Issue No. 009

TMDA

Tanzania Medicines & Medical Devices Authority

Newsletter

ISSUE NO. 009
MAY, 2021

TMDA COMMENDED BY PIC FOR ESTABLISHING STATE OF THE ART LABORATORY IN MWANZA

CONTENTS

Welcome Note From the Director General

Dear reader,

IT'S time again for our 9th edition of this newsletter and I feel incredibly honored to update you on progress that have been made since the very last 8th edition. Between October 2020 and now a number of notable achievements have been recorded by TMDA that worth reporting for wider circulation.

I would like to first of all begin by regrettably recalling the demise of our beloved – President John Pombe Magufuli who sadly passed away on 17th March 2021 from heart complications which he endured for many years. We will always remember him and usher his philosophy and exemplified loyalty to this nation, he demonstrated during his term in office. May our almighty God rest his soul in eternal peace at heaven.

As it is always the case, once such unpredictable events happens, our Constitution compels us to fill the gap and not create any vacuum in leadership and therefore on the flip side, we congratulate Hon. Samia Suluhu Hassan for being sworn-in to become the 6th President of the United Republic of Tanzania. We love you "mama" and we will always accord you and your government the necessary support including implementing all the directives as they will be issued from time to time.

In that order we also congratulate the Vice President of the United Republic of Tanzania, Hon. Dr. Phillip Isidory Mpango (the former Minister of Finance and Planning) for taking oath and accepting to serve as the second in command after our Madame President.

The confirmation of Dr. Dorothy Gwajima to extend her role as the Minister of Health, Community Development, Gender, Elderly and Children is also positively applauded. The appointments of Prof. Abel Makubi and Dr. Aifello Sichalwe as the Permanent Secretary (Health) and Chief Medical Officer (CMO) respectively is likewise acknowledged. TMDA will always follow your orders when discharging its duties of protecting and promoting public health by ensuring that medicines, medical devices and diagnostics remain safe, efficacious and of good quality.

The present edition amongst others covers stories on visits paid by the Parliamentary Investment Committee (PIC) at TMDA Laboratory in Mwanza as part of its legislative duty to supervise investments made by all public institutions. It also highlights the visit paid by the Ministerial Advisory Board (MAB) at the Tunduma and Kasumulu boarders. Various public education campaigns structured to sensitize our stakeholders on the capacity of our laboratories to test products have also been articulated. Legal actions taken by TMDA for those who were captured smuggling regulated products have also featured in this edition. Pictorial presentations as displayed in this edition also sends clear-cut message of many other undertakings that TMDA was engaged-in since the last version of this newsletter.

Apart from President Magufuli, we also lost one of our staff – Mr. John Shallanda whom we will always remember as he devoted his time, energy and enthusiasm to take us to a number of locations as he was serving as the driver of our vehicles. Rest in peace brother.

Enjoy your reading.

Adam M. Fimbo
Director General

TMDA
Tanzania Medicines & Medical Devices Authority

Editorial Note

Dear our Esteemed Reader,

IN the same pace and momentum we are presenting again to you our 9th edition of this Newsletter. The current edition supersedes the 8th which was issued back in October 2020. In this new edition we have tried to put together all notable events which had happened since October 2020 with the overall intention of educating the public on the roles and functions of TMDA.

Let me take the opportunity to once again thank Mr. Adam M. Fimbo – the Director General of TMDA for his guidance, leadership and editorial contribution to this edition. He has been quite supportive and helpful of which, we at TMDA community, are greatly indebted.

Just like the previous editions, this platform had been instrumental and a game-changer when it comes to sharing of information and events related to TMDA roles and responsibilities. Many stakeholders have commended TMDA for designing, innovating and actively using this newsletter to reach out to the wider community. We will continue to issue more editions and disseminate up to remote areas where access to information is a mounting challenge.

One of the pivotal items which have been covered in this edition includes results of service delivery survey (SDS) which was conducted to determine the level of our customer satisfaction. The survey had indicated that about 80% of our customers were satisfied with the services we offer. This is a great achievement and denotes the endeavours, courage and determination that had been put in place by TMDA staff in understanding and meeting customer needs and expectations. The satisfaction threshold has increased from 42% recorded in 2004 to 80% for our external customers. This upward trend has been attributed to many factors of which one is the successful implementation of the quality management system (QMS) which resulted into attaining ISO 9001 certification. Meeting customer needs and expectations is one of the fundamental components or pillars of QMS.

Nevertheless, the SDS survey outcome indicated further that around 53% of our external customers were not aware of the recent changes of functions and name of the then Tanzania Food and Drugs Authority (TFDA) to the current one - Tanzania Medicines and Medical Devices Authority (TMDA). We are therefore devising measures to change this status quo and through this Newsletter, upcoming editions and other mechanisms as highlighted in our Communication and Customer Care Strategy, we will unequivocally create more awareness to the public.

Finally, we always welcome constructive criticism, inputs and feedback for improvement of the forthcoming editions of this Newsletter.

Thank you and enjoy your reading!

Gaudensia Simwanza
Manager Communication &
Public Education

TMDA COMMENDED BY PIC FOR ESTABLISHING STATE OF THE ART LABORATORY IN MWANZA

THE Parliamentary Committee on Public Investments and Capital (PIC) has commended TMDA for setting-up an ultra-modern laboratory in Mwanza region. The complement was made by members of the Committee who visited the laboratory on 17th March 2021. Around 14.5 billion TShs were used to construct and equip the laboratory which was commissioned back in 2016.

Addressing the audience which included apart from members of the Committee, TMDA staff and media representatives, the PIC Chair - Hon. Atupele Mwakibete (MP) asserted his satisfaction to the construction work and how the building was expertly designed to ensure that medical products are tested to standards.

He further alluded-to his positive reflection on what TMDA is doing in protecting and promoting public health including cementing on the fact that value for money was observed in completing the project.

Apart from the complements forwarded, the Committee conversely directed the TMDA Management to find solutions on challenges reported which embraced reliance on experts from outside the country to repair and maintain equipment installed in the laboratory. The need for installing an electrical stabilizing device was also directed as it was noted that the area where the laboratory is located has experienced an erratic and sometimes faulty electrification.

While thanking the Committee for the visit, the Chairman of the Ministerial Advisory Board for TMDA (MAB) Mr. Eric Shitindi assured the Committee that their directives will be implemented timely and that TMDA will strive to improve regulatory services in the Lake Zone.

MAB VISITS TUNDUMA AND KASUMULU PORTS OF ENTRY

BETWEEN February 22nd and 23rd, 2021, members of the Ministerial Advisory Board of the Ministry of Health, Community Development, Gender, Elderly and Children for TMDA (MAB) visited Tunduma and Kasumulu ports of entry located in Mbeya region – Southern Highlands Zone. The intention of this visit was to oversee and monitor the implementation of port activities related to regulation of medicines, medical devices and diagnostics.

The Board members were welcomed and hosted by the ports' authorities including the Customs department who introduced and escorted them as they were walking around.

The two ports operate as One Stop Border Posts (OSBP) whereby all government institutions are housed to offer services to customers who intend to import or export their products (i.e. medicines, medical devices and diagnostics) into and out of the country respectively.

In a welcoming gesture, the TMDA Director General, Mr. Adam Fimbo, reiterated to MAB members that the Management has stationed one officer (Mr. Christian Mbwillo) to oversee port activities including stamping release orders on permits issued. Mr. Mbwillo's short presentation noted that in the year 2019/20, a total of 388 consignments were inspected and approved at the two border posts whereby 375 passed through Tunduma and 13 Kasumulu.

Mr. Ernest Daudi who is in-charge of the Tunduma Customs Office asserted that Tunduma port covers a 50 square kilometers boundary and has atleast 250 illegal entries used to clandestinely pilferage unauthorized products into and out of the country.

On the flip side, speaking in-front of MAB members, Mrs. Juliana Mbano who is in-charge of Kasumulu OSBP highlighted that the port covers a total area of around 32 square kilometers which brings a mounting challenge to fight illegal smuggling of products into the country.

On his remarks, the MAB Chair, Mr. Eric Shitindi, commended the TMDA leadership for setting-up a good infrastructure to effectively control importation and exportation of products regulated by TMDA at the two ports and insisted on conducting joint operations to fight smuggling. He further urged port staff to work in close cooperation as we are all civil servants serving the same government.

MAMA SAMIA SULUHU HASSAN – OUR 6th TERM PRESIDENT:

HEARTFELT CONGRATULATIONS TO YOU

THE Ministerial Advisory Board (MAB), Management and staff of TMDA wishes to offer our heartfelt congratulations to Her Excellence Samia Suluhu Hassan for being sworn-in as the 6th President of the United Republic of Tanzania.

The smooth transition of power after the demise of the late President (Magufuli), as typified in our Constitution, portrays the political stability of our nation and how we value democratic processes. Indeed your calm taking over of power has utterly amazed many other nations and this continues to bond us together including upholding humanity.

We at TMDA will continue to work with your government under the Ministry responsible for health and strive to bolster systems for medical products regulation. We will always obey orders and directives that are geared towards strengthening public health and economic systems.

As one of the leading regulatory authorities in Tanzania we will push for the national agenda on industrial revolution to assist the private and public sectors to set up pharmaceutical and medical device industries which will in-turn improve livelihood by providing employment opportunities.

Always on your service and may almighty God be with you as you lead our nation.

CONGRATULATING REMARKS FOR APPOINTMENT OF PERMANENT SECRETARY – MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Prof. Abel Makubi

THE appointment of Prof. Abel Makubi as the Permanent Secretary of the Ministry of Health, Community Development, Gender, Elderly and Children has been received with jubilant gesture. Ever since he began working as the Chief Medical Officer (CMO) under the same Ministry, Prof. Makubi had demonstrated tremendous skills and competence in his position which undoubtedly has been key in his appointment.

Much as he has been trusted by the President, we believe he will supervise the health sector to the highest standards of service delivery and assist in reducing morbidity and mortality levels in our country.

There are still mounting challenges in the health sector which needs collective responsibilities to galvanize and sort them out and Prof Makubi is the right person to guide us through.

We at TMDA will accord him all necessary support in his tenure and assure him tireless efforts in protecting and promoting public health. We will strive to improve systems for adequate regulation of medicines, medical devices and diagnostics.

Welcome onboard Prof and wish you the very best.

80% of TMDA Customers are Satisfied: Results of Service Delivery Survey

Introduction

THE Tanzania Medicines and Medical Devices Authority (TMDA) goal is to maintain a high level of customer and other stakeholders' satisfaction through excellence in service delivery. To achieve this customer and stakeholders' feedback is pivotal as it informs the Authority on how it fairs in service delivery including gaps as perceived by stakeholders. Service Delivery Survey (SDS) is one of the ways that an organization can capture customer's and other stakeholders' feedback.

Aim and objectives

TMDA has recently undertaken its 4th SDS in 2020 with the overall objective of examining the level of stakeholder's satisfaction with services offered. Specifically, the survey was meant to provide insights on areas where TMDA is doing well and in areas that need to be addressed to improve service to attain customer satisfaction.

Methodology

The survey was conducted in 14 regions namely Dar es Salaam, Tanga, Arusha, Mtwara, Mbeya, Njombe, Katavi, Manyara, Tabora, Dodoma, Mwanza, Geita, Ruvuma and Singida.

A total number of districts covered within the aforementioned regions was 28 that splited into 50% urban and 50% rural.

Stakeholders who participated in the survey included employees (211), households (1629), permit and laboratory customers (151) and regulated customers (641). The regulated customers included hospitals, health centers, dispensaries, wholesale and retail pharmacies, veterinary shops and accredited drugs dispensing outlets (ADDOs).

Key findings

Overall, stakeholders and the general public appreciate the role of TMDA in the country.

The Authority is on track in terms of fulfilling its mission in the society.

The Authority has managed to reduce falsified products in the market through regulation, frequent inspections and market surveillance programmes.

Steadily the quality of services rendered by TMDA to its stakeholders continues to increase.

TMDA Rated as the preferred employer and an effective regulator with sound systems in place and good working conditions.

The rating is above 80% across stakeholder groups.

Conclusions

TMDA have improved its rating from external customers from 42% (2004) to 80% (2020). There is high demand on TMDA services in the country as reported by both general public and customers. Customers have scored very high on TMDA employees on all attributes as well as on quality of services. TMDA have good organization image and reputation to both general public and customers.

However, awareness for both TMDA and its Clients' Service Charter (CSC) is below the targeted indicators in the strategic plan. The findings indicate that 53% of the general public is not aware of TMDA, while 52% of its customers are not aware of its CSC. Based on these findings, TMDA will continue to improve its service delivery to satisfy its customers and stakeholders. TMDA value its customers and stakeholders for their continued support in services rendered as well as feedback on improvement of the organization.

TMDA will continue to conduct such surveys after every three (3) years as they have proven to be effective in determining the needs and expectations of customers.

TMDA QC LABORATORIES – MEDIA ENGAGEMENT

IN its efforts to create more awareness on its roles in regulation of medicines, medical devices and diagnostics and reach out to a wider community, the Tanzania Medicines and Medical Devices Authority (TMDA) had recently invited representatives from various media platforms to visit and take coverage of its laboratories located in Dar es Salaam and Mwanza regions.

> "We test face masks in our laboratory for microbial content, bacterial filtration, parasite density, efficiency, breathability and splash resistance."

This planned engagement took place between 18th and 23rd January, 2021 in Mwanza and 3rd to 5th March, 2021 in Dar es Salaam laboratories respectively.

The intention of the event was to educate and pragmatically orient the media representatives to allow them construe what TMDA is doing in laboratory analysis and thereafter use their platforms to create awareness to the public. It was envisaged that by doing this, there would be more coverage on the capacity of TMDA in analysis of medicines, medical devices and diagnostics.

Ultra-modern equipment available within TMDA laboratories were demonstrated and appreciated by the media team including how they operate. Installation, calibration and maintenance techniques were explained including how staff are trained to make them more proficient and competent.

Speaking to journalists in Mwanza, the Head of TMDA laboratory in Lake Zone - Mr. Bugusu Nyamweru narrated "We've targeted to expand the scope of sample analysis in the lake zone and countrywide and we invite researchers, institutions and other stakeholders to utilize our laboratory". Mr. Nyamweru further lamented that the laboratory has a number of equipment and one which is classical, sophisticated and widely used is Liquid Chromatography - Mass Spectroscopy - Mass Spectroscopy (LCMS/MS) which is used to identify impurities in drug samples.

Mr. Lameck Kapilya, who is working as the drug analyst in the same laboratory asserted that the laboratory is equipped with the 'Dissolution Testing Apparatus' which works by mimicking what is happening in the human stomach. "The machine can determine the time it takes for a drug to be absorbed before distribution in the human body" said Mr. Kapilya. Mr. Kapilya further explained that the sample solutions collected from the dissolution testing machine, are commonly analyzed using High Performance Liquid Chromatography (HPLC) to identify levels of active pharmaceutical ingredients present in drug products.

On his part, Analyst Jovinary Rwezahura, demonstrated that the laboratory has at its disposal - the Microwave Plasma Atomic Emission Spectrophotometer (MP - AES) which is used to identify levels of heavy metals in drug, food, soil and other samples. "Human beings can tolerate an acceptable level of heavy metals which do not cause harm but to the contrary in case of exceeded amounts", said Rwezahura. He asserted "high levels can cause brain

damage, disruption of the nervous system and memory loss". "Likewise individuals may experience diarrhea, vomiting, shortness of breath, tingling in hands and feet, kidney and liver dysfunction", Mr. Rwezahura cemented.

While in Dar es Salaam laboratory, the Laboratory Technician Mr. Saxon Mwambene underlined: "We are after people's health, so we test condoms, gloves, diapers and sanitary pads to ascertain their quality and safety profiles." Mr. Mwambene demonstrated the Universal Tensile Machine (UTM) which was located in the medical devices laboratory and clarified that it works to identify the tensile strength of surgical sutures, condoms and rubber in general. According to him, the medical devices laboratory has other machines apart from UTM to embrace an Electrical Leak Tester (for identifying minor holes in condoms), Automated Wet Package Seal Integrity – AWPSI and Visual Leak Tester (for testing minor holes in gloves).

Mr. Revocatus Makonope who also works in the medical devices laboratory within the microbiology section said "We test face masks in our laboratory for microbial content, bacterial filtration, parasite density, efficiency, breathability and splash resistance." "All these test parameters are in BS EN 14683: 2014 standard.

Winding-up the media tour and study visit, the TMDA Director General – Mr. Adam Fimbo addressed reporters by thanking them for accepting to visit and further narrated that the Dar es Salaam based laboratory is one of the WHO prequalified laboratories in Africa. He alluded to the significance of this status quo as that, it portrays the TMDA laboratory as one of the best and reliable in testing samples of medicines, medical devices and diagnostics. With this state of affair, many countries have sent their samples to the TMDA laboratory for testing to include Uganda, Zambia, Malawi, Burundi, Lesotho, Kingdom of Eswatini (formerly Swaziland), Rwanda and Ghana. A couple of study visits have also been paid by many experts from many other countries for training and orientation purpose.

Mr. Fimbo further explained that apart from the two laboratories visited by the media people, TMDA has also a network of 25 mini-labs located in regional referral hospitals and ports of entry which are used to screen suspicious samples collected from the market. He lastly notified journalists the intention of TMDA to open-up another laboratory within the TMDA premises which is under construction in Dodoma.

"We are after people's health, so we test condoms, gloves, diapers and sanitary pads to ascertain their quality and safety profiles."

STEPPING-UP PUBLIC EDUCATION CAMPAIGNS: TMDA CONQUERS BABATI

PUBLIC education is one of the key roles of TMDA. The Authority has been taking various initiatives to ensure that the public is aware of its functions in promoting and protecting public health. A couple of public education programmes including outreach campaigns have been organized to inform stakeholders and the general public on overall TMDA roles in regulating the quality, safety and efficacy of medicines, medical devices and diagnostics.

To step-up the pace, TMDA has recently out-stretched its public education campaigns to reach people living in remote areas particularly those residing in rural and semi urban localities.

Between 2nd and 5th February 2021, the TMDA Communications and Public Education Manager - Ms. Gaudensia Simwanza and her team staged a public education campaign in Babati district - Manyara region.

During this week she attracted big crowds to witness and listen to messages delivered intended to create awareness on rational use of medicines. The audience were educated on appropriate selection of medicines, the need for a prescription issued by the medical practitioner and appropriate use of medicines.

More than 4,970 individuals attended the campaign over the entire week and most of them were from wards and villages to include Baloa, Singu, Kimotko, Halla, Bagara, Nakwa and Nyunguu. Livestock keepers, entrepreneurs, business experts and farmers were all available.

From his side Mr. Elia Nyeura – the TMDA Northern Zone Senior Inspector who was also present, urged attendees in Singu ward to always seek medical attention including diagnostic services before using any medicine.

He promptly reiterated on the recent emergency of drug resistance due to irrational use which has resulted into lack of efficacy. The under-reporting of adverse drug reactions was also alluded-to by him and how this has slowed down initiatives taken by TMDA in monitoring the safety of medicines circulating in our market.

While receiving feedback from attending participants, it was noted that most of them were satisfied with the efforts put forward by TMDA to educate the public and they requested for sustainable campaigns particularly targeting those living in rural areas.

To keep-up the pace and ensure continuous message delivery, educational materials to include publications, brochures and other IEC materials were distributed in the areas visited.

TMDA plans to increase the level of public awareness on its functions to about 80 percent of the general population by 2025.

ANTI-TB MEDICINES CIRCULATING IN THE MARKET ARE OF ACCEPTABLE QUALITY, SAYS RESEARCHERS

IN the recent publication of the Journal of Medical Research and Health Education, scientists reported that Anti-TB medicines that were circulating on Tanzanian market for the period between 2012 and 2018 were of acceptable quality.

The findings are a result of a prospective cross- sectional study conducted by researcers from TMDA, Muhimbili University of Health and Allied Sciences (MUHAS) and the Kilimanjaro Christian Research Institute (KCRI). The study was led by MS. Kissa Mwamwita, Head of Clinical Trials Control and Pharmacovigilance, TMDA. The researchers assessed the quality of Anti- -Tuberculosis Medicines in Tanzania for the stated period.

During the study period, about 777 samples of anti-tuberculosis medicine were collected from ports of entry, Medical Stores Department (MSD) and healthcare facilities in 16 regions of Tanzania Mainland. All collected samples were subjected to quality screening using Global Pharma Health Fund (GPHF) Mini-Lab kits.

Samples collected from MSD and healthcare facilities yielded doubtful screening results and ten percent (10%) of all those that complied were subjected to tier II confirmatory testing using full pharmacopoeia monographs at the TMDA Quality Control Laboratory which is prequalified by the World Health Organization.

According to the report, collected samples complied with the requirements of both GPHF minilab protocol and respective compendial monographs were subjected to screening (777) and confirmatory testing (46), respectively. From the samples collected from medicine distribution outlets 71.3% (176/247) did not comply with product information requirements as per TMDA labelling requirements and approved product information.

Furthermore, the compliance of all 247 samples with the evaluated GPHF minilab protocol requirements is in-line with reported performance in the previous year reports in terms of identification and semi quantitative determination by using TLC, physical inspection and simple disintegration test

Also, the compliance of all 46 samples to the respective pharmacopeia monograph requirements was equally similar to PMS results for the period between 2009–2013 These results suggest that, the anti-tuberculosis agents were of acceptable quality and that the implemented TMDA quality assurance systems including marketing authorization and post marketing surveillance programs are effective.

However, the study calls for need for Authorities to address the issues highlighted in the study to include lack of adherence to TMDA labelling requirements, need to provide adequate and clear information to users, patient as well as healthcare providers to ensure rational use of the respective medicinal products.

The use of substandard and falsified (SF) anti-tuberculosis (ant-TB) medicines may lead to treatment failure and development of drug resistance. SF medicinal products are claimed to be more prevalent in developing countries with high burden of tuberculosis disease. National Medicines Regulatory Authorities therefore, should ensure that the quality of these life-saving medicines is systematically monitored.

PICTORIAL

Minister of Health, Community Development, Gender, Elderly and Children, Dr. Dorothy Gwajima (MP), Addressing the Media on Outcome of Special Operation Inspection of Business Premises Dealing with Medicine and Medical Devices which was Conducted Countrywide Between 15th to 20th March,2021.

The Chairman of Ministerial Advisory Board (MAB), Mr. Erick Shitindi, Presenting his Remark During the Press Conferee held on 5th May 2021 in Dodoma to Reveal the Findings on Special Operation Inspection of Premises Dealing with Medicines and Medical devices which was Conducted Countrywide Between 15th to 20th March, 2021.

The Ministerial Advisory Board (MAB) Together with TMDA Management team are in a group photo Immediately after Visiting the Ongoing Construction of Central Zone Office Project in Dodoma. The Project is Expected to be Completed on June 2021 under National Housing Cooperation as a main Contractor

PICTORIAL

Parliamentary Committee on Public Investments and Capital (PIC) visited the TMDA Mwanza Laboratory

Some Equipment of the TMDA Mwanza Laboratory

PICTORIAL

Technical Inspection of Equipment at Ports of Entry Prior to Regulatory Duties

1st Stakeholders Meeting on Regulation of Tobacco Products

PICTORIAL

Handing Over of TMDA Service Delivery Survey Report

2nd Stakeholders Meeting on Regulation of Tobacco Products

PICTORIAL

Service Delivery Survey Data Collection team

Parliamentary Committee on Public Investments and Capital (PIC) visited the TMDA Mwanza Laboratory

Fare Well to TMDA Retired Staff

TMDA conducts its 4th Service Delivery Survey

PICTORIAL

TMDA's Quality and Risk Management Officials Posing for a group photo with TBS Risk Committee Immediately After their Study Visit to TMDA Offices to Learn About Risk Management System and its Activities. The Study Tour was Held on 31st March 2021 at TMDA Offices in Dar es Salaam

Members of Workers Council Visit Horohoro Border Post

Sports are Healthy

TMDA Commemorates World Women's Day 2021

Some equipment of the TMDA Quality Control laboratory

TMDA APPOINTS THE NEW DIRECTOR OF MEDICAL PRODUCTS CONTROL

ON 1st of March 2021, TMDA appointed Dr. Yonah Hebron Mwalwisi to become the new Acting Director of Medical Products Control (DMC). The incumbent replaces Mr. Akida Msallah Khea who was the Acting DMC since October 2018. Mr. Khea has recently joined the World Health Organization (WHO).

Prior to this new position, Dr. Mwalwisi was the Manager of Medicines and Complementary Products Analysis of the TMDA Laboratory located in Dar es Salaam. He had also served as the Zone Assistant Manager in the Lake Zone. During his tenure, he accrued an experience of over 20 years serving in different positions.

Dr. Mwalwisi is a holder of Bachelor of Pharmacy degree which he attained at the Muhimbili University of Health and Allied Sciences (MUHAS) back in 1998. He also acquired his Masters of Science degree in Pharmaceutical Analysis from Strathclyde University, Glasgow, Scotland in 2003. He currently possesses a Doctor of Philosophy degree (PhD) which he completed at St. Julius Maximilians' Wurzburg University in Wurzburg, Germany in 2017.

Having working in the laboratory for so many years, Dr. Mwalwisi played a significant role in orchestrating and ensuring that the TMDA Laboratory is prequalified by WHO to become one of the best performing laboratories in Africa. The TMDA Laboratory had been prequalified by WHO since 2011 and maintained that status quo to-date – thanks to Dr. Mwalwisi and his team for this noteworthy contribution.

Coupled with the amassed knowledge, laboratory experience and taking part in other regulatory functions to embrace dossier evaluation, conducting Good Manufacturing Practice (GMP) inspections, Good Clinical Practice (GCP) inspections and Good Laboratory Practice (GLP) inspections, to mention a few, Dr. Mwalwisi brings in a new verve, dynamism and character within the Directorate of Medical Products Control.

The entire Management Team and staff welcomes Dr. Mwalwisi and promises toaccord him full cooperation and support to make his new role smooth and in broader context attain our overall mission and vision.

Congratulations!!

Akida Khea's Legacy as he joins World Health Organization (WHO)

THE then TMDA Acting Director of Medicines and Medical Devices (DMC), Mr. Akida Khea who served for almost 16 years at various managerial positions, has left the office for another post at World Health Organization (WHO).

Mr. Khea's leadership ability was noted back in 2005 when he was appointed as the first Manager for Cosmetics Registration Section until 2008 when he was again appointed to lead the newly introduced Section of Medical Devices Assessment. He successfully served in this post until 2014 when he was appointed as the Manager of Medicines Registration and Evaluation before becoming the Acting Director on 24th October, 2018.

Due to his exemplary work experience including taking part in a number of assignments at international arena, Mr. Khea got a new post at the WHO from 1st March 2021 as the Technical Officer and he will be based in Copenhagen, Denmark.

During his tenure, he registered a number of notable achievements to include man to man management, great technical ability and attention to details.

Mr. Khea was a principled and astute person with remarkable humility that will always be remembered within the TMDA community.

The legacy he is leaving behind during his time at TMDA will always be cherished and honoured.

We thank Mr. Akida Khea and wish him all the best in his new role within WHO.

Good luck in your future endeavors!!

THE ROLE OF TMDA QC LAB IN DECISION MAKING

REGULATORY decisions on quality of medical products are made through testing of samples in a laboratory. It is through laboratory testing that regulators can ascertain the quality of a product and decide whether to register or take products out of the market.

The Tanzania Medicines and Medical Devices Authority (TMDA) as the regulatory authority in Tanzania has established two state of the art laboratories in Dar es Salaam and Mwanza regions. Both laboratories have been equipped with ultra-modern equipment and function by following high levels of standards.

> "This laboratory is in the process of accreditation by renowned accreditation bodies to include the Southern African Development Community Accreditation Service (SADCAS),"

Equipment installed are sophisticated and have high capacity in terms of operation. The same have been set-up by following all the requirements of design qualification, installation qualification, operational qualification and performance qualification.

The laboratories have amassed qualified analysts with adequate knowledge on testing of human medicines, veterinary medicinal products, medical devices and diagnostics. The personnel employed undergo periodic competence assessment through the proficiency testing scheme.

The laboratories have been instrumental in analysing products and assisting TMDA in decision making process. Through these laboratories many products have been registered or withdrawn from the market after obtaining results of analysis.

Speaking during the visit of the Parliamentary Committee on Public Investments and Capital (PIC), Mr. Adam M. Fimbo who is the sitting-in Director General of TMDA narrated that the TMDA has invested heavily on equiping its laboratories and it has installed equipment worth 5 billion TShs at its Mwanza laboratory. The same kind of investment was made in Dar es Salaam.

"Our country like any other country is facing a mounting challenge of falsified and substandard medical products and in curbing the stuation, we have decided to invest in quality control testing and build capacity of our analysts," asserted Mr. Fimbo.

According to Mr. Fimbo, currently the rate of falsified and sustandard medicines in the market across the country is only at one percent. This status quo has been contributed largely due to existence of the laboratories to test and identify such products.

On her part, the TMDA's Lake Zone Manager – Ms. Sophia Ally Mziray recently reiterated that the Mwanza laboratory stands as a king-pin in testing samples collected in the Lake Zone area which covers 6 regions namely – Mwanza, Kagera, Geita, Mara, Shinyanga and Simiyu.

"This laboratory is in the process of accreditation by renowned accreditation bodies to include the Southern African Development Community Accreditation Service (SADCAS)," said Ms. Mziray.

The Head of TMDA's Lake Zone Laboratory - Mr. Bugusu Nyamweru demonstrated the major equipment available in the Chemistry and Microbiology laboratories in Mwanza to embrace High Performance Liquid Chromatography (HPLC), Liquid Chromatography Mass Spectroscopy (LC-MS-MS), UV Spectrophotometer and Micro Plasma Atomic Emission Spectrometer (MP-AES).

"Our trained staff utilize the installed equipment and validate or develop pharmacopoieal or non pharmacopoieal methods respectively to test samples of products collected in the lake zone," said Nyamweru.

The Dar es Salaam laboratory had acquired WHO prequalification since January 2011 and it has maintained this status quo todate through regular audits conducted by WHO.

CONFISCATION OF FALSIFIED ALBEN BLUE 25% WITH BATCH NO. 019394

THE Tanzania Medicines and Medical Devices Authority (TMDA) has encountered the existence of falsified veterinary medicine with brand name ALBEN BLUE 25% and printed batch No. 019394 circulating on the market.

TMDA's Director General Mr. Adam Fimbo, said through the inspection conducted, the falsified product purported to be manufactured by Nerix Pharma for Vetagro and Pulper Co. Ltd Nairobi, Kenya was detected.

"The authority will continue to conduct regular post marketing surveillance and inspections to detect any other substandard and falsified products that might cross borders and reach our market," said Mr. Fimbo.

According to Mr. Fimbo, the suspected batch was subjected to laboratory analysis and the results revealed that the batch does not contain the claimed active pharmaceutical ingredient.

He cited the discrepancies of information on the container labels between the genuine and falsified product including colour of the label, animal paints and manufacturing dates were key in detection of the falsified product. The fasified product had light blue labels while the colour was light green for the genuine product.

He further asserted that the confiscated batch with a manufacturing date of November 2019 and expiring date of October 2022 was detected to be falsified due to inconsistency in the appearance of the container labels of the product.

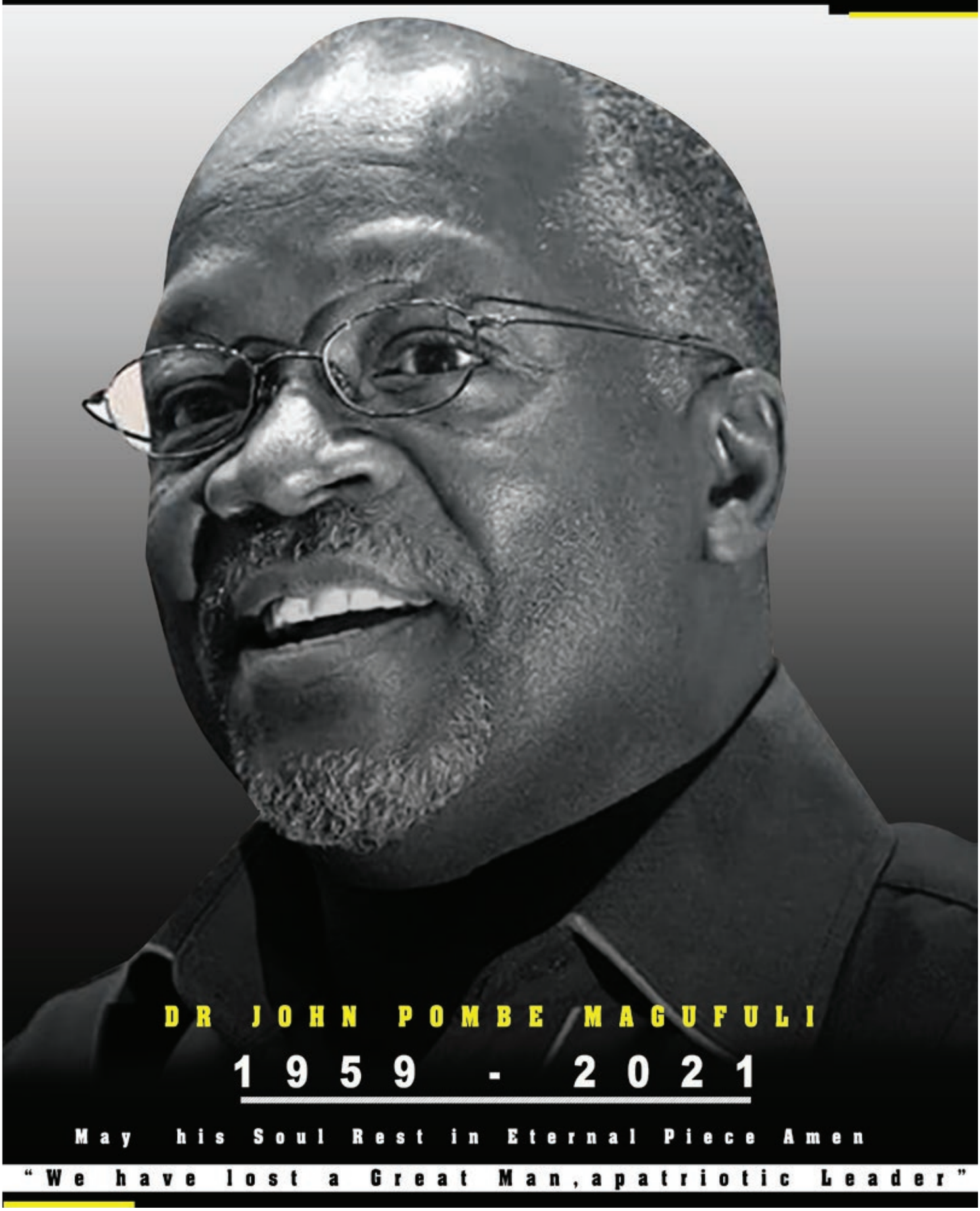
Mr. Fimbo then directed "farmers including the general public to be extra vigilant and scrutinize the labels to detect the falsified product and report to any nearby TMDA office or police station in case they would come across the same."

In connection to this, Mr. Fimbo further urged the public to report any suspected substandard or falsified Medical products that they may encounter including all unscrupulous dealers engaged in the illegal and unlawful manufacturing, smuggling and selling of such kind of products for prompt regulatory actions to be taken by the Authority.

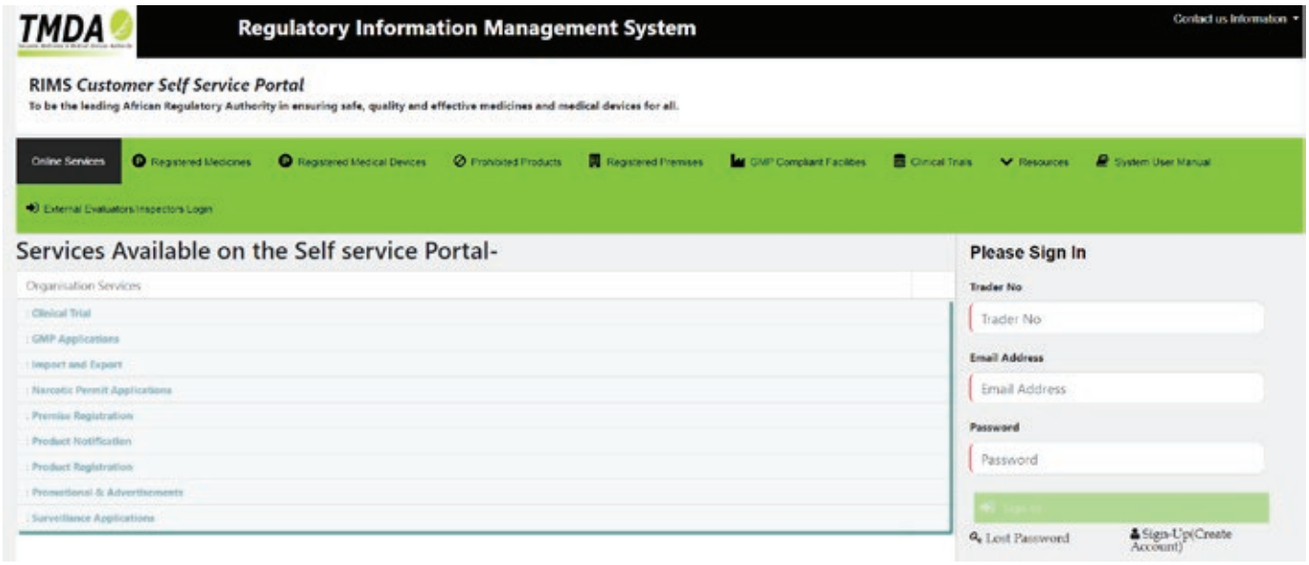
"The alleged culprits who were caught with falsified products are under Police custody for further interrogation to identify the entire network of those involved in the manufacturing, distribution and sale of this falsified batch in the country," explained Mr. Fimbo.

"The Authority will continue to conduct regular post marketing surveillance and inspections to detect any other substandard and falsified products that might cross borders and reach our market,"

CONDOLENCES



REGULATORY INFORMATION MANAGEMENT SYSTEM: NEW KID ON THE BLOCK



IN early May 2020 TMDA launched a new web-based Regulatory Information Management System or its acronym RIMS to replace the existing Integrated Management Information System (IMIS).

The move came as a result of challenges experienced in the previous system and the overall intention of advancing the IT features to be more user friendly and up-to-date.

The newly introduced system has integrated the financial management system as well as the Tanzania Electronic Single Window System. The advanced system has instrumentally revolutionised the management of data including providing an efficient platform for processing of applications.

With the current system, applications for marketing authorization of medicinal products are now accepted and processed online. This new development will unequivocally streamline and improve services by responding to customer queries timely as this had been a challenge for many years. It is envisaged that the services offered by TMDA will be extra effective and retrieval of data will be quick.

The process of automating TMDA services began back in 2011 whereby TMDA in collaboration with Trade Mark East Africa (TMEA) invested heavily in development of a Management Information System (MIS). Since then, the Authority has continued to improve its systems including developing the Laboratory Management Information System (LIMS), Human Resource Management Information system and Financial Services Management System.

The interface with the Tanzania Electronic Single Window System will without doubt expedite issuance of import permits and clearance of consignments at ports of entry.

TMDA always strives to establish and improve its services including automation of its processes in order to promote transparency, accountability and minimizing time to deliver services.

FROM KNOWLEDGE TO PRACTICE:

CUSTOMER CARE REFRESHER TRAINING OFFERED TO TMDA FRONT-LINE WORKERS

AS part of its quality management system and in order to refresh on skills and broaden the knowledge, TMDA had organized a training on good customer care to its 30 staff between 27th and 29th January 2021. This three days training which was conducted in Kibaha, Coast region targetted front-line workers attending customers on regular basis. Staff from headquarter and zone offices attended the training which was facilitated by experienced staff and line managers.

The training aimed at orienting participants on customer care principles with the overall intention of improving service delivery. The TMDA Director General Mr. Adam Fimbo graced the opening proceedings and on his remarks he lamented on the significance of offering good service to customers and how they impact on existence of TMDA.

"I want you to remember that when you serve a customer you stand on behalf of TMDA, you are trusted and employed by the government for that purpose and so you are obliged to apply your knowledge, attitude and professionalism when serving customers to meet and exceed their needs and expectations".Mr. Fimbo reiterated.

> "TMDA will strive to offer quality regulatory services in pursuit of protecting public health and environment using competent and dedicated staff".

Mr. Fimbo further insisted to participants that this training was aimed at remindingfront - desk officers to focus on TMDA philosophy which states that; "TMDA will strive to offer quality regulatory services in pursuit of protecting public health and environment using competent and dedicated staff".

TMDA organizes such training programmes on regualr basis to refresh its staff on customer care principles and application to bolster service delivery.

TMDA CONFISCATES GOVERNMENT MEDICINES IN SOUTHERN ZONE

TMDA Southern Zone office has intercepted and seized government owned contraceptives worth 300,000/- that were found sold in private pharmacies.

The TMDA Southern Zone Manager - Dr. Engelbert Mbekenga narrated that they commissioned an intelligence team to secretly investigate the entire scheme which resulted into detecting medicines with Medical Stores Department (MSD) logo being sold in the private sector which is contrary to the law. The seized medicines were generic brands used for birth control to include Microgynon (3,360 pills) and Medroxyprogesterone (60 bottles).

According to Dr. Mbekenga, they were tipped by concerned whistleblowers and used intelligence technique to identify the culprits and on 31st January, 2021, two suspects were arrested at one of the private pharmacies in Newala district, Mtwara region.

"We have arrested Mr. Jamaly Sadick - a resident of Newala district together with his son who were caught right-hand selling the government medicines and both are under Police custody" he said.

Dr. Mbekenga said they have opened-up a preliminary investigation file at the Police Station and investigation is ongoing.

TMDA urges all dealers of medical products to refrain from distributing and selling government owned medicinal products in their private outlets as this is contrary to the Tanzania Medicines and Medical Devices Act, Cap 219.

WESTERN LAKE ZONE OFFICE TO BE OPENED IN GEITA REGION

TMDA plans to open-up its Western Lake Zone Office in Geita in May 2021 with the overall aim of bringing services closer to the public. The newly established office will serve the following regions – Geita, Kagera and Shinyanga.

The Western Lake Zone Office will add-up to the already exisiting Eastern Lake Zone Office which serves Mwanza, Mara and Simiyu regions.

The new office will be located at Geita Gold Market building which is at the heart of the city center.

Services to be offered by this office will include - registration of premises, inspection of outlets, and post marketing surveillance of regulated products, issuance of import and export permits, monitoring of adverse drug reactions (ADRs) and events (AEs) as well as providing public education.

The TMDA Director General, Mr. Adam Fimbo, when announcing the decision to estab;ish such office alluded that the office will reduce incoveniences to customers and the general public who were compelled to travel to Mwanza to seek TMDA services.

"This new zone office will be under Dr. Edgar Mahundi who has been transfered from the Western Zone office which is currently in Tabora for smooth transition and managerial experience" Mr. Fimbo said.

Other TMDA Zone Offices are located in Dar es Salaam, Arusha, Mbeya, Mwanza, Dodoma, Mtwara and Tabora making a total of eight zone offices.

OBITUARY

Mr. JOHN SHALANDA
1969-2020

On 21 December, 2020 the TMDA family lost one of its members, Mr. John Mponzi Shalanda, who passed away at Dar Group Hospital after a short time illness. Our father and brother, served as a sector driver at TMDA Sub Head Offices, in Dar es Salaam.

Mr. Shalanda will be remembered for his humbleness and the precious moments shared with him will be treasured

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

TMDA
Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ISO 9001: 2015 CERTIFIED

PUBLIC NOTICE

DESIGNATION OF TMDA AS REGULATOR OF TOBACCO PRODUCTS

1. Pursuant to Section 18 of the Tobacco Products (Regulations) Act, Cap 121, the Minister of Health, Community Development, Gender, Elderly and Children has designated the Tanzania Medicines and Medical Devices Authority (TMDA) as the regulator of tobacco products.

2. This designation has been delineated in the Tobacco Products (Regulations) (Designation of Inspectors) Notice, GN 360, published on 30/4/2021.

3. In accordance with this designation, the TMDA will now assume the roles of inspection, enforcement and regulation of tobacco products.

4. It should be noted that, prior to this directive, there was no regulator of such products in Tanzania and this has unequivocally contributed to upsurge of non-communicable diseases (NCDs) related to tobacco use.

5. In connection to this, the TMDA is currently consolidating a framework for regulation of such products and all dealers and stakeholders will be notified on the next steps to streamline the process.

6. The Tobacco Products (Regulations) (Designation of Inspectors) GN No. 360 published on 30/4/2021 can be accessed **here**.

Issued by

Director General
Tanzania Medicines and Medical Devices Authority (TMDA)
P. O. Box 1253, Dodoma
P. O. Box 77150, Dar es Salaam
Tell: +255-658 445222/777 700002
Hotline: 0800110084
Email: info@tmda.go.tz
Website: www.tmda.go.tz

GOVERNMENT NOTICE NO. 360 published on 30/4/2021

THE TOBACCO PRODUCTS (REGULATIONS) ACT,
(CAP. 121)

NOTICE

(*Made under section 18)*

THE TOBACCO PRODUCTS (REGULATIONS) (DESIGNATION OF INSPECTORS) NOTICE, 2021

WHEREAS, pursuant to section 3 of the Tobacco Products Regulations Act, Cap. 121 provides for policy objective of the Act as to reduce tobacco use and its consequent harm by:

(a) protecting persons under eighteen and other non smokers from inducements to use tobacco products;
(b) protecting non smokers from exposure to tobacco smoke;
(c) ensuring that the population is adequately informed about the risk of using tobacco products and exposure to second hand tobacco smoke and about the benefits available for quitting smoking;
(d) ensuring that tobacco products are modified to reduce harm to such an extent as may be technologically and practically possible; and
(e) promoting a climate that will lead to a smoking-free atmosphere in all walks of life.

AND WHEREAS, section 18 of the Act, empowers the Minister responsible for health to designate a body corporate or public officer to be an inspector for the purposes of enforcement of this Act;

AND COGNISANT of the mandates vested in the Tanzania Bureau of Standards under section 22(3) of the Act for its role of being designated to be an analyst and its role to perform the functions and exercise the powers necessary for the discharge of duties conferred to an analyst under the Act;

AND BEING AWARE of the role of the public institutions to maintain link and enhance collaboration and the need to foster effective implementation of the Act;

TMDA
Na Jamii

TBC
Ijumaa Saa 12:30 Jioni
Jumatatu Saa 3:00 Asubuhi (MARUDIO)

ITV TANZANIA
Jumatano Saa 1:00 usiku
Alhamisi Saa 7:00 Mchana (MARUDIO)

Clouds
Jumanne Saa 12:30 Jioni
Jumatano Saa 7:00 Mchana (MARUDIO)

azamtv
Jumanne Saa 12:30 Jioni
Jumatano Saa 7:00 Mchana (MARUDIO)

Director General
Tanzania Medicines and Medical Devices Authority (TMDA)
P. O. Box 1253, Dodoma
P. O. Box 77150, Dar es Salaam
Tell: +255 222450512/2450751/2452108
Toll free: 0800110084
Email: info@tmda.go.tz
Website: www.tmda.go.tz