TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

WHISTLEBLOWING POLICY

March, 2020

P. O. Box 77150, Mabibo, Off Mandela Road, Dar es Salaam, Tel: +255-22-2450512/2450751/ 2452108, Fax: +255-22-2450793, Website: www.tmda.go.tz, Email: info@tmda.go.tz, Toll Free 0800110084

VISION

To be the leading Regulatory Authority in ensuring safe, quality and effective, medicines, medical devices diagnostics and other health related products for all.

MISSION

To protect and promote public health by ensuring quality, safety and effectiveness of, medicines, medical devices, diagnostics and other health related products.

PHILOSOPHY

TMDA strives to offer quality regulatory services in the pursuit of protecting public health and environment by using competent and dedicated staff.

CORE VALUES

a. Integrity:

b. Customer focus:

c. Quality:

d. Teamwork:

e. Accountability:

f. Transparency:

QUALITY POLICY STATEMENT

TMDA is committed to provide quality services in response to customer needs and expectations. TMDA shall strive to balance the interests of our stakeholders without compromising quality, safety and effectiveness of medicines, medical devices and diagnostics by managing the Authority with utmost professionalism.
TMDA is committed to comply with the requirements of ISO 9001:2015 Standard and continually improve effectiveness of Quality Management System. It shall manage and provide resources for continuous improvement of our services to ensure customers' satisfaction."

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

KPI	-	Key Performance Indicators
MAB	-	Ministerial Advisory Board
MAH	-	Marketing Authorization Holder
MCPE	-	Manager Communications and Public Education
MLS	-	Manager Legal Services
MoHCDGEC	-	Ministry of Health, Community Development, Gender, Elderly and Children
MPME	-	Manager Planning, Monitoring and Evaluation
TMDA	-	Tanzania Medicines and Medical Devices Authority
TMDAA	-	Tanzania Medicines and Medical Devices Act
TUGHE	-	Tanzania Union of Government and Health Employees

ACKNOWLEDGEMENTS

This is the first Whistleblowing Policy to be crafted by the Tanzania Medicines and Medical Devices Authority (TMDA). The drafting process was done by the following TMDA employees:-

- Adv. Iskari Chotusinga Fute - Manager Legal Services
- Ms. Steria Cosmas Sanga - Principal Human Resources Officer
- Adv. Martha Malle - Legal Officer
- Mr. James Ndege - Senior Librarian
- Mr. Daffi Muhale - Internal Auditor
- Mr. Alex Juma - Drug Registration Officer
- Ms. Catherine Mkwazi - Personal Secretary

The drafting team relied on their experiences and expertise on administrative issues, legal affairs, auditing, pharmaceutical knowledge and regulatory affairs. The team also made references to a number of whistleblowing policies published by different institutions of which we are highly indebted.

Special gratitude is owed to the Section and Zone Managers for their commendable inputs at different development stages of this policy document particularly during their meeting which was held on 23rd March, 2020 for deliberation. The TMDA Management is also thanked for approving this document for wider circulation and ultimate use.

Lastly, the Ministerial Advisory Board (MAB) is acknowledged for the guidance, constructive discussions and endorsement of the document during its 2nd ordinary meeting for the year 2020 which was held on 8th January, 2020.

Chrispin Mesiaki Severe
DIRECTOR OF BUSINESS SUPPORT

DEFINITION OF TERMS

In the context of this Policy, the following words or phrases are defined as follows:-

Designated officer

Means authorized person appointed to receive reports on whistleblowing matters;

Ethics

Means a standard of conduct which indicates how a person should behave based on moral duties and virtues arising from the principles of right and wrong;

Good faith

Means any complaint based on an honest belief held on reasonable grounds that their disclosure was true at the time it was made will be deemed to have been made in good faith, even if after investigation it proves to have been inaccurate. The motives of the complainant are irrelevant to the seriousness with which each complaint must be treated;

Improper conduct

Means any conduct which is proved and constitutes a breach of integrity;

Investigator

Means a person assigned to conduct an investigation on an improper conduct;

Whistleblowing

Means the act of telling TMDA about any alleged wrongdoing that can be classified in many ways like – violation of law, regulations, or threat to public interest/national security, as well as fraud, corruption etc. A whistleblowing concern is different from a grievance, in that the former has a public or organisational interest aspect to it, whereas the latter relates to the private interests of the person concerned (involving, for example, discrimination or bullying); and

Whistleblower

Means a person(s) who exposes any kind of information or activity that is deemed illegal, unethical or not correct to TMDA.

FOREWORD

The Tanzania Medicines and Medical Devices Authority (TMDA) did not have a Whistleblower Policy before. Nevertheless, the Authority has been receiving information from various stakeholders on existence of substandard or falsified medical products circulating on the market through different channels which were not very well coordinated. Complaints on safety concerns and product quality defects have also been forwarded through phone calls or anonymous letters and memos from stakeholders. The suggestion box installed at the entrance of all main offices had likewise been used to collect information from stakeholders.

Much as the information receiving and feedback system was not very well streamlined and in order to comply with the Whistleblower and Witness Protection Act, of 2015; the TMDA has decided to craft this Whistleblowing Policy. The Policy intends to provide for a more systematic approach by defining a clear and straight forward procedure of submitting complaints or concerns from both internal staff and external stakeholders. It further aims at detailing concerns of serious importance that need to be reported and differentiate from issues that need not be reported to allow for appropriate action(s) to be taken by TMDA.

From our experience, we construe that there are quite a number of unscrupulous dealers who always plan to manipulate or deliberately adulterate products the TMDA is regulating, those who are engaged in clandestine manufacturing or illicit trading of substandard and falsified products as well as those who intend to be engaged in fraud of any nature including misappropriation of TMDA funds to mention a few. All these unethical individuals need to be reported for disciplinary action to be taken and more importantly for protection and promotion of public health.

Above all, it is understood that whistleblowing may lead to possible retaliation, harassment or victimization of whistleblowers. I would like to assure all whistleblowers that they will be protected and their identity or any sort of confidentiality maintained at all times.

The TMDA pledges to set adequate resources for effective implementation of this Policy including protecting all whistleblowers

as delineated in this document. We urge all stakeholders including internal staff to read what has been outlined in this Policy document and notify us (blow the whistle) in case of any wrongdoing.

Lastly, the crafting of this Policy document has considered the current malpractices and taken on board all elements of whistleblowing as implemented, executed and enforced by other agencies in and outside the country. Additions and further inputs from stakeholders are still welcome for improvement of this document.

Adam Mitangu Fimbo

ACTING DIRECTOR GENERAL

1. INTRODUCTION

Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) responsible for regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics. The functions of TMDA are provided for in the Tanzania Medicines and Medical Devices Act, Cap. 219 which include but not limited to the following:-

(i) Regulation of all matters relating to quality, safety and efficacy of human and veterinary medicines, herbal medicines, medical devices and diagnostics;

(ii) Regulation of importation, manufacturing, labeling, marking or identification, storage, promotion, sell and distribution of medicines, herbal medicines, medical devices and diagnostics;

(iii) Ensuring that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analyzed and acted upon;

(iv) Ensuring that clinical trials on medicines, medical devices and herbal medicines are being conducted in accordance with prescribed standards;

(v) Foster co-operation between the TMDA, other institutions or organizations and other stakeholders;

(vi) Promote rational use of medicines, medical devices and herbal medicines including providing the public with unbiased information; and

(vii) Attend to and where possible, take legal measures on complaints made by consumers against manufacturers of products regulated by TMDA.

In discharging its functions, the TMDA interact with many stakeholders and its mission is to protect and promote public health. Due to this interaction, many complaints and concerns had been

brought forward to TMDA in recent times but their handling had not been very systematic. In order to address the gap, TMDA has crafted this Whistleblowing Policy to outline procedures for reporting actions that violate TMDA Act, or regulations or that constitutes fraudulent, unethical or other misconduct practices.

Whistleblowing also applies when an employee raises a concern about wrongdoing or malpractice in the workplace that has a public interest aspect. The wrongdoings can be related to a range of issues, such as product defects, social care, financial mismanagement and environmental damage. Whistleblowing is important to protect and reassure the workforce, and to maintain a healthy working culture and an efficient organization.

For TMDA to function effectively and achieve its vision, it needs to comprehensively set up a system of receiving complaints and concerns from whistleblowers and address them accordingly. The implementation of this Policy will be in line with the TMDA's core values which embrace integrity, teamwork approach, customer focus, accountability, quality and transparency.

In this respect, the Whistleblowing Policy has been developed and outlines amongst others, the types of whistleblowing, issues to be reported, issues not to be reported, protection of whistleblowers and responsibilities of different TMDA staff on handling whistleblowing matters. Other items include confidentiality, records retention and procedures for preliminary and further investigations after receiving complaints and concerns from whistleblowers. Objectives, scope and rationale of developing this Policy have also been highlighted.

2. SCOPE OF THIS POLICY

The main scope of this Policy is to help TMDA stakeholders to report issues that might impact TMDA reputation, behavior of its employees or any other complaints. The Policy applies to both internal whistleblowers (TMDA employees, management and MAB) and external stakeholders.

3. RATIONALE FOR THIS POLICY

This Policy has been crafted to provide and maintain the welfare and wellbeing of TMDA staff and as such we fully endorse the principles and practice of Freedom of Expression. We are committed

to high standards of openness and transparency in all aspects of the organization and will treat whistleblowing as a serious matter.

In line with the TMDA's commitment to openness, probity and accountability, members of staff are encouraged to report concerns, which will be taken seriously, investigated and appropriate action taken in response. As guided by law whistleblowers will be protected against all forms of victimization.

The Policy will help to prevent mismanagement, corruption, illegality or any other wrongdoing that compromises the TMDA integrity. A well working whistleblowing mechanism is a cost-effective early warning system that allows emerging problems to be quickly identified and responded to.

This Policy has also taken into account the Whistleblower and Witness Protection Act, 2015, the Tanzania Medicines and Medical Devices Act, Cap 219 and TMDA Strategic Plans.

4. TYPES OF WHISTLEBLOWING

There are four (4) types of whistleblowing as described below:-

(a) Open whistleblowing – the person making the report does so openly without seeking protection of their identity. This is possible only when the whistleblower feels it is safe and acceptable to raise concerns openly. Such an approach makes investigation easier, as it is easier to gather information, to clearly understand motives and to avoid witch-hunts.

(b) Confidential whistleblowing – the identity of the person making the report is known to its recipient, but will not be disclosed without their consent, unless required by law. This approach recognizes the likely anxiety faced by potential whistleblowers and seeks to minimize the risk they face or perceive themselves to face.

(c) Anonymous whistleblowing – the person making the report does not identify himself/herself at any stage to anyone. This approach can make it difficult to properly investigate claims of corruption, misconduct, unethical practices or

violations of TMDA Act and may inhibit feedback to the whistleblower. Nonetheless, any report of malpractice received anonymously must be taken seriously and investigated within the limits of what is possible.

(d) Malicious whistleblowing - every report made of alleged corruption or mismanagement will be taken in good faith and investigated accordingly. However, it may, in some cases, transpire that such allegations have been made in bad faith or even with malicious intent. It is necessary that all staff of TMDA are protected from such false accusations.

Therefore, any whistleblower proven to have deliberately made wrongful allegations or to have acted in bad faith to the detriment of TMDA may face repercussions. Any proven acts of malicious wrongful accusations against staff members of TMDA will be treated as a serious misconduct and responded to accordingly.

Any staff member of TMDA proven to have maliciously made wrongful allegations or have acted in bad faith to the detriment of TMDA should be reported to the management of TMDA, to be dealt with in accordance with rules and regulations. False and malicious allegations should be treated as a disciplinary offence.

5. POLICY OBJECTIVES

5.1 General Objective

The overall purpose of this Policy is to provide a confidential, open or anonymous reporting process for the TMDA's employees and other stakeholders to report suspicions or evidence of malpractice, or concerns regarding serious violations of the TMDA's Act, regulations and any serious misconduct.

5.2 Specific Objectives

The specific purposes of this Policy are to:-

(i) Ensure the safety and security of individuals who report actual or suspected wrongdoing;

(ii) Reduce the risk of mismanagement or corruption in the operations of TMDA;

(iii) Safeguard the reputation of TMDA;

(iv) Encourage a culture of openness and integrity amongst TMDA employees and other stakeholders;

(v) Provide employees and stakeholders on proper procedures in disclosing cases of improper conduct;

(vi) Manage disclosures of improper conduct in an appropriate and timely manner;

(vii) Provide fair treatment to both the whistleblower and the alleged wrongdoer when a disclosure of improper conduct is made; and

(viii) Enable TMDA to adhere to the high standards of accountability in its work place.

6. ISSUES TO BE REPORTED

The issues to be reported under this Whistleblowing Policy are:-

6.1 Violations and breaches of the Tanzania Medicines and Medical Devices Act, Cap 219 and regulations;

6.2 When another person has not complied with TMDA Act or is in the process of breaking or is likely to break the Act which imposes an obligation to that person;

6.3 Misuse of TMDA funds and assets;

6.4 Abuse of power by any TMDA employee;

6.5 Unsafe practices at work;

6.6 Neglect of customers;

6.7 Abuse of customers;

6.8 Breach of confidentiality;

6.9 Unethical practices and breach of code of conduct;

6.10 Act of covering wrongdoing; and

6.11 Criminal offences (e.g. fraud, bribery, corruption, money

laundering, supporting or involvement in terrorism) and any other related offences as stipulated under the Prevention and Combating of Corruption Act, Cap 330.

6.12 Product related issues such as:-

(a) Promotion or advertising of a medicinal product or device outside the TMDA approved indications for use;

(b) A company's medicinal product, medical devices or diagnostics manufacturing processes do not meet their design and manufacturing responsibilities;

(c) Marketing a medicinal product, medical device or diagnostics without the appropriate TMDA authorization;

(d) Importation of medicinal product, medical devices or diagnostics into Tanzania mainland that do not meet legal requirements for admission to the country;

(e) A third party outside the medicinal product or medical device company forges or falsifies any permit or certificate to market a product in Tanzania mainland;

(f) A manufacturer or marketing authorization holder (MAH) knowingly deceives the TMDA. For example, the manufacturer hides information from the TMDA, or falsifies documents, etc. given to the TMDA; and

(g) Manufacturing, packaging, repackaging, relabeling, stocking, selling or distributing substandard or falsified medicinal products, medical devices or diagnostics.

7. ISSUES NOT TO BE REPORTED

The issues not to be reported under this Policy are:-

7.1 Issues for which appropriate procedures already exist. These include TMDA Staff Grievances, Harassment and Bullying, Complaints and Feedback relating to other matters. Complaints should be handled in accordance with the existing Complaints Handling Procedure within

TMDA;

7.2 Personal grievances, which should be reported and deliberated through the TMDA Staff meetings or reported through normal channel; and

7.3 Rumours, unsubstantiated claims or allegations and gossips.

8. TO WHOM SHOULD A REPORT BE MADE

8.1. TMDA Employees

All concerns originating from internal staff should be reported to the relevant Head of Section or Unit, or in the case of suspected theft or fraud to the Chief Internal Auditor. Where this is not felt to be appropriate, a report may be made orally or in writing to any one of the following:-

(a) Director General;

(b) Chairman of the MAB;

(c) Director of Medical Products Control;

(d) Director of Laboratory Services;

(e) Director of Business Support;

(f) Zone Managers; or

(g) Any other relevant authorities.

8.2. External Stakeholders

External stakeholders should submit their concerns through the TMDA Whistleblower Reporting Form available in hardcopy at all TMDA offices and also electronically at www.tmda.go.tz/whistleblowing or by regular mail or letter at the following addresses:-

Director General,

Tanzania Medicines and Medical Devices Authority,

P. O. Box 1253,

Dodoma.

Or

P. O. Box 77150,
Dar es Salaam.
Phone: +255 22 2452108/2450512/2450751
Mobile: +255 658 445 222/777 700 002/685 701 735
Toll Free: 0800110084

Or

ZONE OFFICES ADDRESSES						
Lake Zone	Northern Zone	Eastern Zone	Southern Highlands Zone	Central Zone	Southern Zone	Western Zone
Nyasaka Road Nyakato Buzuruga P.O. Box 543 Mwanza	Sakina Street P.O. Box 16609 Arusha	New Baga-moyo Road Victoria Area P.O. Box 31356 Dar es Salaam	NHIF Building, 3rd Floor P.O. Box 6171 Mbeya	P.O. Box 1253 Dodoma	PSSSF Building P. O. Box 1447 Mtwara	TUWASA Building P.O. Box 520 Tabora

9. PROCEDURE FOR WHISTLEBLOWING AND MAKING A DISCLOSURE

An employee or external stakeholder may raise a concern by telephone, in person or in writing by filling out the Whistleblower Reporting Form appended as Annex 1. The earlier the concern is expressed, the easier it will be to take action. The following information will need to be provided:-

- The nature of a concern and why it is believed to be true.
- The background and history of the concern (giving relevant dates).

Although it is not expected to prove beyond doubt the truth of a suspicion, a whistleblower will need to demonstrate to the person contacted that there is a genuine concern relating to suspected wrongdoing or malpractice within the TMDA and there are reasonable grounds for the concern.

A whistleblower may wish to discuss the concern with a colleague first and may find it easier to raise the matter if there are two (or more) persons who have had the same experience or concerns.

A whistleblower may wish to invite TUGHE, professional association representative or a friend to be present for support during any meetings or interviews in connection with the concerns raised.

In case the whistleblower feels the use of the above mentioned methods may not be effective, may report the matter to Chairman of MAB or any other relevant authorities. Whistleblowing may be made in the form of sign language. Where a whistleblower makes a disclosure orally or by sign language, a Designated Officer shall cause the disclosure to be put in writing containing the same particulars as specified in the Whistleblower Reporting Form.

Where the whistleblower is illiterate, the information to be put in the form shall be read, interpreted and explained to the whistleblower in a language the whistleblower understands. In the case of a person who is blind or with some other physical disability, but literate, particulars in the form shall be read, interpreted and explained to the whistleblower in a language the whistleblower understands.
The whistleblowers should report wrongdoings at an early stage; therefore concerns should be raised as soon as the person has a reasonable suspicion. In such cases, it is the responsibility of the person receiving the report to instigate appropriate investigations and to seek evidence (perhaps with help from the whistleblower).

10. RESPONSIBILITIES OF THE DIRECTOR GENERAL

The Director General shall have the following responsibilities:-

a) Receiving complaints or concerns whether openly, confidentially or anonymously;

b) Assessing how serious and urgent the risk is;

c) Handle and make decisions on complaints or concerns and in doing so, he may consult the Chairman of MAB;

d) Forward the matter to other relevant authorities for any necessary action as the case may be;

e) Depending on the nature of the concern, delegate the matter to any of the directors, zone managers, designated officer or any other person(s) from within or outside TMDA to conduct investigation or to take any other action pursuant to this Policy;

f) Ensure all employees and other stakeholders are aware of this Whistleblowing Policy and procedures;

g) Promptly determine what professional assistance, internal or external expertise such as auditors, counsel or other experts if any, is needed in order to conduct the investigation and analysis of results; and

h) Take disciplinary action for malicious reporting (untrue or false information).

11. RESPONSIBILITIES OF THE DESIGNATED OFFICER

For the purposes of this Policy the Designated Officer shall be the Manager responsible for Communication and Public Education, who shall have the following responsibilities:-

a) Maintain a Whistleblower Register to record each complaint or concern and the date of the complaint received;

b) Identify complaints that involve serious matter with material impact or involving Senior Management and report to the Director General;

c) Analyze whether the information received should be treated as a whistleblowing complaint or concern and assess whether the concern can best be dealt with under this Policy or Complaints Handling Procedure and how urgent or serious the risk is;

d) Advise the Director General on the course of action to be taken regarding the received complaints or concerns; and

e) Prepare monthly, quarterly, mid-yearly and annual reports on whistleblowing matters including reports to be submitted for Management Review Meetings under TMDA Quality Management System.

12. PROTECTION OF WHISTLEBLOWERS

Whistleblowers shall be protected if:-

a) The disclosure is made in good faith;

b) The whistleblower has reasonable cause to believe that the information disclosed and an allegation of wrongdoing contained in it is substantially valid; and

c) The disclosure is made in accordance with the provisions of Whistleblower and Witness Protection Act, 2015 and Prevention and Combating of Corruption Act, Cap 329.

The protection of whistleblowers shall also take into account the following:-

i) The whistleblower's identity and such other confidential information of the whistleblower shall not be disclosed;

ii) TMDA shall not dismiss or victimize anyone on the basis that they have made an appropriate lawful disclosure in accordance with this Policy;

iii) In case of any form of victimization, harassment or retaliation, the whistleblower shall report to the Director General whom shall take appropriate disciplinary action to protect the whistleblower; and

iv) The civil and criminal liability shall not be imposed against the whistleblower.

13. CONFIDENTIALITY

The information received from the whistleblower shall not be disclosed to unauthorized person. Identity of a person who made complaints or concern anonymously shall remain confidential except where required by the law.

All concerns will be treated confidentially and every effort will be made not to reveal the identity of a whistleblower if this is his/her wish. If disciplinary or other proceedings follow the investigation, it may not be possible to take action as a result of the disclosure without help, so the whistleblower may be asked to come forward as

a witness. If the whistleblower agrees to this, he/she may be offered advice and support.

14. REWARD AND COMPENSATION OF WHISTLEBLOWERS

For the purpose of promoting and facilitating reporting of wrongdoing , a whistleblower maybe rewarded or compensated. The TMDA shall set aside a budget for rewarding and compensating of whistleblowers on annual basis. The Director General shall have the discretion to determine the nature of a reward or compensation of a whistleblower depending on the complaint or concern.

15. PRELIMINARY AND FURTHER INVESTIGATIONS

The designated officer in conjunction with the Manager for Legal Services (MLS) and any other senior officer(s) appointed by the Director General will undertake or commission whatever preliminary investigations and consultations necessary to establish whether or not a further and formal enquiry should be instigated. If it is decided not to establish a formal enquiry, the whistleblower shall be informed in writing with reasons within 20 working days of receipt of the disclosure. If further investigation is deemed necessary it shall be organized by the MLS unless he/she is the subject of the disclosure in which case the Director General shall act.

The investigation may be conducted by an appointed investigator who shall lead a small group (not less than 3) of senior staff of the TMDA or an outside agency appointed by the Director General. The investigating body will report its findings to the Director General and he/she shall:-

a) Take no further action save to inform the whistleblower of the decision and reasons for it;

b) Refer the matter for appropriate action within existing TMDA procedures;

c) Refer the matter to the TMDA MAB; and

d) Refer the matter to police or other appropriate authorities in the case of alleged criminal activities.

16. INDEPENDENT REVIEW

When all internal procedures have been exhausted and the whistleblower is still dissatisfied with the outcome, may ask for the matter to be referred for independent review. The independent review shall be conducted by a person or persons appointed by the Director General or MAB.

The purpose of the independent review will be:-

a) To rule out on whether the TMDA's internal investigation has been properly handled;

b) Where it is judged that the investigation was properly handled, to rule out on whether the response to the disclosure was reasonable in all circumstances.

c) The powers of the person or persons conducting the independent review will include making binding recommendations of the following nature:
   i. Ordering a further internal investigation.

   ii. Ordering the TMDA to reconsider the findings of the investigation.

d) Additionally, there shall be power to:-

   i. make non-binding observations relating to the substantive disclosure for the institution to consider.

   ii. rule, in appropriate cases, that
   - the whistleblower was actuated by malice, or some other personal or improper motive and whether the whistleblower should be required to make a contribution to the costs incurred in external review.

   - the disclosure was without substance or merit, and whether the whistleblower should be required to make a contribution to the costs incurred in external review.

e) The independent review will not entail oral hearings, but the

reviewer will have the power to interview the whistleblower or any other persons, including those who had been involved in the handling of the disclosure. New evidence or relevant material will be considered at the discretion of the reviewer, but will normally be admitted only if it had not been reasonably available at the earlier stages of the internal investigation.

f) The report of the independent review will be submitted to the Director General or Chairman of MAB as the case may be for further action.

17. INDEPENDENT ADVICE

Independent and confidential advice may be obtained at any point in this whistleblowing processes from any appointed entity. Oversight of these procedures shall be the responsibility of the Director General who shall receive details of all cases brought under this Policy and shall make periodic reports to the MAB.

18. MONITORING AND EVALUATION

The Manager for Planning, Monitoring and Evaluation (MPME) will continuously monitor and evaluate effectiveness of this Whistleblowing Policy in order to ensure successful achievement of objectives, strategies and targets set out in the Strategic Plan. The monitoring and evaluation of the Policy will be conducted quarterly based on the annual work plan and budget. Key Performance Indicators (Table) shall be monitored and measured monthly, quarterly, mid-yearly and annually.

Table: Key Performance Indicators

S/N	Output Indicators	S/N	Outcome Indicators
	Number of IEC materials on whistleblowing developed and disseminated.		Level of general public awareness on whistleblowing Policy;
	Number of stakeholders sensitized on whistleblowing policy		Level of external and internal whistleblower satisfaction; and

	Number of whistleblower complaints and concerns received		Percentage of whistleblower complaints resolved.
	Number of whistleblower complaints and concerns attended and closed		Number and percentage of serious offenders blacklisted
	Number of investigations conducted		
	Number and time of feedbacks provided to whistleblowers		

The MPME shall write a report which shall include a summary of the concerns raised, to which section or unit they are related, the person to whom the concerns are related (if not confidential) and any lessons learned. The report shall be presented before the Management of TMDA for appropriate deliberations and decision making.

19. RECORDS RETENTION

The Director General shall retain all records and investigations relating to any complaint or concern for a period of five (5) years. All such documents should be treated as confidential and must be kept on file as part of the TMDA records.

20. BIBLIOGRAPHY

The Whistleblower and Witness Protection Act, 2015, No. 38, Vol. 96, ISSN 0856-0331X, Government Printer, Dar es Salaam, United Republic of Tanzania.

The National Board of Accountants and Auditors (2019), NBAA Whistle Blowing Policy, pp.1-11, Dodoma, United Republic of Tanzania.

Centre for Law and Democracy, (2016)., Analysis of the Whistleblower and Witness Protection Act, 2015, United States of America, www.law-democracy.org

Deloitte (2019) Whistleblower Policy, pp. 1-13, Deloitte Touche Tohmatsu, Australia

Department for Business Innovation & Skills. "Whistleblowing Guidance for Employers and Code of Practice". https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/415175/bis-15-200-whistleblowing-guidance-for-employers-and-code-of-practice.pdf (Accessed: March 16, 2020).

Insurance Regulatory Authority, (2017)., Whistleblowing Policy, Nairobi, Kenya.

MNRB Holdings Berhad. "Whistleblowing Form". https://www.mnrb.com.my/sites/default/files/Whistleblowing_E_Form.pdf (Accessed: March 16, 2020)

National Audit Office, (2014)., Government Whistleblowing Policies, United Kingdom.

Nottinghamshire Country Council. "Whistleblowing policy". https://www.nottinghamshire.gov.uk/jobs-and-working/working-for-us/whistleblowing-policy (Accessed: March 16, 2020).

Public Works and Roads – North West Provincial Government (2018)., Whistle-Blowing Policy 2018/19, Republic of South Africa.

The Global Fund, (2019)., Whistle-blowing Policy and Procedures for

the Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland.

Transparency International Kenya, (2015)., Comprehensive Legislation on Whistleblower Protection in Kenya. The URAIA Trust, Nairobi, Kenya.

U.S. Food and Drug Administration. "Medical Device Safety: Reporting Allegations Regulatory Misconduct". https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct (Accessed: March 16, 2020).

UTT Microfinance PLC, (2017)., UTT – MFI Whistle Blowing. Unit Trust of Tanzania, Dar es Salaam, Tanzania.

Annex

TMDA	WHISTLEBLOWER REPORTING FORM	TMDA/DG/ LS/F/001 Rev No: 00

Please provide the following details for any suspected serious misconduct or any breach or suspected breach of TMDA Act or regulation that may adversely impact TMDA. Please note that you may be called upon to assist in the investigation, if required.

Note: Please follow the guidelines as laid out in the Whistleblowing Policy

REPORTER'S CONTACT INFORMATION (This section may be left blank if the reporter wish to remain anonymous)	
NAME	
DESIGNATION	
DEPARTMENT/AGENCY	
CONTACT NUMBER	
E-MAIL ADDRESS	
SUSPECT'S INFORMATION	
NAME *	
DESIGNATION	
DEPARTMENT/AGENCY *	
CONTACT NUMBER	
E-MAIL ADDRESS	
WITNESSES'S INFORMATION (if any)	
NAME	
DESIGNATION	
DEPARTMENT/AGENCY	
CONTACT NUMBER	
E-MAIL ADDRESS	

COMPLAINT: Briefly describe the misconduct / improper activity and how you know about it. Specify what, who, when, where and how. If there is more than one allegation, number each allegation and use as many pages as necessary.
1. What misconduct / improper activity occurred or likely to occur?*
2. Who committed or is planning to commit the misconduct / improper activity?*
3. When did it happen and when did you notice it?*
4. Where did it or is likely to happen?*
5. Is there any evidence that you could provide us? If yes please attach
6. Are there any other parties involved other than the suspect stated above?
7. Do you have any other details or information which would assist us in the investigation?
8. Any other comments or recommendations for mitigation?

Date:	Signature:
Note: All information disclosed shall be treated confidentially In case of any form of victimization, harassment or retaliation, the whistleblower shall report to the Director General whom shall take appropriate disciplinary action to protect the whistleblower The civil and criminal liability shall not be imposed against the whistleblower Feedback shall be provided to all whistleblowers	