# TMDA

Tanzania Medicines & Medical Devices Authority

# Newsletter

Issue No: 008 | October, 2020


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Newsletter




## EDITORIAL TEAM

# Welcoming Note from the Director General

It is utterly with great honour I invite you to the 8th edition of our newsletter where you will access information on the progress attained by the Authority in protecting and promoting public health.

Just like other similar editions, this platform continues to disseminate information on milestones attained by the Authority in regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics.

Amongst others, the current edition covers report related to the appointment of the new Ministerial Advisory Board to TMDA (MAB) which will serve for three years beginning May 2020. We thank the Minister of Health, Community Development, Gender, Elderly and Children – Hon. Ummy A. Mwalimu for the appointment. The new Board Chair – Mr. Eric Shitindi and other members are congratulated and on the flip side we thank also the outgoing Board Chair Ambassador, Dr. Ben Moses and his members for completing their tenure. We wish you success and prosperity in your future engagements.

In its endeavours to deliver good quality services to its customers and ensure their satisfaction, the Authority has reviewed its Clients' Service Charter (CSC) and we unveiled the new edition (4th) at a colourful launching ceremony which was presided over by the Chief Medical Officer (CMO) on behalf of the Permanent Secretary - Ministry of Health, Community Development, Gender, Elderly and Children on 29th June 2020. The coverage of the occasion has been added in this edition.

The Authority has further invested heavily in improving regulatory services through information and communication technology. The information management system has been upgraded to integrate other services that were formerly not provided through online services portal. This has noticeably improved service delivery and reduced the turn-around time for many services offered. The newly upgraded system is now termed as Regulatory Information Management System or its acronym RIMS. The same have also been delineated in this edition.

The edition also illuminates other key items that are worth noting to include involvement of TMDA in facilitating investment in pharmaceutical and medical devices manufacturing, completion of diagnostics laboratory at TMDA, designating Mwanza laboratory for antiseptics and disinfectants testing and launching of new identification cards for inspectors. The visits made by the Permanent Secretary to TMDA offices in Mwanza as well as MAB members at Sirari boarder have also been covered. Lastly, we bid farewell to our long-serving staff who have retired and with sorrow express sadness to the demise of one of our members of staff.

It is my unequivocal hope that you will find this current edition useful, informative and that you will get time to go through.

**Enjoy your reading!**

**Adam M. Fimbo**
**Director General**

# Editorial Note

## Dear our Esteemed Reader,

**GAUDENSIA SIMWANZA**
**EDITOR**

The 8th edition of TMDA Newsletter has finally been crafted. This version has taken considerable time and energy of our staff to its current shape.

First and foremost, on behalf of the editorial team, let me begin by offering my heartfelt congratulations to Mr. Adam M. Fimbo who is the Chief Editor following his recent appointment and confirmation to become the third Director General of TMDA. I would ostensibly like to express my sincere gratitude for his dynamic leadership, tireless support and guidance throughout the refinement and approval of this edition.

As it is customary, this Newsletter had been instrumental in portraying various images in what TMDA has achieved in its mission to regulate the quality, safety and efficacy of medicines, medical devices and diagnostics. As it has also been prefaced by the Chief Editor, we always strive to use this platform to iron-out periodic milestones attained within a given reporting timeframe. In this connection, the edition covers stories and pictorials on notable occasions that TMDA had been engaged with since the last (7th) edition.

We still have a daunting task of protecting and promoting public health including most crucially reaching out to most remote areas to disseminate information on TMDA roles and responsibilities. The recent legislative amendment which resulted into change of name from TFDA to TMDA and shifting of regulatory functions for food and cosmetics to Tanzania Bureau of Standards (TBS), has prompted us to create more awareness on the changes and promulgate the new functions of TMDA which embraces regulation of medicines, medical devices and diagnostics.

Through this edition and other media platforms we will undoubtedly maintain the momentum on information sharing so that all consumers become aware of our roles, which would in-turn impact on their health and protect them from consuming poor quality, unsafe and ineffective medical products.

Above all, constructive criticism, inputs of good gesture and feedback will always be welcomed for improvement and bolstering of the forthcoming editions of this Newsletter.

As always, enjoy your reading!

# NEW TMDA BOARD INAUGURATED

The Minister of Health, Community Development, Gender, Elderly and Children, Hon. Ummy A. Mwalimu, officially inaugurated the Ministerial Advisory Board (MAB) she appointed, at a colourful ceremony held at Ministry's premises in Dodoma on 16 June, 2020.

In her remarks during the launching, the Minister directed the newly appointed Board members to effectively oversee the Authority's performance to create enabling business environment for small and medium enterprises including encouraging investment in the pharmaceutical and medical devices industry.

Ms. Mwalimu further urged the Board to ensure that TMDA performs its functions in a more facilitative manner and avoid acting as policemen.

***"I have been saying many times that TMDA should support and create conducive environment for business operations to excel and regulatory decisions should focus on ensuring sustainability in industrial and ultimately economic growth" said Hon. Ummy A. Mwalimu.***

The Minister further reiterated, despite that the main role of TMDA is to protect public health by controlling the quality, safety and efficacy of medicines, medical devices and diagnostics, measures must deliberately be taken to minimise fees and charges.

Forging cooperation and working in close collaboration with the parent Ministry were added directives to the newly appointed Board. Other key issues that the new MAB is compelled to oversee embraces – setting up strategic plans, highlighting priorities and measuring performance and ensuring the mission and vision of TMDA are attained.

***"The new Board is also entitled to review and verify TMDA audited CAG and IAG reports," Ms. Ummy A. Mwalimu.***

The Minister finally urged the new MAB members to relook into salaries, promotions and other employment benefits for TMDA employees to safeguard their social welfare and well-being.

***"Let me assure you that the Health Ministry will closely cooperate with you and ensure that TMDA is on the right track," Ms Ummy A. Mwalimu.***


On the flip side, Minister Ummy A. Mwalimu commended the outgoing Board which was under the chairmanship of Ambassador Dr. Ben Moses for notable achievements registered during their tenure.

Some of these achievements highlighted were abolition of more than 20 categories of fees and charges on services rendered by TMDA that has consequently reduced burden to manufactures, traders and more importantly consumers.

She further cited other milestones to include attaining Maturity Level 3 status of the World Health Organization (WHO) as one of the regulatory authorities with best systems for regulation of medicines, medical devices and diagnostics in Africa; certification of management systems to ISO 9001:2015 standards since 2009; accreditation and prequalification of TMDA Laboratory to ISO/IEC 17025:2015 standards; establishment of eight zone offices and construction of new office and laboratory in Mwanza.

MAB is responsible for advising the Minister for health on matters pertaining to TMDA's strategic and overarching matters. The Board is established pursuant to the Tanzania Medicines and Medical Devices Act, Cap. 219 and the Executive Agencies Act, Cap. 245.

The MAB was appointed on 12th May 2020 and will serve for a period of three years. The current membership comprises of seven members and Mr. Eric Shitindi is the appointed chairperson. Other Members include Prof. Said Aboud, Prof. Appolinary Kamuhabwa, Mr. Mick Kiliba, CPA Zaina Thabit and Mr. Daudi Msasi. The Director General of TMDA (Mr. Adam M. Fimbo) serves as the Secretary to the Board.

# PERMANENT SECRETARY VISITS TMDA MWANZA LABORATORY

On 16th September 2020, the Honorable Permanent Secretary, Ministry of Health, Community Development, Gender, Elderly and Children responsible for health matters - Prof. Mabula Daudi Mchembe, visited the TMDA Mwanza Laboratory for the first time.

During this visitation, Prof. Mchembe who was accompanied by members of Ministerial Advisory Board (MAB) and the TMDA Management, commended the Authority for setting up the state of the art office infrastructure to serve the people residing in the lake zone. As he was escorted in the tour of the office he also had time to visit the laboratory located in the same building.

The PS was particularly impressed with the laboratory including the major and minor equipment installed for testing of various products. He was nevertheless, baffled by the fact that such equipment were not utilized as required.

***"I direct the Management to craft a comprehensive plan to create awareness on the existence of this laboratory so that it can be known and the modern equipment available used effectively", he instructed.***

He went on by alluding that, "With the equipment available in this laboratory you can run various tests to embrace for instance determination of heavy metals in fish products from Lake Victoria, detection of cyanide in water systems, autoclaving of used hospital garments etc ", lamented Prof. Mchembe.

The Regional Medical Officer who was in attendance during the tour further pleaded to the Authority to consider his request to utilize the autoclaving machine which according to him was not functioning in the regional hospital in Mwanza.

The PS further urged laboratory experts to make better use of the laboratory by conducting research on resistance to drugs and toxicity profiles in regulated products to protect public health.

***"I look forward to witnessing TMDA being engaged in research on drug resistance to allow for treatment policy changes in clinical practice" Prof. Mchembe***

In his remarks when speaking to a group of TMDA staff working at the zone office, the Permanent Secretary, further directed the Management to strengthen enforcement and be facilitative in service delivery to customers.

The TMDA Director General, Mr. Adam M. Fimbo, before welcoming the PS to speak to staff, briefed that the Mwanza Laboratory is subdivided into two (2) main sections - Medicines Chemical Laboratory and Microbiology Laboratory and that they are responsible for conducting chemical and microbiological analyses respectively.

***"The Mwanza TMDA Laboratory is one of the State of the Art Laboratories equipped with modern equipment for testing the quality of medicines, medical devices and diagnostics. The laboratory assists TMDA in making regulatory decisions based on science and the same has been instrumental in detecting substandard and falsified products found in the Lake Zone in many occasions". Mr. Fimbo.***

While thanking the PS for paying a courtesy call, the Chairman of MAB, Mr. Eric Shitindi, nodded the directives issued and promised the PS to ensure effective implementation of the same.

# MAB VISITS SIRARI PORT OF ENTRY

On 14th September, 2020 members of the Ministerial Advisory Board (MAB) visited Sirari Port of Entry in Mara region prior to their scheduled Board meeting in Mwanza.

The visitation was led by the MAB Chair - Mr. Eric Shitindi who accompanied other board members for this familiarization mission. Sirari is one of the 15 ports of entry in the country which have been authorized by TMDA to allow entry into the country for medicines, medical devices and diagnostics.

During the visit, MAB members were pleased with TMDA Management's commitment in setting up an import and export control system at this one stop border post (OSBP). Members had a chance to walk around and briefed on the functions and challenges facing staff at this port.

In his remarks, Sirari Drug Inspector, Mr. Frank Mhini illuminated that there had been significant bump in imports at the port as compared to year 2019 as an estimated 120 consignments were authorized for entry between January and August, 2020.

Addressing port staff who welcomed MAB members at the port, the MAB chair, Mr. Shitindi hailed the cooperation amongst government institutions at the port which included the Tanzania Ports Authority (TPA), Tanzania Revenues Authority (TRA), Government Chemist Laboratory Agency (GCLA), Tanzania Bureau of Standards (TBS), Tanzania Atomic Energy Agency (TAEC), Tanzania Shipping Agencies Corporation (TASAC), Tanzania Plant Health (TPH), Port Health Authority, Immigration and Police Force Unit.

Mr. Shitindi urged port staff to continue maintaining the good co-operation, observed including adhering to code of conduct, work ethics and prioritizing the broader interests of the nation in day-to-day port operations.

The Board further pledged to address the challenges of staff shortage, border patrols and others as presented by port staff.

Mr. Shitindi urged port staff to continue maintaining the good co-operation, observed including adhering to code of conduct, work ethics and prioritizing the broader interests of the nation in day-to-day port operations.

# 4TH EDITION OF THE CLIENTS' SERVICE CHARTER LAUNCHED

On 29th June 2020, TMDA launched its fourth edition of the Clients' Service Charter (CSC). The Charter is a commitment to offer services within the timeline as agreed by customers. CSC outlines services and standards to clients and help strengthening the relationship between TMDA and its esteemed stakeholders.

The launching ceremony was graced by the Chief Medical Officer (CMO), Prof. Abel Makubi, who on behalf of the Ministry of Health, Community Development, Gender, Elderly and Children commended TMDA for introducing CSC. The event was occasioned at TMDA Conference hall, Ubungo External, Mabibo area in Dar es Salaam.

***"Let me take this opportunity to congratulate TMDA for making this happening. But let me also urge you to monitor the Charter and make sure that all key aspects indicated are effectively implemented," Prof Makubi lamented.***

The revised Charter amongst other items, highlights What TMDA does; Client's basic rights; Client's responsibilities; How to communicate with TMDA; and How to present comments or complaints as well as mechanism for submission of reports, remarks and suggestions on TMDA activities.

Culminating his speech at the occasion, Prof. Makubi further underpinned the government's commitment in supporting TMDA operations and facilitating TMDA's strategic plans implementation.

On his part, TMDA Director General, Mr. Adam M. Fimbo, pleaded to the Chief Guest that TMDA was determined to continue providing quality services to its clients.

He further urged other government entities and institutions to reciprocate TMDA's ambitions in order to ensure that clients have access to quality services in a timely manner as this will uphold productivity.

***"It is our desire to provide high quality services to our clients by involving competent and dedicated staff in service delivery and being honest to clients and institution," TMDA Director General Mr. Adam M. Fimbo.***

Mr. Fimbo also raised optimism by alluding that the newly launched Charter would help TMDA to measure and evaluate the services delivered to clients and make improvements whenever necessary.

***"The Charter will help to improve work ethic, discipline and responsibility to service delivery," Mr. Fimbo.***

The monitoring and evaluation tool will be developed to measure performance of the Charter so as to ensure good quality service delivery and ultimately customer satisfaction.

TMDA Director General, Mr. Fimbo, also reiterated TMDA's commitment to provide correct and timely information to clients and the public at large on regulated products.

***"We will work to ensure that the quality of service delivery meet our client's expectations in line with the existing laws, regulations and guidelines" - Mr. Fimbo.***

Since the first edition, TMDA had been revising its subsequent editions of the CSC for the purpose of measuring service delivery, determining customer satisfaction and re-engineering its processes to meet these objectives.

# APPOINTMENT AND CONFIRMATION OF NEW DIRECTOR GENERAL

**Adam M. Fimbo**
**Director General**

The Minister for Health, Community Development, Gender, Elderly and Children, Hon. Ummy A. Mwalimu, has appointed and confirmed Mr. Adam Mitangu Fimbo to be the 3rd TMDA Director General from 23rd September, 2020.

Before this new appointment, he was the Acting Director General since 24th October 2018 following his predecessor Mr. Hiiti B. Sillo who had joined the World Health Organization (WHO).

Mr. Fimbo is a pharmacist by profession, holding a MSc. Degree in Clinical Trials from the University of London-U.K and MSc in Pharmaceutical Services and Medicines Control from the University of Bradford-U.K. He attained his Bachelor degree of Pharmacy at the Muhimbili University of Health and Allied Sciences.

Prior to this new position, he was the Director of Medicines and Cosmetics at the then Tanzania Food and Drugs Authority (TFDA) between 2010 and 2018.

The newly appointed Director General has an experience of over 15 years in management and leadership with regard to regulatory affairs. He has also served as Secretary in various Technical Committees including a Committee for Registration of Human and Veterinary Medicines; Pharmacovigilance and Clinical trials.

After his Bachelor degree studies, Mr. Fimbo joined TFDA in 2003 as a Drug Registration Officer and he has worked in various positions including being the Head of Department of Pharmacovigilance and Clinical Trials.

The TMDA Management and Staff congratulates Mr. Fimbo and wishes him all the best in discharging his duties as the Director General.

# NEW INSPECTOR'S ID CARDS INTRODUCED BY TMDA

"Inspectors play a big role in protecting public health, it is you who ensures good quality, safe and **efficacious products** circulate on the market for ongoing public consumption" Prof. Mchembe stressed.

On 16th September 2020 the Permanent Secretary – Ministry of Health, Community Development, Gender, Elderly and Children responsible for health - Prof. Mabula Daudi Mchembe stepped up to the podium and inaugurated the new Identity Cards (ID) to be used by inspectors when inspecting medicines, medical devices and diagnostics in the country.

The colorful inauguration event took place at TMDA conference hall in Mwanza and was witnessed by members of the Ministerial Advisory Board (MAB), Mwanza Regional Medical Officer, inspectors from various Councils in the Lake Zone, TMDA Management team and staff.

Speaking during the occasion, Prof. Mchembe directed inspectors to adhere to their codes of conduct and ethics while discharging their duties. "Inspection of medical products needs serious attention and if not properly managed it would inadvertently tarnish a good image of the government with serious repercussions to the community" he underscored.

***"Inspectors play a big role in protecting public health, it is you who ensures good quality, safe and efficacious products circulate on the market for ongoing public consumption" Prof. Mchembe stressed.***

The TMDA Director General, Mr. Adam M. Fimbo who spoke before inviting the chief guest, alluded that the design and introduction of revised IDs was compelled by reported malpractices whereby fake inspectors had been forging the existing cards and pose as real inspectors during inspection activities throughout the country for monetary gain. The new cards have been encoded with security features to impede any falsification by unscrupulous individuals.

While delivering thanks giving remarks, the Chairman of MAB, Mr. Eric Shitindi, assured the Guest of Honor that the Board will continue to effectively monitor the use of these cards including advising the Ministry on good inspection practices to protect public health.

About 524 cards were launched and these have been circulated to all inspectors across the country. Inspectors are from TMDA and Councils whom have been gazetted in Government Gazette as required by the Tanzania Medicines and Medical Devices Act, Cap 219.

# TMDA ENGAGEMENT IN PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRIAL DEVELOPMENT

In supporting government's drive towards industrialized economy, the Tanzania Medicines and Medical Devices Authority (TMDA) had been on the forefront to facilitate investment in pharmaceutical and medical devices manufacturing. In the past five years, TMDA has been providing technical support to investors who sought to set up factories in Tanzania.

***"The TMDA has offered technical support which led to setting up of 16 industries in the country," part of the statement issued by the Director General, Mr. Adam M. Fimbo".***

The gesture has also been acknowledged by the Minister for Health, Community Development, Gender and Elderly, Ms Ummy A. Mwalimu, who commended on the efforts while inaugurating the newly appointed Ministerial Advisory Board to TMDA (MAB).

***"The TMDA should focus and be part of the industrialization agenda currently being promulgated by the government. You should endeavor that whatever you do relate to or contributes towards industrial growth" Ms. Ummy stated. "Refrain from hunting, especially of small and medium scale enterprises, instead, nurture them so that they can grow and hike investment."***

On the other hand, Honorable Minister hailed the Director General – Mr. Adam M. Fimbo and staff for their dedication and commitment in supporting pharmaceutical and medical devices manufacturing investment in the country.

***"The Management and staff have made tremendous efforts in supporting the industry as I have been informed that you have been visiting construction sites on regular basis and offer your advice and technical guidance on complying with Good Manufacturing Practices" she lamented.***

Manufacturers intending to establish new manufacturing facilities are required to submit architectural drawings and other details as provided for in the guiding documents issued from time to time by TMDA. Approvals from NEMC, BRELA and TIC are prerequisites when contemplating to invest in this field and need also to be submitted.

TMDA puts much emphasis on compliance with Good Manufacturing Practices as it is through this that medicines of assured quality, safe and efficacious will be manufactured and consumed by the public.

As of October 2020, 17 factories are at different stages of construction. For some of these, construction has been completed and manufacturing operations commissioned. Different dosage forms to include oral solids, oral liquids, large and small volume parenterals, dry powders for suspension, creams and ointments are or will be manufactured. Most of these factories are built in Dar es Salaam and Coast regions and few in Morogoro and Arusha regions.

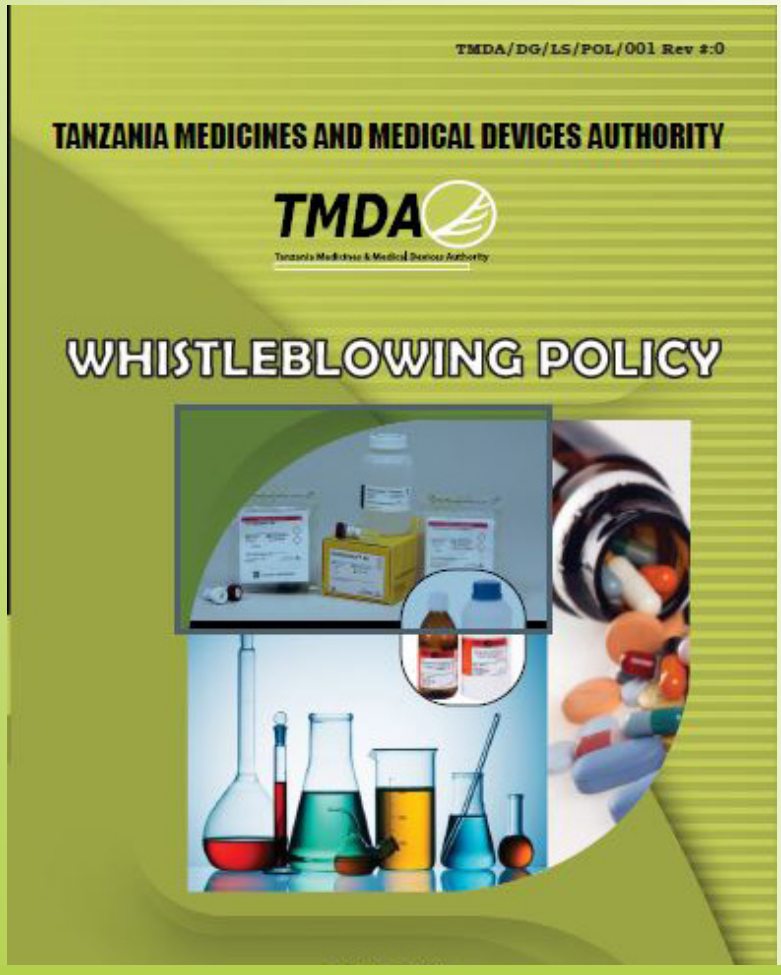
Adding up to 14 existing factories, Tanzania will soon register a total of 31 pharmaceutical and medical devices manufacturing facilities. This is a great achievement in terms of expanding employment opportunities, per capita increase and overall economic growth.

# TMDA APPROVES WHISTLEBLOWING POLICY

The Tanzania Medicines and Medical Devices Authority (TMDA) has approved the Whistleblowing Policy for the purpose of inviting and encouraging stakeholders to report any malpractice concerning safety, quality and effectiveness of medicines, medical devices and diagnostics.

The TMDA Director General, Mr. Adam Fimbo, revealed that 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" he said.

Mr. Fimbo explained, the Authority has decided to craft its Whistleblowing Policy so as to streamline the information receiving and feedback system and to comply with the Whistleblower and Witness Protection Act, of 2015. "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" he said.




Mr. Fimbo assured all whistleblowers that, they will be protected and their identity to or any **sort of confidentiality** maintained at all times due to possible retaliation, harassment or victimization.

The DG went on by saying that, "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".

Mr. Fimbo assured all whistleblowers that, they will be protected and their identity to or any sort of confidentiality maintained at all times due to possible retaliation, harassment or victimization.

TMDA pledges to set adequate resources for effective implementation of this Policy including protecting all whistleblowers as delineated in the document approved. TMDA stakeholders including internal staff are urged to read what has been outlined in the Policy document and provide notification (blow the whistle) in case of any wrongdoing.


# COMPLETION OF CONSTRUCTION OF A NEW LABORATORY FOR TESTING DIAGNOSTICS

**This New Laboratory has been built to expand the capacity of TMDA to specifically analyze the quality of diagnostics. Availability of diagnostics of acceptable quality, safe and that are effective in performing tests is of supreme importance to ensure the public is protected against the use of substandard, falsified and non-performing products.**

Regulation of quality, safety and performance of diagnostics is mandated under the Tanzania Medicines and Medical Devices Act, Cap 219. Diagnostics refers to devices whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes. Diagnostics include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used for example for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

As part of vigilance and surveillance role on quality and safety of diagnostics, the TMDA by using internally generated resources has completed the construction of the New Laboratory which will be dedicated for analytical testing of diagnostics. The laboratory is based in Dar es Salaam within the already existing TMDA Main Laboratory building.

This New Laboratory has been built to expand the capacity of TMDA to specifically analyze the quality of diagnostics. Availability of diagnostics of acceptable quality, safe and that are effective in performing tests is of supreme importance to ensure the public is protected against the use of substandard, falsified and non-performing products.

While the New Laboratory will concentrate on testing diagnostics including those sampled through Post Marketing Surveillance programme, registration or marketing authorization will continue. Information gathered during pre-marketing phase is not sufficient to justify quality, safety and performance of diagnostics circulating on the market as new batches are introduced on routine basis.

The TMDA is currently procuring equipment, chemicals, reagents and standards for this laboratory. Equipment like Real Time PCR, Microscopes, Biosafety Cabinets and Vaccum Concentrators have been ordered awaiting delivery. Plans are to begin by testing the performance of mRDTs, HIV test kits, UPTs and other simple common diagnostics.

Our esteemed customers, the general public and other stakeholders will officially be informed through our website and other means of communication when this laboratory will be fully operational.

# PICTORIALS


*Director General of TMDA, Mr. Adam Fimbo elaborating on rational use of medicines, medical devices and diagnostics to stakeholders who visited the TMDA pavilion during the 44th Dar es Salaam International Trade Fair (Sabasaba).*

*The Minister of Health, Community Development, Gender, Elderly and Children, Hon. Ummy Mwalimu (MP), seated at the centre in a group photo with the newly appointed members of the Ministerial Advisory Board (MAB) for TMDA and the Management following its inauguration on 17th June, 2020 in Dodoma.*

*A group photo of participants who attended the training on Cohort Event Monitoring of Dolutegravir (DTG) at TMDA Conference Hall in Dar es Salaam from 28th-29th September, 2020. The training was attended by healthcare providers from 21 Care and Treatment Centres (CTC) from 8 regions of Tanzania.*


*A team of the TMDA Southern Highlands zone staff led the Acting Zonal Manager Mrs. Anitha Mshigati providing education on the roles of TMDA, the proper use of medicines and medical devices as well as how to report Adverse Drug Reactions to students and teachers of Loleza Girls High School in Mbeya on 09th October, 2020.*

*Director General of TMDA, Mr. Adam Fimbo, handing over drawings of the Central Zone office building to the Contractor, National Housing Corporation (NHC), Engineer Haikamen Mlekio in a brief ceremony which was attended by Ms. Neema Mbwambo a Consultant from Ardhi University and other stakeholders including TMDA staff on 12th April 2020*


*TMDA Manager for Communication and Public Education, Ms. Gaudensia Simwanza, hands over 100 cartons of sanitary pads and baby diapers to Segerea Prison Ward representatives as part of corporate social responsibility on 13th July 2020.*

# PICTORIALS


*TMDA Northern Zone Acting Manager, Mr. Proches Patrick, elaborationg on rational use of medicines and medical devices to some students who visited the TMDA pavillion during then Nane Nane Exhibitions from 01st to 08th August, 2020.*


*The Deputy Minister for Health, Community Development, Gender, Elderly and Children, Dr. Godwin Mollel (fourth right), in a group photo with TMDA Lake Zone Staff during the official visit at TMDA Zone Offices in Mwanza*

*TMDA Southern Zone Manager, Dr. Englebert Bilashoboka, presenting TMDA documents to Kilwa's District Executive Director, Mr. Renatus Mchau, on 11th September, 2020.*

*TMDA Western Zone Manager, Dr. Edgar Mahundi, presenting TMDA documents to Kigoma's Regional Commisioner, CP. Thobias Andengenye, on 13th October,2020.*

# PICTORIALS


*Mr. James Ndege, Senior Information and Education Officer from TMDA, elaborating on the drawings painted on TMDA vehicle to farmers who attended the Nanenane Exhibitions held between 1st and 8th August, 2020 in Nyakabindi Grounds, Simiyu*

*A member of TMDA Workers Council, Mr. Moses Magoma stressing a point when contributing to an agenda during a meeting that was held from 3rd to 4th September, 2020 in Morogoro. TMDA Workers Council meets biannually to discuss matters related to employees.*


*The joyful TMDA staff holding the trophy that was awarded to the Authority after emerging the first run up winner at the 15th Mwanza East African Trade Fair held between 28th August and 5th September, 2020. The trophy was presented to TMDA by the Permanent Secretary from the Ministry of Industry and Trade, Prof. Riziki Shemdoe during the opening ceremony that was held in Mwanza on 1st September, 2020*

*TMDA has been encouraging its staff to participate in sports and physical exercise activities to improve mental and physical health and also as one of the ways to reduce non communicable diseases. TMDA EZ striker (right), Mr. Geofrey Mwendo fighting for the ball against TMDA HQ player (left), Dr. Alex Nkayamba in a friendly match that was held at Mabibo Hostel grounds on 03rd October, 2020.*

*The Director General of TMDA, Mr. Adam Fimbo, listening to staff (not in picture) during an ordinary meeting held on 25th September, 2020 at Eastern Zone Office based in Dar es Salaam*

*Journalists (Standing) and TMDA staff posing for a group photo with the guest of honour Mr. Anza Ndossa the Morogoro Regional Assistant Administrative Secretary (seated in the middle) at the Joint Editors and Journalists sensitization meeting held in Morogoro on 28 to 29th July 2020*

# REMDESIVIR USE FOR COVID-19: PANIC IN THE SOCIAL MEDIA

Upon expiration of the patent; which is usually between 10 to 20 years depending on the Intellectual Property Rights and laws governing the respective countries, other companies will take part in the marketing and distribution of this drug for the treatment of COVID-19.

Social media had been flocking with coverage of posts related to the use of the branded medicinal products containing active ingredient commonly known as Remdesivir in recent time. According to a statement issued by TMDA Director General, Mr. Adam Fimbo the medicines containing this active ingredient marketed by the brand names "Covifor "and "Jubi-R" are manufactured in India by Hetero Labs Limited and Jubilant Generics Limited respectively.

The statement further revealed that these injectable products are in packages whose labels indicate that they are not allowed to be distributed in the United States, Canada and the European Union. The labels also contain the words "Not for distribution in US, Canada and EU" which have raised concerns as to whether or not the medicines distributed in other parts of the world are unsafe or sub-standard, and unsuitable for human consumption.

Mr. Fimbo clarified that the use of such words in labelling is a common practice in the pharmaceutical sector and it has been used purposely to prevent distribution of the medicines in the United States, Canada and the European Union where Remdesivir has been granted patent.

Remdesivir was first discovered by Gilead Limited which is a company based in the United States of America and the product is currently authorized for use by the Food and Drug Administration (US-FDA) for the treatment of COVID-19 disease under Emergency Use Authorization (EUA) procedure.

Emergency Use Procedure (EUA) is used by the US-FDA for the approval of medicines which are still undergoing clinical trials and awaiting official approval for human use

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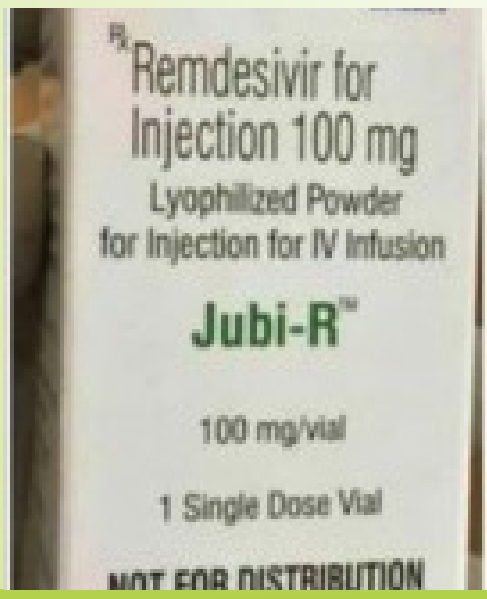



# REMDESIVIR USE FOR COVID-19: PANIC IN THE SOCIAL MEDIA

*CONTINUED FROM PAGE 16*

in order to treat or prevent rapid and highly contagious diseases with no alternative medication such as COVID-19, Ebola and others.

Meanwhile, Covifor and Jubi-R are manufactured by the two Indian companies after being granted special permit by Gilead Limited to manufacture generic versions so they can be distributed to other countries (a total of 127 thus far) globally in accordance with the agreement excluding the United States, Canada and countries in the European Union.

The exclusion of the countries in the agreement requires description of the terms in the label of products that are manufactured for sale in other countries other than the United States, Canada and countries in the European Union.

Upon expiration of the patent; which is usually between 10 to 20 years depending on the Intellectual Property Rights and laws governing the respective countries, other companies will take part in the marketing and distribution of this drug for the treatment of COVID-19.

Mr. Fimbo, insisted that, the medicinal products named Covifor and Jubi-R are nevertheless, not yet registered by TMDA for use in the country. However, Mr. Fimbo has called upon members of the public and stakeholders to seek information regarding quality and safety of products regulated by the Authority through its Headquarter Offices or Zone Offices located in Dodoma, Mwanza, Tabora, Mbeya, Arusha, Mtwara and Dar es Salaam.

Upon expiration of the patent; which is usually between 10 to 20 years depending on the Intellectual Property Rights and laws governing the respective countries, other companies will take part in the marketing and distribution of this drug for the treatment of COVID-19.

# MWANZA LABORATORY DESIGNATED FOR TESTING ANTISEPTICS AND DISINFECTANTS

He said, the laboratory **will enhance scientific and** regulatory decision making and offer services to many other TMDA stakeholders including small and medium size manufacturers, researchers, academicians, students, healthcare workers and others in demand of testing their antiseptics and disinfectants for quality assurance.

TMDA has designated its newly established Mwanza laboratory for testing antiseptics and disinfectants. Speaking on the Authority's plans in attaining this milestone, the Director of Laboratory Services, Dr. Danstan Hipolite Shewiyo, alluded that the designing, equipment acquisition, laboratory staff training, method development and validation have all been finalized and the launching of the laboratory is expected to be in December 2020.

***"Progress made so far embraces machine qualification, training of staff, method development and procurement of reagents, consumables and standards before kick starting" Dr. Danstan.***

Dr. Shewiyo further expressed that, according to the initial design, the Laboratory will be subdivided into Microbiology and Chemistry sections. The TMDA Mwanza Laboratory is already equipped with other modern and state of the art equipment for testing other products.

He said, the laboratory will enhance scientific and regulatory decision making and offer services to many other TMDA stakeholders including small and medium size manufacturers, researchers, academicians, students, healthcare workers and others in demand of testing their antiseptics and disinfectants for quality assurance.

As a means of protecting and promoting public health, Tanzania is scaling up prevention, care and treatment of those suffering from various infections and this compels the need for high quality and efficacious antiseptics and disinfectants.

The designation of such a laboratory is yet another landmark set by the Authority in its efforts to expand accessibility to reliable laboratory services in the country.

Above all, TMDA will continue to strengthen its laboratory capacity to support evidence based regulatory decision in relation to the quality, safety and effectiveness of antiseptics, disinfectants and other regulated products.

# TMDA Website Viewers Surpasses 50,000

The recent improvements and modifications in terms of content and design of the TMDA website have significantly attracted more viewers with most importantly positive feedback. In one year time lapse, between August 2019 and August 2020, the TMDA website has attracted more than 50,000 viewers.

The website is a One Stop Information Center utilized by the Authority to communicate and connect with its customers and stakeholders. It also acts as an interface for customers to access TMDA services which have currently been automated.

Earlier, in May 2020, the TMDA website which operates under the E-government Agency guidelines was updated to accommodate the latest regulatory changes as well as the newly introduced online systems for various TMDA services.

Moreover, these reinforcements have also focused on setting up a navigation system for counting viewers who visits the website on daily, monthly and weekly bases including cumulatively. This system helps the Authority to monitor and count the number of viewers or customers who access our website.

The addition and arrangement of drop-downs with clear links which are familiar with those dealing with regulatory functions to include medicines, medical devices and diagnostics, clinical trials and vigilance, laboratory services and zone offices have enabled quick access and timely retrieval of information.

Nevertheless, despite the improvements the TMDA will continue to update its website to keep up with the rampant technological advancements including changes in the regulatory environment for medicines, medical devices and diagnostics.

Inspite of the website, the Authority has conversely subscribed to other social media platforms to include facebook, instagram and tweeter to reach out to its customers. The same are updated on regular basis and we urge the public to follow us through these alternative means of communication.

Nevertheless, despite the improvements the TMDA will continue to update its website to keep up with the rampant technological advancements including changes in the regulatory environment for medicines, medical devices and diagnostics.

# OVER 12,000 IMPORT AND EXPORT PERMITS HAVE BEEN ISSUED IN 2019

TMDA has approved a total of 12,137 import and export permits cumulatively in the period of 2019/20 equivalent to an exponential increase of 1,085 permits compared to previous year 2018/19.

According to the 2019/20 progress report issued by the Director General, Mr. Adam M. Fimbo, the upsurge in numbers has been attributed to hand-working, commitment and improved service delivery.

In this connection, Mr. Fimbo revealed that, TMDA had installed an electronic system for import and export applications that was developed to streamline processes and bolster efficiency.

***"This upward trend in number of permits issued clearly denotes that the newly introduced electronic system for import applications has spruced up efficiency and now customers can access and print permits straight from the system without physically visiting TMDA offices." Director General reported.***

The IT solution has reduced the turnaround time for issuing permits and now import permits are issued within 24 hours for products that have been registered or meet TMDA requirements.

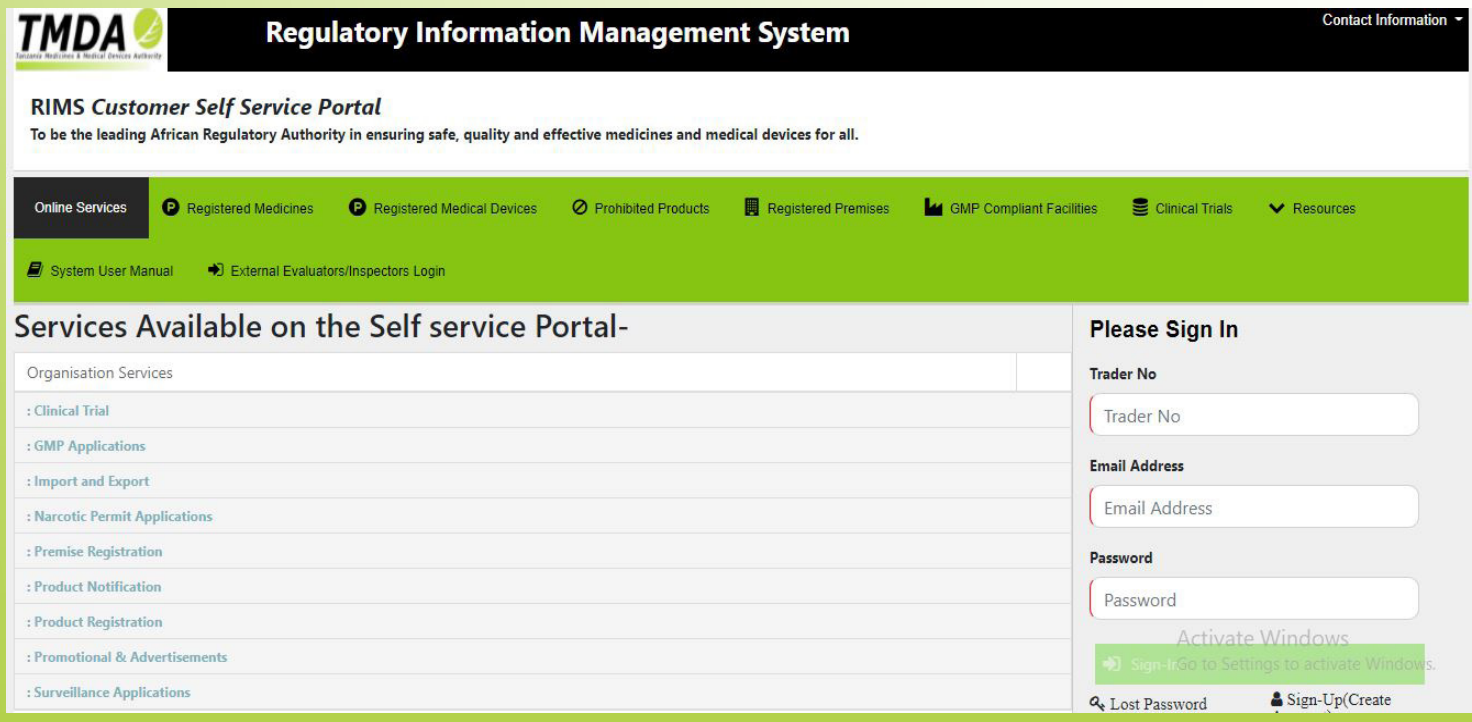
The electronic system has also reduced the TMDA staff and customer interaction and therefore any sorts of collusion have been minimized to a greater extent.

One of the TMDA's responsibilities in the regulation of medicines, medical devices and diagnostics is to control importation and exportation of medical products. The process entails issuance of import and export permits to any consignment, inspection at ports of entry and laboratory analysis of the product samples prior to shipment.

According to the Tanzania Medicines and Medical Devices Act, Cap 219, any person intending to import or export products regulated by TMDA, whether a company, a business entity or an individual must obtain a permit issued by TMDA.

According to the Tanzania Medicines and Medical Devices Act, Cap 219, any person intending to import or export products regulated by TMDA, whether a company, a business entity or an individual must obtain a permit issued by TMDA.

Apart from installation of the electronic import and export system, the Authority has also strengthened inspection at ports of entry by stationing adequate inspectors, deploying Minilab kits for sample testing and supplying enough ICT equipment. This has enabled the Authority to curb importation of substandard and falsified medicines, medical devices and diagnostics in the country.



# 88% of Customers are Satisfied with TMDA Services

The tool has enabled the Authority to critically assess its service delivery mechanisms including pragmatically measuring at a quick glance, customer satisfaction levels.

Between May and September 2020, 88% of customers have responded that they were satisafied with services offered by TMDA. This finding came through a mini survey introduced by TMDA to capture on daily basis, information on customer satisfaction levels once they visit TMDA offices. The survey is done through special exit interview forms (both in english and swahili) which have been simplified to accrue data on customer satisfaction levels.

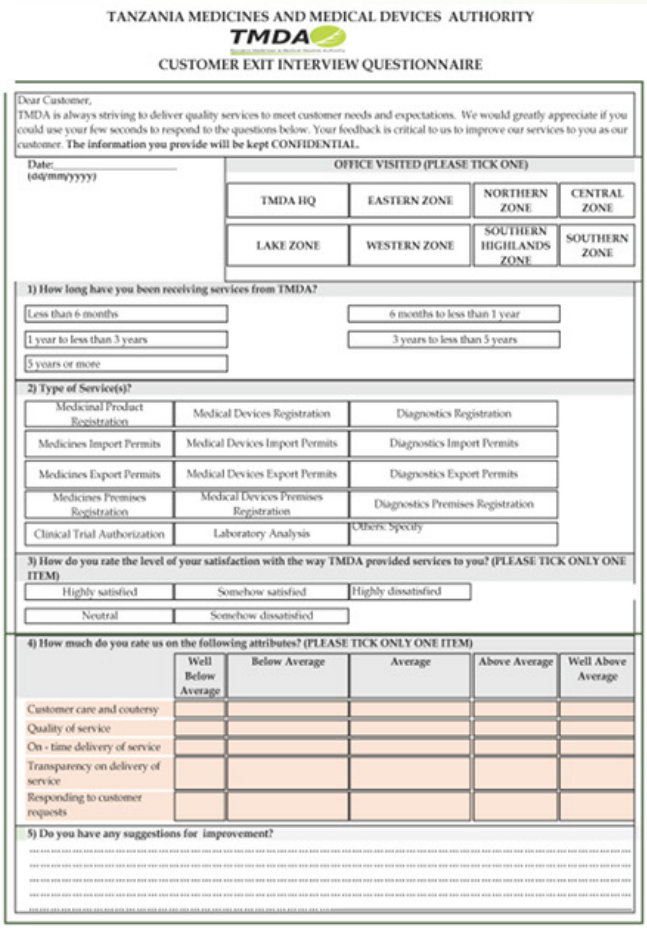
A total of 134 customers filled out the forms which were stationed at headquarter and zone offices and responses rated using the five Likert scale system. Customers were sensitized and requested to fill in the forms before disembarking TMDA premises.

The designated forms provides an avenue for customers to rate the quality of service offered including time spent, accesibility, convenience and staff conduct while delivering service. The forms further provides a room for customers to share opinions or suggestions on improvement of services.

Upon receiving the filled in forms, the Authority analyses the responses and issues feedback to customers through this Newsletter and other dissemination platforms.

The tool has enabled the Authority to critically assess its service delivery mechanisms including pragmatically measuring at a quick glance, customer satisfaction levels.

The TMDA will continue to conduct such mini surveys as they have proven to be effective in determining the needs and expectations of customers.



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

CUSTOMER EXIT INTERVIEW QUESTIONNAIRE

Dear Customer,

TMDA is always striving to deliver quality services to meet customer needs and expectations. We would greatly appreciate if you could use your few seconds to respond to the questions below. Your feedback is critical to us to improve our services to you as our customer. **The information you provide will be kept CONFIDENTIAL.**

Date:_____ (dd/mm/yyyy)

OFFICE VISITED (PLEASE TICK ONE)

| | | | |
|---|---|---|---|
| TMDA HQ | EASTERN ZONE | NORTHERN ZONE | CENTRAL ZONE |
| LAKE ZONE | WESTERN ZONE | SOUTHERN HIGHLANDS ZONE | SOUTHERN ZONE |

**1) How long have you been receiving services from TMDA?**

| | |
|---|---|
| Less than 6 months | 6 months to less than 1 year |
| 1 year to less than 3 years | 3 years to less than 5 years |
| 5 years or more | |

**2) Type of Service(s)?**

| | | |
|---|---|---|
| Medicinal Product Registration | Medical Devices Registration | Diagnostics Registration |
| Medicines Import Permits | Medical Devices Import Permits | Diagnostics Import Permits |
| Medicines Export Permits | Medical Devices Export Permits | Diagnostics Export Permits |
| Medicines Premises Registration | Medical Devices Premises Registration | Diagnostics Premises Registration |
| Clinical Trial Authorization | Laboratory Analysis | Others. Specify |

**3) How do you rate the level of your satisfaction with the way TMDA provided services to you? (PLEASE TICK ONLY ONE ITEM)**

| | | |
|---|---|---|
| Highly satisfied | Somehow satisfied | Highly dissatisfied |
| Neutral | Somehow dissatisfied | |

**4) How much do you rate us on the following attributes? (PLEASE TICK ONLY ONE ITEM)**

| | Well Below Average | Below Average | Average | Above Average | Well Above Average |
|---|---|---|---|---|---|
| Customer care and courtesy | | | | | |
| Quality of service | | | | | |
| On - time delivery of service | | | | | |
| Transparency on delivery of service | | | | | |
| Responding to customer requests | | | | | |

**5) Do you have any suggestions for improvement?**

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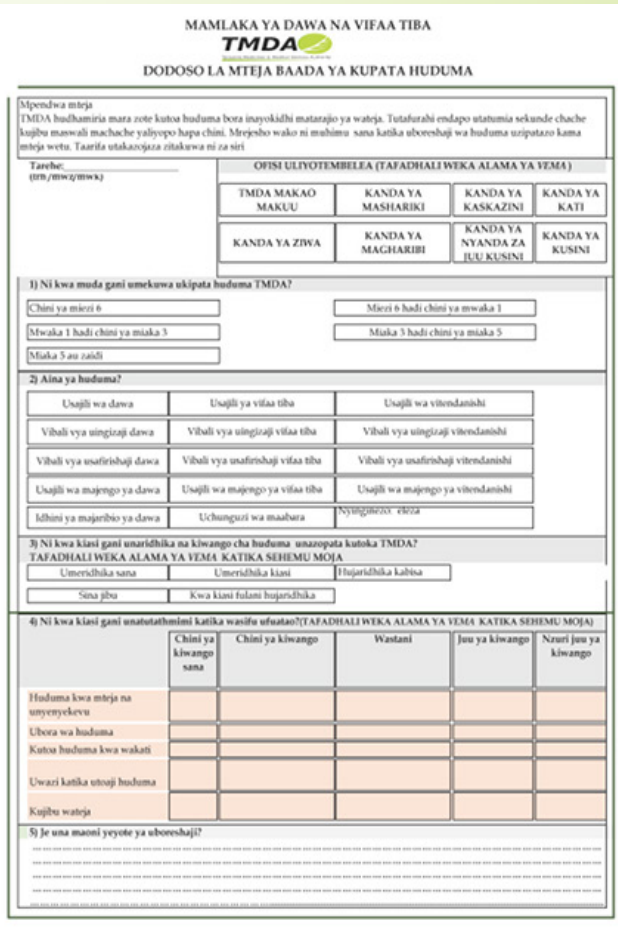

MAMLAKA YA DAWA NA VIFAA TIBA

TMDA

DODOSO LA MTEJA BAADA YA KUPATA HUDUMA

Mpendwa mteja

TMDA hudhamiria mara zote kutoa huduma bora inayokidhi matarajio ya wateja. Tutafurahi endapo utatumia sekunde chache kujibu maswali machache yaliyopo hapa chini. Mrejesho wako ni muhimu sana katika uboreshaji wa huduma uzipatazo kama mteja wetu. Taarifa utakazojaza zitakuwa ni za siri

Tarehe:_____ (dd/mm/yyyy)

OFISI ULIYOTEMBELEA (TAFADHALI WEKA ALAMA YA *VEMA*)

| | | | |
|---|---|---|---|
| TMDA MAKAO MAKUU | KANDA YA MASHARIKI | KANDA YA KASKAZINI | KANDA YA KATI |
| KANDA YA ZIWA | KANDA YA MAGHARIBI | KANDA YA NYANDA ZA JUU KUSINI | KANDA YA KUSINI |

**1) Ni kwa muda gani umekuwa ukipata huduma TMDA?**

| | |
|---|---|
| Chini ya miezi 6 | Miezi 6 hadi chini ya mwaka 1 |
| Mwaka 1 hadi chini ya miaka 3 | Miaka 3 hadi chini ya miaka 5 |
| Miaka 5 au zaidi | |

**2) Aina ya huduma?**

| | | |
|---|---|---|
| Usajili wa dawa | Usajili ya vifaa tiba | Usajili wa vitendanishi |
| Vibali vya uingizaji dawa | Vibali vya uingizaji vifaa tiba | Vibali vya uingizaji vitendanishi |
| Vibali vya usafirishaji dawa | Vibali vya usafirishaji vifaa tiba | Vibali vya usafirishaji vitendanishi |
| Usajili wa majengo ya dawa | Usajili wa majengo ya vifaa tiba | Usajili wa majengo ya vitendanishi |
| Idhini ya majaribio ya dawa | Uchunguzi wa maabara | Nyingineyo eleza |

**3) Ni kwa kiasi gani unaridhika na kiwango cha huduma unazopata kutoka TMDA? TAFADHALI WEKA ALAMA YA *VEMA* KATIKA SEHEMU MOJA**

| | | |
|---|---|---|
| Umeridhika sana | Umeridhika kiasi | Hujaridhika kabisa |
| Sina jibu | Kwa kiasi fulani hujaridhika | |

**4) Ni kwa kiasi gani unatutathmini katika wasifu ufuatao?(TAFADHALI WEKA ALAMA YA *VEMA* KATIKA SEHEMU MOJA)**

| | Chini ya kiwango sana | Chini ya kiwango | Wastani | Juu ya kiwango | Nzuri juu ya kiwango |
|---|---|---|---|---|---|
| Huduma kwa mteja na unyenyekevu | | | | | |
| Ubora wa huduma | | | | | |
| Kutoa huduma kwa wakati | | | | | |
| Uwazi katika utoaji huduma | | | | | |
| Kujibu wateja | | | | | |

**5) Je una maoni yeyote ya uboreshaji?**

.....

.....

.....

.....

# BIDDING FAREWELL TO OUR LONG SERVING STAFF

**ROSEMARY AARON**

Success and failures will come and go in our lives but the memory of working with such an inspirational personality like you will never fade away. Wish you all the best in your new journey.

**CPA- SADI KAJUNA**

You are leaving the office but your legacy will stay here with us forever. Thank you for everything.

**MWANAMANI MSHANA**

You have been a true leader and a great inspiration for every one of us here. You shall always be remembered for what you have done for the Authority. Wish you all the best.

Our beloved retirees Sadi Kajuna, Rosemary Aaron and Mwanaamani Mshana.

You have been loyal and hardworking employees of the Authority at all times of your service and this has inspired many of us. We would like to wish you good luck for the next chapter of your lives.

It had been an extraordinary experience for us to work with you. Now you are retiring but your years of service will always be remembered. Your supportive and encouraging personality as well as dedication and hardworking attitudes are examples for each one of us to follow.

We hope that you achieve more in what lies ahead of you and continue to inspire us with the passion that you live behind. The memories we shared will always be treasured.

**We wish you all the very best in your retirement. Goodluck!!!!**

# OBITUARY

***Dr. Osidai Solomon Kivuyo***

On Wednesday 12th of August 2020, TMDA announced the demise of our beloved staff and brother – Dr. Osidai Solomon Kivuyo. Indeed the passing of Dr. Kivuyo was accorded with great sorrow, sympathy, bitterness and sadness amongst fellow employees.

Dr. Kivuyo joined TMDA on 01st April, 2016 and served as the Drug Registration Officer for four years in the Medicines Evaluation and Registration Section. He was undoubtedly one of memorable companion, loyal to the Authority and dedicated to his job.

Dr. Kivuyo died suddenly while asleep at the age of 33 years and his contribution to TMDA and the nation at large will always be remembered. We will usher and cherish his positive attitude, laughter and joy that keeps resonating into our minds.

**MAY GOD REST DR. KIVUYO'S SOUL IN ETERNAL PEACE AMEN**

TMDA/DG/CPE/CT/001, Rev#:03

# TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

Tanzania Medicines & Medical Devices Authority

# CLIENTS' SERVICE CHARTER

4th Edition

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October, 2020