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**NATIONAL DRUG AUTHORITY**

**RISK TREATMENT PLAN FOR THE FY 2023-2024**

**ANNUAL RISK TREATMENT PLAN**

**HEAD OFFICE**

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# **Introduction**

National Drug Authority (NDA) has a legal mandate of regulating quality, safety and effectiveness of medicines, medical devices, diagnostics and other related health products to ensure that the public health is promoted and protected. To accomplish this mandate, NDA developed its risk management manual and started implementing its framework in 2021. Further efforts have been dedicated in review of this framework in order to improve risk management processes based on industry best practices and guidelines. The main objective of the framework is to provide guidance to NDA to manage risks effectively through application of risk management processes at all levels and within regulatory functions.

Since 2021, The Authority has been preparing and implementing Risk Treatment Plans and improving the implementation.

# **Objectives**

## **Overall Objective**

The overall objective of this risk treatment plan is to ensure risk treatment actions are effectively and efficiently implemented

## **Specific Objectives**

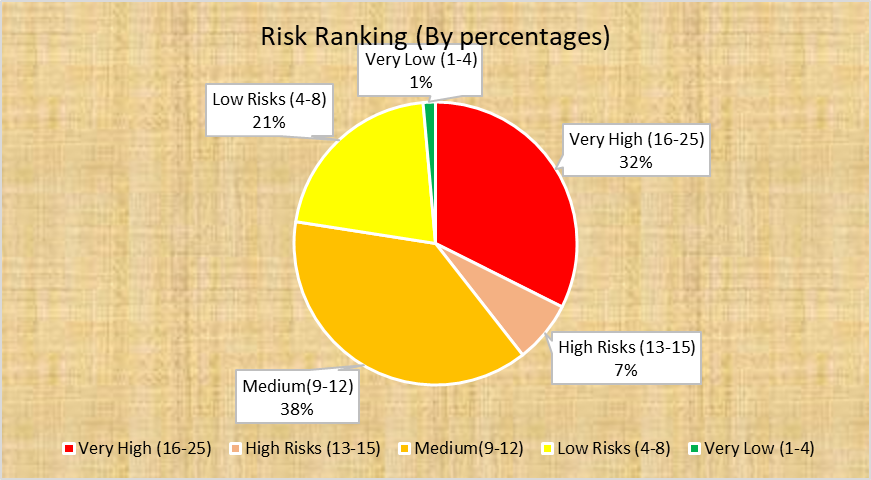
1. To identify potential risk for the financial year 2023/24
2. To prepare appropriate treatment actions and prepare implementation plan for identified risks
3. To ensure that appropriate Risk Treatment plan are efficiently and effectively implemented

# **Approach and Methodology**

## **Identification of potential risk for the financial year 2023/24**

The review and update of the 2022/23 Risk Register will give raise to the new Risk register for the financial year 2023/24. Any new or emerging risks will be identified, analyzed and evaluated by following procedures outlined in items BDE.FORM 421 (Risks and Opportunities assessment form) of the Risk Management Framework.

By the start of the last FY, 71 risks were identified and recorded in the Risk Register. 23 (32%) were rated as very high risks, 5 (7%) as high risks, 27(38%) as medium risk, 5(8%).



**Figure 1: Summary of potential risks for financial year 2023/24**

The risk evaluation criteria used is provided for the t risk management manual

| **Score** | **Risk rank** | **Evaluation Criteria (Management Control Action (MCA)** |
| --- | --- | --- |
| 1 to 4 | Very Low | No mitigation, no action is required, the risk is ALARP. Monitor to ensure that the risk remains tolerable at this level. |
| 5 to 8 | Low | Maintain assurance that the risk remains tolerable at this level. Monitor and manage by routine procedures, unlikely to need specific application of resources (managers and key staff). |
| 9 to 12 | Medium | Tolerable if the cost of reduction would exceed the improvement gained. Mitigate through management by specific reviews and monitoring of procedures (Managers) but regular monitoring should occur. |
| 13 to 15 | High | Tolerable only if risk reduction is impractical or if cost is disproportionate to the improvement gained. Mitigate by implementing controls to reduce the risk to as low as is reasonably practicable. Where this cannot happen, continual monitoring should occur. |
| 16 to 25 | Very High | Intolerable, the risk cannot be justified, expect in extraordinary circumstances. Mitigate by ceasing all related activities. |

# **Operationalization of Risk Treatment Action Plan**

## **Preparation of Implementation Plan**

For effective and efficient implementation of the risk treatment action plan the following should be done

1. Risk owners (through process owners) should cascade the risk treatment plan by preparing detailed implementation plan in a format provided in Appendix III:
2. The implementation plan should be linked with the work plan and budget as well as daily implementation of other activities to maximize the potential for curbing identified risks.

# **Reporting, Monitoring and Evaluation**

A key element to effective risk management is on-going monitoring, evaluation and communication of risk information to the appropriate management level. The framework for the reporting, monitoring and evaluation on Implementation of risk treatment plan within NDA shall base on the organizational structure and normal reporting procedures as well as risk reporting structure stipulated in The Risk Management Manual (BDE MAN 012). Framework for monitoring of implementation of Risk Treatment Plan is provided in Annex I

## **Reporting**

Reports on the implementation Risk Treatment Plan shall be prepared after monitoring

## **Performance criteria**

Performance on implementation of risk treatment plan shall be assessed based on criteria stipulated in **Table 1**.

**Table 1: Criteria for assessing implementation of risk treatment plan**

|  |  |  |
| --- | --- | --- |
| S/N | **Performance** | **Interpretation** |
| 1 | 80% and above | Implemented |
| 2 | from 40% to 79% | Partially implemented |
| 3 | Below 40% | Not implemented |

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# **Financing of Risk Management Plan**

Ideally risk management plans need to be prepared before a budgeting session such that the agreed risk treatment actions which have financial implication are reflected in the Authority’s Work Plan and Budget. Since this plan has been prepared after the budgeting cycle, Risk owners and Management will align implementation of this plan with available resources.

7. Planned Risk Management activities in the FY23/24

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Planned Risk Management activities**  **as per the plan** | **Expected output** |  | **Action** | **Time/period** |
|  | Convene the peer review (coordinators meeting**)** | Peer review report, Drafts of, Risk Treatment Plan, Risk Register and EYRMR) |  | Convene peer review meeting | July 2023 |
| 2. | Review and/or conduct risk assessments in all Directorates/Departments/Units and major projects and events in NDA. Facilitate risk identification and assessment sessions | Approved Risk Register: |  | - Register review and/or  Conduct risk assessment with all business units to facilitate the identification | July 2023 |
| 3. | Development of risk response strategies | Action to be implemented to mitigate the identified risks |  | Mitigation actions for all Risks identified and budgeted for (if necessary) | July 2023 |
| 4. | Monitor risk implementation | Quarterly monitoring reports |  | Risk actions implemented at process level | 23/24 |
| 4. | Develop institutional BCP and DRP | Approved BCP and DRP |  | Procure the services of the consultant to review the drafts | July, 2023 |
| 5. | Creating a risk aware-culture through maintaining and continuously improving capacity within NDA through training (accredited) and awareness | Conduct a number of training sessions for all staff both at head office and in the regions.  Make presentations on risk management at management |  | * An external trainer to be sought to train the Board, Management and Staff. * The RMO will conduct Risk Management training in all regional offices. | Thought the year |
| 6. | Establish a Risk Peer Review Team | Peer Review Team |  | PRT was established but members are not fully appointed with TORs |  |
| 7. | Validation of Risk Management activities in all regions and Ports of Entry | Progress reports from the visits are presented to various stakeholders at various intervals |  | Visiting all regions and Ports of Entry | Quarterly |
| 8. | Publication of Risk Management Policy and application of tools/forms | Communicated risk management policy to all staff of NDA (circulation of the Manual and all the tools) |  | The policy is shared through the QMS servers. More awareness workshop on risk management are going to be conducted. |  |
| 9. | Review Risk Management Methodologies and processes | Approved risk assessment methodologies and processes |  | Risk Methodology will be reviewed and approval sought |  |
| 10. | Drafting of individual key risk indicators for the top risks | Analysis report of key risk indicators per agreed frequency |  | Analysis of key risk indicators will be conducted |  |
| 11 | Evaluate control effectiveness | * Combined assurance Plan * Assurance Report on controls assessed |  | The Risk Management unit will collaborate with Internal Audit/QMS to develop the combined assurance plan. |  |
| 12. | Ensure risk management processes and methodologies are reviewed independently | * Performance Audit report * Status report on risk management implementation |  | Collaboration with internal audit/QMS will be sought in order to review the entire risk management process. |  |

## **Appendix I: Risk Treatment Plan Monitoring Framework**

## 

| **Treatment action** | **Indicator description** | **Baseline** | **Indicator value** | | | | | **Data collection instrument and methods** | **Frequency of reporting** | **Means of verification** | **Responsible person(s)** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Cumulative Target Value** | **Q1** | **Q2** | **Q3** | **Q4** |
| **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 | Quarterly |  | | DIE |
| 2. Introduce an automated track and trace system | A functioning Trace &Track system | 0 | 1 |  |  |  | 1 | Review of documents/system | Quarterly | System installation | | DIE |
| 3.  (a)  Conduct inspection to monitor medicines and biocidal imported under special conditions | Percentage of consignments imported under special conditions monitored | 0 | 80% |  |  |  |  | Review of progress reports | Quarterly | Approved reports | | DIE (Control of imports) |
| .  (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 | Quarterly | Approved reports | | Medical Devices |
| 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 | Quarterly | Monitoring reports | | Manager Herbal Medicines |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 5. Review and implement routine inspection checklist | Revised checklist in place | 0 |  |  |  |  |  | Review of Documents | Once | Approved revised checklist | | DIE /GMP |
| % of routine inspections conducted using revised checklist | 0 |  |  |  |  |  | Review Inspection reports | Quarterly | Inspection reports | |
| 6.    Conduct inspectors training on intelligence techniques | Number of inspectors trained |  |  |  |  |  |  | Review of progress reports | Annually | Training records | | DIE/Inspectorate |
| 7. Conduct sensitization of Whistleblowing Policy to NDA staff | % of staff sensitized | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Sensitization records | | SA |
| 8. Review and widen scope of PMS | Number of products increased in PMS |  |  |  |  |  |  | Review of PMS program | Quarterly | Approved PMS Program and reports | | DPMS |
| 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 | Once | Approved Plan | | SA /PRO |
| % implementation of the plan | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Implementation reports | | SA / PRO |
| 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 | Once | Approved procedure | | SA/PRO |
| %of stakeholders sensitized disaggregated by categories | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Sensitization records | | SA/PRO |
| 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 | Once | Approved procedure | | DIE/QMS |
| 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 | Quarterly | Sensitization records | | DPS/MPV |
| 15. Regular Monitoring of all drug-related promotions and adverts running both in the media and print |  | 0 |  |  |  |  |  |  |  |  | | DPS/MDP |
| 16. Regional offices to regularly disseminate drug safety information to the public. |  | 0 |  |  |  |  |  |  |  |  | | DIE/Head Regions |
| 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 | Quarterly | Training records | | DPS/MPV |
| 3.    Conduct monitoring and evaluation of implementation of pharmacovigilance roadmap | Number of monitoring reports | 0 | 4 |  |  |  |  | Review of performance evaluation records | Quarterly | Monitoring reports | | DPS/MPV |
| 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 | Quarterly | Sensitization records | | DPS/MPV |
| 5.    Integrate ADR reporting forms into Ministry Health Management Information System (HMIS) | Functional integrated HMIS in place | 0 | 1 |  |  |  |  | Physical verification of HMIS | Once | ADR Forms in HMIS | | DPSMPV/HICT |
| 8.    Establish database for processing field safety reports for medical devices | Functional database in place | 0 | 1 |  |  |  |  | Review of records | Once | Physical verification of the database | | MMDV |
| 9.    Provide feedback to reporters after receiving ADRs | % of feedback to reporters | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Copy of feedback | | MPV |
| 9 (b).    Provide feedback to reporters after receiving and AEs | % of feedback to reporters | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Copy of feedback | | MMDV |
| 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 | Once | Approved accounting manual | SA/IA/DHRMA | |
| 5.     Approve and disseminate estate management guideline | Approved estate management guideline in place | 0 | 1 |  |  |  |  | Review of progress reports | Once | Approved guideline | DHRMA | |
| % of staff with approved estate management guideline | 0 |  |  |  |  |  | Review of HRA documents | Once | Distribution List and sensitization records | DHRMA | |
| 7.     Inspect availability of performance reporting of contracts given to service providers | % of contracts with performance reports | 0 |  |  |  |  |  | Review of procurement records | Quarterly | Performance Reports | HPDU | |
| 8. Hire highly skilled guards |  | 0 |  |  |  |  |  |  |  |  | DHRA | |
| 9.     Conduct regular sensitization on relevant laws, guidelines and standard operating procedure on asset management | Number of sensitization conducted | 0 | 4 |  |  |  |  | Review of progress reports | Quarterly | Sensitization records | HPDU/DHRMA | |
| % of staff sensitized | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Sensitization records | DHRMA | |
| 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 | Once | Approved reviewed the regulations | HBPD/DCS/SA | |
| 2. Prepare annual risk-based inspection plan at regional offices | Annual risk-based inspection plans in place | 0 | 9 |  |  |  |  | Review of inspection records | Once | Approved inspection plans | Head regions/ Managers | |
| 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 | Quarterly | Installation reports | HICT/DCS | |
| 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 | Once |  | DCS | |
| 5.Prepare and implement Laboratory business plan | Laboratory Business Plan in place | 0 | 1 |  |  |  |  | Review of progress reports | Once | Approved Business plan | DLS | |
| 6. Staff sensitization on code of ethics | % of staff sensitized | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Sensitization records | DHRMA | |
| 7. Develop and implement a stringent fraud policy | A Fraud Policy approved | 0 | 1 |  |  |  |  | Progress report | Quarterly | Approved Fraud policy | BPD | |
| 8. Strengthen resource mobilization and exercising priority spending | Meticulous cash flow management | 0 |  |  |  |  |  | Progress report | Quarterly |  | NDA | |
| 9. Engage Ministry of Finance to clear MoH arrears |  | 0 |  |  |  |  |  |  |  |  | FIN | |
| 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 |  |  |  |  |  |  |  |  |  | DCS/FIN | |
| 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 |  |  |  |  |  |  |  |  |  | DHRA | |
| 12. Put in place a system where the supplier delivers an E-invoice plus the delivery note to the registry |  |  |  |  |  |  |  |  |  |  | HICT | |
| 13. Review the entire approval process. Develop Internal Service Level Agreement with other departments. | Internal service development |  |  |  |  |  |  |  |  |  | DCS/FIN | |
| Unavailability of ICT services (Cyber risk) |  |  |  |  |  |  |  |  |  |  |  | |
| 1. Develop and implement a BCP & DRP | An approved BCP & DRP | 0 | 2 |  |  |  |  | Document review | Once | Report | HICT/RMO/HBPD | |
| 2.    Conduct periodic testing of ICT disaster recovery plans. | ICT disaster recovery plan tested | 0 | 1 |  |  |  |  | Review of progress reports | Once | Report of testing of ICT disaster recovery plan | HICT/RMO | |
| 3.    Conduct periodic testing of BCP | BCP testing conducted | 0 | 1 |  |  |  |  | Review of progress reports | Once | BCPTesting report | RMO/HICT/HBPD | |
| 4.    Prepare schedule for preventive maintenance of power backup system | Schedule for power backup system in place | 0 | 1 |  |  |  |  | Review of progress reports | Once | Approved Schedule | HICT | |
| 5.    Prepare schedule for preventive maintenance of generators | Schedule for preventive maintenance of generators in place | 0 | 1 |  |  |  |  | Review of progress reports | Once | Approved Schedule | DHARMA | |
| 6.    Upgrade power back up system at NDA offices | Number of hours for power backup | 3 | 9 |  |  |  |  | Review of progress reports | Quarterly | Installation/Upgrading reports | HICT | |
| 7.    Report on adherence to Service Level Agreement | % of adherence to Service Level Agreement | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Performance reports | HICT | |
| 8. continuous update of the clinical trials databases | % of the clinical trial database updated | 0 |  |  |  |  |  |  |  |  | DPS/CT | |
| 9. automate the clinical trial application system | % of the system automated | 0 |  |  |  |  |  |  |  |  | DPS/CT | |
| 10. Develop an electronic system to facilitate signal detection |  | 0 |  |  |  |  |  |  |  |  | DPS | |
| 11. use of Non-disclosure agreements (NDAs) with all internal, external parties accessing PV safety data | No. of NDAs signed | 0 |  |  |  |  |  |  |  |  | DPS/MPV | |
| 12. Setup of Hot site for redundancy, systems upgrades | No of upgrades | 0 |  |  |  |  |  |  |  |  | HICT | |
| 13. infrastructure upgrade, Repair of faulty equipment |  | 0 |  |  |  |  |  |  |  |  | HICT | |
| 14. Update security policies, Sensitize users to be aware of social engineering, | No of staff sensitized | 0 |  |  |  |  |  |  |  |  | HICT | |
| 15. Turn on multifactor authentication for your online accounts. |  | 0 |  |  |  |  |  |  |  |  | HICT | |
| 16. Increased Monitoring network and systems with advanced tools |  | 0 |  |  |  |  |  |  |  |  | HICT | |
| 17. Improve on surveillance and physical security |  | 0 |  |  |  |  |  |  |  |  | HICT | |
| 18. Implement geo-mapping automated system to easily locate the licensed outlets and determine distance. |  | 0 |  |  |  |  |  |  |  |  | DIE/HICT | |
| Fire outbreak | | | | | | | | | | | | |
| 1.    Conduct firefighting and rescue training to at least 50% of staff annually | % of trained staff | 0 | 50 |  |  |  |  | Review of progress reports | Quarterly | Training records | DHRA | |
| 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 | Quarterly | Installation reports | HICT | |
| 3.    Conduct awareness training on emergency exit plan to staff | % of trained staff | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Training records | DHRA | |
| 4.    Designate firefighting champions | Number of designated fire fighting champions | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Appointment letter | DHRA | |
| 5.    Conduct regular firefighting drill exercises at all offices | Number of offices conducted firefighting drill exercise | 0 | 9 |  |  |  |  | Review of progress reports | Quarterly | Firefighting drill exercise report | DHRA | |
| 6.    Inspection of NDA new tower building | Inspection conducted at NDA tower | 0 | 1 |  |  |  |  | Review of progress reports | Quarterly | Building Inspection report | DHRA/RMO | |
| 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 | Quarterly | Communication records | DHRA | |
| 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 | Quarterly | Installation records | DLS | |
| 9.    Conduct periodic inspection of electrical systems at NDA buildings | Number of buildings conducted Electrical system Inspection | 0 | 3 |  |  |  |  | Review of progress reports | Quarterly | Inspection report | DHRA | |
| 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 | Quarterly | Maintance services Reports | HICT/DHRA | |
| 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 | Once | Approved | DLS/MMD | |
| 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 | Once | Approved | DLS/MMD | |
| % of assessors involved in dissemination workshops | 0 | 100 |  |  |  |  | Review of progress report | Quarterly | Dissemination records | MDL | |
| 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 | Quarterly | PMS Reports | DIE/PMS | |
| 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 | Quarterly | PMS Reports | MMDV | |
| 4.    Identify countries to sign mutual agreement for recognition and reliance | Number of countries identified | 0 | 10 |  |  |  |  | Review of progress report | Once | List of identified countries | DIE/DPAR | |
| 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 | Once | Appointment letter | MQMS | |
| 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 | Once | Sensitization records | MQMS | |
| 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 | Once | Approved schedule | MQMS | |
|  | % implementation of scheduled follow-ups | 0 |  |  |  |  |  | Review of progress reports | Quarterly | Progress report | MQMS | |
| 4.    Conduct training on auditing techniques to QMS auditors | % of auditors trained | 0 |  |  |  |  |  | Review of progress report | Quarterly | Training records | MQMS | |
| 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 | Once | Approved schedule | MQMS | |
| % implementation of scheduled follow-ups | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Progress report | MQMS | |
| 6.    Conduct awareness training on QMS and Risk Management | % of staff trained on QMS and risk Management |  |  |  |  |  |  | Review of progress reports | Quarterly | Training records | MQMS/RMO | |
| 7. Invest in strengthening the Quality Management Systems across the organization. |  | 0 |  |  |  |  |  |  |  |  | SA/QMS | |
| 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 | Once | Approved Procedure | HBPD/PM&EO | |
| 2.    Conduct project risk analysis for each project at NDA. | % of project conducted risk analysis | 0 | 100 |  |  |  |  | Review of progress reports | Quarterly | Risk analysis reports | RMO/HBPD | |
| 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 | Quarterly | Stakeholders analysis reports | PME | |
| 4.    Institute use of project management software | Project management software instituted | 0 | 1 |  |  |  |  | Review of progress reports | Once | Software installation records | HBPD/HICT | |
| 5.    Appoint and train project focal persons on project management | Focal persons on project management appointed and trained | 0 | 1 |  |  |  |  | Review of progress reports | Once | Appointment letter and training records | HBPD | |
| 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 |  |  |  |  |  |  |  |  | DPS/CT | |
| 7. Propose to management to carryout consultation with the directorate before approval of the training plan |  | 0 |  |  |  |  |  |  |  |  | DPS/CT | |
| 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 |  |  |  |  |  |  |  |  | SA/HICT | |
| 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 |  |  |  |  |  |  |  |  | SA/QMS | |
| 11. Publish more frequent reports on the activity of NDA and respond timely to all media issues. |  | 0 |  |  |  |  |  |  |  |  | PRO | |
| 12. Involving management (Directors) to avail internal Auditors. |  | 0 |  |  |  |  |  |  |  |  | SA/IA | |
| 13. Strengthen third party due diligence review processes. |  | 0 |  |  |  |  |  |  |  |  | DHRA | |
| 14. Reevaluate the reorder levels. |  | 0 |  |  |  |  |  |  |  |  | PDU | |
| 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 | Once | Physical verification of installed biometric access control system | HICT | |
| 2.    Provide secured rooms including cabinets/shelves for storage of samples and exhibits | Number of rooms provided |  |  |  |  |  |  | Review of progress reports | Once | Asset inventory | DHRA | |
| Number of cabinets/shells provided |  |  |  |  |  |  | Review of progress reports | Once | Asset inventory | DHRA | |
| 3.    Procure special labelled samples collection bags | Number of special labelled samples collection bags | 0 |  |  |  |  |  | Review of progress reports | Once | Delivery note | HPDU | |
| 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 | Quarterly | Training records | DLS/DIE/IC | |
| 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 | Quarterly | Training records | HLS | |
| 2.    Conduct dissemination workshops on Laws, Regulations and Guidelines to stakeholders. | % of stakeholders attending workshops on Laws, Regulations and Guidelines | 0 |  |  |  |  |  |  |  |  | HLS | |
| 3. Routine document screening before receipt by registry. |  | 0 |  |  |  |  |  |  |  |  | DPS/CT | |
| 4. Revision of current Regulations to offer guidance on the use of investigational products outside the clinical trial setting | Number of revised regulation | 0 |  |  |  |  |  |  |  |  | DPS/MPV | |
| 5. Expand the scope of the existing law and regulations to address the legal gaps. |  | 0 |  |  |  |  |  |  |  |  | DIE/LEGAL | |
| 6. Consider advocacy actions to streamline the legal and regulatory framework for operational effectiveness | Number of stakeholders meeting conducted in a year | 0 |  |  |  |  |  |  |  |  | SA/LEGAL | |
| 7. Consider actions to streamline the legal and regulatory framework for operational effectiveness. |  | 0 |  |  |  |  |  |  |  |  | SA/LEGAL | |
| 8. Advocacy strategy should include actions to engage key stakeholders to seek consensus on necessary revisions. |  |  |  |  |  |  |  |  |  |  | HLS | |
|  |  |  |  |  |  |  |  |  |  |  | HLS | |
| 9. Training management and the Drug Authority on judicial review. |  |  |  |  |  |  |  |  |  |  | HLS | |
| 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. |  |  |  |  |  |  |  |  |  |  | HLS | |
| 11. Improved liaison with the Legal Department to ensure compliance |  | 0 |  |  |  |  |  |  |  |  | HLS | |
| 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 | Quarterly | Progress reports | DHRA | |
| 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 | Quarterly | Progress reports | DHRA | |
| 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 | Quarterly | Progress reports | DHRA | |
| 4.    Secure sport ground for staff at NDA for regular exercise and training | Number of sport grounds secured |  | 95 |  |  |  |  | Review of progress report | Once | Progress reports | DHRA | |
| 5. Install Security Devices like CCT Cameras | Number of cameras installed |  |  |  |  |  |  |  |  |  | DHRA | |
| 6.Improve on surveillance and physical security, Conduct firefighting and rescue training to at least 50% of staff annually | % of staff trained |  |  |  |  |  |  |  |  |  | DHRA | |
| 7. vehicle tracking system should be prioritized | Number of vehicle tracking systems installed |  |  |  |  |  |  |  |  |  | DHRA | |
| Staff turn over | | | | | | | | | | | | |
| 2.     Develop and implement incentive schemes | incentive schemes in place |  |  |  |  |  |  | Review of progress report | Once | Progress reports | DHRA | |
| 4.     Sensitize and train staff on conducting Training Need Assessments (TNA) | % of staff sanitized Training Need Assessments(TNA) |  |  |  |  |  |  | Review of progress report | Once | Progress reports | DHRA | |
| 5. Recruit more procurement staff | Number of staff recruited | 0 |  |  |  |  |  |  |  |  | DHRA | |
| 6. Continuous training of Board of Survey members | Number of staff trained | 0 |  |  |  |  |  |  |  |  | DHRA | |
| Inappropriate exposure of samples leading to possible damage or compromise of results. | | | | | | | | | | | | |
| 1. Avail HVAC system |  | 0 | 1 |  |  |  |  | Review of progress report | Quarterly |  | DLS | |
| Delayed coding and analysis of samples | | | | | | | | | | | | |
| 1.Enhanced sensitization of the inspectors to forward samples with full documentation. | Number of inspectors sensitized | 0 |  |  |  |  |  | Review of progress report | Quarterly | Progress reports | DLS | |
| 2. Reject samples with incomplete documentation | Number of samples rejected. | 0 |  |  |  |  |  | Review of progress report |  |  | DLS | |
| 3. Automation of the process (sample receipt, analysis and coding) | % of the process automated | 0 |  |  |  |  |  | Review of progress report |  |  | DLS | |
| 4. Set up a structure in place to capture and track feedback from suppliers. Develop complaint handling procedures. |  | 0 |  |  |  |  |  |  |  |  | DIE/HICT | |
| 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 |  |  |  |  |  | Review of progress report |  |  | DLS | |
| contamination of samples being tested due to the use of un clean glassware. | | | | | | | | | | | | |
| 1. Procure glassware washing machine. | Number of machines procured | 0 |  |  |  |  |  |  |  |  | DLS | |
| Laboratory Accidents occur | | | | | | | | | | | | |
| 1. Enhance PPEs |  | 0 |  |  |  |  |  |  |  |  | DLS | |
| 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 |  |  |  |  |  |  |  |  | DVS | |
| 2. Working with Police during enforcement activities (Assistant Inspector of Police) as per the law |  | 0 |  |  |  |  |  |  |  |  | DVS | |
| 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 |  |  |  |  |  |  |  |  | DVS | |
| 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 |  |  |  |  |  |  |  |  |  |  | |
| 2. Expedite formulation of new regulations for general applications to all veterinary trials. | Development of new regulations | 0 |  |  |  |  |  |  |  |  | DVS | |
| Entry errors on the CNF list, register and certificate of registration. | | | | | | | | | | | | |
| 1. Revised assessment template to improve the vigilance. |  | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 2. Continuous training of the assessors. | Number of assessors trained | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 3. Errors routed to the resource that does drafting | % of errors routed | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 4. Maker-checker process implemented. (QA process) |  | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 5. Full automation of the register. |  | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 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 |  |  |  |  |  |  |  |  | DPAR | |
| 2. DPAR has further restricted distribution of information to senior assessors within the Directorate. |  | 0 |  |  |  |  |  |  |  |  | DPAR | |
| 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 |  |  |  |  |  |  |  |  | DHRA | |
| Under staffing | | | | | | | | | | | | |
| 1. Recruiting new staff to fill the positions in the organogram | Number of new staff recruited | 0 |  |  |  |  |  |  |  |  | DHRA | |
| Delay in implementing research | | | | | | | | | | | | |
| 1. Hiring consultants on specific assignments. Constitute a research committee/Scientific advisory committee with interest and experience in Research |  | 0 |  |  |  |  |  |  |  |  | DPS | |
| 2. use temporary staff and hire research assistants to support the research activities |  | 0 |  |  |  |  |  |  |  |  | DPS | |
| chain of evidence for impounded drugs compromised. | | | | | | | | | | | | |
| 1. Procure bigger office space to address the poor storage challenge. | Procurement of bigger office space | 0 |  |  |  |  |  |  |  |  | DIE | |
| 2. Engage Uganda police to designate NDA premises as places for securing police evidence on drugs and surgical appliances. |  | 0 |  |  |  |  |  |  |  |  | DIE | |
| 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 |  |  |  |  |  |  |  |  | SA | |
| Confidential information is publicly released/Leakage of sensitive information | | | | | | | | | | | | |
| 1. Awareness on the Internal and External communication and relationship management. |  | 0 |  |  |  |  |  |  |  |  | PRO | |
| 2. Archival of physical records in the central registry. Backup the information. Ensure that every staff signed the confidentiality forms |  | 0 |  |  |  |  |  |  |  |  | PRO | |
| 3. Stringent security checks both before staff are hired and after they’ve left. |  | 0 |  |  |  |  |  |  |  |  | PRO | |
| **REGIONS** | | | | | | | | | | | | |
| Forged academic documents submitted for persons to be in charges. | | | | | | | | | | | | |
| 1.Give DDIs & regional staff, tools enabling them verify academic documents submitted to them | %ge of DDIs supported with tools | 0 | 100 |  |  |  |  |  |  |  | DIE | |
| 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 in-charges | | | | | | | | | | | | |
| Close outlets with absentee in charges (manned by unqualified attendants) | No. of outlets with absentee in charges closed | 0 |  |  |  |  |  |  |  |  | DIE | |
| Integrate data on regions to prevent multiple in-charges | Integrated data base |  |  |  |  |  |  |  |  |  |  | |
| Smuggling of drugs across the boarders -Uganda - south Sudan, Kenya TZ & DRC boarders | | | | | | | | | | | | |
| Establish port of entry in the regions. E.g. in Elegu (for Northern reg., Suam, Lwakhakha for Eastern region) | No. of POE established |  |  |  |  |  |  |  |  |  |  | |
| Increase boarder routine inspection and vigilance | No. of boarder surveillance visits | 4 | 4 | 1 | 1 | 1 | 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 |  |  |  | 1 |  |  |  |  | |
| illegal, unlicensed drug outlets operating (and Hawkers) | | | | | | | | | | | | |
| Carry out sensitization to stakeholders | Number of engagements/sensitizations |  |  |  |  |  |  |  |  |  |  | |
| Have more severe penalties given to offenders | Reviewed Act - NDP/A Act |  |  |  |  |  |  |  |  |  |  | |
| Implement GDP | No. of wholesalers inspected for GDP |  |  |  |  |  |  |  |  |  |  | |
| Impound and close the outlet until compliance | No. of illegal outlets impounded |  |  |  |  |  |  |  |  |  |  | |
| Impound and arrest all hawkers and charge them | No. of Hawkers charged |  |  |  |  |  |  |  |  |  |  | |

**THE END**