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## SADC Regulatory Agencies step up comprehensive strategy to curb falsified medical products



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## Word from the Director General

**I**T is with great pleasure to invite you again to our latest edition of this incredible forum where you get to know all the tremendous milestone and transformation made within the Authority in ensuring safety of the public health.



The Authority has experienced massive changes as from 1st July 2019 in its regulatory functions whereby the control of cosmetics and food products has been shifted to the Tanzania Bureau of Standards (TBS) following the Finance Act, 2019 which in turn led to the transformation of name from the then Tanzania Food and Drugs Authority (TFDA) to Tanzania Medicines and Medical Devices Authority (TMDA).

This move intends to strengthen the regulatory functions specifically controlling quality, safety and effectiveness of medicines, medical devices and diagnostics.

TMDA has continuously invested in human and material resour-

es with the aim of strengthening its regulatory framework including product market surveillance system; product registration and evaluation; and import and export control to ensure products regulated in the market meet pre-set standards.

TMDA is dedicated to serve its stakeholders with professionalism without compromising quality safety and effectiveness of regulated products to meet customer satisfaction and expectations.

Like the previous editions of this forum, this newsletter provides an insight of various regulatory events and activities undertaken by the Authority in the cause of protecting and promoting public health.

I hope you will find it useful and very informative.

Enjoy your reading!

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

## Editorial Note

**Dear our Esteemed Reader,**

**I**t is with great pride and pleasure that I welcome you to our 7th edition of Newsletter.

First and foremost, I would like to extend my sincere heartfelt gratitude to the Chief Editor Mr. Adam Fimbo who is also the TMDA Acting Director General, for his tireless support and guidance throughout the production process of this edition of newsletter.

In this edition you will encounter name change of our newsletter from the then TFDA to TMDA Newsletter. These changes have no great impact on the useful information, feature articles and design provided in this important forum.

Among other things, this newsletter contains information on the

progress made by TMDA in relation to regulation of medicines, medical devices and diagnostics in the pursuit of protecting and promoting public health; the role of TMDA in enhancing the government agenda of Industrialization; and the success story of the Fifth Phase Government.

I trust that, this forum will provide you with adequate information pertaining to quality, safety and effectiveness of medicines, medical devices and diagnostics.

However, all constructive criticism and feedback will be taken into account for the development of our upcoming editions of the  $\Delta$ 1TMDA Newsletter.

Enjoy Reading!!

**Gaudensia Simwanza**  
**Editor**





The Permanent Secretary (Health), Dr. Zainab Chaula, (seated at the centre) in a group photo with participants during a training on Good Manufacturing Practices (GMP) for SADC National Medicines Regulatory Authorities (NMRA) Pharmaceutical Inspectors soon after the opening ceremony on 15th August, 2019 in Dar es Salaam.

## SADC REGULATORY AGENCIES STEP UP COMPREHENSIVE STRATEGY TO CURB FALSIFIED MEDICAL PRODUCTS

**M**EMBER States of the Southern African Development Community (SADC) have stepped up comprehensive and results oriented strategies to control the circulation and consumption of substandard and falsified medical products. It has been learned that this is a critical problem that derails economic growth and development of the African Continent.

“Our main goal is to ensure the availability of quality, safe and effective medicines and vaccines for all,” said the Permanent Secretary (Health) Dr. Zainab Chaula.

Dr. Chaula further noted that, that was why all governments across the world have been struggling to put in place some measures that will protect public health, in accordance with the Sustainable Development Goals (SDGs) 2030.

The Permanent Secretary was speaking in Dar es Salaam recently at the official opening of the Training Workshop on good manufacturing practice (GMP) Inspection for SADC Regulators which drew together

around 30 medical products inspectors from 14 SADC Member States.

A two-week training which was held from the 12th to 23 August 2019 was sponsored by the World Bank and co-organised by the SADC Implementing Team under ZAZIBONA and the Tanzania Medicines and Medical Devices Authority (TMDA).

As part of the proposed strategies SADC countries, Tanzania included, established regulatory Agencies to regulate quality safety and efficacy medical products. “In Tanzania we are proud with the TMDA as it has been working hard to set – up systems for regulation of medicines, medical devices and diagnostics,” noted Dr. Chaula.

She further noted that, it was due to their efforts and sustained commitment that TMDA have recently attained Maturity Level 3 status through the World Health Organisation (WHO) benchmarking process.

Dr. Chaula described substandard and falsified medical products as a serious challenge in many parts of Africa which required strategic and

broad-based approaches with the aim of effectively protect public health.

The PS commended SADC countries with the approach of imparting knowledge and skills to new inspectors in the region to effectively conduct GMP inspections, this in turn would allow products of good quality, safe and efficacy to be manufactured and circulated in our member state countries.

She urged participants to expedite approach processes of medicines in their respective regulatory bodies to make them freely available and timely.

The PS pleaded for regional cooperation particularly on technical capacity building, information sharing and taking speedy regulatory actions on substandard and falsified medical products crossing our borders.

“It is through these types of initiatives that technical requirements will be streamlined and a common platform established in regulation of medical products in the region,” she said.

Dr. Chaula further called for full commitment and support of the



*Inspectors for medicines and medical devices from SADC member states in a working group session during GMP Elementary training for SADC-NMRAs Pharmaceuticals Inspectors, held in Dar es Salaam on 15th August, 2019.*

Tanzanian Government towards the SADC harmonisation initiatives including being part of the process of ratifying the Treaty for Establishment of African Medicines Agency (AMA)

For his part, the Acting Director General of TMDA, Mr. Adam Fimbo, mentioned some of the notable achievements among others included organizing, conducting joint dossier assessment sessions and GMP inspections.

Mr. Fimbo further noted that under the SADC Medicines Regulatory Harmonization (MRH) programme, these have also been bolstered by the determination, efforts and commitment of five SADC member states namely Zambia, Zimbabwe, Botswana and Namibia, famously abbreviated as ZAZIBONA, which has been an instrumental in this process. “We have just joined this winning team to spearhead the initiative and bring in more vigor and energy in the SADC region.”

He highlighted “the benefits of harmonization have begun to be realized and now we have a mutual understanding and confidence of working together in various matters related to regulation of medical products,” Adding:

Through these harmonization initiatives, we have been able to meet regularly and discuss matters related to convergence of regulatory requirements with an overall objective of try-

**“the benefits of harmonization have begun to be realized and now we have a mutual understanding and confidence of working together in various matters related to regulation of medical products,”**

ing to find a way to avoid duplication of work and streamline our processes towards ensuring that medicines are regulated using a common and standardized approach,” Mr. Fimbo explained.

According to Mr. Fimbo “Capacity building is still a constant process that needs to be carried out over and over again and particularly when new staff is added to any organization. This has been the reason for organizing this training targeting elementary staff that have recently joined or never attended GMP inspection training before.”

He supposed that at the end of the day the training was to establish new inspectors with new skills and knowledge when conducting inspection of manufacturing premises to ensure that medical products are consistently pro-

duced and controlled to the required quality standards appropriate to their intended use and specifications. As GMP inspection is a pre-requisite for marketing authorization, medical products would then be able to be registered and allowed to circulate in the markets.

Tanzania is a member of SADC Economic Community and as regulators, TMDA is part of the SADC MRH initiative. This SADC MRH programme began in the year 2015 and ever since it has been able to harmonize a number of regulatory technical guidelines and procedures.

TMDA is also a member of the East African Harmonization Programme, the AVAREF Harmonization Initiative for Clinical Trials and the GALVMed sponsored Harmonization Programme for Veterinary Immunological Products. The New Partnership for Africa’s Development (NEPAD) Planning and Coordinating Agency plays a coordinating role under the auspices of the African Medicines Regulatory Harmonization (AMRH) programme which also takes on board other harmonization initiatives across Africa.

The training brought together participants from countries like Angola, Botswana, Comoro, Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia and Zimbabwe (listed here strictly in alphabetical orders).

## MAMLAKA YA DAWA NA VIFAA TIBA



Certified to ISO 9001:2015



**NI** Miaka 4 ya  
**MAFANIKIO**

2015-2019

- 01 Yafikia Ngazi ya Tatu ya WHO ya ubora wa mifumo ya udhibiti (Maturity Level 3) na kuiweka Tanzania kuwa nchi ya kwanza Afrika kufikia hatua hiyo
- 02 Kufikia na kushikilia Cheti cha Ithibati cha ISO 9001:2015
- 03 Kusajili zaidi ya bidhaa 15,000 za dawa na vifaa tiba baada ya kujiridhisha na ubora, usalama na ufanisi wake hivyo kuongeza wigo wa upatikanaji wa bidhaa na kulinda afya za wananchi
- 04 Kusogeza huduma kwa wananchi kwa kujenga maabara ya kisasa jijini Mwanza na kuweka mitambo yenye uwezo wa kupima kwa ufanisi usalama na ubora wa bidhaa
- 05 Kuongeza bajeti kutoka 34.64 Bilioni hadi 53.31 Bilioni sawa na 53.8%. Hii imewezesha utoaji huduma kwa ufanisi na kutoa gawio kwa Serikali kila mwaka hadi kufikia Tshs bilioni 29.1
- 06 Kutoa msaada wa kiufundi kwa ajili ya kuanzishwa viwanda vya dawa vipya 4 nchini na vifaa tiba hivyo kuchangia katika uwekezaji nchini
- 07 Kuanza kutumia mifumo ya kielektroniki katika utoaji huduma za vibali ambapo sasa vibali vinatolewa ndani ya saa 24



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HOTLINE  
 0800110084

# PICTORIAL



H. E. President Dr. John Magufuli (seated at the center), in a group photo with Chief Executive Officers, Board Chairmen from different government parastatals (including TMDA) and other high ranking officials after receiving contributions and dividends during the handing over ceremony held at the Chamwino State House, in Dodoma on 24th November 2019.



TMDA Western Lake Zone Acting Manager, Ms. Sophia Mziray (2nd right), hands over a computer set and printer to the Geita Referral Hospital Acting Medical Officer In-Charge, Dr. Shabani Massawe. TMDA strives to improve reporting of adverse drug reactions (ADR) by providing ICT equipment to different health centres, Geita being one of them.



TMDA Eastern Zone Manager, Mr. Adonis Bitegeko speaks during an official opening of Medicines and Medical Devices Inspectors capacity building training held in Mtwara Region from 4th to 8th November, 2019. First right is the Acting Regional Medical Officer Mr. Seveus Kamala, 2nd right is Acting Regional Administrative Secretary Mr. Rensus Manghogwela and left is Mtwara Regional Pharmacist Mr. Mussa Nassoro.



Participants in a laboratory Training require for and themordy of latexy condom in group photo with facilitate from UNFPA/ USAID. the trairng was hearthy at TMDA / who Pre-Colifaide laboratoty and Dar es Salaam from four eighy November 2019.



Participants in a training on the Trainers Course on Pharmacovigilance through PAVIA project that was organized by TMDA in collaboration with University of Verona Italy, held in Dar es Salaam from 21 - 25 October, 2019, in a group photo with facilitators.

Members of the TMDA workers council in a group photo in one of their biannual meetings aimed at discussing various institutional issues. The meeting was held in Morogoro from 3rd to 4th September 2019.



# PICTORIAL



Deputy Minister of Health, Community Development, Gender, Elderly and Children, Dr. Faustine Ndungulile (1st left), insisting a point on the importance of an Online Permit Application System which has brought tremendous improvement and advancement in customer service delivery done by TMDA. He said this on 29th August, 2019 during a benchmarking visit from the Members of the Budgetary Committee of the Zanzibar Representative.



The TMDA Acting Director General, Mr. Adam Fimbo, hands over 45 cartons of sanitary pads, 10 cartons of baby diapers and a variety of medicines for the prisoners to the Segerea Prison Ward, SSP George Wambura, as part of the Authority's community social responsibility (CSR). Others are Dr. Bernard Nyaongo of Segerea Prison Dispensary and Acting Medical Officer In-Charge, Inspector Shukrani Rububula.



Acting Manager of Microbiology Analysis, Ms. Catherine Luanda (right), elaborating the process of analyzing microbiology samples to the Deputy Minister of the Ministry of Health, Community Development, Gender, Elderly and Children, Dr. Faustine Ndungulile (2nd left) and members of the Budgetary Committee of Zanzibar Representative when they visited TMDA on 29th August, 2019.



TMDA Good Manufacturing Practices (GMP) inspectors Ms. Gloria Matemu (1st left), Ms. Chimpaye Julius (2nd left) and Manager for Inspection and Enforcement, Mr. Emmanuel Alphonse (1st right), on their official duty of inspecting construction progress of a new veterinary vaccines manufacturing facility by Hester Biosciences Africa Ltd, by located at EPZA Kibaha, Coast Region. Together with them is Ms. Christina Sokoine from Hester Biosciences Africa Ltd.



TMDA Evaluators prudently evaluating dossiers for Registration and Marketing Authorization of Human and Veterinary Medicines.



TMDA Evaluators prudently evaluating dossiers for Registration and Marketing Authorization of Human and Veterinary Medicines.

# TMDA pays over 29bn/ dividends to government

As a way of implementing President Dr. John Magufuli's directives that required all the 91 public institutions that are supposed to pay dividends to the central government are doing so, the Tanzania Medicines and Medical Devices Authority (TMDA) has paid a dividend of Tzs 12.475 billion.

Speaking in Dodoma, on 24th November, 2019 after handing over a dummy cheque worth Tzs 12.475 billion for the financial year 2018/19, the Chairman of Ministerial Advisory Board to TMDA (MAB), Ambassador Dr. Ben Moses said "Our duty as an advisory board is to properly oversee the authority fulfills efficiently its mandate and responsibilities of promoting and protecting public health. And at the same time implementing the government's directives for the development of our country. Adding:

In fact, we commend the management and staff of TMDA for working hard and tirelessly to attain these achievements, and we will ensure they become sustainable," he explained.

Dr. Moses said that TMDA has continued implementing the Fifth Phase Government's directives under President Dr. John Magufuli's leadership, that is why for the last four years since this government came to power, TMDA has paid a tune of TZs 29.1 billion in total.

In another development, TMDA Acting Director General, Mr. Adam Fimbo, has said that his authority would continue controlling quality, safety and effectiveness of medicines, medical devices and diagnostics so



H.E. President Dr. John Magufuli receives a dummy cheque of dividend worth TZS 12.475bn from the Chairman of the Ministerial Advisory Board to TMDA (MAB) Hon. Amb. Dr. Ben Moses, being accompanied by representative of the TMDA Acting Director General, Dr. Danstan Hipolite at a handing over ceremony held at Chamwino State House, in Dodoma on 24th November 2019. First Left is the Minister for Finance and Planning Dr. Philip Mpango and the Speaker of the National Parliament Hon. Job Ndugai (Mp).

as to safeguard public health. Adding that, TMDA will also continue well managing government resources so that they become productive and hence contribute to the National Gross Domestic Product (GDP) as per the government's requirement.

Meanwhile, Mr. Fimbo said the authority has increased its budget from 34.64bn/- to 53.31bn/- in the financial year 2015/16 and 2018/19 respectively, which is equivalent to 53.8 per cent.

This has enabled the authority to offer service delivery efficiently and has been providing dividends to the government for the last four years

**“Our duty as an advisory board is to properly oversee the Authority fulfills efficiently its mandate and responsibilities of promoting and protecting public health. And at the same time implementing the government's directives for the development of our country”**

amounting to 29.1 bn/-.

Last year President Dr. John Magufuli directed the newly appointed Treasury Registrar (TR), Mr Athumani Mbutuka, to ensure that all the 91 public institutions that are supposed to pay dividends to the central government are doing so.

According to the Head of State, in the 2014/2015 financial year, only 24 public entities gave dividends to the government amounting to 130.69bn/-.

In 2015/2016, twenty-five public institutions remitted dividends amounting to 249.3bn/ while in 2016/2017 the number of institutions increased to 38, whose total dividends amounted to 677bn/-.



The Ministerial Advisory Board (MAB) for TMDA in a group photo.

# TMDA cautions on falsified Gentrison cream

**T**HE Tanzania Medicines and Medical Devices Authority (TMDA) has cautioned the public on the presence of falsified batch of medicine known as Gentrison 10 mg in the market of Tanzania.

According to a statement issued by TMDA Acting Director General, Mr. Adam Fimbo highlighted that the falsified medicine Batch No. GNTROX030 produced on 21st April, 2019 with expiration date 20th April, 2022 was allegedly manufactured by a Korean based company known as Shin Poong Pharm Company Limited.

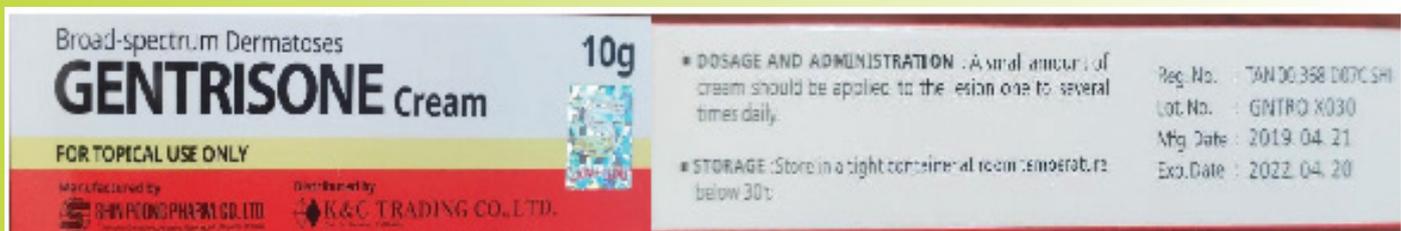
It was further revealed that a total of 4188 tubes of the medicine were found in various medicines premises located in five regions namely Dar es Salaam, Mwanza, Mtwara, Arusha, Dodoma and Tabora. Meanwhile, the Authority has ordered all the identified falsified Gentrison to be surrendered to TMDA Offices including its Zonal Offices located in Mwanza, Simiyu, Arusha, Mbeya, Dar es Salaam, Dodoma, Mtwara and Tabora.

The measures taken by TMDA are an indication that the authority is serious in protecting and promoting public

health from the identified unsafe products.

Furthermore, the statement noted that TMDA has very efficient systems in the surveillance of the products it regulates not only in the market but also control to all the 32 ports of entry.

However, Mr. Fimbo has said that the war against falsified medicines should not be left to TMDA alone, but has urged the public to join hands with the authority in combating falsified and substandard medical products by reporting to TMDA on suspected products.



*A picture of Falsified Gentrison Cream found in the market.*

TMDA new employees have been urged to observe quality management principles when performing their daily duties pertaining to the authority's regulatory matters.

Speaking during a quality and risk awareness training, the representative of the Director-General, Mr. Akida Khea, called upon the new staff to observe and implement quality systems when carrying out their duties.

A two day training had aimed at equipping the new TMDA staff with the needed requirements of ISO 9001 standard which the Authority is implementing. Among other things the training outlined requirements of quality management standard as stipulated in the ISO 9001:2015.

Since 2009 TMDA has been implementing quality management systems in delivering quality services for its esteemed customers in ensuring quality, safety and effectiveness of medicines, medical devices and diagnostics as a way of protecting public health.

TMDA attained a quality certificate after complying with the requirements of ISO 9001 standard currently updated to ISO 9001:2015, following

## TMDA staff urged to observe quality aspects in performing regulatory duties



*Director of Medicine and product control, Mr Akida Khea and participants in a group photo during the official opening of awareness training on quality management system and risk management of which TMDA is implementing.*

series of audits by the ISO certifying board by the name ACM/UKAS based in the United Kingdom.

Furthermore, among other things, in order to maintain its certificate and

improve quality of services provided, the Authority has been conducting regular trainings on fundamentals of quality and risk management to its staff.

# TMDA participates in 4th Annual SADC industrialisation week

**F**OR the first time in its history, Tanzania hosted the 4th Annual SADC Industrialization Week that brought together over 3000 participants, including 1576 exhibitors.

During that landmark event in the country that took place at the Julius Nyerere International Convention Centre, the Tanzania Medicines and Medical Devices Authority (TMDA) also participated and showcased its services and products.

At the exhibition, potential investors and business people dealing with products which are regulated by TMDA such as medicines, medical devices and diagnostics visited the authority's pavillion to get proper and important information on how to invest and trade in medical products.

Due to the education awareness offered by TMDA officials during the event, potential investors have shown interest in investing in the pharmaceutical industry in the country, mainly attracted by the conducive business environment done by the Fifth Phase Government under President Dr John Magufuli.

Some of the participants from SADC Member States commended TMDA's achievements in the regulation of the products including attaining the World Health Organisation (WHO) Maturity Level 3, and being the first country in Africa to reach that rank.



*TMDA's Manager for Communication and Public Education, Ms. Gaudensia Simwanza, on right, discussing something with Mr. Rutta Kahamba during the 4th Industrialization week at the TMDA pavillion.*

However, they have urged the Authority to share that experience to sister countries to also build such capacity in the region, so as to assure the quality, safety and effective medicines, medical devices and diagnostics circulating in the market.

For her part, the SADC Executive Secretary Ms. Stergomena Tax called on the delegates including TMDA to

utilise the trade opportunities created by the SADC Free Trade Area, which is an integrated market of the 16 countries.

The SADC market has a combined population of 327million and a combined Gross Domestic Product (GDP) of about USD 599 billion as of 2016.

When gracing the meeting the Tanzanian President, His Excellency Dr. John Magufuli, called upon the African countries to redouble their efforts so as to industrialise their economies, which should go in line with the theme of the event titled "A Conducive Environment for Inclusive and Sustainable Industrial Development, increased intra-regional trade, and job creation."

The 4th Annual SADC industrialisation week that took place from the 5th to 9th August, 2019 had aimed at accelerating sustainable industrial development in the region.

Apart from the President, the event was also attended by other high ranking government officials from the SADC Member states and development partners.



# Introduction of electronic system surges TMDA's permits issuance by 200 pc

**T**ANZANIA Medicines and Medical Devices Authority (TMDA) has issued a total of 26,478 permits in the financial year 2018/19 compared to 13,018 issued in 2015/16, which is an equivalent to an increase of 203 per cent.

This has been achieved through the use of electronic system which has enabled customers to submit applications and pay fees online before being issued with the permit within 24 hours.

According to a statement issued recently by TMDA's Acting Director General, Mr. Adam Fimbo the authority has succeeded to increase the importation and exportation control of medicine and medical devices within and outside the country through an electronic system.

Fimbo further noted that the issuance of permits to customers has been facilitated largely through an integrated management information system (TMIS) which is used to keep information and data of TMDA comprising of products, buildings registered and those of customers, whereas they can bring their applications online without going physically to the offices.

"In implementing the directives given by President Dr John Magufuli issued in May, 2017 which aimed at speeding up the delivery of cargo at the Port, the authority has also instructed its inspectors to work for 24 hours throughout the week. Adding:

That move has enabled the authority to successfully achieve and exceed the goals set in the controlling of quality,

## *An outlook of the initial stage of capturing the applicant details and premise details in the permit application process.*

safety and efficacy of medicines, medical devices, and diagnostics so as to protect public health," Fimbo noted.

Mr. Fimbo further said: "Within these four years under the leadership of President Dr Magufuli we have managed to implement a programme of monitoring the quality of products on the market, known as post marketing surveillance programme – (PMS). Adding:

About 1,136 samples of human medicines were collected and analysed in this period, where the 96 per cent continued to meet quality criteria," he noted.

According to Mr. Fimbo, TMDA has introduced an electronic system known as adverse drug reactions (ADR) reporting tool" for monitoring the public reporting of adverse drug reactions

and medical devices by using mobile phones or computers.

He further explained that TMDA officials in the year 2017/2018, conducted inspection and destroyed a total of 140,705.25 tonnes of unsafe pharmaceutical products and medical devices for human use worth 22,394,078,744 shillings compared to around 664.68 tonnes that were destroyed in 2018/19.

Mr Fimbo noted that TMDA has strengthened laboratory activities so as to increase surveillance equipment including the installation of 25 minilab kits at the ports of entries and some at referral hospitals in favour of the preliminary screening of the product.

Survey results show that the samples examined have met criteria of quality and safety standards to an average of 90 per cent.

Meanwhile, Fimbo said the authority has increased its budget from 34.64bn/- in the financial year 2015/16 to 53.31bn/- in the financial year 2018/19, which is equivalent to 53.8 per cent.

This has enabled the authority to offer service delivery efficiency and has been providing dividends to the government for the last four years amounting to 29bn/-.

TMDA was established in 2003 and operates under the Ministry of Health, Community Development, Gender, Elderly and Children. TMDA was formerly known as the Tanzania Food and Drug Authority (TFDA) before its obligations were changed from July last year when the Finance Act of 2019 made amendment to the authority's law.

**TMDA outlook of the Online Service Portal, which has enabled customer to submit applications and paying fees online before being issued with permits within 24 hours.**

# TMDA, NIMR team to establish online medical research monitoring

The Tanzania Medicines and Medical Devices Authority (TMDA) and the Medical Institute for Medical Research (NIMR) have formulated an electronic system for monitoring of trial researches for medicines in order to simplify and assist the control within the institutions that oversee ethics and professionalism in medical research aimed at ensuring the safety of medicines.

This was revealed at the 2nd Annual General Meeting on the project aimed at following up and ensuring the safety of medicines that took place at TMDA offices in Dar es Salaam in late September last year, and was attended by experts from various universities and colleges, hospitals and other research institutions in the country.

Representing TMDA Acting Director General, Mr. Akida Khea said that the launch of the electronic follow up system was part of streamlining health research ethics and medicines regulation in Tanzania (SMERT) success story because researches done concerned medicines, hence any adverse reactions must be published.

He said: “Initially reports were conveyed in print, but now through this new system research finding will be

**“Before the introduction of the new electronic system there was a big challenge of waiting for a very long time before researches were permitted. This affected research implementation by taking long periods to be completed.”**

conveyed through online application whereas a researcher will be required to fill in a report about the research he plans to do on medicines. Adding:

The system allows any person from any part of the world to register their trials and thus, they will be able to be seen and acknowledged by other people. And this will eliminate duplication.

For his part, Mbeya NIMR Director and Project’s main researcher

(Tanzania-UK) Dr. Nyanda Elias said “Before the introduction of the new electronic system there was a big challenge of waiting for a very long time before researches were permitted. This affected research implementation by taking long periods to be completed.”

For his part, NIMR Director for coordination and research development Dr Paulo Kazyoba explained that research on health must undergo ethical examination whether it was a trial for new drugs or looking for information from the people.

The representative from St Andrews University in the United Kingdom, Dr Wilber Sabiiti said: “Tanzania is serious in conducting research, hence it finds the opportunity in its professional research capacity and medicines control and decided to apply for sponsorship from us. We supported their endeavours and gave them financial support, and have been successful.”

Sabiiti who is an expert in inventions of new medicines said that when a new disease is discovered trial of medicines must be examined for safety of the user.

He said as of now the world is like a village, people’s health needs national and global experts in health, hence those doing researches are required to ensure nobody within and outside the country is allowed to conduct researches that would endanger people’s health.



*SMERT PROJECT participants in a group photo during the 2nd Annual Meeting, held at TMDA offices in Dar es Salaam on 26th September, 2019 whose theme was, “Building Tanzania’s Capacity for Clinical Research and Pharmacovigilance.”*



# UKURASA WA

Tumeboresha Sekta ya Afya

"Tumeboresha  
 Sekta ya Afya"

Yaliyofanywa katika Sekta ya Afya ndani ya miaka minne ya Serikali ya Awamu ya Tano



**Adam Fimbo**  
 Kaimu Mkurugenzi Mkuu (TMDA)

## TMDA YAONGEZA USIMAMIZI wa Dawa, Vifaa Tiba na Vitendanishi

- Yawa ya kwanza Afrika kwa udhibiti bora na salama wa dawa, vifaa tiba na vitendanishi.
- Imekidhi ithibati ya ISO 9001:2015: Maabara yake ina tambuliwa na Shirika la Afya Duniani (WHO Prequalified).
- Imesajili bidhaa salama na bora 20,247 za dawa na vifaa tiba ili kulinda afya ya jamii; imeimarisha mifumo sasa bidhaa katika soko ni salama kwa 96%.
- Imeanzisha maabara ya kisasa Mwanza ili kusogeza huduma kwa wananchi.
- Imechangia gawiwo kwa Serikali kiasi la sh bilioni 29.1; imeongeza bajeti ya utendaji kazi kwa 53.8 %.
- Imetoa msaada wa kiufundi sasa viwanda vipya vya dawa 12 vinajengwa nchini;
- Inatoa vibali ndani ya saa 24 kwa njia ya TEHAMA

**Kwa hisani ya**  
 Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto pamoja na Taasisi zake



Wizara ya Afya,  
 Maendeleo ya Jamii,  
 Jinsia, Wazee na  
 Watoto



Mamlaka ya Dawa  
 na Vifaa Tiba  
 (TMDA)



Mamlaka ya Maabara  
 ya Mkemia Mkuu wa  
 Serikali (GCLA)



Bohari ya Dawa  
 (MSD)



Hospitali ya Taifa  
 Muhimbili (MNH)



Hospitali ya Rufaa ya  
 Kanda ya Kaskazini  
 (KCMC)



Taasisi ya Tiba ya  
 Mifupa Muhimbili  
 (MOI)



Mfuko wa Taifa wa  
 Bima ya Afya (NHIF)



Taasisi ya Saratani  
 ya Ocean Road



Mpango wa Taifa  
 wa Taifa wa Damu



Hospitali ya Rufaa  
 ya Kanda Bugando  
 (BMC)



Hospitali ya  
 Benjamin  
 Mkapa



Taasisi ya Chakula  
 na Lishe Tanzania  
 (TFNC)



Hospitali ya Rufaa  
 ya Kanda Mbeya



Taasisi ya Moyo  
 Jakaya Kikweto



Taasisi ya Taifa ya  
 Utafiti wa Magonjwa  
 ya Binadamu (NIMR)

# TMDA



Tanzania Medicines & Medical Devices Authority



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