TMDA
Tanzania Medicines & Medical Devices Authority

Newsletter

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Congratulations to Minister Hon. Ummy A. Mwalimu for being Reappointed to the Ministry of Health

INSIDE

WELCOMING NOTE FROM THE DIRECTOR GENERAL

The 11th edition of our Newsletter is on the horizon once again. As always, we are delighted to continue using the platform to share with you progress made on regulation of medicines, medical devices, diagnostics and tobacco products. Since the last edition (Issue No. 10), TMDA has witnessed tremendous momentum on a number of eye-catching activities and milestones planned to be attained as highlighted hereunder.

I would like to begin by recapping the appointment of the new Minister of Health – Honourable Ummy A. Mwalimu (Mp) who was reinstated to the Ministry of Health by the President of the United Republic of Tanzania on 8th January 2022. The appointment of the new Minister also coincided with the change of name of the Ministry from the Ministry of Health, Community Development, Gender, Elderly and Children to the Ministry of Health. We welcome again the Honourable Minister who also served in the same Ministry between 2015 and 2020 during the 5th phase government. The outgoing Minister of the then Ministry of Health, Community Development, Gender, Elderly and Children – Honourable Dr. Dorothy O. Gwajima is also acknowledged for her energy, charisma and enthusiastic demeanour which propelled and transformed our way of working. She will be remembered by TMDA for authorizing a number of Regulations and her deliberate efforts made in combating pilferage of medicines and medical devices from public health facilities. We wish her best of luck on her new role as the Minister of Community Development and Gender.

Apart from the high ranking appointments, this edition also covers stories on Tanzania's bid to host the African Medicines Agency (AMA), participation of TMDA at Dubai 2020 Expo, hosting of staff from the Botswana Medicines Regulatory Authority (BOMRA) and the Zanzibar Health Research Institute (ZAHRI) at TMDA and retaining of the WHO Certificate for Prequalification of TMDA - Dar es Salaam based Laboratory.

The visit paid by TMDA delegation at the Tanzania Cigarette Company (TCC) to acclimatize with the manufacturing operations has also been covered. The visit of the Ministerial Advisory Board (MAB) members to ports of entry located in the northern corridor of the country has as well been articulated. Approval of the TMDA Organisational Structure by the President of the United Republic of Tanzania on 28th of December 2021 is likewise highlighted.

A narrative on adverse consequences of irrational use of erectile dysfunction drugs and emergency contraceptive pills has notably been reiterated to educate and urge you to refrain from their use. A mix of pictorial presentations as it has always been the case in previous editions, has also been included to entice reading.

Enjoy your reading!
Adam M. Fimbo
Director General

EDITORIAL NOTE

I am honored to present to you our 11th edition of the TMDA Newsletter. This Newsletter is issued bi-annually as a way of communicating and publicizing different activities undertaken within the Authority since the last edition.

I feel indebted to express my gratitude to the Director General who is the Chief Editor for his guidance and leadership towards achieving institutional goals and exemplary support that indeed made it possible to have this edition published once again.

TMDA plays a critical role in upholding and enhancing Tanzania's reputation as the leading Regulatory Authority and center of excellence in Africa. To protect the public, we closely monitor the content of health product advertisements to ensure that these do not contain misleading or incorrect information. In addition, as myriad health products become available in the market today and patients increasingly consume multiple products concurrently, TMDA use different communication channels to proactively provide public education and create awareness on rational use of therapeutic products. These efforts promote culture of shared responsibility in medical products safety and empower consumers with a better understanding of the benefits and risks associated with such products.

As an organization embracing a broad spectrum of expertise and specialties, TMDA is in a unique position to address some of the most challenging and pressing issues in medical products control through sharing of information to our valued customers.

TMDA will put more efforts in ensuring that the public is timely provided with unbiased information on safety, quality and effectiveness of regulated products in various platforms including this unique one - TMDA Newsletter.

I once again urge you to read this 11th edition which is furnished with educative, useful, informative and interesting articles on various achievements, setbacks and strategies taken by the Authority to meet its primary goal of protecting and promoting public health.

Besides, I also welcome constructive criticism and feedback for future improvement of our upcoming editions of this Newsletter.

Thank you and enjoy your reading!
Gaudensia Simwanza
Manager, Communication and Public Education

EDITORIAL TEAM

Congratulations to Minister Hon. Ummy A. Mwalimu for being Reappointed to the Ministry of Health

The appointment of Hon. Ummy Mwalimu (Mp) as the Minister of Health has been received with a jubilant gesture. On 8th January 2022, the President of the United Republic of Tanzania, H.E Samia Suluhu Hassan restructured her cabinet and reappointed Minister Ummy A. Mwalimu (Mp) to lead the Ministry of Health (MoH).

Much as she has been trusted by the President, we are likewise gratified for her appointment as she has demonstrated great ability, tenacity and leadership in overseeing the MoH. We believe she will lead the health sector to the highest standards of service. The appointment of the new Minister also coincided with the change of name of the Ministry from the then Ministry of Health, Community Development, Gender, Elderly and Children to the Ministry of Health.

Bearing in mind the fact that between 2015 to 2020 the then Ministry responsible for Health was also led by her, we are unequivocal that she will continue to exemplify tremendous skills and competence in her new office as she has proven so. Focusing on the minority and the general health sector, she was able to improve access to medicines in hospitals, access to health care and strengthen the national health insurance scheme.

Hon. Ummy Mwalimu (Mp)

Hon. Dr. Dorothy Gwajima

Following her recent appointment, Hon. Ummy has kick-started her tenure by portraying a vision that targets strengthening of primary health care delivery, finalizing the legislative process towards Universal Health Coverage, improving reproductive and child health (RCH) and bolstering the supply chain system.

As always, TMDA will accord her all-necessary support in her tenure and we pledge to work with her in protecting and promoting public health. We will strive to improve systems for adequate regulation of medicines, medical devices, diagnostics and tobacco products.

On the other hand, the outgoing Minister of the then Ministry of Health, Community Development, Gender, Elderly and Children, Hon. Dr. Dorothy Gwajima, is also acknowledged for her energy, charisma and enthusiastic

demeanour which propelled and transformed our way of working. She will be remembered by TMDA for authorizing a number of Regulations and her deliberate efforts made in combating pilferage of medicines and medical devices from public health facilities. We wish her best of luck on her new roles as the Minister of Community Development and Gender.

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MBA Visit Ports of Entry

MAB Visits Port of Entries in Northern Zone

The Ministerial Advisory Board (MAB) is charged with the responsibility of overseeing and setting-up the strategic direction of TMDA including measuring its performance to ensure the mission and vision are attained. In this context, the MAB visited the Port of Entries (PoEs) located in Tanga, Kilimanjaro and Arusha regions prior to its 8th scheduled meeting held between 13th and 25th February, 2022 in Arusha.

The visitation which involved six (6) official PoEs, was led by the MAB Chair, Mr. Eric Shitindi, who was accompanied by other board members and the Management team.

During this visit the delegation was welcomed by Regional Commissioners of each respective region to include Mr. Adam Malima (Tanga), Mr. Stephen Kigaigai (Kilimanjaro) and Mr. John Mongela (Arusha). The RCs commended TMDA for the work well done at each courtesy call and advised the Authority to bolster various regulatory matters discussed.

At some stage during the visit, MAB members were pleased with the Authority's Management commitment in setting-up an import and export control system in all six PoEs visited namely Horohoro,

Tanga Port, Holili, Tarakea, KIA and Namanga One Stop Border Post.

On the flip side, MAB members had a chance to walk around and were briefed on the roles of TMDA and challenges that hinders performance of regulation activities at PoEs.

In his remarks, Holoholo Drug Inspector, Ms. Husna Adam, illuminated that there had been a significant bump in imports of medical devices at the port as compared to the previous year.

Addressing staff working at the PoEs, Mr. Shitindi hailed the cooperation amongst government institutions at the PoEs which included the Tanzania Ports Authority (TPA) Tanzania Revenues Authority (TRA), Government Chemist Laboratory Agency (GCLA), Tanzania Bureau of Standards (TBS), Tanzania Atomic Energy Agency (TAEC), Immigration and Police Force Unit.

Mr. Shitindi urged port staff to continue maintaining the good working relation observed including adhering to code of conduct, work ethics and prioritizing the broader interests of the Nation when performing enforcement duties.

In concluding, the Board directed Management to urgently solve the addressed challenges that are within their capacity to include staff allocation specifically to PoEs that have scarcity while looking for permanent solutions. Meanwhile, the Board pledged to address all presented challenges including staff shortage, border patrols and warehouse.

Speaking at the end of the tour, the Director General, Mr. Adam Fimbo, thanked the Board for the time spent to acclimatize with the activities performed at the PoE. Mr. Fimbo reiterated that, through this tour MAB members have seen a bigger picture of broad and sensitive job done by TMDA in protecting and promoting public health.

The Board was established pursuant to the Tanzania Medicines and Medical Devices Act, Cap. 219 and the Executive Agencies Act, Cap. 245. The current MAB members were appointed on 12th May 2020 and will serve for a period of three years. The current membership comprises of seven members to include Mr. Eric Shitindi (Chairperson), Prof. Said Aboud, Prof. Appolinary Kamuhabwa, Mr. Mick Kiliba, CPA Zaina Thabit and Mr. Daudi Msasi. The Director General of TMDA (Mr. Adam M. Fimbo) serves as the Secretary to the Board.

Adverse consequences of irrational use of levonorgestrel containing products

Levonorgestrel is an active moiety in emergency contraceptive pills that is commonly used to prevent pregnancy after unprotected sex or after failure of another birth control method. It works by preventing a woman's egg from fully developing. It may also prevent the attachment of the woman's egg to the wall of the uterus (womb). To obtain optimal efficacy, it should be taken as soon as possible within 72 hours of intercourse.

Products containing levonorgestrel which have been registered by TMDA to be used in Tanzania include Microlut, Hyan, Pill 72, Usage 1.5, Undo 72, Acelevo, Emerginor, Unosure 72, Trust Daisy 1, Trusty Daisy 2, P2, Depregdina and Famy Pop. Though there are many other different brands of levonorgestrel pills, they all work the same way. All brands have the same content of active ingredient with the same effectiveness.

These products need to be used as emergency contraceptives and as a backup method to prevent pregnancy. They are not recommended to be used routinely or as a regular form of birth control as it has been the case in Tanzania of recent. For instance, if one had used a condom which accidentally broke-up or slipped, then you can opt for these kinds of products.

Additionally, these pills should be used only once in an emergency and in one menstrual cycle. If these pills are used more than once in the menstrual cycle, their effectiveness is uncertain and can lead to pregnancy if unprotected sex occurs. It is recommended to get advice from your nearest health specialist, doctor or pharmacist before using these pills to gain a better understanding of family planning methods and to be provided with appropriate and long-term contraceptive control.

When used arbitrarily, chances of unexpected pregnancy are higher. Likewise, other effects such as irregular menstruation due to irregular hormones in the body are likely to occur. This can disrupt the natural process of reproductive functions in women causing side effects like pain, discomfort, mood and psychological changes and depression. Besides, some women may even further develop reproductive problems during their childbearing age.

Thus, particular attention should be paid to younger generations who intend to use these pills. They should first seek advice from health experts regarding the use of these products including understanding the side effects of misusing them. Moreover, these pills do not prevent pre-existing pregnancy or injure a baby that has already developed in the womb.

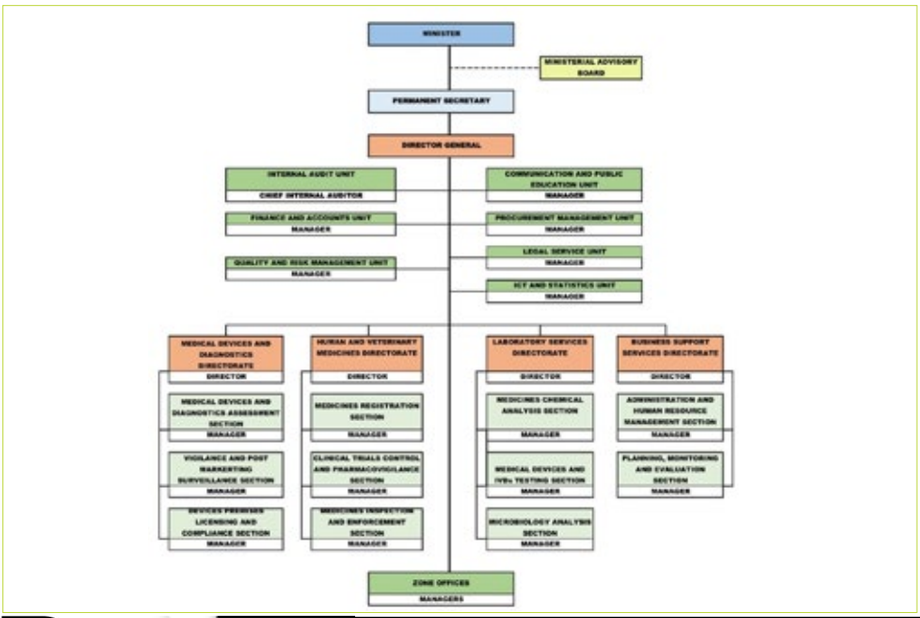
New TMDA Organizational Structure Approved

On 28th December 2021, the President of the United Republic of Tanzania, H.E. Samia Suluhu Hassan, approved the new organizational structure of Tanzania Medicines and Medical Devices Authority (TMDA).

TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment by the Parliament of the Tanzania Food, Drugs and Cosmetics Act, Cap 219. TMDA is responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and tobacco products.

However, the change from TFDA to TMDA shifted the functions of regulating the quality and safety of food and cosmetics to the Tanzania Bureau of Standards (TBS) through the Standards Act, Cap 130. Following the changes in responsibilities, TMDA developed a new organizational structure to accommodate the current operations of the Authority. The new structure has taken into account the need to strengthen the regulation of medicines, medical devices, diagnostics and tobacco products.

Either, the new structure outlines how TMDA activities are directed in order to achieve its goals including roles, and responsibilities. The major change in the new structure as compared to the previous structure is the introduction of a new Directorate for Medical Devices and Diagnostics which has three Sections that are Medical Devices and Diagnostics Assessment Section, Vigilance and Post Marketing Surveillance Section and Devices Premises Licensing and Compliance Section. Mainly, the approved structure consists of four Directorates and its Sections, Seven Units and Eight zone offices as follows;



- DIRECTORATES; Medical Devices and Diagnostics, Human and Veterinary Medicines, Laboratory Services and Business Support.
- UNITS; Internal Audit, Finance and Accounts, Quality and Risk Management, Communication and Public Education, Procurement Management, Legal Services and ICT and Statistics.
- ZONE OFFICES; Northern zone, Eastern zone, Central zone, Western zone, Southern zone, Eastern Lake zone, Western Lake zone and Southern Highlands zone.

Tanzania Joins the World to Commemorate No Tobacco Day

On 31st May of each year all nations joins together to commemorate the World No Tobacco Day. Countries remembers this day by educating the public on health risks and environmental impacts of tobacco use. The main goal of the day is to reduce and ultimately eliminate tobacco use in order to protect public health and the environment. According to World Health Organization (WHO), the slogan for the year 2022 was "Tobacco: The Threat to Our Environment.

To mark the World No Tobacco day, Tanzania like other countries conducted a variety of public awareness programmes including outreach educational campaigns, radio and TV programmes, feature articles and publications that aimed at creating awareness to the public on the health and environmental effects of tobacco.

> "We believe that the slogan if implemented will give tobacco users another important reason to stop consuming the products and achieve the goal of protecting public health and the environment" Hon. Ummy alluded to.

In 2007, Tanzania signed and ratified the International Convention Framework on Tobacco Control (WHO - FCTC) coordinated by WHO to be part of the countries determined to control the use of tobacco in general. According to the Convention, member states have established policy guidelines and strategies for controlling tobacco products. Article 18 of the Convention requires member states to fulfill their responsibility to protect the environment and health society due to the effects of tobacco agriculture and crop production.

As a member of WHO FCTC Tanzania is responsible for developing various strategies to control and reduce the use of tobacco products so as to protect the public against the effects of using such products and reduce the burden on medical service costs.

Speaking to representatives from Media houses in Dodoma, the Minister of Health Hon. Ummy A. Mwalimu said that the 2022 theme aimed at raising public awareness about the environmental impact of tobacco use beginning from agriculture, production, distribution and waste management. "We believe that the slogan if implemented will give tobacco users another important reason to stop consuming the products and achieve the goal of protecting public health and the environment" Hon. Ummy alluded to.

Minister Ummy further elaborated that considering the health and environmental effects of tobacco products and in accordance with the Tobacco Products Control Act, Chapter 121, Tanzania Medicines and Medical Devices Authority (TMDA) has been mandated to regulate tobacco products in the country through Government Gazette GN 360 dated 30 April, 2021. TMDA has begun the work of regulating these products to protect public health. Likewise, the International Convention Framework on Tobacco Control (WHO - FCTC) recommends to countries to set-up a robust system

of controlling tobacco products.

Minister Ummy assured the public that Tanzania will continue to participate in the national and international efforts to control the use of tobacco products so as to eradicate the health effects of its use. Emphasis will be put in place to encourage the public to stop smoking for those who smoke, preventing the use of children under 18 and educating those who have not yet started to stop indulging in tobacco use.

Furthermore, Ms. Ummy directed TMDA to conduct an evaluation on effects of shisha products in order to find out the level of safety and quality so as to have scientific based decision in protecting and promoting public health.

According to WHO, the use of tobacco products causes the deaths of nearly half of its users and more than approximately 8 million people die each year worldwide as a result of tobacco use. 7 million deaths thus resulting from active smoking while 1.2 million is due to second hand smoking (passive smoking).

WHO has also identified that a large percentage of the population in developing countries is the most affected by the use of tobacco products compared to developed countries. This is also reflected in Tanzania where approximately 14,700 deaths resulting from tobacco use are recorded per year. A study conducted in the country in 2018 by the National Bureau of Statistics (NBS) and Chief Statistician of the Revolutionary Government of Zanzibar (OCGS) showed that; 8.7% of Tanzanians equivalent to 2.6 million people consume tobacco.

Studies show that approximately 65% of smokers dispose cigarette filters on the street, beaches and lakes. Similarly, many catechisms of electronic cigarette butts end up being thrown into canals and roads resulting in serious environmental damage. Improper disposal of tobacco products along with their residues is hazardous to the environment since they are made of non-perishable raw materials, such as coils metal, plastics, atomic controls and batteries.

> Tanzania will continue to participate in the national and international efforts to control the use of tobacco products so as to eradicate the health effects of its use

It is estimated that approximately 25 million tons of tobacco waste is produced annually due to the life cycle of tobacco. Almost all cigarettes commercially contain a chemical filter called celulose acetate; This chemical cannot degrade and is one of the sources of pollution.

There are more than 7,000 chemicals released into the environment due to the use of cigarettes, 70 of which have been proven to cause cancer.

Best Journalists of the Year 2021: TMDA Accolades Top Performers

Since 2018 the Tanzania Medicines and Medical Devices Authority (TMDA) has been organizing and staging annual extra-curricular gatherings targeting the media industry in the country to show case its roles and responsibilities for wider coverage. During the last retreat which was held in Arusha for editors and journalists residing on the northern corridor of the country, it was agreed to introduce an award to journalists who best perform in reporting TMDA's regulatory roles and functions.

To put matters into perspective, during the same event in Mbeya which invited journalists from the southern highlands zone regions, the TMDA awarded best journalists of the year 2021 – 2022 in different categories. Amongst the

- Mr. Andrew Challe - representative of Matukio Daima Media
- Mr. Suca from Tumaini Media who won the TV category
- Ms. Averine Kitomari of Habari Leo, the winner of Newspaper category
- Ms. Veronica Mrema of Boresha Radio who won the Radio category
- Ms. Grace Mwakalinga from IPP Media in Mbeya who was the overall winner

awardees were:

Speaking during the colourful awards ceremony which was held on 28th April, 2022 in Mbeya Region, TMDA Director General, Mr. Adam Fimbo, reaffirmed that the aim of these accolades was to recognize and acknowledge the work well done by journalists who reported most on what TMDA is doing. Mr. Fimbo further pledged to continue awarding winners during the forthcoming events slated on annual basis. He further pleaded all media experts to explore the opportunity after this gesture.

Speaking after receiving the radio category award, Ms. Veronica Mrema expressed her gratitude to TMDA for introducing such accolades and thanked the Authority for recognizing her exemplary work.

She went on by asserting that, "This is a unique honor for us journalists to be renowned by a reputable institution like TMDA, and the move has created awareness and motivation to write and report more on regulatory matters amongst media houses in the country,".

Prior to the awards ceremony, invited media editors from Mbeya, Njombe, Rukwa and Songwe regions presided over a working session aimed at sensitizing them on functions and roles of TMDA in regulating medicines, medical devices, diagnostics and tobacco products.

At the end, journalists were encouraged to write and report on regulatory issues and reminded to continue using their profession in educating and promoting public health.

Botswana Medicines Regulatory Authority benchmarks TMDA

Between 25th and 29th April, 2022, delegates from Botswana Medicines Regulatory Authority (BOMRA) paid a visit to TMDA with the aim of benchmarking on regulatory systems for medical products in Tanzania.

This visit which was led by members of BOMRA Management and some Heads of various departments essentially intended to familiarize with the TMDA's functions and scope in regulatory systems to include products and premises registration, import and export control, pharmacovigilance, ICT management, quality and risk management systems and laboratory services.

The visit was triggered by the milestones attained by TMDA in the regulation of medicines, medical devices and diagnostics. TMDA attained Maturity Level 3 status through benchmarking done by World Health Organization (WHO).

In his welcoming remarks, the TMDA Director General, Mr. Adam Fimbo, welcomed delegates from BOMRA and underscored the importance of fostering regional cooperation amongst SADC Member States. He further elaborated that the visit was part of implementation of the Memorandum of Understanding (MoU) which TMDA signed with BOMRA. He likewise called upon joint efforts and measures to be sustained to ensure that medical products in the region are robustly regulated for quality, safety and effectiveness.

On their part, BOMRA delegates expressed their gratitude to TMDA for hosting them and pledged to maintain the partnership for prosperity of both countries and the SADC region at large.

During their quick-stay at TMDA an array of regulatory aspects were discussed and presented to embrace overall responsibilities, legal framework and mandate.

As part of SADC, TMDA, BOMRA and other countries have been taking part in the regional harmonization initiative that aims at converging regulatory requirements to have a common understanding and streamlining of procedures.

TMDA Empowers ZAHRI to Strengthen Clinical Trials Control

Officials from the Zanzibar Health Research Institute (ZAHRI) visited TMDA on February, 2022 to benchmark on the systems for control of clinical trials as part of the implementation of the work packages assigned to members of the consortium implementing the ASCEND Project.

During their visit the officials participated in a mentorship training programme that was facilitated by TMDA on areas of clinical trials. TMDA Director General, Mr. Adam Fimbo, officiated the training session and assured the commitment of TMDA to support ZAHRI and other members of the consortium in attaining the goals of the project.

The training was centred around regulation of clinical trials mainly review and assessment of applications to conduct clinical trials and inspection of clinical trial sites to ensure clinical trials are conducted in compliance with Good Clinical Practices (GCP) and Good Clinical Laboratory Practices (GCLP).

Moreover, the training also focused on how to review and evaluate all safety information (adverse events) raised from clinical trials, clinical trial regulations, guidelines and standard operating procedures (SOPs).

Dr. Mayassa Ally on behalf of the delegation thanked TMDA for the great partnership with ZAHRI which will without doubt strengthen clinical trials control in the United Republic of Tanzania.

The ASCEND project foucses on Moving Tanzania's Clinical Research Ethics and Medicines Regulatory Capacity to the next level: Fostering Medicine Quality, Safety and GCP Clinical Trials. It is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).

The project is implemented across seven (7) different consortium members to include the TMDA as the lead institution of the project, National Institute for Medical Research (NIMR), Muhimbili University of Health and Allied Sciences (MUHAS) and Kilimanjaro Clinical Research Institute (KCRI). Others are Zanzibar Food and Drugs Agency (ZFDA), Zanzibar Health Research Institute (ZAHRI) and St. Andrews University based in Scotland, UK.

PICTORIAL NEWS

Symposium on ASCEND Project presented effectively during the NIMR- Annual Joint Scientific Conference held on 17th -19th May 2022 in Dar es salam

PICTORIAL NEWS

Members of ASCEND Steering Committee met on 8th April, 2022 in Dar es Salaam to discuss the implementation status of the project.

PICTORIAL NEWS

Sensitising journalists on TMDA functions

A visit to TCC industry by TMDA officials to acclimatise on tobacco product manufacturing processes

PICTORIAL NEWS

Regional Councils Inspectors Trained on the Principles and Procedures of Inspection

Regional, Municipal and District Levels Leaders Sensitised on TMDA Functions at Central Zone

PICTORIAL NEWS

Inspection of Tobacco products in the Market

Inspection of Infusion Water and Medical Gases Manufacturing Plants at Southern Highlands Zone

Control of Medical Products in The Country

PICTORIAL NEWS

Public Education Outreach Programmes

PICTORIAL NEWS

Establishment of TMDA School Clubs

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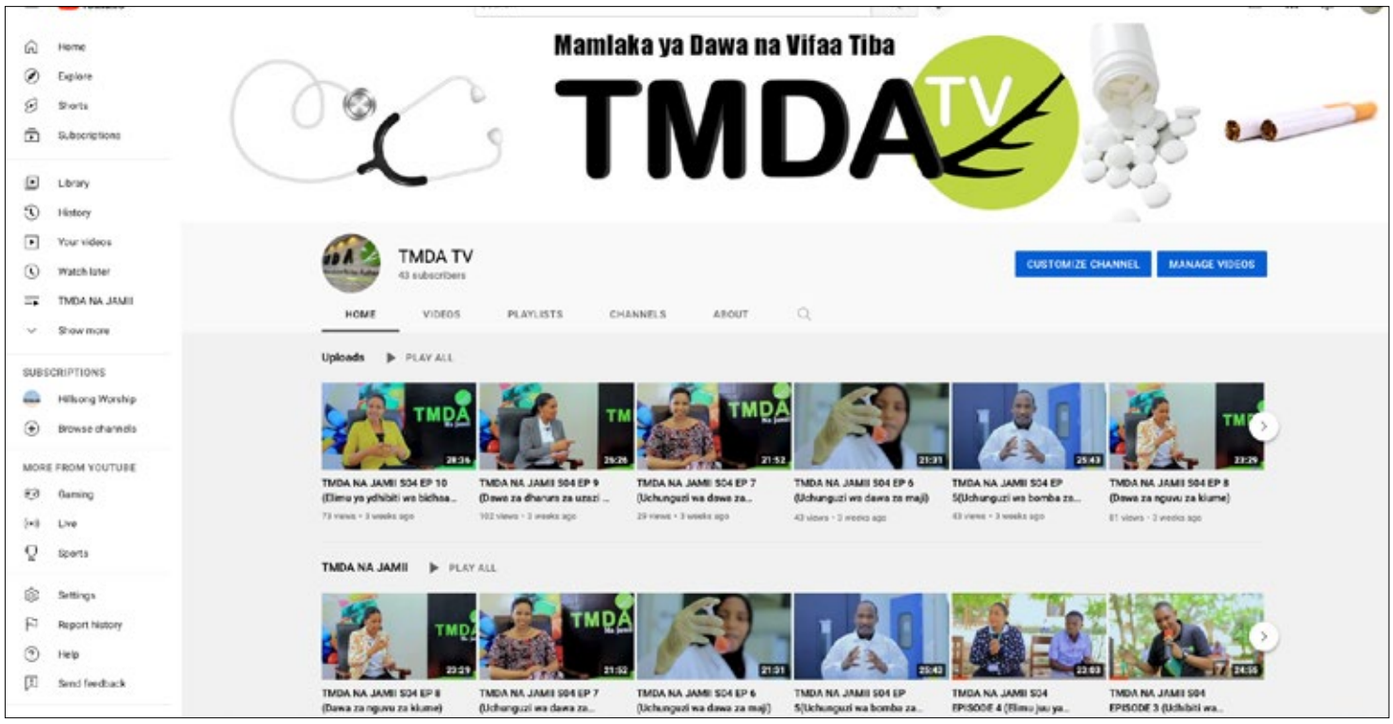
Stakeholders involvement in protecting and promoting public health

Establishment of TMDA Online TV



PICTORIAL NEWS

Together we Protects and Promotes Public Health

PICTORIAL NEWS

TMDA workers Council in a group photo

Staff Meeting

PICTORIAL NEWS

The Joy of Victory in Sports

TMDA Sports and Wellness

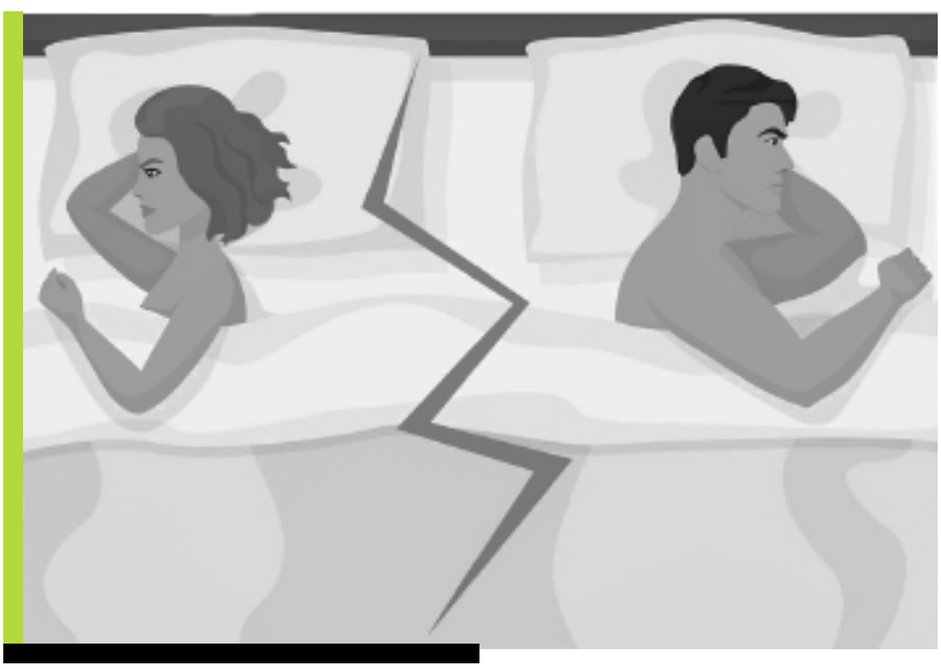
Irrational Use of Phosphodiesterase - 5 (PDE5) Inhibitors: Urgent Action Needed

Phosphodiesterase type 5 (PDE5) inhibitors are a group of medications most commonly used to treat Erectile Dysfunction (ED). Their ability to improve symptoms of ED was discovered accidentally while researchers were examining their potential use for high blood pressure and angina.

Sildenafil, vardenafil, tadalafil, and avanafil are types of PDE5 inhibitors which are indicated for the treatment of men with ED. PDE5 inhibitors block an enzyme in the walls of blood vessels and cause blood vessels to relax which leads to increased blood flow to certain areas of the body. This effect means that they can help manage conditions such as ED and pulmonary hypertension.

ED is the persistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance. Factors such as cardiovascular disease, hypertension, diabetes, hypercholesterolemia and smoking have been strongly associated with an increased prevalence of ED.

TMDA, as one of its important role in promoting and protecting public health in the country, ensures the quality, safety and effectiveness of these kinds of



medicines by conducting a proper evaluation during registration process. Several PDE5 inhibitors have been registered by TMDA to include Sildenafil (brand names - Evoke, Erecto, Zwagra, Silmet, Njoi and Viagra), Tadalafil (brand names - Saheal and Cialis) and Vardenafil (brand name - Levitra).

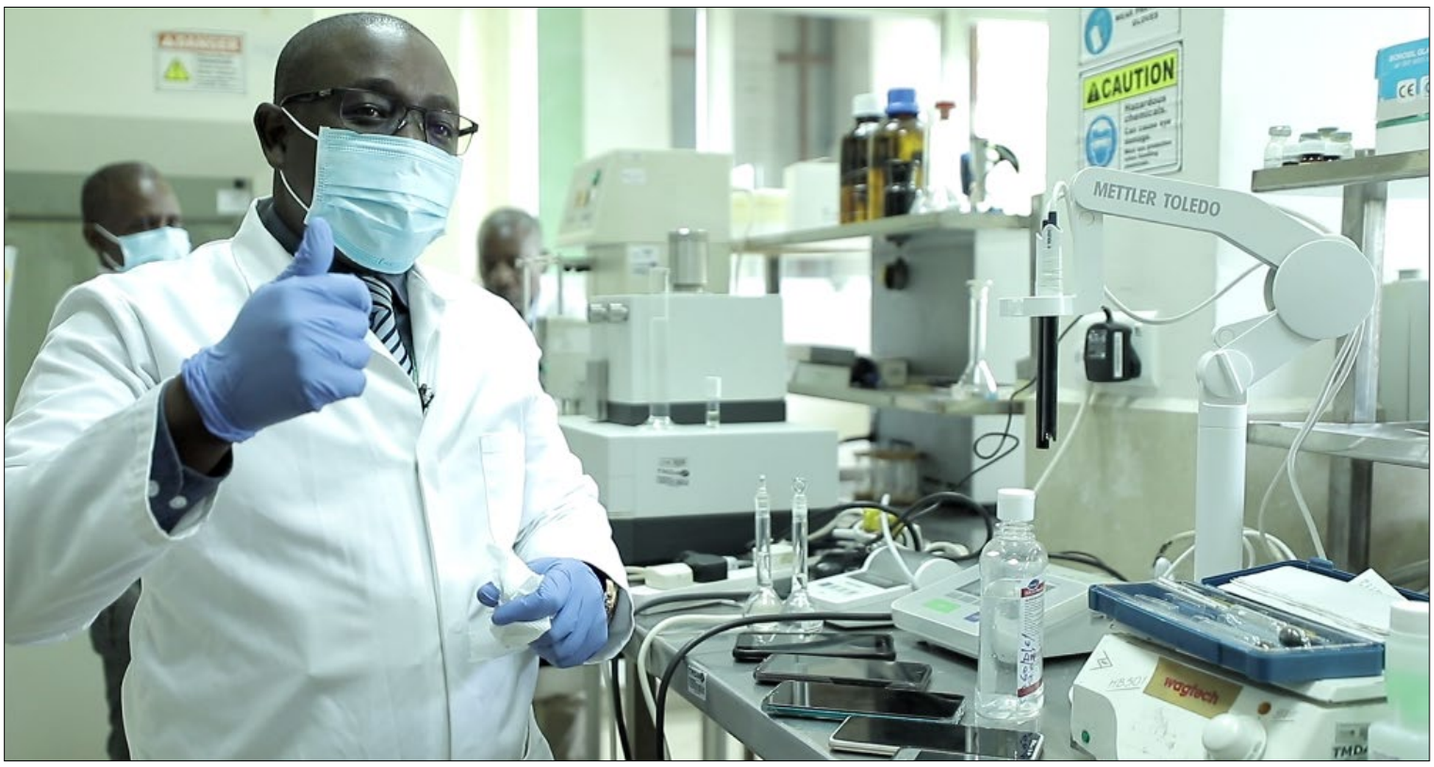
Despite the benefits of these medicines in treating ED, reports of their irrational use are rampant. Anecdotal reports of sudden deaths of young and elderly men in hotels, lodges and guest houses after PDE5 inhibitors use have been on the rise of recent. Urgent action is needed to reverse these preventable mortality cases.

The misuse of these products may lead to a condition known as priapism or prolonged erection. This causes penis pain for a long time and if left unchecked can damage the soft veins inside the penis leading to permanent disability. Other risks embrace damage to the eyes, blindness and deaths as highlighted above.

Patients with ED should first consult with their health specialists to get medical advice including health checkups before treatment. Over the counter dispensing and use of these products is dangerous to your health. It should be noted that ED may also be caused by other factors such as excessive alcohol consumption, lack of exercise, body size (obesity), smoking, stress, having too few male hormones and the food you eat. Lifestyle changing may help cure or significantly reduce ED.

Play your part to protect and promote your health by refraining from irrational use of these products.

TMDA's Laboratory Pre-Qualification and Expansion of its Scope



The TMDA Laboratory has been an integral part in conducting regulatory activities within the Authority. The Laboratory has been undergoing enormous changes including expansion and uprooting of new buildings, installation of state of the art analytical equipment, staff placement and training as well as method development and validation.

The Authorities' commitment and innovation in improving and updating laboratory service delivery systems in-line with the changing needs and expectations of its esteemed customers has been recorded as one of the factors that enabled the Laboratory to be pre-qualified by the World Health Organization (WHO) and maintain the status since January 2011.

The pre-qualification status has been attained following a number of audits and inspections in all areas of analysis to assess their effectiveness. WHO has been continuously conducting audits whereby in late 2021 WHO inspectors conducted a surveillance audit to assess the compliance to ISO/IEC17025:2017 standard requirements and Good Practices for Pharmaceutical Quality Control Laboratories. The laboratory was then found

to comply with the requirements and maintained its pre-qualification status.

The TMDA Laboratory is mandated to perform analysis of regulated products to include medicines, medical devices, herbal drugs, drug adjuvants, packaging materials and tobacco products. Of recent through the Laboratory Analysis of Medical and Non-Medical Products Regulations, 2021, GN 685, the Laboratory has now been mandated to analyse other non-regulated products (for commercial purpose) to include soil samples, human biological specimens originating from health facilities, animal biological specimens drawn from different species, research samples, samples of herbal medicines originating from traditional healers, environmental samples suspected to contaminate water and food chain and hospital supplies samples to include aprons, bed sheets, medical equipment and others.

The TMDA Laboratory is amongst the 57 pre-qualified quality control laboratories in the world as per the WHO list of pre-qualified laboratories of June, 2021.

All interested individuals and organizations are invited to use the TMDA Laboratory for analytical services.

WHO has been continuously conducting audits whereby in late 2021 WHO inspectors conducted a surveillance audit to assess the compliance to ISO/IEC17025:2017 standard requirements and Good Practices for Pharmaceutical Quality Control Laboratories.

Awareness on Effects of Tobacco Use: Student's Peer Pressure

"I commend TMDA for this initiative which will help students change their perception and observe rational use of medicines and medical devices. The education imparted to these students will also reach out to their families and henceforth protect the whole society" asserted Mr. Justimani.

TMDA had been developing and implementing a series of educational programmes to raise awareness on its functions in promoting and protecting public health. Educational programmes are designed and aired using various strategies to reach out to a large number of stakeholders and the general public. Implementation of public awareness programmes has been a key component in sensitizing public on rational use of medicines, medical devices and diagnostics.

Recently, TMDA has extended its educational campaigns to students in secondary schools through establishment of school clubs. Establishment of such clubs whose main role is to share and disseminate information on an array of regulatory matters has attracted students who have joined them. Knowledge and educational messages imparted to students can easily be passed over to other members of the society.

Between 24th and 28th of January 2022, TMDA visited and established 15 school clubs in some selected secondary schools based in Singida and Dodoma Regions. The event went along with sensitization seminars on the functions of the Authority and rational use of regulated products. Among other things, sensitization work-streams emphasized on the regulation of tobacco products specifically the effects of using tobacco to human health. Students expressed their concern on the upsurge use of tobacco products amongst youth especially in secondary and primary schools.

Speaking during the establishment of the school club, the Nzuguni Secondary School Headmaster Mr. Rodgers Justimani commended the move that TMDA is making in educating the public.

He further said that reaching schools through clubs will help students quit tobacco use and

engagement in irrational use of regulated products.

"I commend TMDA for this initiative which will help students change their perception and observe rational use of medicines and medical devices.

The education imparted to these students will also reach out to their families and henceforth protect the whole society" asserted Mr. Justimani.

On the flip side, Mr. Eric Ngowo, Meriwa Secondary School teacher who was appointed as the school club supervisor affirmed that, the established club will play a great role in creating and promoting not only student's health but also discipline since smoking and tobacco use to students is against school regulations.

Mr. Ngowo urged the Authority to open-up school clubs in other schools since secondary students are at risk of converging onto unscrupulous use of tobacco products while others are already in the use due to peer group influence.

The responses to students in the visited schools were positive following sensitization events and they pledged to share the knowledge to others. To date, TMDA has established 65 school clubs in Dar es Salaam, Pwani, Morogoro Singida and Dodoma regions. The Authority will continue establishing and developing these clubs in all its eight zones to reach out to a great number of students in secondary schools in Tanzania for the aim of protecting public health.

Wellness Programme and Engagement in Sports Activities

The Tanzania Medicines and Medical Devices Authority (TMDA) has approved the Wellness Programme that highlights different strategies designed to create a work environment and culture of participating in sporting activities. This is in line with the national strategy to fight Non-Communicable Diseases (NCDs) which are on the rise in recent times.

As part of implementation of the programme, TMDA staff took center stage in the Inter-Parastatal and Non-Parastatal Sports Federation of Tanzania (SHIMMUTA) sporting event which was organized in Morogoro region Tanzania between.....and.....

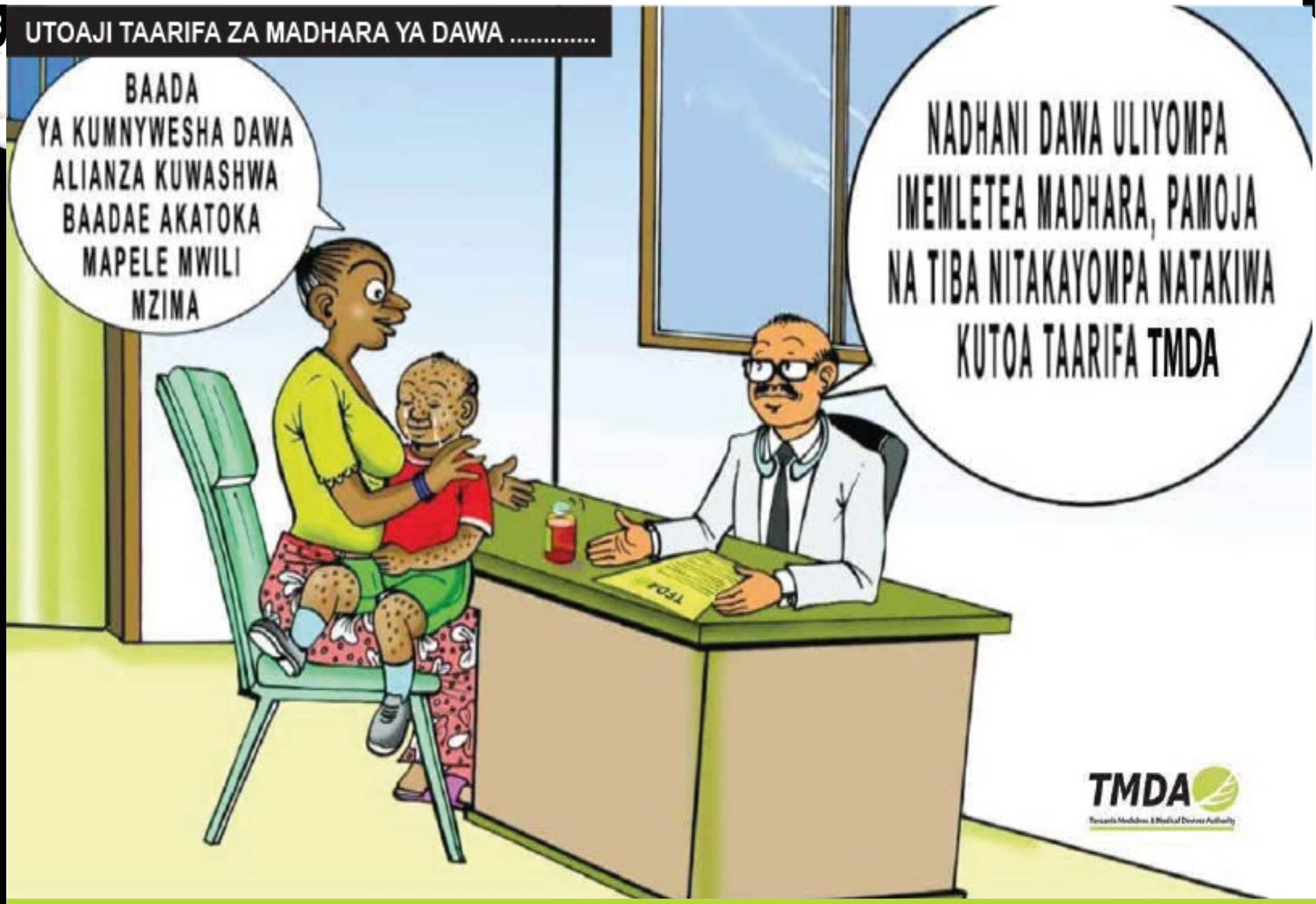
This was the second year; TMDA was participating in the event and the team showed much improvement in all games to include netball, football and cards playing. There was a great stamina and skill improvement to staff as compared to the previous year.

Speaking on behalf of the TMDA Queens and TMDA FC, the Sports Coordinator, Mr. Jaffary Mtoro, expressed appreciation to the Management for their continuous support to the team and he alluded that "seeing the top Management

at the event had given the team extra energy and impetus to commit more". During the games, the TMDA football team advanced to quarter finals where they played against TBS, in a match that ended 2 nil winning against them.

The Secretary of TMDA Sports Committee, Dr. Seif Magayane pledged that the SHIMMUTA 2022 will be different, and he boasted "trophies and medals are to be expected in 2022 as the team has begun preparations early on.

TMDA Management will continue to support the events including setting aside more budget and authorizing more staff to attend future sporting events for better health and well-being. This will significantly reduce the chances of developing NCDs and improving staff performance.


UTOAJI TAARIFA ZA MADHARA YA DAWA .....
BAADA YA KUMNYWESHA DAWA ALIANZA KUWASHWA BAADAE AKATOKA MAPELE MWILI MZIMA
NADHANI DAWA ULIYOMPA IMEMLETEA MADHARA, PAMOJA NA TIBA NITAKAYOMPA NATAKIWA KUTOA TAARIFA TMDA
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