actions to deter unauthorized products reaching the market (Establish and implement plan for the signed MoUs between NDA and other MDAs and traditional institutions.	Plan in place	0	1					
	% implementation of the plan	0						
13. Establish and implement procedures for internal coordination for planning and sensitization of different categories of stakeholders.	Procedure for internal coordination in place	0	1			5	4	20
	%of stakeholders sensitized disaggregated by categories	0						
14. (a) Review procedure for conducting inspection of medicines and biocidal to include risk based criteria for planning inspection activities including format for planning such inspection	Revised procedure in place	0	1					

14. (b) Conduct sensitization on pharmacovigilance vigilance to stakeholders including village leaders, celebrities, religious, political, and other influential figures in the community to sensitize reporting	%of stakeholders sensitized disaggregated by categories	0						
15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print		0						
16. Regional offices to regularly disseminate drug safety information to the public.		0						
2. Train inspectors and assessors on enforcement of pharmacovigilance regulations and Good Vigilance Practice (GVP)	% of inspectors and assessors trained	0						
3. Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap	Number of monitoring reports	0	4					
4. (a) Conduct regular sensitization to healthcare providers and focal person/zones on reporting of ADRs	%of health care providers sensitized disaggregated by categories	0						
5. Integrate ADR reporting forms into Ministry Health Management Information System (HMIS)	Functional integrated HMIS in place	0	1					
8. Establish database for processing field safety reports for medical devices	Functional database in place	0	1					
9. Provide feedback to reporters after receiving ADRs	% of feedback to reporters	0						
9 (b). Provide feedback to reporters after receiving and AEs	% of feedback to reporters	0	100					
Failure to manage Authority's assets effectively;								
1. Review frequency of asset verification procedure for asset management								

2. Revise and disseminate NDA accounting manual	Revised accounting manual in place	0	1					
5. Approve and disseminate estate management guideline	Approved estate management guideline in place	0	1					
	% of staff with approved estate management guideline	0						
7. Inspect availability of performance reporting of contracts given to service providers	% of contracts with performance reports	0				4	4	16
8. Hire highly skilled guards		0						
9. Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management	Number of sanitization conducted	0	4					
	% of staff sensitized	0	100					
Lack of sufficient revenues to sustain NDA activities (Revenue losses)								
1. Review fees and charges regulations	Reviewed fees and charges regulations in place	0	1					
2. Prepare annual risk-based inspection plan at regional offices	Annual risk-based inspection plans in place	0	9					
3. Institute system alert to cover all service associated with revenues collection	% of service associated with revenues collection with system alert	0						
4. Designate person to make follow-up of outstanding invoices and debts	Engage MoH to clear the outstanding debt	0	1					
5.Prepare and implement Laboratory business plan	Laboratory Business Plan in place	0	1					
6. Staff sensitization on code of ethics	% of staff sensitized	0	100					
7. Develop and implement a stringent fraud policy	A Fraud Policy approved	0	1					
8. Strengthen resource mobilization and exercising priority spending	Meticulous cash flow management	0						
9. Engage Ministry of Finance to clear MoH arrears		0						
10. a) Regular training of staff on matters of accountability and budget expenditure. b) Finance should not advance funds to the whole department until the members in default account for the funds, additionally, The newly upgraded Finance system(BC 360) is now able to execute budget checks	a) Number of staff trained b) Budget checks execution							
11. To do a remapping of the Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry physical address.	Mapping of the system							
12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry								
13. Review the entire approval process. Develop Internal Service Level Agreement with other departments.	Internal service development					4	4	16
Unavailability of ICT services (Cyber risk)								
1. Develop and implement a BCP & DRP	An approved BCP & DRP	0	2					
2. Conduct periodic testing of ICT disaster recovery plans.	ICT disaster recovery plan tested	0	1					
3. Conduct periodic testing of BCP	BCP testing conducted	0	1					
4. Prepare schedule for preventive maintenance of power backup system	Schedule for power backup system in place	0	1					
5. Prepare schedule for preventive maintenance of generators	Schedule for preventive maintenance of generators in place	0	1					
6. Upgrade power back up system at NDA offices	Number of hours for power backup	3	9					
7. Report on adherence to Service Level Agreement	% of adherence to Service Level Agreement	0						
8. continuous update of the clinical trials databases	% of the clinical trial database updated	0						
9. automate the clinical trial application system	% of the system automated	0						
10. Develop an electronic system to facilitate signal detection		0						

11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data	No. of NDAs signed	0						
12. Setup of Hot site for redundancy, systems upgrades	No of upgrades	0						
13. infrastructure upgrade, Repair of faulty equipment		0						
14. Update security policies, Sensitize users to be aware of social engineering,	No of staff sensitized	0						
15. Turn on multifactor authentication for your online accounts.		0						
16. Increased Monitoring network and systems with advanced tools		0						
17. Improve on surveillance and physical security		0						
18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance.		0						
Fire outbreak								
1. Conduct firefighting and rescue training to at least 50% of staff annually	% of trained staff	0	50					
2. Install automatic fire suppression and fighting devices in ICT server room at NDA buildings	Automatic fire suppression and fighting devices in place	0	2					
3. Conduct awareness training on emergency exit plan to staff	% of trained staff	0	100					
4. Designate firefighting champions	Number of designated fire fighting champions	0						
5. Conduct regular firefighting drill exercises at all offices	Number of offices conducted firefighting drill exercise	0	9					
6. Inspection of NDA new tower building	Inspection conducted at NDA tower	0	1			4	4	16
7. Communicate emergency number for fire rescue department of Police to all NDA offices	Number of TMDA offices communicated with emergence numbers	0	9					
8. Procure designated cabinets for storage of volatile and flammable for the laboratory	Number of laboratories installed with designated cabinets for storage of volatile and flammable	1	2					
9. Conduct periodic inspection of electrical systems at NDA buildings	Number of buildings conducted Electrical system Inspection	0	3					
10. Conduct periodic maintenance services for fire detection, suppression and fighting systems	Number of maintenance services performed for fire detection, suppression and fighting systems	0	4					
Approval of non-existing or non GMP/quality audit compliant oversees manufacturing facilities								
1. Develop guidelines on submission of applications of quality audit for medical devices manufacturing facilities	Guidelines on submission of applications of quality audit for medical devices manufacturing facilities in place	0	1					
2. Develop and disseminate guidelines for conducting desk review of medical devices	Guidelines for conducting desk review of medical devices in place	0	1					
	% of assessors involved in dissemination workshops	0	100			4	4	16
3. (a) Conduct PMS of medicines and biocidal approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100					
3. (b) Conduct PMS of products approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100					
4. Identify countries to sign mutual agreement for recognition and reliance	Number of countries identified	0	10					
Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification								
1. To appoint QMS focal person to each section/unit to enhance implementation of documented procedures	Number of sections with QMS focal person							
2. Sensitization to process owners on the acceptance and positive attitude towards non conformances	Number of process owners (Managers& head of unit sensitized	0						
3. Develop and implement schedule for regular follow-up on QMS review meetings deliberations	Schedule for regular follow-up on QMS review meetings deliberations in place	0	1					
	% implementation of scheduled follow-ups	0						
4. Conduct training on auditing techniques to QMS auditors	% of auditors trained	0				4	4	16

5. Establish and implement schedule for institutional self-assessment on WHO-GBT and GPQCL requirements	Schedule for institutional self-assessment on WHO-GBT and GPQCL requirements in place	0	1					
	% implementation of scheduled follow-ups	0	100					
6. Conduct awareness training on QMS and Risk Management	% of staff trained on QMS and risk Management							
7. Invest in strengthening the Quality Management Systems across the organization.		0						
8								
Underperformance, delays or failure of NDA projects								
1. Develop and implement SOP for developing, approval, implementation and reporting of projects.	Developed SOP in place	0	1					
2. Conduct project risk analysis for each project at NDA.	% of project conducted risk analysis	0	100					
3. Conduct stakeholders' analysis associated with each project to determine their need and expectations	% of stakeholders analyzed for their needs and expectations	0	100					
4. Institute use of project management software	Project management software instituted	0	1					
5. Appoint and train project focal persons on project management	Focal persons on project management appointed and trained	0	1					
6. Establish a prequalified list of expert reviewers. Conduct individual and group training on selected, problematic CT processes with intention of co-opting more internal reviewers.		0						
7. Propose to management to carryout consultation with the directorate before approval of the training plan		0						
8. a) An ICT steering committee needs to be setup to guide the process for all changes. b) A clear implementation plan should be in place that supports parallel change over ,		0				4	4	16
9. Collaboration and strategic alliances with other Government Agencies and international drug regulatory authorities to work on price capping		0						
10. Developing guidelines in line with the law to avoid complaints		0						
11. Publish more frequent reports on the activity of NDA and respond timely to all media issues.		0						
12. Involving management (Directors) to avail internal Auditors.		0						
13. Strengthen third party due diligence review processes.		0						
14. Reevaluate the reorder levels.		0						
Loss of product samples or exhibits								
1. Install biometric access control systems to all storage rooms	number of storage rooms with biometric access control systems							
2. Provide secured rooms including cabinets/shelves for storage of samples and exhibits	Number of rooms provided							
	Number of cabinets/shells provided							
3. Procure special labelled samples collection bags	Number of special labelled samples collection bags	0						
4. Regular staff training on procedures for handling of product samples, exhibits and dossiers	% of staff trained on procedures for handling of product samples, exhibits and dossiers	0	95					
Non-compliance to Legal requirements								
1. Conduct regular staff trainings and dissemination on relevant laws, regulations and guidelines.	% of staff trained on relevant laws, regulations and guidelines.	0	95					
2. Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders.	% of stakeholders attending workshops on Laws, Regulations and Guidelines	0						
3. Routine document screening before receipt by registry.		0						

4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting	Number of revised regulation	0				4	4	16
5. Expand the scope of the existing law and regulations to address the legal gaps.		0						
6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness	Number of stakeholders meeting conducted in a year	0						
7. Consider actions to streamline the legal and regulatory framework for operational effectiveness.		0						
8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions.								
9. Training management and the Drug Authority on judicial review.								
10 a) Conduct regular staff training and dissemination on relevant laws, b) regulations and guidelines c) Conduct dissemination workshops on Laws, d) Regulations and Guidelines to stakeholders.								
11. Improved liaison with the Legal Department to ensure compliance		0						
Staff safety, security and occupational health hazards								
1. Sensitize staff on workers Compensation	% of staff sensitized on benefits of workers Compensation Fund		95			4	4	16
2. Provide sufficient number of ergonomic chairs to cover all staff	% of staff provided with ergonomic chairs to cover all staff		50					
3. Sensitize staff on wellness programme including regular check up	% of staff sensitized on wellness programme including regular check up		95					
4. Secure sport ground for staff at NDA for regular exercise and training	Number of sport grounds secured		95					
5. Install Security Devices like CCT Cameras	Number of cameras installed							
6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually	% of staff trained							
7. vehicle tracking system should be prioritized	Number of vehicle tracking systems installed							
Staff turn over								
2. Develop and implement incentive schemes	incentive schemes in place					4	4	16
4. Sensitize and train staff on conducting Training Need Assessments (TNA)	% of staff sanitized Training Need Assessments(TNA)							
5. Recruit more procurement staff	Number of staff recruited	0						
6. Continuous training of Board of Survey members	Number of staff trained	0						
Inappropriate exposure of samples leading to possible damage or compromise of results.								
1. Avail HVAC system		0	1			4	4	16
Delayed coding and analysis of samples								
1.Enhanced sensitization of the inspectors to forward samples with full documentation.	Number of inspectors sensitized	0				4	4	16
2. Reject samples with incomplete documentation	Number of samples rejected.	0						
3. Automation of the process (sample receipt, analysis and coding)	% of the process automated	0						
4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures.		0						
Use of Invalid reference standards since validity is not indicated on the bottle.								
1. Analysts required to attach a copy of the certificate of analysis for reference standards used during analysis.	Copies attached	0				4	4	16
contamination of samples being tested due to the use of un clean glassware.								
1. Procure glassware washing machine.	Number of machines procured	0				4	4	16
Laboratory Accidents occur								
1. Enhance PPEs		0				4	4	16
Litigation arising out of the legally challenged appointment of non-pharmacists as drug inspectors.								

1. Application to court to set aside the out of court settlement		0				4	4	16
2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law		0						
Antimicrobial resistance occurs in both human and animals due to toxicities in veterinary drugs.								
1. Develop a module in NDAMIS to capture Import quantities of Vet drugs to monitor the antimicrobial use in the country		0				4	4	16
Scope of available regulation is narrow, only for ectoparasiticides								
1. Recruitment of other cadre of staff and function-specific training of assessors.	Number of cadre staff recruited					4	4	16
2. Expedite formulation of new regulations for general applications to all veterinary trials.	Development of new regulations	0						
Entry errors on the CNF list, register and certificate of registration.								
1. Revised assessment template to improve the vigilance.		0				4	4	16
2. Continuous training of the assessors.	Number of assessors trained	0						
3. Errors routed to the resource that does drafting	% of errors routed	0						
4. Maker-checker process implemented. (QA process)		0						
5. Full automation of the register.		0						
Disclosure of confidential information in an application to an unauthorized person.								
1. Strengthening controls by restricting access to dossiers to person with signed confidentiality undertaking.		0				4	4	16
2. DPAR has further restricted distribution of information to senior assessors within the Directorate.		0						
Shortage of Infrastructure and facilities to meet the NDA's needs.								
1. Monitoring the time a client parks to create space for the upcoming clients		0				4	4	16
Under staffing								
1. Recruiting new staff to fill the positions in the organogram	Number of new staff recruited	0				4	4	16
Delay in implementing research								
1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research		0			Fully Implemented	4	4	16
2. use temporary staff and hire research assistants to support the research activities		0						
chain of evidence for impounded drugs compromised.								
1. Procure bigger office space to address the poor storage challenge.	Procurement of bigger office space	0				4	4	16
2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances.		0						
Failure to facilitate the process of improving the legal mandate of NDA and the proposed extended mandate on food and cosmetics safety								
1. NDA Authority to engage and support MOH in undertaking high level lobbying with key stakeholders and have the Bill fast tracked in Parliament		0				4	4	16
Confidential information is publicly released/Leakage of sensitive information								
1. Awareness on the Internal and External communication and relationship management.		0				4	4	16
2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms		0						
3. Stringent security checks both before staff are hired and after they've left.		0						
REGIONS								
Forged academic documents submitted for persons to be incharges.								
1.Give DDIs tools enabling them verify academic documents submitted to them	%ge of DDIs supported with tools	0	100			4	4	16
2.NDA to liaise with various professional councils to have in place a shared data base of all qualified/registered health personnel		1	1					
Absentee incharges								

Close outlets with absentee in charges (manned by unqualified attendants)	No. of outlets with absentee in charges closed	0				4	4	16
Smuggling of drugs across the boarders -Uganda - south Sudan & DRC boarders								
Establish port of entry in tguhe region. E.g. in Eleju						4	4	16
Increase boarder routine inspection and vigilance	No. of boarder surveillance visits	4	4	1				
Delayed basic testing of suspected substandard, falsified and counterfeit products								
Establish well equipped mini labs in the regions	One mini lab equipped	1	1			4	4	16
illegal, unlicensed drug outlets operating (and Hawkers)								
Have more severe penalties given to offenders						2	2	4
Impound and close the outlet until compliance	%ge of illegal outlets impounded							
Impound and arrest all hawkers and charge them	No. of Hawkers charged							

Data collection instrument and methods	Frequency of reporting	Means of verification	Responsible person(s)
Review of staff records	Quarterly		DIE
Review of documents/system	Quarterly	System installation	DIE
Review of progress reports	Quarterly	Approved reports	DIE (Control of imports)
Review of progress reports	Quarterly	Approved reports	Medical Devices
Review of performance evaluation records	Quarterly	Monitoring reports	Manager Herbal Medicines
Review of Documents	Once	Approved revised checklist	DIE /GMP
Review Inspection reports	Quarterly	Inspection reports	
Review of progress reports	Annually	Training records	DIE/Inspectorate
Review of progress reports	Quarterly	Sensitization records	SA
Review of PMS program	Quarterly	Approved PMS Program and reports	DPMS
Review of documents	Once	Approved Plan	SA /PRO
Review of progress reports	Quarterly	Implementation reports	SA / PRO
Review of documents	Once	Approved procedure	SA/PRO
Review of progress reports	Quarterly	Sensitization records	SA/PRO
Review of MCIE documents	Once	Approved procedure	DIE/QMS

Review of progress reports	Quarterly	Sensitization records	DPS/MPV
			DPS/MDP
			DIE/Head Regions
Review of progress reports	Quarterly	Training records	DPS/MPV
Review of performance evaluation records	Quarterly	Monitoring reports	DPS/MPV
Review of progress reports	Quarterly	Sensitization records	DPS/MPV
Physical verification of HMIS	Once	ADR Forms in HMIS	DPSMPV/HICT
Review of records	Once	Physical verification of the database	MMDV
Review of progress reports	Quarterly	Copy of feedback	MPV
Review of progress reports	Quarterly	Copy of feedback	MMDV

Review of progress reports	Once	Approved accounting manual	SA/IA/DHRMA
Review of progress reports	Once	Approved guideline	DHRMA
Review of HRA documents	Once	Distribution List and sensitization records	DHRMA
Review of procurement records	Quarterly	Performance Reports	HPDU
			DHRA
Review of progress reports	Quarterly	Sensitization records	HPDU/DHRMA
Review of progress reports	Quarterly	Sensitization records	DHRMA
Review of progress reports	Once	Approved reviewed the regulations	HBPD/DCS/SA
Review of inspection records	Once	Approved inspection plans	Head regions/ Managers
Review of progress reports	Quarterly	Installation reports	HICT/DCS
Review of progress reports	Once		DCS
Review of progress reports	Once	Approved Business plan	DLS
Review of progress reports	Quarterly	Sensitization records	DHRMA
Progress report	Quarterly	Approved Fraud policy	BPD
Progress report	Quarterly		NDA
			FIN
			DCS/FIN
			DHRA
			HICT
			DCS/FIN
Document review	Once	Report	HICT/RMO/HBPD
Review of progress reports	Once	Report of testing of ICT disaster recovery plan	HICT/RMO
Review of progress reports	Once	BCPTesting report	RMO/HICT/HBPD
Review of progress reports	Once	Approved Schedule	HICT
Review of progress reports	Once	Approved Schedule	DHARMA
Review of progress reports	Quarterly	Installation/Upgrading reports	HICT
Review of progress reports	Quarterly	Performance reports	HICT
			DPS/CT
			DPS/CT
			DPS

			DPS/MPV
			HICT
			HICT
			HICT
			HICT
			HICT
			HICT
			DIE/HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Installation reports	HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Appointment letter	DHRA
Review of progress reports	Quarterly	Firefighting drill exercise report	DHRA
Review of progress reports	Quarterly	Building Inspection report	DHRA/RMO
Review of progress reports	Quarterly	Communication records	DHRA
Review of progress reports	Quarterly	Installation records	DLS
Review of progress reports	Quarterly	Inspection report	DHRA
Review of progress reports	Quarterly	Maintance services Reports	HICT/DHRA
Review of progress reports	Once	Approved	DLS/MMD
Review of progress reports	Once	Approved	DLS/MMD
Review of progress report	Quarterly	Dissemination records	MDL
Review of PMS records	Quarterly	PMS Reports	DIE/PMS
Review of PMS records	Quarterly	PMS Reports	MMDV
Review of progress report	Once	List of identified countries	DIE/DPAR
Review of Progress Reports	Once	Appointment letter	MQMS
Review of progress report	Once	Sensitization records	MQMS
Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress report	Quarterly	Training records	MQMS

Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress reports	Quarterly	Training records	MQMS/RMO
			SA/QMS
Review of PME document	Once	Approved Procedure	HBPD/PM&EO
Review of progress reports	Quarterly	Risk analysis reports	RMO/HBPD
Review of progress reports	Quarterly	Stakeholders analysis reports	PME
Review of progress reports	Once	Software installation records	HBPD/HICT
Review of progress reports	Once	Appointment letter and training records	HBPD
			DPS/CT
			DPS/CT
			SA/HICT
			SA/QMS
			PRO
			SA/IA
			DHRA
			PDU
Review of progress records	Once	Physical verification of installed biometric access control system	HICT
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Delivery note	HPDU
Review of progress records	Quarterly	Training records	DLS/DIE/IC
Review of progress records	Quarterly	Training records	HLS
			HLS
			DPS/CT

			DPS/MPV
			DIE/LEGAL
			SA/LEGAL
			SA/LEGAL
			HLS
			HLS
			HLS
			HLS
			HLS
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
			DHRA
Review of progress report	Once	Progress reports	DHRA
Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
Review of progress report	Quarterly		DLS
Review of progress report	Quarterly	Progress reports	DLS
Review of progress report			DLS
Review of progress report			DLS
			DIE/HICT
Review of progress report			DLS
			DLS
			DLS

			DVS
			DVS
			DVS
			DVS
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DHRA
			DHRA
			DPS
			DPS
			DIE
			DIE
			SA
			PRO
			PRO
			PRO
			DIE

			DIE

Treatment action action	Indicator description	Baseline	Indicator value		Status of Implementation	Residual Risk		
			Cumulative Target Value	Action undertaken		Likelihood	Impact	Rating
Existence of falsified, substandard and unauthorized products on the market-NDA/OPR/DIE-PMS/R001								
1. Contribute to the development of a National supply chain transition road map		0			Partially Implemented			
2. Introduce an automated track and trace system	A functioning Trace &Track system	0	1					
3. (a) Conduct inspection to monitor medicines and biocidal imported under special conditions	Percentage of consignments imported under special conditions monitored	0	60%					
. (b) Conduct inspection to monitor medical devices and diagnostics imported under special conditions	Percentage of consignments imported under special conditions monitored	0	100					
4. Monitor implementation of action plan to promote/support local drug manufacturing and domestic medical products manufacturing facilities 2023/24	Number of monitoring reports (NO of local manufacturers inspected)	0	4					
5. Review and implement routine inspection checklist	Revised checklist in place	0						
	% of routine inspections conducted using revised checklist	0						
6. Conduct inspectors training on intelligence techniques	Number of inspectors trained							
7. Conduct sensitization of Whistleblowing Policy to NDA staff	% of staff sensitized	0						
8. Review and widen scope of PMS	Number of products increased in PMS							
10. Collaboration with MDA on actions to deter unauthorized products reaching the market (Establish and implement plan for the signed MoUs between NDA and other MDAs and traditional institutions.	Plan in place	0	1					
	% implementation of the plan	0						
13. Establish and implement procedures for internal coordination for planning and sensitization of different categories of stakeholders.	Procedure for internal coordination in place	0	1					
	%of stakeholders sensitized disaggregated by categories	0				1	4	4
14. (a) Review procedure for conducting inspection of medicines and biocidal to include risk based criteria for planning inspection activities including format for planning such inspection	Revised procedure in place	0	1					

14. (b) Conduct sensitization on pharmacovigilance vigilance to stakeholders including village leaders, celebrities, religious, political, and other influential figures in the community to sensitize reporting	%of stakeholders sensitized disaggregated by categories	0						
15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print		0						
16. Regional offices to regularly disseminate drug safety information to the public.		0						
2. Train inspectors and assessors on enforcement of pharmacovigilance regulations and Good Vigilance Practice (GVP)	% of inspectors and assessors trained	0						
3. Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap	Number of monitoring reports	0	4					
4. (a) Conduct regular sensitization to healthcare providers and focal person/zones on reporting of ADRs	%of health care providers sensitized disaggregated by categories	0						
5. Integrate ADR reporting forms into Ministry Health Management Information System (HMIS)	Functional integrated HMIS in place	0	1					
8. Establish database for processing field safety reports for medical devices	Functional database in place	0	1					
9. Provide feedback to reporters after receiving ADRs	% of feedback to reporters	0						
9 (b). Provide feedback to reporters after receiving and AEs	% of feedback to reporters	0	100					
Failure to manage Authority's assets effectively;								
1. Review frequency of asset verification procedure for asset management								

2. Revise and disseminate NDA accounting manual	Revised accounting manual in place	0	1					
5. Approve and disseminate estate management guideline	Approved estate management guideline in place	0	1					
	% of staff with approved estate management guideline	0						
7. Inspect availability of performance reporting of contracts given to service providers	% of contracts with performance reports	0						
8. Hire highly skilled guards		0				4	4	16
9. Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management	Number of sanitization conducted	0	4					
	% of staff sensitized	0	100					
Lack of sufficient revenues to sustain NDA activities (Revenue losses)								
1. Review fees and charges regulations	Reviewed fees and charges regulations in place	0	1					
2. Prepare annual risk-based inspection plan at regional offices	Annual risk-based inspection plans in place	0	9					
3. Institute system alert to cover all service associated with revenues collection	% of service associated with revenues collection with system alert	0						
4. Designate person to make follow-up of outstanding invoices and debts	Engage MoH to clear the outstanding debt	0	1					
5.Prepare and implement Laboratory business plan	Laboratory Business Plan in place	0	1					
6. Staff sensitization on code of ethics	% of staff sensitized	0	100					
7. Develop and implement a stringent fraud policy	A Fraud Policy approved	0	1					
8. Strengthen resource mobilization and exercising priority spending	Meticulous cash flow management	0						
9. Engage Ministry of Finance to clear MoH arrears		0						
10. a) Regular training of staff on matters of accountability and budget expenditure. b) Finance should not advance funds to the whole department until the members in default account for the funds, additionally, The newly upgraded Finance system(BC 360) is now able to execute budget checks	a) Number of staff trained b) Budget checks execution							
11. To do a remapping of the Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry physical address.	Mapping of the system							
12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry								
13. Review the entire approval process. Develop Internal Service Level Agreement with other departments.	Internal service development					4	4	16
Unavailability of ICT services (Cyber risk)								
1. Develop and implement a BCP & DRP	An approved BCP & DRP	0	2					
2. Conduct periodic testing of ICT disaster recovery plans.	ICT disaster recovery plan tested	0	1					
3. Conduct periodic testing of BCP	BCP testing conducted	0	1					
4. Prepare schedule for preventive maintenance of power backup system	Schedule for power backup system in place	0	1					
5. Prepare schedule for preventive maintenance of generators	Schedule for preventive maintenance of generators in place	0	1					
6. Upgrade power back up system at NDA offices	Number of hours for power backup	3	9					
7. Report on adherence to Service Level Agreement	% of adherence to Service Level Agreement	0						
8. continuous update of the clinical trials databases	% of the clinical trial database updated	0						
9. automate the clinical trial application system	% of the system automated	0						

10. Develop an electronic system to facilitate signal detection		0						
11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data	No. of NDAs signed	0						
12. Setup of Hot site for redundancy, systems upgrades	No of upgrades	0						
13. infrastructure upgrade, Repair of faulty equipment		0						
14. Update security policies, Sensitize users to be aware of social engineering,	No of staff sensitized	0						
15. Turn on multifactor authentication for your online accounts.		0						
16. Increased Monitoring network and systems with advanced tools		0						
17. Improve on surveillance and physical security		0						
18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance.		0						
Fire outbreak								
1. Conduct firefighting and rescue training to at least 50% of staff annually	% of trained staff	0	50					
2. Install automatic fire suppression and fighting devices in ICT server room at NDA buildings	Automatic fire suppression and fighting devices in place	0	2					
3. Conduct awareness training on emergency exit plan to staff	% of trained staff	0	100					
4. Designate firefighting champions	Number of designated fire fighting champions	0						
5. Conduct regular firefighting drill exercises at all offices	Number of offices conducted firefighting drill exercise	0	9					
6. Inspection of NDA new tower building	Inspection conducted at NDA tower	0	1			4	4	16
7. Communicate emergency number for fire rescue department of Police to all NDA offices	Number of TMDA offices communicated with emergence numbers	0	9					
8. Procure designated cabinets for storage of volatile and flammable for the laboratory	Number of laboratories installed with designated cabinets for storage of volatile and flammable	1	2					
9. Conduct periodic inspection of electrical systems at NDA buildings	Number of buildings conducted Electrical system Inspection	0	3					
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Approval of non-existing or non GMP/quality audit compliant oversees manufacturing facilities								
1. Develop guidelines on submission of applications of quality audit for medical devices manufacturing facilities	Guidelines on submission of applications of quality audit for medical devices manufacturing facilities in place	0	1					
2. Develop and disseminate guidelines for conducting desk review of medical devices	Guidelines for conducting desk review of medical devices in place	0	1					
	% of assessors involved in dissemination workshops	0	100			4	4	16
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3. (b) Conduct PMS of products approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100					
4. Identify countries to sign mutual agreement for recognition and reliance	Number of countries identified	0	10					
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1. To appoint QMS focal person to each section/unit to enhance implementation of documented procedures	Number of sections with QMS focal person							
2. Sensitization to process owners on the acceptance and positive attitude towards non conformances	Number of process owners (Managers& head of unit sensitized	0						
3. Develop and implement schedule for regular follow-up on QMS review meetings deliberations	Schedule for regular follow-up on QMS review meetings deliberations in place	0	1					
	% implementation of scheduled follow-ups	0						
4. Conduct training on auditing techniques to QMS auditors	% of auditors trained	0				4	4	16

5. Establish and implement schedule for institutional self-assessment on WHO-GBT and GPQCL requirements	Schedule for institutional self-assessment on WHO-GBT and GPQCL requirements in place	0	1					
	% implementation of scheduled follow-ups	0	100					
6. Conduct awareness training on QMS and Risk Management	% of staff trained on QMS and risk Management							
7. Invest in strengthening the Quality Management Systems across the organization.		0						
8								
Underperformance, delays or failure of NDA projects								
1. Develop and implement SOP for developing, approval, implementation and reporting of projects.	Developed SOP in place	0	1					
2. Conduct project risk analysis for each project at NDA.	% of project conducted risk analysis	0	100					
3. Conduct stakeholders' analysis associated with each project to determine their need and expectations	% of stakeholders analyzed for their needs and expectations	0	100					
4. Institute use of project management software	Project management software instituted	0	1					
5. Appoint and train project focal persons on project management	Focal persons on project management appointed and trained	0	1					
6. Establish a prequalified list of expert reviewers. Conduct individual and group training on selected, problematic CT processes with intention of co-opting more internal reviewers.		0						
7. Propose to management to carryout consultation with the directorate before approval of the training plan		0						
8. a) An ICT steering committee needs to be setup to guide the process for all changes. b) A clear implementation plan should be in place that supports parallel change over ,		0				4	4	16
9. Collaboration and strategic alliances with other Government Agencies and international drug regulatory authorities to work on price capping		0						
10. Developing guidelines in line with the law to avoid complaints		0						
11. Publish more frequent reports on the activity of NDA and respond timely to all media issues.		0						
12. Involving management (Directors) to avail internal Auditors.		0						
13. Strengthen third party due diligence review processes.		0						
14. Reevaluate the reorder levels.		0						
Loss of product samples or exhibits								
1. Install biometric access control systems to all storage rooms	number of storage rooms with biometric access control systems							
2. Provide secured rooms including cabinets/shelves for storage of samples and exhibits	Number of rooms provided							
	Number of cabinets/shells provided							
3. Procure special labelled samples collection bags	Number of special labelled samples collection bags	0						
4. Regular staff training on procedures for handling of product samples, exhibits and dossiers	% of staff trained on procedures for handling of product samples, exhibits and dossiers	0	95					
Non-compliance to Legal requirements								
1. Conduct regular staff trainings and dissemination on relevant laws, regulations and guidelines.	% of staff trained on relevant laws, regulations and guidelines.	0	95					
2. Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders.	% of stakeholders attending workshops on Laws, Regulations and Guidelines	0						
3. Routine document screening before receipt by registry.		0						

4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting	Number of revised regulation	0				4	4	16
5. Expand the scope of the existing law and regulations to address the legal gaps.		0						
6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness	Number of stakeholders meeting conducted in a year	0						
7. Consider actions to streamline the legal and regulatory framework for operational effectiveness.		0						
8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions.								
9. Training management and the Drug Authority on judicial review.								
10 a) Conduct regular staff training and dissemination on relevant laws, b) regulations and guidelines c) Conduct dissemination workshops on Laws, d) Regulations and Guidelines to stakeholders.								
11. Improved liaison with the Legal Department to ensure compliance		0						
Staff safety, security and occupational health hazards								
1. Sensitize staff on workers Compensation	% of staff sensitized on benefits of workers Compensation Fund		95			4	4	16
2. Provide sufficient number of ergonomic chairs to cover all staff	% of staff provided with ergonomic chairs to cover all staff		50					
3. Sensitize staff on wellness programme including regular check up	% of staff sensitized on wellness programme including regular check up		95					
4. Secure sport ground for staff at NDA for regular exercise and training	Number of sport grounds secured		95					
5. Install Security Devices like CCT Cameras	Number of cameras installed							
6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually	% of staff trained							
7. vehicle tracking system should be prioritized	Number of vehicle tracking systems installed							
Staff turn over								
2. Develop and implement incentive schemes	incentive schemes in place					4	4	16
4. Sensitize and train staff on conducting Training Need Assessments (TNA)	% of staff sanitized Training Need Assessments(TNA)							
5. Recruit more procurement staff	Number of staff recruited	0						
6. Continuous training of Board of Survey members	Number of staff trained	0						
Inappropriate exposure of samples leading to possible damage or compromise of results.								
1. Avail HVAC system		0	1			4	4	16
Delayed coding and analysis of samples								
1.Enhanced sensitization of the inspectors to forward samples with full documentation.	Number of inspectors sensitized	0				4	4	16
2. Reject samples with incomplete documentation	Number of samples rejected.	0						
3. Automation of the process (sample receipt, analysis and coding)	% of the process automated	0						
4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures.		0						
Use of Invalid reference standards since validity is not indicated on the bottle.								
1. Analysts required to attach a copy of the certificate of analysis for reference standards used during analysis.	Copies attached	0				4	4	16
contamination of samples being tested due to the use of un clean glassware.								
1. Procure glassware washing machine.	Number of machines procured	0				4	4	16
Laboratory Accidents occur								

1. Enhance PPEs		0				4	4	16
Litigation arising out of the legally challenged appointment of non-pharmacists as drug inspectors.								
1. Application to court to set aside the out of court settlement		0				4	4	16
2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law		0						
Antimicrobial resistance occurs in both human and animals due to toxicities in veterinary drugs.								
1. Develop a module in NDAMIS to capture Import quantities of Vet drugs to monitor the antimicrobial use in the country		0				4	4	16
Scope of available regulation is narrow, only for ectoparasiticides								
1. Recruitment of other cadre of staff and function-specific training of assessors.	Number of cadre staff recruited					4	4	16
2. Expedite formulation of new regulations for general applications to all veterinary trials.	Development of new regulations	0						
Entry errors on the CNF list, register and certificate of registration.								
1. Revised assessment template to improve the vigilance.		0				4	4	16
2. Continuous training of the assessors.	Number of assessors trained	0						
3. Errors routed to the resource that does drafting	% of errors routed	0						
4. Maker-checker process implemented. (QA process)		0						
5. Full automation of the register.		0						
Disclosure of confidential information in an application to an unauthorized person.								
1. Strengthening controls by restricting access to dossiers to person with signed confidentiality undertaking.		0				4	4	16
2. DPAR has further restricted distribution of information to senior assessors within the Directorate.		0						
Shortage of Infrastructure and facilities to meet the NDA's needs.								
1. Monitoring the time a client parks to create space for the upcoming clients		0				4	4	16
Under staffing								
1. Recruiting new staff to fill the positions in the organogram	Number of new staff recruited	0				4	4	16
Delay in implementing research								
1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research		0			Fully Implemented	4	4	16
2. use temporary staff and hire research assistants to support the research activities		0						
chain of evidence for impounded drugs compromised.								
1. Procure bigger office space to address the poor storage challenge.	Procurement of bigger office space	0				4	4	16
2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances.		0						
Failure to facilitate the process of improving the legal mandate of NDA and the proposed extended mandate on food and cosmetics safety								
1. NDA Authority to engage and support MOH in undertaking high level lobbying with key stakeholders and have the Bill fast tracked in Parliament		0				4	4	16
Confidential information is publicly released/Leakage of sensitive information								
1. Awareness on the Internal and External communication and relationship management.		0				4	4	16
2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms		0						
3. Stringent security checks both before staff are hired and after they've left.		0						

REGIONS								
Forged academic documents submitted for persons to be incharges.								
1.Give DDIs tools enabling them verify academic documents submitted to them	%ge of DDIs supported with tools	0	100			4	4	16
2.NDA to liaise with various professional councils to have in place a shared data base of all qualified/registered health personnel		1	1					
Absentee incharges								
Close outlets with absentee in charges (manned by unqualified attendants)	No. of outlets with absentee in charges closed	0				4	4	16
Smuggling of drugs across the boarders -Uganda - south Sudan & DRC boarders								
Establish port of entry in tguhe region. E.g. in Eleju						4	4	16
Increase boarder routine inspection and vigilance	No. of boarder surveillance visits	4	4	1				
Delayed basic testing of suspected substandard, falsified and counterfeit products								
Establish well equipped mini labs in the regions	One mini lab equipped	1	1			4	4	16
illegal, unlicensed drug outlets operating (and Hawkers)								
Have more severe penalties given to offenders						2	2	4
Impound and close the outlet until compliance	%ge of illegal outlets impounded							
Impound and arrest all hawkers and charge them	No. of Hawkers charged							

Data collection instrument and methods	Frequency of reporting	Means of verification	Responsible person(s)
Review of staff records	Quarterly		DIE
Review of documents/system	Quarterly	System installation	DIE
Review of progress reports	Quarterly	Approved reports	DIE (Control of imports)
Review of progress reports	Quarterly	Approved reports	Medical Devices
Review of performance evaluation records	Quarterly	Monitoring reports	Manager Herbal Medicines
Review of Documents	Once	Approved revised	DIE /GMP
Review Inspection reports	Quarterly	Inspection reports	
Review of progress reports	Annually	Training records	DIE/Inspectorate
Review of progress reports	Quarterly	Sensitization records	SA
Review of PMS program	Quarterly	Approved PMS Program and reports	DPMS
Review of documents	Once	Approved Plan	SA /PRO
Review of progress reports	Quarterly	Implementation reports	SA / PRO
Review of documents	Once	Approved procedure	SA/PRO
Review of progress reports	Quarterly	Sensitization records	SA/PRO
Review of MCIE documents	Once	Approved procedure	DIE/QMS

Review of progress reports	Quarterly	Sensitization records	DPS/MPV
			DPS/MDP
			DIE/Head Regions
Review of progress reports	Quarterly	Training records	DPS/MPV
Review of performance evaluation records	Quarterly	Monitoring reports	DPS/MPV
Review of progress reports	Quarterly	Sensitization records	DPS/MPV
Physical verification of HMIS	Once	ADR Forms in HMIS	DPSMPV/HICT
Review of records	Once	Physical verification of the database	MMDV
Review of progress reports	Quarterly	Copy of feedback	MPV
Review of progress reports	Quarterly	Copy of feedback	MMDV

Review of progress reports	Once	Approved accounting manual	SA/IA/DHRMA
Review of progress reports	Once	Approved guideline	DHRMA
Review of HRA documents	Once	Distribution List and sensitization records	DHRMA
Review of procurement records	Quarterly	Performance Reports	HPDU
			DHRA
Review of progress reports	Quarterly	Sensitization records	HPDU/DHRMA
Review of progress reports	Quarterly	Sensitization records	DHRMA
Review of progress reports	Once	Approved reviewed the regulations	HBPD/DCS/SA
Review of inspection records	Once	Approved inspection plans	Head regions/ Managers
Review of progress reports	Quarterly	Installation reports	HICT/DCS
Review of progress reports	Once		DCS
Review of progress reports	Once	Approved Business plan	DLS
Review of progress reports	Quarterly	Sensitization records	DHRMA
Progress report	Quarterly	Approved Fraud policy	BPD
Progress report	Quarterly		NDA
			FIN
			DCS/FIN
			DHRA
			HICT
			DCS/FIN
Document review	Once	Report	HICT/RMO/HBPD
Review of progress reports	Once	Report of testing of ICT disaster recovery plan	HICT/RMO
Review of progress reports	Once	BCPTesting report	RMO/HICT/HBPD
Review of progress reports	Once	Approved Schedule	HICT
Review of progress reports	Once	Approved Schedule	DHARMA
Review of progress reports	Quarterly	Installation/Upgrading reports	HICT
Review of progress reports	Quarterly	Performance reports	HICT
			DPS/CT
			DPS/CT

			DPS
			DPS/MPV
			HICT
			HICT
			HICT
			HICT
			HICT
			HICT
			DIE/HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Installation reports	HICT
Review of progress reports	Quarterly	Training records	DHRA
Review of progress reports	Quarterly	Appointment letter	DHRA
Review of progress reports	Quarterly	Firefighting drill exercise report	DHRA
Review of progress reports	Quarterly	Building Inspection report	DHRA/RMO
Review of progress reports	Quarterly	Communication records	DHRA
Review of progress reports	Quarterly	Installation records	DLS
Review of progress reports	Quarterly	Inspection report	DHRA
Review of progress reports	Quarterly	Maintance services Reports	HICT/DHRA
Review of progress reports	Once	Approved	DLS/MMD
Review of progress reports	Once	Approved	DLS/MMD
Review of progress report	Quarterly	Dissemination records	MDL
Review of PMS records	Quarterly	PMS Reports	DIE/PMS
Review of PMS records	Quarterly	PMS Reports	MMDV
Review of progress report	Once	List of identified countries	DIE/DPAR
Review of Progress Reports	Once	Appointment letter	MQMS
Review of progress report	Once	Sensitization records	MQMS
Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress report	Quarterly	Training records	MQMS

Review of progress reports	Once	Approved schedule	MQMS
Review of progress reports	Quarterly	Progress report	MQMS
Review of progress reports	Quarterly	Training records	MQMS/RMO
			SA/QMS
Review of PME document	Once	Approved Procedure	HBPD/PM&EO
Review of progress reports	Quarterly	Risk analysis reports	RMO/HBPD
Review of progress reports	Quarterly	Stakeholders analysis reports	PME
Review of progress reports	Once	Software installation records	HBPD/HICT
Review of progress reports	Once	Appointment letter and training records	HBPD
			DPS/CT
			DPS/CT
			SA/HICT
			SA/QMS
			PRO
			SA/IA
			DHRA
			PDU
Review of progress records	Once	Physical verification of installed biometric access control system	HICT
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Asset inventory	DHRA
Review of progress reports	Once	Delivery note	HPDU
Review of progress records	Quarterly	Training records	DLS/DIE/IC
Review of progress records	Quarterly	Training records	HLS
			HLS
			DPS/CT

			DPS/MPV
			DIE/LEGAL
			SA/LEGAL
			SA/LEGAL
			HLS
			HLS
			HLS
			HLS
			HLS
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Quarterly	Progress reports	DHRA
Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
			DHRA
Review of progress report	Once	Progress reports	DHRA
Review of progress report	Once	Progress reports	DHRA
			DHRA
			DHRA
Review of progress report	Quarterly		DLS
Review of progress report	Quarterly	Progress reports	DLS
Review of progress report			DLS
Review of progress report			DLS
			DIE/HICT
Review of progress report			DLS
			DLS

			DLS
			DVS
			DVS
			DVS
			DVS
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DPAR
			DHRA
			DHRA
			DPS
			DPS
			DIE
			DIE
			SA
			PRO
			PRO
			PRO

			DIE
			DIE

Treatment action action	Indicator description	Baseline	Indicator value					Data collection instrument and methods
			Cumulative Target Value	Q1 Rating	Q2 Rating	Q3 Rating	Q4 Rating	
Existence of falsified, substandard and unauthorized products on the market-NDA/OPR/DIE-PMS/R001								
1. Contribute to the development of a National supply chain transition road map		0						Review of staff records
2. Introduce an automated track and trace system	A functioning Trace &Track system	0	1					Review of documents/system
3. (a) Conduct inspection to monitor medicines and biocidal imported under special conditions	Percentage of consignments imported under special conditions monitored	0	60%					Review of progress reports
. (b) Conduct inspection to monitor medical devices and diagnostics imported under special conditions	Percentage of consignments imported under special conditions monitored	0	100					Review of progress reports
4. Monitor implementation of action plan to promote/support local drug manufacturing and domestic medical products manufacturing facilities 2023/24	Number of monitoring reports (NO of local manufacturers inspected)	0	4					Review of performance evaluation records
5. Review and implement routine inspection checklist	Revised checklist in place	0						Review of Documents
	% of routine inspections conducted using revised checklist	0						Review Inspection reports
6. Conduct inspectors training on intelligence techniques	Number of inspectors trained							Review of progress reports
7. Conduct sensitization of Whistleblowing Policy to NDA staff	% of staff sensitized	0						Review of progress reports
8. Review and widen scope of PMS	Number of products increased in PMS							Review of PMS program
10. Collaboration with MDA on actions to deter unauthorized products reaching the market (Establish and implement plan for the signed MoUs between NDA and other MDAs and traditional institutions.	Plan in place	0	1					Review of documents
	% implementation of the plan	0						Review of progress reports
13. Establish and implement procedures for internal coordination for planning and sensitization of different categories of stakeholders.	Procedure for internal coordination in place	0	1					Review of documents
	%of stakeholders sensitized disaggregated by categories	0		4	4	20	4	Review of progress reports
14. (a) Review procedure for conducting inspection of medicines and biocidal to include risk based criteria for planning inspection activities including format for planning such inspection	Revised procedure in place	0	1					Review of MCIE documents

14. (b) Conduct sensitization on pharmacovigilance vigilance to stakeholders including village leaders, celebrities, religious, political, and other influential figures in the community to sensitize reporting	%of stakeholders sensitized disaggregated by categories	0							Review of progress reports
15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print		0							
16. Regional offices to regularly disseminate drug safety information to the public.		0							
2. Train inspectors and assessors on enforcement of pharmacovigilance regulations and Good Vigilance Practice (GVP)	% of inspectors and assessors trained	0							Review of progress reports
3. Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap	Number of monitoring reports	0	4						Review of performance evaluation records
4. (a) Conduct regular sensitization to healthcare providers and focal person/zones on reporting of ADRs	%of health care providers sensitized disaggregated by categories	0							Review of progress reports
5. Integrate ADR reporting forms into Ministry Health Management Information System (HMIS)	Functional integrated HMIS in place	0	1						Physical verification of HMIS
8. Establish database for processing field safety reports for medical devices	Functional database in place	0	1						Review of records
9. Provide feedback to reporters after receiving ADRs	% of feedback to reporters	0							Review of progress reports
9 (b). Provide feedback to reporters after receiving and AEs	% of feedback to reporters	0	100						Review of progress reports
Failure to manage Authority's assets effectively;									
1. Review frequency of asset verification procedure for asset management									

2. Revise and disseminate NDA accounting manual	Revised accounting manual in place	0	1					Review of progress reports
5. Approve and disseminate estate management guideline	Approved estate management guideline in place	0	1					Review of progress reports
	% of staff with approved estate management guideline	0						Review of HRA documents
7. Inspect availability of performance reporting of contracts given to service providers	% of contracts with performance reports	0			16	8	16	16	Review of procurement records
8. Hire highly skilled guards		0							
9. Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management	Number of sanitization conducted	0	4						Review of progress reports
	% of staff sensitized	0	100						Review of progress reports
Lack of sufficient revenues to sustain NDA activities (Revenue losses)									
1. Review fees and charges regulations	Reviewed fees and charges regulations in place	0	1						Review of progress reports
2. Prepare annual risk-based inspection plan at regional offices	Annual risk-based inspection plans in place	0	9						Review of inspection records
3. Institute system alert to cover all service associated with revenues collection	% of service associated with revenues collection with system alert	0							Review of progress reports
4. Designate person to make follow-up of outstanding invoices and debts	Engage MoH to clear the outstanding debt	0	1						Review of progress reports
5.Prepare and implement Laboratory business plan	Laboratory Business Plan in place	0	1						Review of progress reports
6. Staff sensitization on code of ethics	% of staff sensitized	0	100						Review of progress reports
7. Develop and implement a stringent fraud policy	A Fraud Policy approved	0	1						Progress report
8. Strengthen resource mobilization and exercising priority spending	Meticulous cash flow management	0							Progress report
9. Engage Ministry of Finance to clear MoH arrears		0							
10. a) Regular training of staff on matters of accountability and budget expenditure. b) Finance should not advance funds to the whole department until the members in default account for the funds, additionally, The newly upgraded Finance system(BC 360) is now able to execute budget checks	a) Number of staff trained b) Budget checks execution								
11. To do a remapping of the Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry physical address.	Mapping of the system								
12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry					16	16	16	16	

13. Review the entire approval process. Develop Internal Service Level Agreement with other departments.	Internal service development								
Unavailability of ICT services (Cyber risk)									
1. Develop and implement a BCP & DRP	An approved BCP & DRP	0	2						Document review
2. Conduct periodic testing of ICT disaster recovery plans.	ICT disaster recovery plan tested	0	1						Review of progress reports
3. Conduct periodic testing of BCP	BCP testing conducted	0	1						Review of progress reports
4. Prepare schedule for preventive maintenance of power backup system	Schedule for power backup system in place	0	1						Review of progress reports
5. Prepare schedule for preventive maintenance of generators	Schedule for preventive maintenance of generators in place	0	1						Review of progress reports
6. Upgrade power back up system at NDA offices	Number of hours for power backup	3	9						Review of progress reports
7. Report on adherence to Service Level Agreement	% of adherence to Service Level Agreement	0							Review of progress reports
8. continuous update of the clinical trials databases	% of the clinical trial database updated	0							
9. automate the clinical trial application system	% of the system automated	0							
10. Develop an electronic system to facilitate signal detection		0							
11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data	No. of NDAs signed	0							
12. Setup of Hot site for redundancy, systems upgrades	No of upgrades	0							
13. infrastructure upgrade, Repair of faulty equipment		0							
14. Update security policies, Sensitize users to be aware of social engineering,	No of staff sensitized	0							
15. Turn on multifactor authentication for your online accounts.		0							
16. Increased Monitoring network and systems with advanced tools		0							
17. Improve on surveillance and physical security		0							
18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance.		0							
Fire outbreak									
1. Conduct firefighting and rescue training to at least 50% of staff annually	% of trained staff	0	50						Review of progress reports
2. Install automatic fire suppression and fighting devices in ICT server room at NDA buildings	Automatic fire suppression and fighting devices in place	0	2						Review of progress reports
3. Conduct awareness training on emergency exit plan to staff	% of trained staff	0	100						Review of progress reports
4. Designate firefighting champions	Number of designated fire fighting champions	0							Review of progress reports
5. Conduct regular firefighting drill exercises at all offices	Number of offices conducted firefighting drill exercise	0	9						Review of progress reports
6. Inspection of NDA new tower building	Inspection conducted at NDA tower	0	1		16	16	16	16	Review of progress reports
7. Communicate emergency number for fire rescue department of Police to all NDA offices	Number of TMDA offices communicated with emergence numbers	0	9						Review of progress reports
8. Procure designated cabinets for storage of volatile and flammable for the laboratory	Number of laboratories installed with designated cabinets for storage of volatile and flammable	1	2						Review of progress reports
9. Conduct periodic inspection of electrical systems at NDA buildings	Number of buildings conducted Electrical system Inspection	0	3						Review of progress reports
10. Conduct periodic maintenance services for fire detection, suppression and fighting systems	Number of maintenance services performed for fire detection, suppression and fighting systems	0	4						Review of progress reports
Approval of non-existing or non GMP/quality audit compliant oversees manufacturing facilities									

1. Develop guidelines on submission of applications of quality audit for medical devices manufacturing facilities	Guidelines on submission of applications of quality audit for medical devices manufacturing facilities in place	0	1						Review of progress reports
2. Develop and disseminate guidelines for conducting desk review of medical devices	Guidelines for conducting desk review of medical devices in place	0	1						Review of progress reports
	% of assessors involved in dissemination workshops	0	100						Review of progress report
3. (a) Conduct PMS of medicines and biocidal approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100		16	16	16	16	Review of PMS records
3. (b) Conduct PMS of products approved after desk review and waivers	% of products approved through desk review and waiver sampled and tested	0	100						Review of PMS records
4. Identify countries to sign mutual agreement for recognition and reliance	Number of countries identified	0	10						Review of progress report
Not sustaining ISO certifications, WHO Maturity Level 3 and Prequalification									
1. To appoint QMS focal person to each section/unit to enhance implementation of documented procedures	Number of sections with QMS focal person								Review of Progress Reports
2. Sensitization to process owners on the acceptance and positive attitude towards non conformances	Number of process owners (Managers& head of unit sensitized	0							Review of progress report
3. Develop and implement schedule for regular follow-up on QMS review meetings deliberations	Schedule for regular follow-up on QMS review meetings deliberations in place	0	1						Review of progress reports
	% implementation of scheduled follow-ups	0							Review of progress reports
4. Conduct training on auditing techniques to QMS auditors	% of auditors trained	0			16	16	16	16	Review of progress report
5. Establish and implement schedule for institutional self-assessment on WHO-GBT and GPQCL requirements	Schedule for institutional self-assessment on WHO-GBT and GPQCL requirements in place	0	1						Review of progress reports
	% implementation of scheduled follow-ups	0	100						Review of progress reports
6. Conduct awareness training on QMS and Risk Management	% of staff trained on QMS and risk Management								Review of progress reports
7. Invest in strengthening the Quality Management Systems across the organization.		0							
8									
Underperformance, delays or failure of NDA projects									
1. Develop and implement SOP for developing, approval, implementation and reporting of projects.	Developed SOP in place	0	1						Review of PME document
2. Conduct project risk analysis for each project at NDA.	% of project conducted risk analysis	0	100						Review of progress reports
3. Conduct stakeholders' analysis associated with each project to determine their need and expectations	% of stakeholders analyzed for their needs and expectations	0	100						Review of progress reports
4. Institute use of project management software	Project management software instituted	0	1						Review of progress reports

5. Appoint and train project focal persons on project management	Focal persons on project management appointed and trained	0	1						Review of progress reports
6. Establish a prequalified list of expert reviewers. Conduct individual and group training on selected, problematic CT processes with intention of co-opting more internal reviewers.		0							
7. Propose to management to carryout consultation with the directorate before approval of the training plan		0			16	16	16	16	
8. a) An ICT steering committee needs to be setup to guide the process for all changes. b) A clear implementation plan should be in place that supports parallel change over ,		0							
9. Collaboration and strategic alliances with other Government Agencies and international drug regulatory authorities to work on price capping		0							
10. Developing guidelines in line with the law to avoid complaints		0							
11. Publish more frequent reports on the activity of NDA and respond timely to all media issues.		0							
12. Involving management (Directors) to avail internal Auditors.		0							
13. Strengthen third party due diligence review processes.		0							
14. Reevaluate the reorder levels.		0							
Loss of product samples or exhibits									
1. Install biometric access control systems to all storage rooms	number of storage rooms with biometric access control systems								Review of progress records
2. Provide secured rooms including cabinets/shelves for storage of samples and exhibits	Number of rooms provided								Review of progress reports
	Number of cabinets/shells provided								Review of progress reports
3. Procure special labelled samples collection bags	Number of special labelled samples collection bags	0							Review of progress reports
4. Regular staff training on procedures for handling of product samples, exhibits and dossiers	% of staff trained on procedures for handling of product samples, exhibits and dossiers	0	95						Review of progress records
Non-compliance to Legal requirements									
1. Conduct regular staff trainings and dissemination on relevant laws, regulations and guidelines.	% of staff trained on relevant laws, regulations and guidelines.	0	95						Review of progress records
2. Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders.	% of stakeholders attending workshops on Laws, Regulations and Guidelines	0							
3. Routine document screening before receipt by registry.		0							

4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting	Number of revised regulation	0			16	16	16	16	
5. Expand the scope of the existing law and regulations to address the legal gaps.		0							
6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness	Number of stakeholders meeting conducted in a year	0							
7. Consider actions to streamline the legal and regulatory framework for operational effectiveness.		0							
8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions.									
9. Training management and the Drug Authority on judicial review.									
10 a) Conduct regular staff training and dissemination on relevant laws, b) regulations and guidelines c) Conduct dissemination workshops on Laws, d) Regulations and Guidelines to stakeholders.									
11. Improved liaison with the Legal Department to ensure compliance		0							
Staff safety, security and occupational health hazards									
1. Sensitize staff on workers Compensation	% of staff sensitized on benefits of workers Compensation Fund		95						Review of progress report
2. Provide sufficient number of ergonomic chairs to cover all staff	% of staff provided with ergonomic chairs to cover all staff		50						Review of progress report
3. Sensitize staff on wellness programme including regular check up	% of staff sensitized on wellness programme including regular check up		95						Review of progress report
4. Secure sport ground for staff at NDA for regular exercise and training	Number of sport grounds secured		95		16	16	16	16	Review of progress report
5. Install Security Devices like CCT Cameras	Number of cameras installed								
6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually	% of staff trained								
7. vehicle tracking system should be prioritized	Number of vehicle tracking systems installed								
Staff turn over									
2. Develop and implement incentive schemes	incentive schemes in place				16	16	16	16	Review of progress report
4. Sensitize and train staff on conducting Training Need Assessments (TNA)	% of staff sanitized Training Need Assessments(TNA)								Review of progress report
5. Recruit more procurement staff	Number of staff recruited	0							
6. Continuous training of Board of Survey members	Number of staff trained	0							
Inappropriate exposure of samples leading to possible damage or compromise of results.									
1. Avail HVAC system		0	1		16	16	16	16	Review of progress report
Delayed coding and analysis of samples									

1.Enhanced sensitization of the inspectors to forward samples with full documentation.	Number of inspectors sensitized	0			16	16	16	16	Review of progress report
2. Reject samples with incomplete documentation	Number of samples rejected.	0							Review of progress report
3. Automation of the process (sample receipt, analysis and coding)	% of the process automated	0							Review of progress report
4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures.		0							
Use of Invalid reference standards since validity is not indicated on the bottle.									
1. Analysts required to attach a copy of the certificate of analysis for reference standards used during analysis.	Copies attached	0			16	16	16	16	Review of progress report
contamination of samples being tested due to the use of un clean glassware.									
1. Procure glassware washing machine.	Number of machines procured	0			16	16	16	16	
Laboratory Accidents occur									
1. Enhance PPEs		0			16	16	16	16	
Litigation arising out of the legally challenged appointment of non-pharmacists as drug inspectors.									
1. Application to court to set aside the out of court settlement		0			16	16	16	16	
2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law		0							
Antimicrobial resistance occurs in both human and animals due to toxicities in veterinary drugs.									
1. Develop a module in NDAMIS to capture Import quantities of Vet drugs to monitor the antimicrobial use in the country		0			16	16	16	16	
Scope of available regulation is narrow, only for ectoparasiticides									
1. Recruitment of other cadre of staff and function-specific training of assessors.	Number of cadre staff recruited				16	16	16	16	
2. Expedite formulation of new regulations for general applications to all veterinary trials.	Development of new regulations	0							
Entry errors on the CNF list, register and certificate of registration.									
1. Revised assessment template to improve the vigilance.		0			16	16	16	16	
2. Continuous training of the assessors.	Number of assessors trained	0							
3. Errors routed to the resource that does drafting	% of errors routed	0							
4. Maker-checker process implemented. (QA process)		0							
5. Full automation of the register.		0							
Disclosure of confidential information in an application to an unauthorized person.									
1. Strengthening controls by restricting access to dossiers to person with signed confidentiality undertaking.		0			16	16	16	16	
2. DPAR has further restricted distribution of information to senior assessors within the Directorate.		0							
Shortage of Infrastructure and facilities to meet the NDA's needs.									
1. Monitoring the time a client parks to create space for the upcoming clients		0			16	16	16	16	
Under staffing									
1. Recruiting new staff to fill the positions in the organogram	Number of new staff recruited	0			16	16	16	16	
Delay in implementing research									

1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research		0			16	16	16	16	
2. use temporary staff and hire research assistants to support the research activities		0							
chain of evidence for impounded drugs compromised.									
1. Procure bigger office space to address the poor storage challenge.	Procurement of bigger office space	0			16	16	16	16	
2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances.		0							
Failure to facilitate the process of improving the legal mandate of NDA and the proposed extended mandate on food and cosmetics safety									
1. NDA Authority to engage and support MOH in undertaking high level lobbying with key stakeholders and have the Bill fast tracked in Parliament		0			16	16	16	16	
Confidential information is publicly released/Leakage of sensitive information									
1. Awareness on the Internal and External communication and relationship management.		0			16	16	16	16	
2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms		0							
3. Stringent security checks both before staff are hired and after they've left.		0							
REGIONS									
Forged academic documents submitted for persons to be incharges.									
1.Give DDIs tools enabling them verify academic documents submitted to them	%ge of DDIs supported with tools	0	100		16	16	16	16	
2.NDA to liaise with various professional councils to have in place a shared data base of all qualified/registered health personnel		1	1						
Absentee incharges									
Close outlets with absentee in charges (manned by unqualified attendants)	No. of outlets with absentee in charges closed	0			16	16	16	16	
Smuggling of drugs across the boarders -Uganda - south Sudan & DRC boarders									
Establish port of entry in Iguhe region. E.g. in Eleju					16	16	16	16	
Increase boarder routine inspection and vigilance	No. of boarder surveillance visits	4	4						
Delayed basic testing of suspected substandard, falsified and counterfeit products									
Establish well equipped mini labs in the regions	One mini lab equipped	1	1		16	16	16	16	
illegal, unlicensed drug outlets operating (and Hawkers)									
Have more severe penalties given to offenders					4	4	4	4	
Impound and close the outlet until compliance	%ge of illegal outlets impounded								
Impound and arrest all hawkers and charge them	No. of Hawkers charged								

Frequency of reporting	Means of verification	Responsible person(s)
Quarterly		DIE
Quarterly	System installation	DIE
Quarterly	Approved reports	DIE (Control of imports)
Quarterly	Approved reports	Medical Devices
Quarterly	Monitoring reports	Manager Herbal Medicines
Once	Approved revised checklist	DIE /GMP
Quarterly	Inspection reports	
Annually	Training records	DIE/Inspectorate
Quarterly	Sensitization records	SA
Quarterly	Approved PMS Program and reports	DPMS
Once	Approved Plan	SA /PRO
Quarterly	Implementation reports	SA / PRO
Once	Approved procedure	SA/PRO
Quarterly	Sensitization records	SA/PRO
Once	Approved procedure	DIE/QMS

Quarterly	Sensitization records	DPS/MPV
		DPS/MDP
		DIE/Head Regions
Quarterly	Training records	DPS/MPV
Quarterly	Monitoring reports	DPS/MPV
Quarterly	Sensitization records	DPS/MPV
Once	ADR Forms in HMIS	DPSMPV/HICT
Once	Physical verification of the database	MMDV
Quarterly	Copy of feedback	MPV
Quarterly	Copy of feedback	MMDV

Once	Approved accounting manual	SA/IA/DHRMA
Once	Approved guideline	DHRMA
Once	Distribution List and sensitization records	DHRMA
Quarterly	Performance Reports	HPDU
		DHRA
Quarterly	Sensitization records	HPDU/DHRMA
Quarterly	Sensitization records	DHRMA
Once	Approved reviewed the regulations	HBPD/DCS/SA
Once	Approved inspection plans	Head regions/ Managers
Quarterly	Installation reports	HICT/DCS
Once		DCS
Once	Approved Business plan	DLS
Quarterly	Sensitization records	DHRMA
Quarterly	Approved Fraud policy	BPD
Quarterly		NDA
		FIN
		DCS/FIN
		DHRA
		HICT

		DCS/FIN
Once	Report	HICT/RMO/HBPD
Once	Report of testing of ICT disaster recovery plan	HICT/RMO
Once	BCPTesting report	RMO/HICT/HBPD
Once	Approved Schedule	HICT
Once	Approved Schedule	DHARMA
Quarterly	Installation/Upgrading reports	HICT
Quarterly	Performance reports	HICT
		DPS/CT
		DPS/CT
		DPS
		DPS/MPV
		HICT
		HICT
		HICT
		HICT
		HICT
		HICT
		DIE/HICT
Quarterly	Training records	DHRA
Quarterly	Installation reports	HICT
Quarterly	Training records	DHRA
Quarterly	Appointment letter	DHRA
Quarterly	Firefighting drill exercise report	DHRA
Quarterly	Building Inspection report	DHRA/RMO
Quarterly	Communication records	DHRA
Quarterly	Installation records	DLS
Quarterly	Inspection report	DHRA
Quarterly	Maintance services Reports	HICT/DHRA

Once	Approved	DLS/MMD
Once	Approved	DLS/MMD
Quarterly	Dissemination records	MDL
Quarterly	PMS Reports	DIE/PMS
Quarterly	PMS Reports	MMDV
Once	List of identified countries	DIE/DPAR
Once	Appointment letter	MQMS
Once	Sensitization records	MQMS
Once	Approved schedule	MQMS
Quarterly	Progress report	MQMS
Quarterly	Training records	MQMS
Once	Approved schedule	MQMS
Quarterly	Progress report	MQMS
Quarterly	Training records	MQMS/RMO
		SA/QMS
Once	Approved Procedure	HBPD/PM&EO
Quarterly	Risk analysis reports	RMO/HBPD
Quarterly	Stakeholders analysis reports	PME
Once	Software installation records	HBPD/HICT

Once	Appointment letter and training records	HBPD
		DPS/CT
		DPS/CT
		SA/HICT
		SA/QMS
		PRO
		SA/IA
		DHRA
		PDU
Once	Physical verification of installed biometric access control system	HICT
Once	Asset inventory	DHRA
Once	Asset inventory	DHRA
Once	Delivery note	HPDU
Quarterly	Training records	DLS/DIE/IC
Quarterly	Training records	HLS
		HLS
		DPS/CT

		DPS/MPV
		DIE/LEGAL
		SA/LEGAL
		SA/LEGAL
		HLS
		HLS
		HLS
		HLS
		HLS
Quarterly	Progress reports	DHRA
Quarterly	Progress reports	DHRA
Quarterly	Progress reports	DHRA
Once	Progress reports	DHRA
		DHRA
		DHRA
		DHRA
Once	Progress reports	DHRA
Once	Progress reports	DHRA
		DHRA
		DHRA
Quarterly		DLS

Quarterly	Progress reports	DLS
		DLS
		DLS
		DIE/HICT
		DLS
		DLS
		DLS
		DVS
		DVS
		DVS
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		PRO
		DIE
		DIE