TMDA
Tanzania Medicines & Medical Devices Authority

Newsletter

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PARLIAMENTARY COMMITTEE VISITS TMDA NORTHERN AND LAKE ZONE OFFICES

MAB COMMENDS PORTS OF ENTRY SURVEILLANCE SYSTEMS

Contents

WELCOMING NOTE FROM THE DIRECTOR GENERAL

I am unequivocally delighted again to present to you our 12th edition of the Newsletter after the previous one which was made public last year. As always, the current edition highlights some of the notable achievements and milestones in regulating safety, quality and effectiveness of medicines, medical devices, diagnostics and tobacco products.

Amongst others, the edition covers a narration on how TMDA captured unlawful individuals and gangs engaged in manufacturing and distribution of substandard or falsified (SF) medicines. Supplying substandard or falsified (SF) medicines is not only immoral, but also a crime against humanity.

Of more interest is also an account on a rigorous and comprehensive assessment made by the World Health Organization (WHO) team of assessors who visited TMDA and conducted a re-benchmarking assessment of TMDA systems.

This edition also illuminates on other key issues that are worthy noting to include performance assessment of TMDA mini-lab kits, end-line assessment of PAVIA project and training of trainers on Adverse Events Following Immunization (AEFIs) reporting.

Other articles covered in this edition embraces the visitation of the Parliamentary Standing Committee on Health and Social Welfare to TMDA zone offices in Mwanza and Arusha as well as the Ministerial Advisory Board (MAB) tour at Port of Entries in the Western Zone office including its ports of entries (POEs).

Besides great achievements and milestones reached, the edition also covers other stories to include the way TMDA works hard to attract pharmaceutical investors into the country, awards the TMDA has received for having the best ICT solutions in business environment as well as the Public Relations Excellence Awards of 2022 in the provision of public education programmes.

In a nutshell, this 12th Edition depicts a number of important activities which are of interest and informative to you as the reader.

Enjoy your reading!

Adam M. Fimbo
DIRECTOR GENERAL

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DIRECTOR GENERAL

EDITORIAL NOTE

Dear Esteemed Reader,

I am pretty-much honoured to introduce to you our 12th edition of TMDA Newsletter. It is more than a decade now we are publishing this Newsletter as part of ongoing efforts of TMDA to share regulatory information to our esteemed stakeholders.

Voluntary compliance to TMDA requirements coupled with regular information sharing is key to ease and smoothen our regulatory functions. TMDA has consistently been publishing this Newsletter to reach out to the wider community and raise awareness on regulatory activities conducted within the reporting period.

Of highest note, I would like to thank the Chief Editor, Mr. Adam M. Fimbo, the TMDA Director General for his tireless supervision and dynamic leadership throughout the refinement and approval of this edition.

We still have the task of protecting and promoting public health including sensitizing the public to keep on disclosing unfaithful individuals engaged in clandestine manufacturing and distribution of substandard and falsified (SF) medical products in the country.

In this spectrum, information communicated to you on various media platforms including this Newsletter will update you on what the Authority is doing in ensuring the safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products.

We urge and encourage you to send us feedback on the presented articles through any known channels.

Enjoy Reading!

Gaudensia Simwanza
MANAGER, COMMUNICATION AND PUBLIC EDUCATION

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EDITORIAL TEAM

Parliamentary Committee visits TMDA Northern and Lake Zone offices

Between 24th and 26th September 2022, the Parliamentary Committee on Social Services and Community Development visited TMDA Northern and Eastern Lake Zone Offices located in Arusha and Mwanza regions respectively to oversee various regulatory activities coordinated and conducted by TMDA.

The three day visitation which also engaged the Deputy Minister for Health, Hon. Dr. Godwin Mollel (MP) was led by the Committee Chairman Hon. Stanslaus Nyongo (MP) who accompanied other 30 Committee members.

TMDA Director General, Mr. Adam M. Fimbo presented the performance report before the the Committee on 24th September, 2022 at TMDA - Northern Zone office in Arusha.

During the visit at Namanga One Stop Border Post (OSBP) in Arusha, the Committee members were pleased with the TMDA Management's commitment in setting-up an import and export control system and screening process using Minilab kit before allowing products to enter into the market. Members also got a chance to talk to other law enforcers who briefed on the functions and collaboration available at the port of entry.

The Chairman of the Committee Hon. Stanslaus Nyongo (MP) on behalf of other members, commended the Authority for good job done and advised TMDA to keep on working diligently to safeguard public health because majority are vulnerable from consuming products regulated by the institution.

Moreover, Hon, Nyongo hailed the cooperation amongst government institutions working at the Namanga OSBP which included Tanzania Revenues Authority (TRA), Government Chemist Laboratory Agency (GCLA), Tanzania Bureau of Standards (TBS), Tanzania Atomic Energy (TAEC), Port Health, Tanzania Plant Health (TPH), Immigration and Police Force Unit.

"We have observed by ourselves how TMDA is organized to perform its functions specifically in the inspection of medicines at OSBP in Namanga and Arusha as well as product sample analysis in Mwanza Laboratory. We are indeed satisfied with what TMDA is doing," alluded-to Hon. Nyongo.

He nevertheless, advised the Ministry to allocate more laboratory resources to strengthen control systems.

Whilst in Mwanza the Committee Members were impressed with the set-up of the state-of-the-art office infrastructure and modern equipment within the TMDA Laboratory to serve the people residing in the lake Zone and neighboring countries.

While thanking the Committee members for their working tour to TMDA Northern and Lake Zone offices, the MAB Chairman, Mr, Eric Shitindi noted the directives issued and pledged to the Committee chairman to ensure effective implementation of the same.

MAB commends ports of entry surveillance systems

The Ministerial Advisory Board (MAB) has commended the good work done by TMDA in controlling the importation of products through ports of entry (PoE) in the country. The compliments were alluded-to by the Chairman of MAB, Mr. Eric Shitindi during an official visit of PoEs located in the Western Zone Offices of TMDA between 06th and 10th of March, 2023. All PoEs located in Kigoma, Katavi and Tabora regions were visited to include Regional Referral Hospitals (RRHs), Zone Pharmacovigilance centers, incinerators, medical gas generation plants and blood transfusion service centers.

Mr. Shitindi acknowledged the efforts made by TMDA Management in strengthening product control systems in the country. "We are satisfied with the control systems in place which includes inspection of ports of entry on regular basis to curb the inflow of substandard, falsified and unauthorized medical products into our country".

During the tour, MAB members also paid courtesy call to Regional Commissioners (RCs) of the three regions. While in Kigoma, the respective RC Mr. Thobias Andengenye applauded the move including the existing cooperation between TMDA and other law enforcing agencies in Kigoma region. He further called upon the Authority to continue working with his region to safeguard public health.

On the flip side, the Katavi RC, Ms. Mwanamvua Mrindoko thanked the MAB Chairman and his team for visiting Katavi Regional and pledged full support in upholding the work done by TMDA.

The Tabora Regional Administrative Secretary (RAS) on behalf of RC – Her Excellency Ambassador, Dkt. Batilda Buriani likewise expressed her gratitude to MAB chairman and members for visiting Tabora region. She stressed on maintaining and fostering good cooperation on matters related to TMDA mandate and that her region was always ready to engage and be part of policies that align towards protecting public health.

TMDA MAB Members comprises of Mr. Eric Shitindi (Chairman), Prof. Said Aboud, Prof. Appolinary Kamuhabwa, CPA Zaina Thabit, Mr. Daudi Msasi, Ms. Emma Lekashingo and Mr. Adam M. Fimbo (Secretary).

PR Excellence 2nd Runners-Up Award 2022 lands to TMDA

The Public Relations Excellence Awards 2022 for 2nd runners-up in the category of Public Education which was organized by the Public Society of Tanzaniahas gone to TMDA.

The award was received by the Senior Communication and Public Education Officer, Ms Robeta Feruzi on behalf of the TMDA Director General on 18th February, 2023 at Julius Nyerere International Conference Centre - Dar es Salaam.

Good coordination of well public education programmes, has been a cornerstone for the Authority to reach a wider audience thus delivering its intended messages.

In the year, 2022, TMDA had cumulatively conducted 392 outreach programmes, 27 exhibitions, 114 televised and radio programmes and 31 information and educational printed materials, as well as 23 press releases, 1,098 website updates and five (05) press conferences just to mention a few.

The use of five gigantic television stations namely TBC-1, ITV, Clouds TV,Tumaini TV and UTV which air for 30 minutes, twice a week televised programme popularly known as TMDA na Jamii has been instrumental in reaching out to the wider population in both urban and rural areas.

Feedback from most interviewed individuals reached out in different settings during outreach programmes, have applauded TMDA and recommended that the programme should be sustained as it makes the difference in public education.

TMDA public education strategic objective has consistently featured in all TMDA Strategic Plans since its commencement in 2003. Such well-coordinated educative programmes have been remarkable and assisted the Authority to scoop various awards and recognitions from different stakeholders within and outside the country.

Tanzania attracts more investors in pharmaceutical industries

The Tanzanian Embassy in Algeria invited Tanzanian health institutions to meet with investors in pharmaceutical and medical device manufacturing sector in October 2022. The visit went ahead during the Sixth (6th) "The Professional Pharmacy and Para Pharmacy Trade Show" organized by the Embassy of Tanzania in Algeria.

The visit was part of the efforts made by the Tanzania's Ambassador to Algeria - Major Gen (retired) Jacob G. Kingu who works tirelessly to persuade investors to invest in Tanzania.

During his remarks on the opening day, Ambassador Kingu asserted on the critical point of expanding Tanzanian economy and the need to ensure access to quality health care including adequate medicines and medical devices. "Our responsibility is to ensure that medicines and medical supplies are available, and this is the role that we play here at the Embassy," he further alluded-to.

According to Ambassador Kingu, the Embassy has been advocating for existing investment opportunities in the pharmaceutical industry in Tanzania, with domestic manufacturing capacity currently contributing only 10 to 20% of the demand.

"Our country's investment climate is favorable. What we are pushing now is promoting the added advantage we have as a country in

terms of market size, existence of Medical Stores Department (MSD) as the government procuring agency and close proximity of our country with 8 other countries including those in the EAC and SADC regions. These will allow investors to market their products and hasten productivity" he emphasized.

During the same event, five (5) pharmaceutical manufacturers were visited to include SOPHAL (SOPHAL Site 1, Site 2) Orion Lab, Groupe Industries SAIDAL and Biopharm.

Mr. Paul Sonda, who is the TMDA Senior Pharmaceutical Inspector expressed his appreciation for being invited and reiterated that so far the Authority has not registered any product from Algerian based companies. In his remarks he narrated on the opportunity for Algerian pharmaceutical and medical equipment manufacturers to invest in Tanzania and how this would be potential in increasing their market share. "The government has been working to improve business environment in favor of investors in Tanzania" he lamented.

On his side, SOPHAL Pharmaceutical Company Director General, Mr. Khalil Amry, commented that some Algerian pharmaceutical companies have expressed interest in investing in Tanzania.

"We have been in regular contact with the Embassy Office, and they have invited us to visit Tanzania in July 2022 during the Dar es Salaam International Trade Fair (Saba Saba)). We learned a lot about Tanzania and that the business environment has encouraged us to invest, and we have already applied to the country's Medicines Authority for registration of our products," cemented Mr. Amry

TMDA emerged 2nd Runner-up amongst Institutions with Best ICT Solutions

TMDA has emerged the 2nd runners-up for exemplary performance in the areas of compliance to the e-Government (e-GA) Act Standards and Guidelines for the year 2021/2022.

The Award was presented to TMDA by the Deputy Minister, President's Office, Public Service Management and Good Governance, Hon. Deogratius Ndejembi in Arusha on 8th February, 2023 during the 3rd e-GA Working Session.

The event attracted e-GA stakeholders who are mainly public institutions and other key players to deliberate on the success and challenges facing the ICT industry in smooth implementation of the set legal frameworks aiming to enhance public service.

The assessment of the winners was competitive and coordinated

by e-GA and was done by a team of experts working in the government.

The outcomes of the assessment which recognizes TMDA as one of the few public institutions with the best ICT solutions, has created more impetus in service delivery towards protecting and promoting public health.

ABREMA delegation visits TMDA

The TMDA hosted a delegation from Burundi Food and Medicines Regulatory Authority (ABREMA) between 17th and 19th January 2023. The team which was led by the Director General, Mr. Nduwayo Ildephonse was on a 3-day study tour visit to learn and gain experience on how TMDA operates in regulation of medical products.

The contingent was taken through principles and practices of good regulatory systems, quality management systems, product evaluation and registration, inspection practices, import and export control, pharmacovigilance, clinical trials control, post-market surveillance, regulation of medical devices, human and financial resources management and strategies in place to promote domestic manufacturing.

Speaking at the closing event after the tour, Mr. Nduwayo Ildephonse expressed his gratitude to the TMDA for the warm reception and the unique learning opportunity the visit had offered.

He added that the team had acquired tremendous knowledge which will be reciprocated in building capacity of ABREMA staff once back in Burundi.

On the flip side, the TMDA Director General, Mr. Adam Fimbo, thanked the delegates and welcomed them for further interaction and collaboration in the future as part of implementation of the signed Memorandum of Understanding (MoU) between the two Authorities.

In his concluding remarks, Mr. Fimbo asserted and commended the delegation for their commitment and pretty industrious approach in strengthening their Authority.

He assured them full cooperation and technical support to improve access to medicines as joint efforts are needed to curb substandard and falsified (SF) medicines in the region.

TMDA approves guidelines for good regulatory and reliance practices

In March 2023 TMDA finalized and approved for use newly developed guidelines on "Good Regulatory Practices for Medical Products" and "Good Reliance Practices". The documents have been crafted as a result of ongoing efforts of the Authority to improve perfomance and ensure access to quality and safe medical products to the public.

According to a statement issued by the TMDA Director General, Mr. Adam Fimbo, the Good Regulatory Practices guidelines will provide guidance on good regulatory practices (GRPs) for stakeholders to maintain WHO Maturity Level 3 (ML3) standards including strenghterning medical products control.

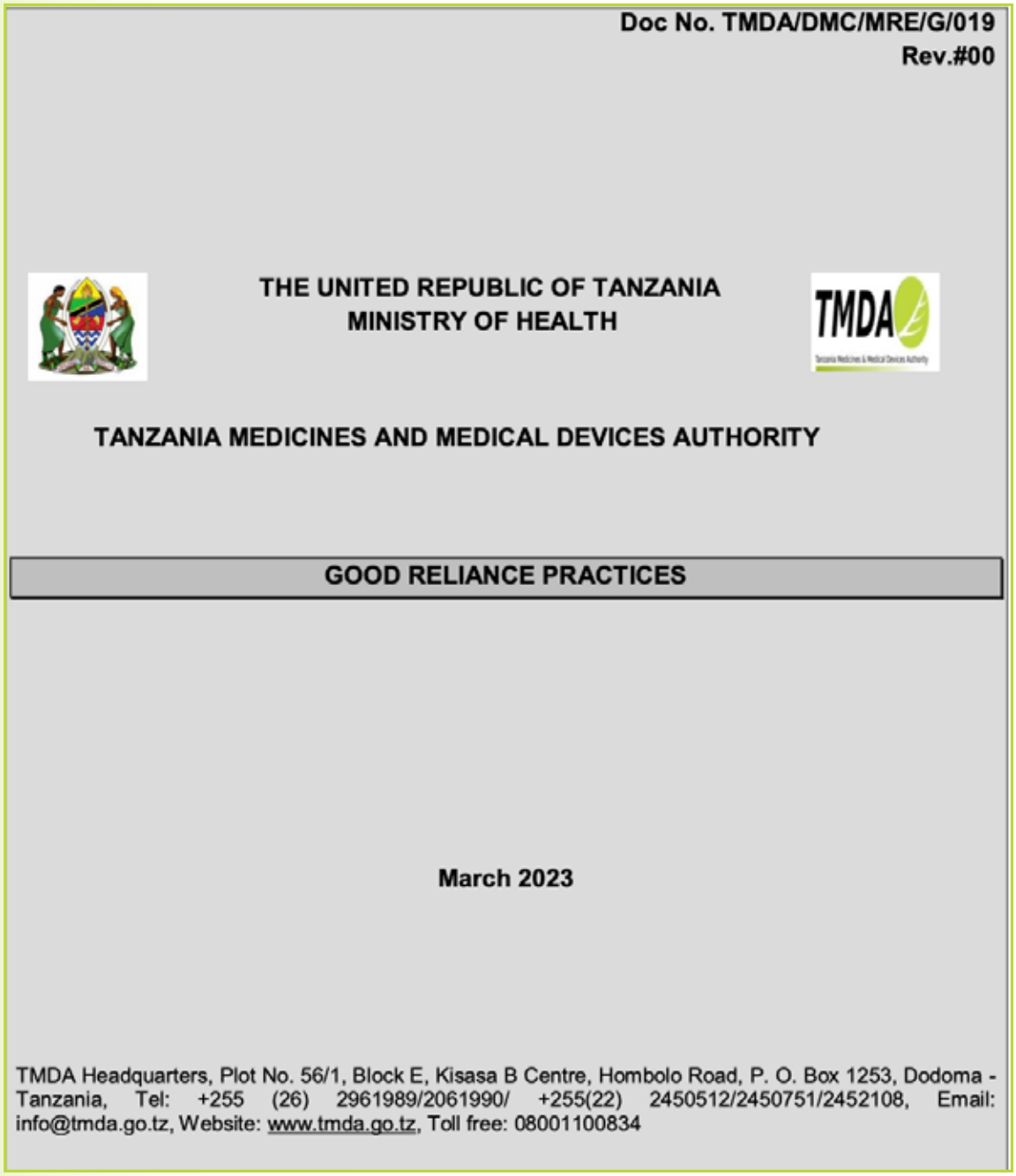
It should be noted that since November 2018, TMDA attained WHO ML-3 and became the first National Regulatory Authority in Africa to attain such recognition. This achievement was made possible by implementing Institutional Development Plans (IDPs) recommended by WHO benchmarking team in May 2018.

The approved GRP guidelines will further help in addressing regulatory challenges such as globalization of markets, complex supply chains, limited global resources and workload.

On the flip side, the Good Reliance Practice guidelines will assist in making decisions based on other National Regulatory Authorities (NRAs).

The guidelines provide for adopting approaches to optimize the use of limited resources and expertise, reducing work duplication and speeding-up approval processes.

Regulated parties and other TMDA intended stakeholders are urged to go through the approved guidelines for effective implementation.



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THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GOOD RELIANCE PRACTICES

March 2023

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Report medical devices incidents and events to save lives

Voluntary reporting of suspected adverse incidents or events related to medical devices by healthcare professionals and consumers is critical to enable the Authority get feedback on the safety of such products circulating on the market. Any debilitating, harmful, toxic or detrimental effect that a medical device has needs to be reported, investigated and prevented.

Medical devices are instruments, apparatuses, implements, medical equipment, machines, contrivances, implants, in vitro reagents or other similar or related articles used for the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment or prevention of diseases, in man or animals.

TMDA urges the public and healthcare providers to report any suspected event or incident occurring after device use by filling out an ORANGE FORM which is

available on the TMDA website (https://www.tmda.go.tz/publications/97) or at the nearest health facility, pharmacy, DMO's office, TMDA zone office or vigilance center.

An electronic reporting tool has also been created to smoothen the reporting of such incidents and events. This is available at https://sqrt.tmda.go.tz. Furthermore, a toll-free number 0800110084 and dialed code number *152*00# can be used for those with mobile phones.

Reporting of device incidents and events will help to safeguard public health.

New diagnostics testing laboratory launched at TMDA

The Tanzania Medicines and Medical Devices Authority (TMDA) has launched its new laboratory dedicated for testing diagnostics in Dar es Salaam. The new lab has been installed with new modern equipment worth 250 million shillings to expand and increase its services of analysing diagnostics. Some of the installed equipment include LED microscopes, refrigerators, biosafety cabinets, centrifuge machine and thermocycler.

Diagnostics Testing Laboratory verifies the performance of rapid diagnostic tests/assays and checks whether a diagnostic is performing within the desired accuracy and sensitivity.

Speaking during the launching event, Ms. Catherine Luanda – the Manager responsible for Medical Devices and IVDs Testing at TMDA lamented that the installation of the new equipment has been pivotal and it will expedite the screening of diagnostics for TMDA clients.

"Availability of modern laboratory equipment is critical in any laboratory and the same will help in testing of diagnostics to obtain reliable results" Ms. Catherine alluded-to. She went on to describe how some of the equipment will be used to carry out performance verification of rapid diagnostic test kits for malaria (MRDTs), HIV – RDT, Syphilis – RDT and Urine Pregnancy test (UPT).

Diagnostics refers to devices whether used alone or in combination and as intended by the manufacturer for the in – vitro examination of specimens derived from human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes.

Paracetamol and antibiotics are the mostly imported medicines in Tanzania

The current data from TMDA importation database shows that about 13,000 human medicines have been imported into Tanzania since 2020. Products containing Acetylsalicylic Acid + Caffeine + Paracetamol are at the top of the list.

Others on the top-five list includes Ampicillin and Cloxacillin combination, Paracetamol, Magnesium + Aluminium + Simethicone, and Goodmorning lung tonic in this order.

TMDA Manager of Medicines Registration, Mr. Felchism Apolinary, said that the highly imported medicines signifies that the same are widely consumed in Tanzania for the past three consecutive years.

Mr. Felchism calls upon investors to grasp the opportunity and invest on manufacturing of active pharmaceutical ingredients (APIs) or finished pharmaceutical products (FPPs) of such medicines in Tanzania. "Investors are encouraged to invest heavily in the pharmaceutical industry sector as the investment environment in Tanzania is conducive and the market is stable" he elaborated.

He added that, TMDA is committed and well organized to provide technical support at all levels of investment in Tanzania specifically to investors who intend to invest in pharmaceutical industry in the country.

TMDA Eastern Zone leads in terms of performance of Mini-Lab Kits

TMDA Quality Control Laboratory was established under Section 14(1) of the Tanzania Medicines and Medical Devices Act, Cap. 219, to carry out analysis of regulated products. TMDA has three laboratories located at TMDA sub-Head office in Dar es Salaam, Mwanza and at Head office in Dodoma. The established laboratories are complemented by 25 Quality Assurance Centers (QAC) across the country.

The purpose of Quality Assurance Centers is to screen consignments of selected group of medicines at port of entries before and after entering the Tanzanian market. They also facilitate monitoring of quality of registered medicines to safeguard public health.

All established QAC are equipped with Mini-Lab kits for detecting substandard and falsified (SF) medical products.

TMDA, located its 25 Mini-Lab kits to 13 regional referral hospitals in Geita, Bukoba, Musoma, Manyara, Kilimanjaro, Mbeya, Katavi, Iringa, Lindi, Mtwara, Songea, and Bukoba. Others are at seven (07) TMDA zone offices and five (05) at Mtukula, Sirari, Kilimanjaro International Airport, Namanga, and Tunduma ports of entry.

Performance assessment of all 25 Mini-Lab Kits in the country has shown that the Eastern Zone Office in Dar es Salaam has done well for two years. A total of 719 samples were screened in 2021/22 and 617 in the 3rd quarter of 2022/23. The assessment further shows that in 2021/22 the lowest performing centre was Kigoma RRH with five (05) samples while the second best was TMDA Eastern Lake Zone Office which screened 478 samples. Samples screened are mainly anti-malarials, anti-TBs, ARVs and painkillers.

Mini-Lab Kit is a simple and relatively easy technique used to quickly test the quality of medicinal products on the field. The Kit is capable of carrying out visual inspection, disintegration test for oral solid dosage forms and thin-layer chromatography (TLC) for identification of active pharmaceutical ingredients (APIs) present in a formulation.

To confirm that all 25 Mini-Lab Kits are working efficiently, TMDA has been providing regular training to experts including ensuring constant supply of reagents including close monitoring of its performance.

Mini-Lab Kit is a simple and relatively easy technique used to quickly test the quality of medicinal products on the field. The Kit is capable of carrying out visual inspection, disintegration test for oral solid dosage forms and Thin-Layer Chromatography (TLC) for identification of Active Pharmaceutical Ingredients (APIs) present in a formulation.

TMDA conducts training on AEFI reporting to healthcare workers in 10 regions

Tanzania Medicines and Medical Devices Authority (TMDA) has conducted the Training of Trainers (ToT) on supportive supervision of monitoring and reporting of adverse events following immunization (AEFI) to 30 participants between 31st January – 3rd February 2023 in Morogoro region. The four-day ToT training aimed at sensitizing and raising awareness to trainers from health care workers reporting of AEFI.

Officiating the training, Director of Medical Devices and Diagnostics, Ms. Kissa Mwamwitwa, urged participants to focus on the presented topics as it was expected the same to be trained to other officers from their respective working stations.

"It is my expectation that you will pay attention to the training provided so that at the end we can all reach the goal intended by TMDA and finally achieve the World Health Organization (WHO) set targets of 60 and 1,197 of Serious and Non-Serious AEFI reports respectively annually", Ms. Kissa said.

The 30 ToT participants came from different administrative councils in 10 regions namely Arusha, Kilimanjaro, Mara, Simiyu, Njombe, Mbeya, Morogoro, Dar es Salaam, Iringa and Singida.

The designation of trainees comprised of District Pharmacists, District Veterinary Officers (DVOs), Medical Officers in charge, Pharmacists in charge, Nursing Matrons and other healthcare workers.

TMDA is committed to expand such training to reach all healthcare workers countrywide to assure the safety, quality and effectiveness of vaccines in the country.

"It is my expectation that you will pay attention to the training provided so that at the end we can all reach the goal intended by TMDA and finally achieve the set targets by WHO of 60 and 1,197 of Serious and Non-Serious AEFI reports respectively annually", Ms. Kissa said.

"Reveal individuals and gangs engaged in substandard medicines": Public urged

The public have been urged to disclose unlawful gangs or individuals engaged in clandestine manufacturing and distribution of substandard and falsified (SF) medical products in the country.

The call was made following the arrest of one resident of Kipawa - Dar es Salaam after being caught to manufacture falsified medicines on 14th April 2023.

TMDA Eastern Zone Drug Inspector, Mr. Japhary Mtoro when speaking to reporters alluded that the suspect was found to single-handedly manufacture substandard or falsified medicines and that the successful operation to snatch him was also coordinated by the help of the Police Force.

"The suspect was caught on the midnight at his place in Kipawa area in Dar es Salaam whereby falsified labels, containers and medicines were found and confisticated". Mr. Japhary lamented,

A total of 537 labels for different types of medicines to include Quinine sulphate and erythromycin, were found within the residence of the suspect after thorough search.

"Three boxes, one containing yellow powder and two others containing white powder, suspected to be raw materials were found. Furthermore, 12 empty plastic cans used to pack falsified medicines were also confiscated". Mr. Japhary explained further.

Supplying falsified medicines is a crime against humanity. All culprits must be located, fetched and taken into custody as they endanger public health.

It is also a serious offence under the Tanzania Medicines and Medical Devices Act, Cap 219.

On her part, the Village leader of, Matembele Street, Ms. Maryglory Mambo, who was cooperating with TMDA and the Police Force during the search, has urged the public to join efforts with TMDA by revealing unscrupulous individuals engaged in such criminal acts.

"Three boxes, one containing yellow powder and two others containing white powder, suspected to be raw materials were found. Furthermore, 12 empty plastic cans used to pack falsified medicines were also confiscated". Mr. Japhary explained further.

Four years of maturity level 3: WHO Re-Benchmarks TMDA

In December 2018, TMDA attained Maturity Level 3 (ML3) of the World Health Organization (WHO) for setting-up a good, robust and functioning regulatory system of regulation of quality, safety and efficacy of medicines. Attainment of this level made Tanzania the first country in Africa to reach the rank.

The ranking was achieved after successful assessment of TMDA systems by WHO using the Global Benchmarking Tool (GBT). The tool is used by WHO to evaluate regulatory systems and determine the level of their maturity as to whether they are functioning with stable and consistent performance.

Since then, TMDA has been striving to maintain the status-quo through strengthening systems to uphold WHO standards and continue to provide quality, effective and efficient regulatory services in the pursuit of promoting and protecting public health.

As a means of follow-up and in tandem with ensuring that standards are maintained, a team of 10 WHO assessors visited TMDA between 27th and 31st March, 2023 to re-benchmark TMDA systems. The exercise aimed at measuring the level of compliance to the benchmarking standards and their effectiveness in regulation of medicines and vaccines.

The assessment which took five working days was completed with a set of issues needing to be addressed by TMDA before formal announcement by WHO on the current maturity status in July, 2023. The TMDA is addressing the issues in the meantime.

Apart from TMDA, other authorities in Africa which have been benchmarked and found to reach ML3 include the Ghana Food and Drugs Authority (Ghana FDA), the National Agency for Food & Drug Administration of Nigeria (NAFDAC), the Egyptian Drug Authority (EDA) and the South African Health Products Regulatory Authority (SAHPRA).

End-line assessment of pavia project

Between 20th August to 2nd September 2022, the PAVIA Project Team conducted an End-Line Assessment of the PAVIA Project. The exercise focused on assessment of implementation of activities conducted by TMDA, National Tuberculosis & Leprosy Program (NTLP), Kilimanjaro Clinical Research Institute (KCRI) and Kibong'oto Hospital (KIDH) in Tanzania. PAVIA Project experts to include Ms. Liza de Groot and Dr. Edine Tiermesma both from KNCV and Dr. Linda Harmark from Lareb, the Netherlands were involved.

The assessment compared implementation of PV activities in Tanzania at baseline when the project was introduced in 2018 and at the end in 2023. The PV assessment tool was used in the assessment including in-depth interviews and zoom calls. The tool covers all aspects of PV system at the national and institutional levels, regulations in place, guidelines approved and in implementation, standard operating procedures (SOPs) and other relevant documents. Others include human resources capacity, existence of reporting centers, reporting infrastructure and tools and performance indicators measuring effectiveness and efficiency of the PV system.

Findings from this assessment have revealed that tremendous progress has been made in strengthening the PV system in Tanzania. Human resources capacity has been built, active surveillance system involving the adoption of a cohort event monitoring (CEM) of drug safety has assisted in improving reporting of ADRs and the spontaneous reporting system has been bolstered and enabled the number of ADR reports to climb to 9,468 as compared to 114 reports in 2018 when PAVIA was introduced.

PAVIA, or in its long form - PharmacoVigilance Africa, was an EDCTP funded project which involved consortium institutions to include Regulatory Authorities from four (4) African countries; Ethiopia, Kingdom of Eswatini, Tanzania, and Nigeria. Others embraced international collaborators including University of Verona (Italy), KNCV and Amsterdam Institute for Global Health Development (AIGHD), the Netherlands.

OBITUARY

Mr Mtani Njegere

On Sunday 6th November 2022, TMDA was banged with tragic and shocking news on the demise of our beloved staff and brother – Mr. Mtani Njegere. The passing away of Mr. Njegere was received with a great sorrow, sympathy, bitterness and sadness amongst employees as he was a loving, gentle and charismatic fellow.

Mr. Njegere died following the Precision Air crash whereby 19 people were killed when the Plane crashed in Lake Victoria while attempting to land at the Bukoba Airport.

The deceased joined TMDA on 2nd August, 2010 and served as a Drug Inspector for 12 years up to 1st April, 2022 when he was appointed the Acting Manager for Clinical Trials and Pharmacovigilance, a position that he served up to his tragic death.

Late Njegere was undoubtedly a hardworking, dedicated person and devoted his life time to his job.

His contribution to TMDA and the nation at large will always be honoured.

MAY THE SOUL OF MR. NJEGERE REST IN ETERNAL PEACE AMEN

SOCIAL WELFARE NEWS

FAREWELL NEWS

Farewell ceremony to Mr. Paul Makaranga, Mr. Didas Mutabingwa, Dr. Glory Omary and Ms. Agnes Mnenei, TMDA retired staff which took place on 17th April, 2023 in Dar es salaam office

SPORTS FOR HEALTH

Pictorial News/Habari Picha

A group photo of TMDA retired officers together with TMDA Director General Mr Adam Fimbo and other officials during the Farewell ceremony which took place on 8th April, 2023 in Dar es Salaam office.

Picha ya pamoja katika hafla ya kuwaaga watumishi wastaafu wa TMDA

TMDA and BRELA officials in a group photo after a short session of sharing experience in implementing quality management system at TMDA offices, on 21st April 2023, in Dar es salaam.

Watalaam wa TMDA na BRELA wakiwa katika picha ya pamoja mara baada ya kubadilishana uzoefu kuhusu mifumo bora ya utendaji kazi

Public awareness throuth exibition

Uelimishaji jamii kupitia maonesho

WHO Re Benchmarking Assessment of National Medicines and Vaccines Regulatory Systems at TMDA HQ premises in Dodoma from 27th -31st March, 2023

Tathmini ya Shirika la Afya Duniani (WHO) kwa TMDA baada ya miaka minne ya kufikia ngazi ya WHO L-3

MAB chairman Mr. Eric Shitindi presenting a trophy to the outgoing Mr. Mick Kiliba as an appreciation for serving as Board member between 2020 to 2022

Mwenyekiti wa Bodi Bw. Eric Shitindi akikabidhi tuzo kwa Mjumbe wa Bodi Bw. Mick Kiliba aliyemaliza muda wake.

Pictorial News/Habari Picha

The Tabora Regional Commissioner Hon. Amb. Dr. Batilda Burian receiving TMDA documents from the MAB Chairman Mr. Eric Shitindi when they officially met on 13th March, 2023 in Tabora region

Mkuu wa Mkoa wa Tabora akipokea nyaraka za TMDA kutoka kwa Mwenyekiti wa Bodi

The Kigoma Regional Commissioner Hon. Thobias Andengenye receiving TMDA documents from the MAB Chairman Mr. Eric Shitindi when they officially met on 17th March, 2023 in Kigoma region

Mkuu wa Mkoa wa Kigoma akipokea nyaraka za TMDA kutoka kwa Mwenyekiti wa Bodi

A panel of health experts from Germany and Subsaharan Countries visited TMDA Northen Zone Office on 3rd September 2022 for regulatory functions familiarisation. The experts were in Arusha from 29th August to3rd September 2022 to discuss the quality, safety and disposal strategies of pharmaceutical products.

Wataalam wa afya kutoka Ujerumani na nchi zilizo kusini mwa jangwa la Sahara wakibadilishana uzoefu wa majukumu ya udhibiti

Members of Ministerial Advisory Board (MAB) in group photos during their official visit to Ports of Entries at Western Zone in Kigoma, Katavi and Tabora regions. The visit which commenced between 06th and 10th March, 2023 aimed at overseeing implementation of the TMDA Mission of protecting and promoting public health.

Wajumbe wa Bodi wakitathmini majukumu ya udhibiti wa TMDA katika vituo vya forodha Kanda ya Magharibi kwa mikoa ya Tabora, Kigoma na Katavi

Participants of Training on Performance Evaluation of In Vitro Diagnostic Medical Devices (IVD's), in a group photo with experts.

Washiriki wa mafunzo ya kujenga umahiri wa wataalam kutathmini vifaa tiba

Social Welfare Committee members of the Zanzibar House of Representatives visiting TMDA Mwanza Laboratory - 11th November 2022

Ugeni wa Kamati ya Huduma za Jamii kutoka Baraza la Wawakilishi Zanzibar

A panel of health experts from Germany and S ubsaharan Countries, visited TMDA Northen Zone Office on 3rd September 2022 for regulatory familiarisation. The experts were in Arusha from 29th August to3rd September 2022 for their meeting aimed at discussing the quality, safety and disposal of pharmaceutical products

Wataalam wa afya kutoka Ujerumani na na nchi zilizo kusini mwa jangwa la Sahara walikutana Arusha kujadili uzoefu wa majukumu ya udhibiti wa dawa nchini

Pictorial News/Habari Picha

The DG, Adam M. Fimbo submitting TMDA performance report before the Parliamentary Committee responsible for Social Service and Community development in Dodoma on 1st September 2022

Mkurugenzi Mkuu na Menejimenti ya TMDA Bw Adam M. Fimbo wakiwa katika picha ya pamoja baada ya uwasilishaji wa Taarifa ya Utendaji kazi wa TMDA katika Kamati ya Kudumu ya Bunge ya Huduma za Maendeleo ya Jamii

Delegates from Quality Control Laboratories of National Medicines Regulatory Authorities from Burundi, Botswana, Zambia, Mozambique, Tunisia and Senegal made a five days study tour to TMDA on how the Laboratory Accredited/ Prequalified on procedures. The mission is organised by AUDA-NEPAD as part of the African Medicines Quality Forum plan of action to strengthen QC Labs. Took place from 3rd to 9th October 2022 in Dar es salam

Ziara ya mafunzo kwa Wataalam wa maabara za Mamlaka nyingine za udhibiti wa dawa barani Afrika, tarehe 3-9 Oktoba 2022 katika ofisi za TMDA Dar Es Salaam

Pictorial News/Habari Picha

WHO Re Benchmarking Assessment of National Medicines and Vaccines Regulatory Systems at TMDA HQ premises in Dodoma from 27th -31st March, 2023

Tathmini ya Shirika la Afya Duniani (WHO) kwa TMDA baada ya miaka minne ya kufikia ngazi ya WHO L-3

Capacity Building to assessors of Medical Devices and Diagnostics experts at Kibaha in Coast Region

Mafunzo ya kuwajengea uwezo wataalam wa ndani katika tathmini vifaa tiba

Awareness training on Mental Health Diseases to TMDA staff as facilitated by Mirembe National Mental Hospital on 15th February, 2023 in Dodoma

Uhamasishaji watumishi wa TMDA kuhusu magonjwa ya afya ya akili

Awareness training on Mental Health Diseases to TMDA staff as facilitated by Mirembe National Mental Hospital on 15th February, 2023 in Dodoma

Watumishi wa TMDA wakipata mafunzo kuhu-su magonjwa ya afya ya akili

Pictorial News/Habari Picha

Stakeholder's engagement in the development of the Action Plan for the promotion of medical products manufacturing facilities, the meeting was held on 6th -7th June, 2022 in Dar es Salaam

Ushirikishaji wadau katika kutengeneza mpango kazi kuhamasisha viwanda vya vifaa tiba nchini

Public Education on Rational Use of Medicines to General Public

Elimu kwa umma kuhusu matumizi sahihi ya dawa

"Together we protect and promote Public Health"

kwa pamoja tunalinda afya ya jamii

TMDA
Tanzania Medicines & Medical Devices Authority

Jarida

Toleo Na. 12 | Aprili 2023

KAMATI YA BUNGE YA TEMBELEA OFISI ZA TMDA ZA KANDA YA KASKAZINI NA KANDA YA ZIWA

MAB YAPONGEZA MIFUMO YA UDHIBITI KATIKA VITUO VYA FORODHA

Yaliyomo

MAELEZO YA AWALI YA MKURUGENZI MKUU

Ninayo furaha kubwa kuwasilisha kwako toleo letu la 12 la Jarida hili ambalo ni mwendelezo wa lile lillowasilishwa kwenu mwaka jana. Kama kawaida, toleo hili linaongelea baadhi ya mafanikio na hatua muhimu za udhibiti wa usalama, ubora na ufanisi wa dawa, vifaa tiba, vitendanishi na bidhaa za tumbaku.

Miongoni mwa mambo mengi yaliyomo humu, toleo hili lina habari juu ya namna TMDA ilivyokamata watu wanaojihusisha na magenge ya utengenezaji na usambazaji wa dawa bandia. Ikumbukwe kwamba uingizaji wa dawa bandia sio tu kwamba ni uvunjifu wa sheria, bali pia ni uhalifu dhidi ya maisha ya binadamu.

Jambo lingine zuri lilipo humu linahusu tathmini ya kina iliyofanywa na timu ya wakaguzi wa Shirika la Afya Duniani (WHO) ambao walitembelea TMDA kufanya kazi hiyo ya ulinganishaji upya wa mifumo ya TMDA endapo inaendelea kukidhi mifumo ya udhibiti ya kimataifa.

Aidha, toleo hili pia linaangazia masuala mengine muhimu ikiwa ni pamoja na tathmini ya utendaji wa maabara hamishika za TMDA, tathmini ya mwisho ya mradi wa PAVIA na mafunzo ya wakufunzi kuhusu ufuatiliaji na utoaji taarifa za madhara yanayoweza kutokea kutokana na matumizi ya Chanjo (AEFIs).

Makala nyingine zilizomo katika chapisho hili ni pamoja na ziara Wajumbe wa Kamati ya Kudumu ya Bunge ya Afya na Ustawi wa Jamii katika ofisi za TMDA kanda zilizopo Mwanza na Arusha sanjari na na ziara ya Wajumbe wa Bodi ya Ushauri ya Wizara katika vituo vya forodha vilivyopo Magharibi mwa nchi yetu.

Kando na mafanikio mengine makubwa yaliyofikiwa, toleo hili pia lina taarifa za anuwai za kusisimua ikiwa ni pamoja na namna Mamlaka inavyofanya kazi kwa weledi ili kuvutia wawekezaji wa viwanda vya dawa nchini, tuzo ambazo TMDA imepokea kwa kuwa na mifumo bora ya kieletroniki ya utoaji huduma katika mazingira rafiki ya biashara pamoja na Tuzo za Umahiri wa Uhusiano wa Umma ya mwaka 2022 katika utoaji wa programu bora za elimu kwa umma.

Kwa muhtasari, Toleo hili la 12 linaonesha idadi ya shughuli muhimu ambazo ni za kuvutia na kuongeza uelewa wa msomaji.

Nakutakia usomaji mwema!

Adam M. Fimbo
MKURUGENZI MKUU

Adam M. Fimbo
MKURUGENZI MKUU

TAHARIRI

Ndugu mpendwa msomaji,

Ninayo heshima kubwa kwa mara nyingine kuwasilisha Jarida la TMDA toleo la 12. Ni zaidi ya muongo mmoja sasa, tumekuwa tukichapisha Jarida hili kama sehemu ya juhudi zinazoendelea za TMDA za kutoa taarifa mbalimbali za udhibiti kwa wadau wetu wapendwa, ikiwa ni pamoja na wewe msomaji.

Utii wa hiari wa matakwa ya sheria ya TMDA ni pamoja na kuwa na taarifa za kutosha na za mara kwa mara za kiudhibiti kwa wadau katika kurahisisha na kufanikisha kazi za udhibiti. TMDA imekuwa ikichapisha Jarida hili ili kuifikia sehemu kubwa ya jamii na kuongeza uelewa juu ya shughuli za udhibiti zinazofanywa ndani ya kipindi ambacho taarifa hii imetolewa.

Kwa uzito wa kipekee, napenda kumshukuru Mhariri Mkuu, Bw. Adam M. Fimbo ambaye pia ni Mkurugenzi Mkuu wa TMDA kwa usimamizi wake thabiti na uongozi mahiri katika kipindi chote cha uandaaji na uidhinishaji wa toleo hili.

Mamlaka ina kazi kubwa ya kulinda afya ya jamii ikiwa ni pamoja na kuendelea kutoa wito kwa jamii kuwafichua watu wasio waaminifu wanaojishughulisha na utengenezaji na usambazaji wa bidhaa za tiba ambazo ni duni na bandia katika soko hapa nchini.

Nachukua fursa hii, kukualika kusoma na kufuatilia taarifa zinazotolewa na TMDA kupitia njia mbalimbali za mawasiliano likiwemo jarida hili ili uweze kufahamu mambo mbalimbali yanayotendeka ndani ya Mamlaka katika kukuhakikishia usalama, ubora na ufanisi wa dawa, vifaa tiba, vitendanishi na bidhaa nyingine zinazohusiana na afya.

Unakaribishwa kutoa maoni, ushauri na mrejesho kupitia njia mbalimbali za mawasiliano ya taasisi ili kuboresha maudhui ya jarida hili.

Karibu usome kwa furaha!

Gaudensia Simwanza
MENEJA, MAWASILIANO NA ELIMU KWA UMMA

Gaudensia Simwanza
MENEJA, MAWASILIANO NA ELIMU KWA UMMA

BODI YA WAHARIRI

Kamati ya Bunge yatembelea ofisi za TMDA za Kanda ya Kaskazini na Kanda ya Ziwa

Kamati ya Bunge ya Kudumu ya Huduma za Jamii na Maendeleo ilitembelea Ofisi za TMDA Kanda ya Kaskazini na kanda ya Ziwa zilizopo jijini Arusha na Mwanza ili kujionea shughuli mbalimbali za udhibiti zinazosimamiwa na TMDA kati ya tarehe 24 na 26 Septemba 2022.

Ziara hiyo iliyokuwa ya siku tatu ilimshirikisha pia Naibu Waziri wa Afya, Mhe. Dkt. Godwin Mollel (Mb) kwa niaba ya Waziri wa Afya, iliongozwa na Mwenyekiti wa Kamati hiyo ya Bunge, Mhe. Stanslaus Nyongo (Mb) aliyeambatana na wajumbe wengine 30 wa Kamati hiyo.

Kwa upande wake, Mkurugenzi Mkuu wa TMDA, Bw. Adam M. Fimbo aliwasilisha taarifa ya utendaji katika Kamati hiyo tarehe 24 Septemba, 2022 katika ofisi ya TMDA - Kanda ya Kaskazini jijini Arusha.

Wakati wa ziara hiyo ya Kamati katika Kituo Jumuishi cha Mpakani cha Namanga (OSBP) kilichoko Arusha iliridhishwa na kazi nzuri za udhibiti za TMDA kwa kuweka mifumo bora ya udhibiti wa uingizaji bidhaa nchini na uchunguzi wa ubora wa dawa kwa kutumia Maabara Hamishika (Mini lab) kabla ya kuruhusiwa kuingia katika soko.

Kamati pia ilipata muda wa kuzungumza na wasimamizi wengine wa sheria katika kituo hicho cha Namananga OSBP kwa lengo la kujifunza ushirikiano uliopo baina ya taasisi nyingine za udhibiti ndani ya Serikali.

Mwenyekiti wa Kamati hiyo Mhe. Stanslaus Nyongo (Mb) kwa niaba ya wajumbe, aliipongeza Mamlaka kwa kazi nzuri inayofanyika na kuishauri TMDA iendelee kufanya kazi kwa bidii ili kulinda afya ya jamii kwa kuwa watu wengi wanaweza kuwa katika hatari ya kupata madhara yatokanayo na matumizi ya bidhaa zisizofaa.

Aidha, Mhe. Nyongo alipongeza ushirikiano uliopo baina ya taasisi za Serikali zinazofanya kazi kwenye kituo cha Namanga OSBP ikiwa ni pamoja na Mamlaka ya Mapato Tanzania (TRA), Wakala wa Maabara ya Mkemia Mkuu wa Serikali (GCLA), Shirika la Viwango Tanzania (TBS), Mamlaka ya Nguvu za Atomiki Tanzania (TAEC), Maafisa afya, Mamlaka ya Afya ya Mimea (TPH), Jeshi la Uhamiaji na Jeshi la Polisi.

"Tumejionea jinsi TMDA ilivyojipanga katika kutekeleza majukumu yake hususani katika ukaguzi wa dawa kwenye kituo jumuishi cha Namanga, Arusha na Uchunguzi wa Maabara ya TMDA jijini Mwanza na tumeridhishwa na kile kinachofanywa na TMDA," alieleza Mhe. Nyongo.

Vilevile, Mhe. Nyongo aliishauri Mamlaka kuimarisha mifumo ya udhibiti ikiwa ni pamoja na kuongeza rasilimali watu zaidi kwenye vituo vya mipakani ikiwa na lengo la kuwahakikishia wananchi usalama wa wa bidhaa za dawa, vifaa tiba na vitendanishi vinavyoingia nchini.

Wakiwa jijini Mwanza, Wajumbe wa Kamati husika walifurahishwa na uwekezaji mkubwa wa vifaa vya kisasa katika Maabara ya TMDA jijini Mwanza ambayo inalenga katika kuwahudumia wananchi wa Kanda ya Ziwa na nchi jirani.

Naye Mwenyekiti wa Bodi ya Ushauri (MAB), Bw. Eric Shitindi aliwashukuru Wajumbe wa Kamati hiyo kwa kufanya ziara husika ya kikazi katika ofisi za TMDA za Kanda na kuwahakikishia wajumbe wa Kamati kuwa Bodi itasimamia utekelezaji wa maagizo na maelekezo ya Kamati yaliyotolewa.

MAB yapongeza mifumo ya udhibiti katika vituo vya forodha

Bodi ya Ushauri ya Wizara ya Afya kwa TFDA (MAB) imeipongeza TMDA kwa uwekezaji wa mifumo ya udhibiti wa uingizaji nchini kwa bidhaa za dawa, vifaa tiba na vitendanishi kwenhye vituo vya forodha (PoE).

Pongezi hizo zilitolewa na Mwenyekiti wa MAB, Bw. Eric Shitindi katika ziara ya kikazi ya MAB iliyofanyika katika Ofisi za TMDA Kanda ya Magharibi kuanzia tarehe 06 hadi 10 Machi, 2023.

Katika ziara hiyo iliyojumuisha wajumbe wa Menejimenti, vituo vyote vya forodha vilivyopo katika mikoa ya Kigoma, Katavi na Tabora vilitembelewa ikiwa ni pamoja na hospitali za rufaa za mikoa, vituo vya uchunguzi wa dawa, matanuri ya kuchomea taka, mitambo ya kuzalisha gesi tiba na vituo vya huduma za uongezaji damu.

Bw. Shitindi aliipopngeza Menejimenti ya TMDA kwa juhudi inazofanya katika kusimamia na kuimarisha mifumo ya udhibiti wa bidhaa nchini. “Sisi kama Bodi Tumeridhishwa na mifumo ya udhibiti iliyopo ambayo inajumuisha ukaguzi wa mara kwa mara wa vituo vya forodha ili kudhibiti bidhaa za tiba zisizokidhi viwango, bidhaa bandia na zisizoruhusiwa kuingia nchini mwetu”. Bw. Shitindi Alisema

Katika ziara hiyo, wajumbe wa MAB pia waliweza kukutana na Wakuu wa Mikoa ya Kigoma, Tabora na Katavi kwa lengo la kufahamiana ambapo wakiwa mkoani Kigoma, Mkuu wa Mkoa huo Bw. Thobias Andengenye aliwapongeza wajumbe hao kwa kuendeleza ushirikiano uliopo kati ya TMDA na taasisi nyingine za udhibiti mkoani hapo na kuahidi kuendelea kushirikiana na Mamlaka katika kulinda afya ya jamii.

Katika hatua nyingine, Mkuu wa Mkoa wa Katavi, Bi. Mwanamvua Mrindoko alimshukuru Mwenyekiti wa MAB na ujumbe wake kwa kutembelea Mkoa wa Katavi na kuahidi kuunga mkono kwa vitendo kazi zinazofanywa na TMDA.

Vile vile, Katibu Tawala wa Mkoa wa Tabora (RAS) kwa niaba ya Mkuu wa Mkoa huo – Mhe. Balozi, Dkt. Batilda Buriani alitoa shukurani zake kwa Mwenyekiti wa MAB na wajumbe kwa kutembelea Mkoa wa Tabora. Alisisitiza kuhusu kudumisha na kukuza ushirikiano mzuri katika masuala yanayohusiana na majukumu ya TMDA na kwamba mkoa wake utaendelea kutoa ushirikiano katika kazi zinazolenga kulinda afya ya jamii.

Wajumbe wa Bodi ya Ushauri (MAB) ni pamoja na Mhe. Eric Shitindi (Mwenyekiti), Prof. Said Aboud, Prof. Appolinary Kamuhabwa, CPA Zaina Thabit, Bw. Daudi Msasi, Bi. Emma Lekashingo na Bw. Adam M. Fimbo (Katibu).

TMDA yashinda tuzo ya umahiri ya uhusiano wa umma

TMDA yawa mshindi wa pili katika Tuzo ya Umahiri ya Uhusiano wa Umma ya mwaka 2022 katika kundi la utoaji bora Elimu kwa Umma iliyotolewa na Chama cha Maafisa Uhusiano na Mawasiliano kwa Umma cha Tanzania (PRST) hapo tarehe 18 Februari, 2023 katika Ukumbi wa Mikutano wa Kimataifa wa Julius Nyerere, Dar es Salaam.

Tuzo hiyo ambayo ilipokelewa na Mkuu wa Kitengo cha Mawasiliano na Elimu kwa Umma kwa niaba ya Mkurugenzi Mkuu wa TMDA Bw. Adam Fimbo baadaye ilikabidhiwa kwake jijini Dodoma, ambaye alipongeza na kushukuru kwa hatua hiyo.

Uratibu mzuri wa TMDA katika programu za elimu kwa umma ambazo zimeweza kuifikia sehemu kubwa ya jamii na kufikisha ujumbe uliokusudiwa ndiyo chachu kubwa ya Mamlaka kufikia mafanikio hayo.

Katika mwaka 2022 pekee, TMDA iliweza kufanya jumla ya mihadhara 392, maonesho 27, vipindi vya televisheni na redio 114, machapisho na vielelezo vya uelimishaji 31, taarifa kwa vyombo vya habari 23, uhuishaji taarifa za tovuti 1,098 na mikutano mitano (05) ya waandishi wa habari

Matumizi ya vituo vinne vikubwa vya televisheni ambavyo ni TBC-1, ITV, Clouds TV na UTV vinavyorusha vipindi vya TMDA na Jamii kwa dakika 30 mara mbili kwa wiki vimesaidia sana Mamlaka kuweza kuwafikia wananchi wengi katika maeneo ya mijini na vijijini.

Maoni yaliyokusanywa na TMDA kutoka kwa watu katika makundi mbalimbali ya kijamii waliohojiwa wakati kufanya programu za uelimishaji umma kwa njia ya mihadhara, walionesha kutazama na kuvutiwa na vipindi vya TMDA katika runinga hivyo kupendekeza kuwa vipindi hivyo kuwa endelevu kwa mwaka mzima kwa kuwa vinaelimisha umma kwa njia rafiki.

Lengo mkakati la elimu kwa umma la Mamlaka limekuwa likiwekwa katika kila Mpango Mkakati wa TMDA wa miaka mitano tangu kuanzishwa kwa Mamlaka mwaka 2003. Programu hizo za elimu zilizoratibiwa vyema zimekuwa zenye manufaa kwa jamii na kuisaidia Mamlaka kujinyakulia tuzo mbalimbali ndani na nje ya nchi.

Tanzania yavutia wawekezaji zaidi viwanda vya dawa nchini

Ubalozi wa Tanzania nchini Algeria ulizialika taasisi za Tanzania zilizoko katika sekta za afya kukutana na wawekezaji wa viwanda vya dawa na vifaa tiba nchini Algeria mwezi Oktoba 2022. Ziara hiyo ilifanyika wakati wa Maonesho ya Sita ya Wafamasia yaliyoandaliwa na Ubalozi wa Tanzania nchini humo.

Ziara hiyo ni sehemu ya jitihada zinazofanywa na Balozi wa Tanzania nchini Algeria - Meja Jenerali Mstaafu Jacob G. Kingu ambaye anafanya kazi kwa bidii kuwashawishi wawekezaji kuwekeza nchini Tanzania.

Katika hotuba yake ya ufunguzi, Balozi Kingu alisisitiza kuhusu umuhimu wa kukuza uchumi kwa kuhakikisha upatikanaji wa huduma bora za afya zikiwemo dawa na vifaa tiba vya kutosha. “Miongoni mwa majukumu ninayofanya katika ubalozi wetu hapa ni kuhakikisha kuwa dawa na vifaa tiba vya kutosha vinapatikana nchini kwetu,” alidokeza Balozi Kingu.

Balozi Kingu alisema kwamba Ubalozi huo umekuwa ukihamasisha wawekezaji wa nje kutumia fursa zilizopo Tanzania kuwekeza katika viwanda vya dawa kwa kuwa uwezo wa viwanda vya ndani kwa sasa unachangia asilimia 10 hadi 20 tu ya mahitaji ya nchi.

“Mazingira ya uwekezaji nchini kwetu ni mazuri, tunachotilia mkazo kwa sasa ni kuelezea faida tuliyonayo kama nchi ya ukubwa wa soko,

uwepo kwa Bohari ya Dawa (MSD) kama wakala wa manunuzi ya dawa Serikalini sanjari na ukaribu wa nchi takribani nane (8) tulizopakana nazo katika ukanda wa Jumuiya ya Afrika Mashariki (EAC) na zilizoko kusini mwa Afrika (SADC). Mazingira haya yatawawezesha wawekezaji kuzalisha kwa wingi na kupata soko” Balozi Kingu alisisitiza.

Wakati wa hafla hiyo, wawekezaji watano (5) wa viwanda vya dawa walitembelewa ambao ni SOPHAL (SOPHAL Site 1, Site 2) Orion Lab, Groupe Industries SAIDAL na Biopharm.

Mkaguzi Mwandamizi wa Dawa wa TMDA, Bw. Paul Sonda alitoa shukrani za dhati kwa mwaliko uliotolewa kwa Mamlaka na kueleza kuwa hadi sasa TMDA haijasajili bidhaa yoyote kutoka katika makampuni ya Algeria. Katika maelezo yake alisema kuwa Tanzania ina fursa kwa watengenezaji wa dawa na vifaa tiba kutoka Algeria kuwekeza nchini. “Serikali ya Tanzania inafanya kazi kubwa ya kuboresha mazingira ya biashara ili kuwavutia wafanyabiashara kuwekeza nchini,” Bw. Sonda alisema.

Katika hatua nyingine, Mkurugenzi Mkuu wa makampuni ya viwanda vya dawa vya SOPHAL, Bw. Khalil Amry, alieleza kuwa baadhi ya makampuni ya dawa ya Algeria yameonesha nia ya kuwekeza nchini Tanzania. “Tumekuwa tukiwasiliana mara kwa mara na Ofisi ya Ubalozi, na wametualika kutembelea Tanzania wakati wa Maonesho ya Biashara ya Kimataifa ya Dar es Salaam (Saba Saba). Tumejifunza mengi kuhusu mazingira mazuri ya uwekezaji biashara Tanzania, yametuvutia na tayari tumetuma maombi TMDA kwa ajili ya usajili wa bidhaa zetu,” alisema Bw. Amry.

TMDA: Mshindi wa pili miongoni mwa taasisi zenye mifumo bora ya utoaji huduma kielekroniki nchini

TMDA imeibuka mshindi wa pili na kuwa mfano wa kuigwa katika kundi la maeneo yanayokidhi Viwango na Miongozo ya Sheria ya Serikali–Mtandao (e-GA) kwa mwaka 2021/2022

Tuzo hiyo iliyotolewa na e-GA, ilikabidhiwa kwa TMDA na Naibu Waziri, Ofisi ya Rais, Menejimenti ya Utumishi wa Umma na Utawala Bora, Mhe. Deogratius Ndejembi jijini Arusha tarehe 8 Februari, 2023 wakati wa Kikao Kazi cha tatu cha Mamlaka ya Serikali-Mtandao.

Ushindanishwaji huo ulishirikisha wadau mbalimbali wa e-GA ambao wengi wao ni taasisi za umma na wadau wengine wakubwa na kujadili utekelezwaji wa maazimio yao kuhusiana na mafanikio na changamoto zinazoikabili tasnia ya TEHAMA katika utekelezaji wa mifumo ya kisheria yenye lengo la kuboresha huduma zitolewazo kwao za taasisi za umma.

Uamuzi wa kuwapata washindi ulikuwa wa ushindani mkubwa ambapo majaji wabobefu katika tasnia hiyo walishirikishwa kupitia uratibu wa e-GA kwa kuzishindanisha taasisi za serikali zinazotoa huduma mbalimbali kwa njia ya TEHAMA.

Matokeo ya umuzi huo ambayo yaliitambua TMDA kama moja ya taasisi chache za umma zenye mifumo bora kabisa ya TEHAMA nchini, yameendela kuibua shauku zaidi Mamlaka kutoa huduma zake kwa umahiri ili kulinda afya ya jamii.

ABREMA watembelea TMDA kujifunza udhibiti

TMDA ilitembelewa na wageni kutoka Mamlaka ya Udhibiti wa Chakula na Dawa nchini Burundi (ABREMA) walioongozwa na Mkurugenzi Mkuu wa Taasisi hiyo Bw. Nduwayo Ildephonse kuanzia tarehe 17 hadi 19 Januari, 2023 ili kujifunza na kupata uzoefu wa namna TMDA inavyofanya kazi katika udhibiti wa bidhaa za dawa na tiba.

Wageni hao walijifunza kuhusu mifumo thabiti ya udhibiti, mifumo ya uhakiki ubora, mifumo ya tathmini na usajili wa bidhaa, taratibu za ukaguzi, udhibiti wa uingizaji na usafirishaji bidhaa nje ya nchi, uchunguzi wa dawa, udhibiti wa majaribio ya dawa, ufuatiliaji wa bidhaa katika soko, udhibiti wa vifaa tiba, usimamizi wa rasilimali watu na fedha na mikakati iliyopo ya kukuza viwanda vya ndani.

Akizungumza katika hafla ya kuhitimisha ziara hiyo, Bw. Nduwayo Ildephonse aliishukuru TMDA kwa mapokezi mazuri na kwa fursa ya kujifunza waliyoipata. Aliongeza kwa kusema kuwa timu yake imejifunza na kupata uzoefu, maarifa na uweledi mkubwa ambao utasaidia kuwajengea uwezo wafanyakazi wa ABREMA watakaporejea nchini Burundi.

Katika hatua nyingine, Mkurugenzi Mkuu wa TMDA, Bw. Adam Fimbo, aliwashukuru wageni kutoka ABREMA kwa kuchagua kuja TMDA kujifunza na aliwakabirisha kwa mara nyingine tena kuja kujifunza ikiwa watakuwa na uhitaji huo ambayo pia ni sehemu ya utekelezaji wa Hati ya Makubaliano (MoU) iliyosainiwa baina ya Mamlaka hizo mbili.

Vilevile, Bw. Fimbo aliupongeza ujumbe huo kwa dhamira na utayari walio nao kuimarisha Mamlaka ABREMA. Aliwahakikishia kuwapatia ushirikiano wa kutosha wa kiufundi ili kuboresha upatikanaji wa dawa kwa kuwa juhudi za pamoja zinahitajika ili kukabiliana na dawa duni na bandia kwenye ukanda Afrika Mashariki.

TMDA yaidhinisha miongozo ya udhibiti bora na usimamizi

TMDA ilikamilisha na kuidhinisha miongozo mipya inayohusu "Mbinu Bora za Udhibiti wa bidhaa za dawa" na "Mifumo Bora ya usimamizi" mwezi Machi, 2023 Nyaraka hizo zimetengenezwa ili kuimarisha juhudi zilizopo za Mamlaka katika kuboresha utendaji kazi na kuhakikisha kwamba dawa na vifaa tiba vilivyopo katika soko ni bora, salama na zenye ufanisi kwa umma.

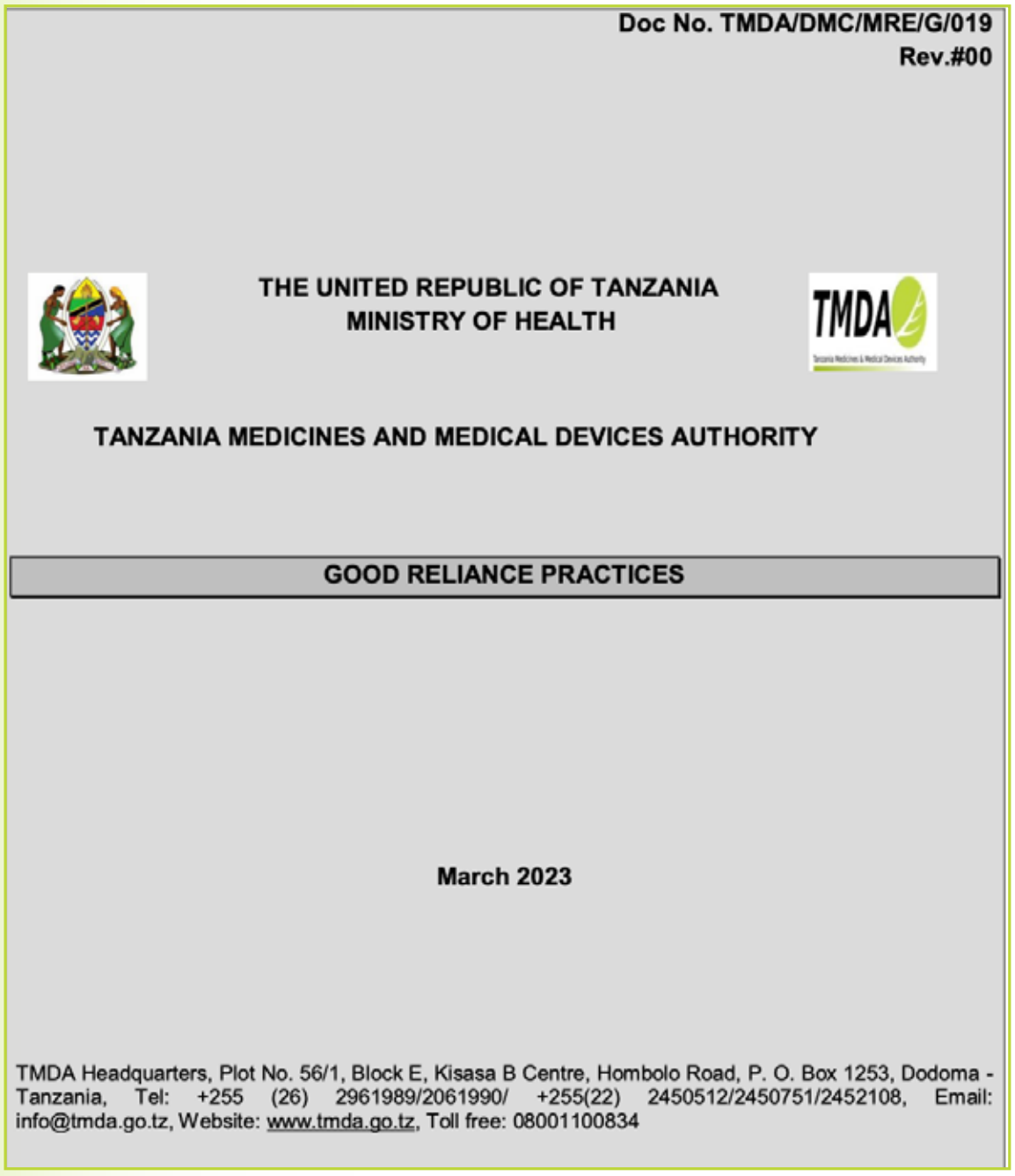
Mkurugenzi Mkuu wa TMDA, Bw. Adam Fimbo ameeleza kwamba miongozo hiyo ya mbinu Bora za Udhibiti itawasaidia wadau kukidhi matakwa bora ya udhibiti (GRPs) ili kuendeleza umahiri wa WHO katika kiwango cha ngazi ya 3 (ML-3) ili kuwa na udhibiti bora wa bidhaa hizo.

TMDA ilifikia kiwango cha ukomavu cha Ngazi ya 3 ya WHO (ML-3) tangu mwezi Novemba 2018 na kuwa Mamlaka ya kwanza ya Udhibiti barani Afrika kupata utambuzi kama huo. Mafanikio haya yalipatikana kutokana na TMDA kuwa na Mipango ya Maendeleo ya Kitaasisi (IDPs) na kuitekeleza kama ilivyopendekezwa na timu ya wakaguzi wa WHO mwezi Mei 2018.

Aidha, miongozo ya GRP iliyoidhinishwa itasaidia kwa kiasi kikubwa kupata ufumbuzi wa changamoto za udhibiti kama vile utandawazi wa masoko, ukiritimba wa michakato ya ugavi na matumizi mazuri ya rasilimali chache za kimataifa zilizopo.

Aidha, miongozo ya Usimamizi Bora husaidia Mamlaka zingine za Kitaifa za Udhibiti (NRAs) kufanya maamuzi madhubuti. Miongozo hiyo huelekeza kupata mbinu za matumizi mazuri ya rasilimali chache na utaalamu hivyo kupunguza kujirudia kwa kazi na kuharakisha michakato ya utoaji idhini.

Wazalishaji, wasambazaji,watumiaji na wadau wengine wa TMDA wanahimizwa kupitia miongozo iliyoidhinishwa kwa ajili ya utekelezaji bora.



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Rev.#00

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GOOD RELIANCE PRACTICES

March 2023

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania, Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108, Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

Toa taarifa ya madhara yatokanayo na kifaa tiba

Utoaji wa taarifa kwa hiyari za matukio yanayodhaniwa kusababishwa na matumizi ya vifaa tiba kupitia kwa wahudumu wa afya pia watumiaji wa bidhaa hizo ni muhimu katika kuisaidia TMDA kupata mrejesho kuhusu usalama na ubora wa vifaa tiba vilivyoko katika soko na kuchukua hatua stahiki.

Athari ya aina yoyote inayohisiwa kusababishwa na matumizi ya vifaa hivyo inapaswa kuripotiwa, Mamlaka ili kufanyiwa uchunguzi kabla kuondolewa katika soko.

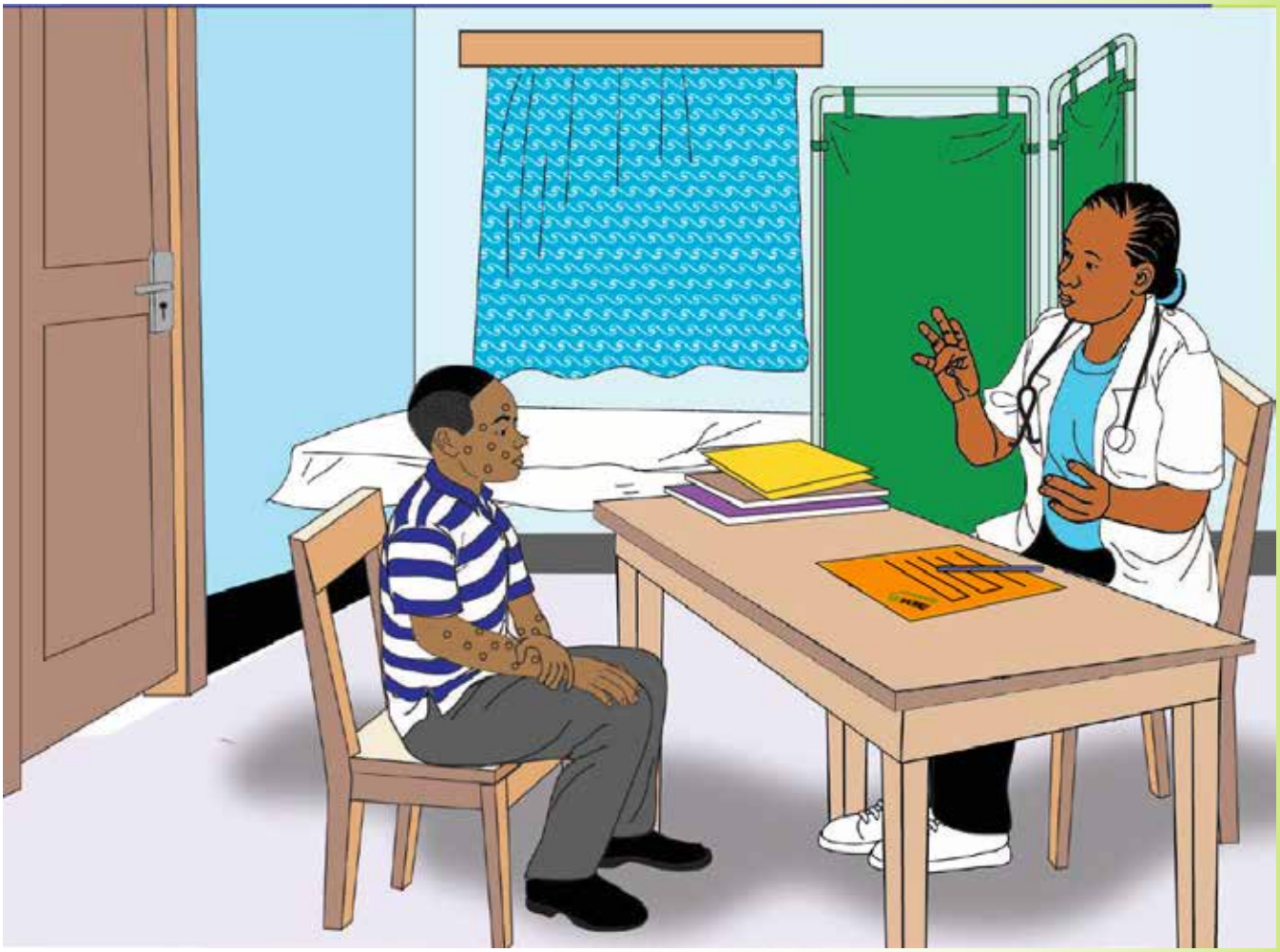
Vifaa tiba ni vyombo, vifaa, mashine, kemikali au kitu chochote kifananacho na hivi kinachotumika katika kutibu, kutambua, kupima, kuchunguza au kuzuia magonjwa ya binadamu au mifugo.

TMDA inawahimiza wananchi na watoa huduma za afya kuripoti tukio lolote linaloshukiwa kutokea baada ya matumizi ya kifaa tiba kwa kujaza FOMU YA RANGI YA CHUNGWA inayopatikana kwenye tovuti ya

TMDA (https://www.tmda.go.tz/publications/97) au katika kituo cha kutolea huduma za afya kilicho karibu, duka la dawa, ofisi ya Mganga Mkuu wa Wilaya, ofisi ya Kanda ya TMDA au katika kituo cha kukusanyia taarifa za madhara.

Pia Mamlaka inatumia njia nyingine za utoaji taarifa ikiwa ni pamoja na nyenzo ya kielektroniki ya kurahisisha upokeaji taarifa za madhara au matukio husika kupitia https://sqrt.tmda.go.tz. Kupiga simu bila malipo 0800110084 au kubofya namba *152*00#.

Kuripoti tukio linatokana na madhara ya kifaa tiba itasaidia kulinda afya ya jamii.



TMDA yazindua maabara mpya ya uchunguzi wa vifaa tiba na vitendanishi

Mamlaka ya Dawa na Vifaa Tiba Tanzania (TMDA) imezindua maabara yake mpya mahususi kwa ajili ya uchunguzi wa vifaa tiba na vitendanishi jijini Dar es Salaam. Vifaa vya maabara hiyo mpya vya kisasa vyenye thamani ya shilingi milioni 250 vimefungwa katika maabara hiyo ili kuongeza wigo wa huduma za Mamlaka za uchunguzi wa vifaa tiba na vitendanishi. Baadhi ya vifaa vilivyowekwa ni pamoja na hadubini za LED, majokofu, makabati ya usalama a viumbe hai, mashine za Centrifuge naThermocycler.

Maabara ya Uchunguzi wa vifaa tiba huchunguza uwezo wa utendaji kazi wa vipimo vya haraka kwa magonjwa ya binadamu (RDT) na kuhakiki bidhaa hizo endapo zinafanya kazi kwa usahihi na ufanisi.

Akizungumza wakati wa uzinduzi huo wa maabara hiyo, Bi. Catherine Luanda ambaye ni Kaimu Meneja wa Uchunguzi wa Vifaa Tiba na Vitendanishi wa maabara hiyo alisema kuwa uwepo wa vifaa hivyo vipya ni muhimu na utaharakisha uchunguzi wa bidhaa za wateja wa Mamlaka.

"Uwepo wa vifaa vya kisasa vya maabara ni muhimu katika maabara yoyote ile na itasaidia kwa kiwango kikubwa katika uchunguzi na kupata majibu ya kuaminika," Bi Catherine alisisitiza.

Aliendelea kueleza kwamba baadhi ya vifaa hivyo vitatumika kufanya uhakiki wa ufanisi wa vipimo vinavyotoa majibu kwa haraka vya Malaria, UKIMWI, Kaswende na ubainishaji wa mimba kupitia mkojo.

Vitendanishi humaanisha kifaa kinachotumika pekee au pamoja na vifaa vingine kama ilivyokusudiwa na mtengenezaji kwa uchunguzi wa magonjwa binadamu au mifugo .

Dawa za kupunguza maumivu na vijiuasumu zaongoza kuingizwa nchini

Takwimu zilizopo za TMDA katika kanzidata zinaonesha kuwa takribani dawa za binadamu kiasi cha 13,000 zimeingizwa nchini Tanzania tangu 2020 ambapo bidhaa zenye viambato hai vya Acetylsalicylic Acid + Caffeine + Paracetamol zinaongoza katika orodha hiyo.

Dawa nyingine katika orodha ya tano bora kwa kuingizwa nchini ni pamoja na Ampicillin na Cloxacillin combination, Paracetamol, Magnesium + Aluminium + Simethicone na Goodmorning lung tonic.

Kaimu Meneja wa Usajili wa Dawa wa TMDA, Bw. Felchism Apolinary, alisema kuwa kiashiria cha dawa zinazoingizwa nchini kwa wingi kutoka nje ya nchi kwa miaka mitatu mfululizo iliyopita humaanisha kwamba zinatumika

kwa wingi nchini.

Bw. Felchism alidokeza kwamba wawekezaji wananweza kuchangamkia fursa hiyo na kuwekeza ndani ya nchi kwa viwanda vya kuzalisha dawa au malighafi za kuzalisha dawa husika

Alifafanua kuwa, "Wawekezaji wanahimizwa kuwekeza kwa kiasi kikubwa katika sekta ya viwanda vya dawa kwani mazingira ya uwekezaji nchini Tanzania ni mazuri na soko ni la uhakika".

TMDA iko makini na imejipanga vyema kutoa msaada wa kiufundi katika ngazi zote za uwekezaji nchini Tanzania hususani kwa wawekezaji wanaopenda kuwekeza katika viwanda vya dawa nchini, Bw. Felichism aliongeza.

TMDA kanda ya mashariki yaongoza kwa upimaji wa sampuli kupitia maabara hamishika (Mini-Lab kits)

Maabara ya Udhibiti Ubora ya TMDA ilianzishwa chini ya Kifungu cha 14(1) cha Sheria ya Dawa na Vifaa Tiba Tanzania, Sura 219 ili kufanya uchunguzi wa bidhaa zinazodhibitiwa. TMDA ina maabara tatu zilizopo katika Ofisi Ndogo ya Makao Makuu ya TMDA Dar es Salaam, Mwanza na Makao Makuu Dodoma. Maabara hizo zilizoanzishwa husaidiwa na vituo 25 vya Uhakiki wa Ubora (QACs) nchini.

Malengo ya QACs ni kukagua na kuchunguza aina ya kundi la dawa zilizopendekezwa katika vituo vya forodha kabla na baada ya kuingia katika soko la Tanzania. Aidha, hurahisisha ufuatiliaji wa ubora wa dawa zilizosajiliwa ili kulinda afya ya Jamii. QACs zote zilizoidhinishwa zina maabara hamishika kwa ajili ya kubaini bidhaa duni na bandia.

TMDA, ilisambaza maabara hamishika 25 katika hospitali 13 za rufaa za mikoa zilizopo Geita, Bukoba, Musoma, Manyara, Kilimanjaro, Mbeya, Katavi, Iringa, Lindi, Mtwara, Songea, na Bukoba. Nyingine 07 zipo katika ofisi saba za kanda za TMDA na tano (05) zipo katika vituo vya forodha vya Mtukula, Sirari, Uwanja wa Ndege wa Kimataifa wa Kilimanjaro, Namanga na Tunduma.

Tathmini ya utendaji kazi wa maabara hamishika zote 25 inaonesha kuwa maabara ya hamishika iliyopo Ofisi ya TMDA Kanda ya Mashariki, Dar es Salaam inaendela kufanya vizuri kuliko nyingine kwa miaka miwili mfululizo sasa. Mwaka 2021/22 iliweza kuchunguza jumla ya sampuli 719 na 617 hadi kufikia robo ya tatu (3) ya mwaka 2022/23. Tathmini hiyo pia inaonesha kwamba mwaka 2021/22 kituo kilichofanya vibaya ni Hospitali ya Rufaa ya Mkoa wa Kigoma iliyochunguza sampuli tano (05) iliyopo katika nafasi ya pili kwa kufanya vizuri ni Ofisi ya TMDA Kanda ya Ziwa Mashariki iliyochunguza sampuli 478. Sampuli zinazoongoza kwa kuchunguzwa zaidi ni za dawa za Malaria, Kifua Kikuu, kufubaza makali ya virusi vya UKIMWI (ARVs) na dawa za kutuliza maumivu.

Mini Lab hurahisisha kuchunguza kwa haraka ubora wa bidhaa za dawa katika soko. Maabara za haina hii huweza kufanya uchunguzi na kubaini viwango vya viambato hai vilivyomo katika dawa husika, uwezo wa kuyeyuka kwa dawa zinazomezwa na kromatografia ya safu nyembamba (TLC) kwa ajili ya kutambua viambata hai vya dawa (APIs) vilivyopo kwenye dawa.

Ili kuthibitisha kuwa maabara husika 25 zinafanya kazi kwa ufanisi, TMDA imekuwa ikitoa mafunzo ya mara kwa mara kwa wataalam na kuhakikisha upatikanaji wa vitendanishi ikiwa ni pamoja na kufuatilia wa ukaribu utendaji wake kazi.

TMDA yatoa mafunzo kwa wakufunzi ya utoaji taarifa za madhara yatokanayo na matumizi ya chanjo kwa mikoa 10

Mamlaka ya Dawa na Vifaa Tiba Tanzania (TMDA) imeendesha Mafunzo kwa Wakufunzi toka mikoa 10 juu ya ufuatiliaji na utoaji wa taarifa za madhara yanayoweza kutokea baada ya matumizi ya chanjo (AEFI) kwa washiriki 30 kuanzia tarehe 31 Januari - 3 Februari, 2023 mkoani Morogoro.

Mafunzo hayo ya siku nne yalilenga kuhamasisha na kuongeza uelewa kwa wakufunzi kutoka kwa watoa huduma wa afya wanaoripoti kuhusu AEFI.

Akifungua mafunzo hayo, Mkurugenzi wa Vifaa Tiba na Vitendanishi, Bi. Kissa Mwamwitwa aliwataka washiriki hao kuzingatia mada zinazowasilishwa kwa kuwa wanatarajiwa kuwafundisha maafisa wengine waliopo katika vituo vyao vya kazi.

"Ni matarajio yangu kwamba mtazingatia mafunzo yanayotolewa ili kufikia malengo yaliyokusudiwa na Mamlaka na hatimaye kuweza kufikia malengo ya Shirika la Afya Duniani (WHO) ya idadi ya taarifa 60 kwa madhara makubwa na 1,197 kwa madhara madogo ya AEFI kwa kila mwaka", Bi. Kissa alisema.

Washiriki hao 30 walitoka katika halmashauri mbalimbali kwenye mikoa 10 ambayo ni Arusha, Kilimanjaro, Mara, Simiyu, Njombe, Mbeya, Morogoro, Dar es Salaam, Iringa na Singida.

Taaluma za wa washiriki wa mafunzo hayo zilijumuisha Wafamasia wa Wilaya, Maafisa Chanjo wa Wilaya (DVOs), Waganga wafawidhi, Wafamasia wasimamizi, Wauguzi na wahudumu wengine wa kada ya afya.

TMDA imepanga kuongeza wigo wa mafunzo hayo ili kuwafikia wafanyakazi wote wa kada ya afya katika mikoa mingine iliyobakia ili kuhakikisha uwepo wa chanjo zenye usalama, ubora na ufanisi nchini.

"Ni matarajio yangu kwamba mtazingatia mafunzo yanayotolewa ili kufikia malengo yaliyokusudiwa na Mamlaka na hatimaye kuweza kufikia malengo ya Shirika la Afya Duniani (WHO) ya idadi ya taarifa 60 kwa madhara makubwa na 1,197 kwa madhara madogo ya AEFI kwa kila mwaka", Bi. Kissa alisema.

Jamii yaaswa kufichua wanaojihusisha na magenge ya dawa bandia

Jamii imeendelea kuaswa kuwafichua watu na magenge yanayojishughulisha na utengenezaji na usambazaji wa kinyemela wa dawa duni na bandia nchini kufuatia kukamatwa kwa Bw. William Japhet Mwangile (39) mkazi wa Kipawa - Dar es Salaam akitengeneza dawa bandia mnamo tarehe 14 Aprili, 2023.

Wito huo umetolewa na Mkaguzi wa Dawa wa TMDA Kanda ya Mashariki, Bw.Japhary Mtoro akiwa katika eneo la tukio na kuzungumza na waandishi wa habari mara baada ya kumkamata mtuhumiwa akitengeneza dawa bandia.

"Mtuhumiwa huyo alinaswa usiku wa manane maeneo ya Kipawa jijini Dar es Salaam ambapo alikutwa na lebo na vifungashio bandia vya dawa". Japhary alisema.

Bw. Japhary aliendelea kusema kuwa jumla ya lebo 537 za aina tofauti za dawa za Quinine sulphate, Erythromycin, na nyinginezo zilipatikana katika makazi ya mtuhumiwa huyo baada ya kufanyiwa upekuzi wa kina.

"Makasha matatu, moja likiwa na aina ya unga wa rangi ya njano na mengine mawili yakiwa na unga mweupe unaodhaniwa kuwa malighafi vilipatikana. Aidha, makopo 12 ya plastiki matupu yaliyotumika kupakia dawa hizo feki pia yalibainika na kutaifishwa". Bw. Japhary alifafanua zaidi.

Katika hatua nyingine, kiongozi wa Kitongoji cha Mtaa wa Matembele, Bi Maryglory Mambo aliyekuwa akishirikiana na TMDA na Jeshi la Polisi katika msako huo amewataka wananchi kuungana na TMDA ili kuwafichua watu wasio waaminifu wanaojihusisha na vitendo hivyo vya uhalifu.

Jamii imekumbushwa kuwa kusambaza dawa bandia ni uhalifu dhidi ya afya ya binadamu. Wahalifu wote wa namna hii lazima wapatikane na kuchukuliwa hatua za kisheria kwani wanahatarisha afya ya jamii. Aidha, jambo hili ni kosa kwa mujibu wa Sheria ya Dawa na Vifaa Tiba Tanzania, Sura 219.

"Makasha matatu, moja likiwa na aina ya unga wa rangi ya njano na mengine mawili yakiwa na unga mweupe unaodhaniwa kuwa malighafi vilipatikana. Aidha, makopo 12 ya plastiki matupu yaliyotumika kupakia dawa hizo feki pia yalibainika na kutaifishwa".Bw. Japhary alifafanua zaidi.

Baada ya miaka minne ya ngazi ya tatu (Ml-3) ya WHO: TMDA yatathminiwa upya

Kuanzia Desemba 2018 hadi sasa, TMDA inatambulika kwa kufikia kiwango cha Ngazi ya 3 ya Umahiri (ML3) cha Shirika la Afya Duniani (WHO) kwa kuwa na mifumo madhubiti na thabiti ya udhibiti wa ubora, usalama na ufanisi wa dawa. Kufikiwa kwa kiwango hicho kuliifanya Tanzania kuwa nchi ya kwanza barani Afrika kufikia daraja hilo.

Nafasi hiyo ilifikiwa baada ya kufaulu katika tathmini iliyofanywa na WHO katika mifumo ya TMDA ya udhibiti kwa kutumia nyenzo maalum ya kimataifa ya tathmini na upimaji (GBT). Nyenzo hii ni maalum kwa WHO kutathmini mifumo ya udhibiti wa ubora, usalama na ufanisi wa dawa na kuamua kiwango cha umahiri kwa taasisi za udhibiti za kitaifa duniani.

Tokea wakati huo, TMDA imekuwa ikiendeea ikiimarisha mifumo hiyo kwa kuzingatia viwango vya WHO na kuendelea kutoa huduma bora za udhibiti zenye ufanisi katika harakati za kukuza na kulinda afya ya jamii.

Baada ya miaka minne kupita, WHO iliifanyia tathmini TMDA kwa mara nyingine ambapo kati ya tarehe 27 na 31 Machi, 2023 ilituma timu ya wakaguzi 10 kuja TMDA kufanya kazi hiyo ikiwa ni njia ya ufuatiliaji na kuhakikisha kuwa viwango hivyo vinakuwa endelevu kwa lengo la kuhakikisha kwamba bidhaa za dawa na chanjo ni salama, bora na zenye ufanisi katika soko.

Tathmini hiyo ilifanyika kwa siku tano ambapo hoja zilizobainika ziliwasilishwa TMDA ili kupata majibu kabla ya kutangazwa rasmi na WHO ngazi ambayo Mamlaka imepata.

Mbali na TMDA, mamlaka nyingine za udhibiti barani Afrika ambazo zimepata ngazi ya WHO ML-3 hadi sasa ni pamoja na Mamlaka ya Chakula na Dawa ya Ghana (Ghana FDA), Wakala wa Kitaifa wa Usimamizi wa Chakula na Dawa ya Nigeria (NAFDAC), Mamlaka ya Dawa ya Misri (EDA) na Mamlaka ya Udhibiti wa Bidhaa za Afya ya Afrika Kusini (SAHPRA).

Mradi wa pavia waleta mafanikio katika utoaji taarifa za madhara ya dawa nchini

Mradi wa PharmacoVigilance Africa (PAVIA) ulifanyiwa tathmini ya mwisho ya utekelezaji wake kati ya tarehe 20 Agosti hadi 2 Septemba, 2022. Zoezi hilo lililenga kutathmini utekelezaji wa miradi yao inayofanywa kwa ushirikiano baina ya TMDA, Mpango wa Taifa wa Kifua Kikuu na Ukoma (NTLP), Taasisi ya Utafiti wa Dawa Kilimanjaro (KCRI) na Hospitali ya Kibong'oto (KIDH) nchini Tanzania. Wataalamu wa timu ya PAVIA waliohusika ni pamoja na Bi. Liza de Groot na Dkt. Edine Tiermesma wote kutoka KNCV na Dk. Linda Harmark kutoka Lareb, Uholanzi.

Tathmini hiyo ililenga katika utekelezaji wa kazi za ufuatiliaji wa usalama wa dawa na chanjo nchini Tanzania toka mradi huo ulipoanzishwa mwaka 2018 na unatarajia kukamilika mwishoni mwa mwaka 2023.

Nyenzo zilizotumika katika tathmini hiyo ni pamoja na mahojiano ya kina ya dodoso na mawasiliano ya teknolojia ya Zoom. Maeneo yaliyotathminiwa ni pamoja na vipengele vyote vya mfumo wa ufuatiliaji wa usalama wa dawa na chanjo katika ngazi ya kitaifa na kitaasisi, kanuni zilizopo, miongozo iliyoidhinishwa kwa utekelezaji, taratibu sanifu za utendaji kazi (SOPs) na nyaraka nyinginezo muhimu. Maeneo mengine yalihusu weledi wa rasilimali watu, vituo vya kutolea taarifa, miundombinu ya kutolea taarifa na viashiria vingine vya utendaji vinavyopima ufanisi wa ufuatiliaji.

Matokeo ya tathmini hiyo yameonesha mafanikio makubwa katika kuimarisha mfumo huo nchini. Wataalam wa kazi hiyo wa ndani wamejengewa uwezo mkubwa na walielimishwa kuhusu mfumo wa ufuatiliaji unaohusisha matukio yanayohusiana na utoaji wa taarifa za usalama wa dawa na chanjo. Taarifa za madhara ya dawa zilizoripotiwa zimepanda hadi 9,468. ikilinganishwa na taarifa 114 zilizokuwepo wakati mradi wa PAVIA ulipoanzishwa mwaka 2018 .

Mradi wa PAVIA unatekelezwa na Mamlaka za Udhibiti wa Dawa kutoka nchi nne (4) za Afrika ambazo ni Ethiopia, Eswatini, Tanzania, na Nigeria. Wadau wengine wa kimataifa wanaohusika na mradi huo ni Chuo Kikuu cha Verona (Italia), KNCV na Taasisi ya Maendeleo ya Afya Ulimwenguni ya Amsterdam (AIGHD), Uholanzi.

Bw. Mtani Njegere

Ilikuwa siku ya Jumapili tarehe 6 Novemba 2022, ambapo TMDA iligubikwa na majonzi baada ya kupokea taarifa za kushtusha juu ya kifo cha mfanyakazi wake mpendwa na ndugu - Bw. Mtani Njegere.

Kifo cha Bw. Njegere kilipokelewa kwa majonzi, simanzi, uchungu na masikitiko makubwa miongoni mwa wafanyakazi wa TMDA kwani alikuwa ni mtu mwenye upendo, mpole na mwenye utashi mkubwa.

Bw. Njegere alifariki dunia kufuatia ajali ya ndege ya Shirika la Precision Air ambapo watu 19 walipoteza maisha wakati ndege hiyo ilipoanguka katika ziwa Victoria wakati ikijaribu kutua katika uwanja wa ndege wa Bukoba.

Marehemu alijiunga na TMDA mnamo tarehe 2 Agosti, 2010 na alihudumu kama Mkaguzi wa Dawa kwa mud awa miaka 12 hadi tarehe 1 Aprili, 2022 alipoteuliwa kuwa Kaimu Meneja wa Majaribio ya dawa, nafasi ambayo aliitumikia hadi mauti yalipomkuta.

Marehemu Njegere alikuwa mchapakazi asiyetiliwa shaka, mtu wa kujituma na alijitolea katika kutekeleza majukumu yake ya kikazi.

Mchango wake kwa TMDA na taifa kwa ujumla utaenziwa daima.

ROHO YA BW. NJEGERE IPATE PUMZIKO LA MILELE MAHALI PEMA PEPONI AMINA

HABARI ZA KIJAMII

Hafla ya kuwaaga watumishi wastaafu wa TMDA tarehe 17 Septemba, 2023

MICHEZO KWA AFYA

Michezo kwa afya

OUR ADDRESS

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