TFDA
Tanzania Food & Drugs Authority
Newsletter Issue No.6
March, 2019

TFDA commemorates 15 years of successful operations

TFDA
Tanzania Food & Drugs Authority

Contents

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Editorial Note

Dear reader,

Welcome to our sixth edition of TFDA Newsletter as our organisation marks 15 years of existence since its inception in 2003. The Authority also emerged the first regulatory body in Africa to be elevated by Word Health Organisation (WHO) into Maturity Level Three in regulating medical products. Many thanks to all of you who in way or another played vital part to it as these contributions are essential to our success.

My utmost tribute goes to the Chief Editor, Mr. Adam Fimbo who doubles as TFDA Acting Director General for general guiance and readership towards achieving the Instutution's goals and agin for exemplary support that indeed made it possible to have this newsletter published.

This Newsletter provides me with a chance to reflect on what TFDA has been able to achieve in the last 15 years or so, particularly in relation to the big picture goals that we have so far put in place.

Among them, is the contribution of our organisation towards the envisaged industrial economy that is clearly outlined in the second National Five Year Development Plan (FYDP II).

Apart from that, this edition contains information, news, photographs and feature articles that elaborate what TFDA has so far been doing in the past 15 years. Upon reading, I believe you will be able to enjoy and give your feedback and comments that will make us able to improve the subsequent Newsletters in future.

Enjoy Reading!
Gaudensia Simwanza
Editor

A word from Acting Director General

Ladies and Gentlemen,

Today, I remain proud and humbled that I have been entrusted with the greatest responsibility of leading this great organization.

There is no commodity in the world more precious than health. TFDA is an institution charged with protecting and promoting the health of over 45 million people, therefore, bears great responsibility and must be held to high standards.

Various publications of TFDA newsletter have been highlighting the role played by this Authority in regulating safety, quality and effectiveness of food, medicines, cosmetics, medical devices as well as diagnostics.

Taking into consideration the fact that information is power, TFDA has continuously been providing timely information to the public to ensure that everyone makes informed choices whilst yousing among regulated products.

I am indeed delighted to welcome our readers to this 6th issue of our biannually newsletter which is full of articles and photographer that will enrich you with information on what we have been doing for the last 15 years by adhering to laws, regulations and guidelines.

I believe this newsletter will let you relax and enjoy as you get several information regarding the beautiful work done by our staff in ensuring that the public health is protected.

Thank you all!
A.M. Fimbo
Acting Director General and Chief Editor

Tanzania Food & Drugs Authority

TFDA
Tanzania Food & Drugs Authority

Celebreting 15 years of successful regulation of quality and safety of food, medicines, cosmetics, medical devices and diagnostics:

"The first African Regulatory Authority to attain the WHO Maturity Level 3

TFDA 15TH 2003 - 2018

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"TFDA - Protecting and Promoting Public Health"

TFDA commemorate 15 years of successful operations

ON July 1st, 2018, the Tanzania Food and Drugs Authority (TFDA) marked the 15th Anniversary in regulating food, medicines, cosmetics, medical devices and diagnostics since it was formally established on July 1, 2003.

As a regulatory body under the Ministry of Health, Community Development, Gender, Elderly and Children, TFDA was established under the Tanzania Food, Drugs and Cosmetics Act, Cap. 219. During this period, when the Authority officially became operational, TFDA has put in place various operating and regulatory systems that have brought about remarkable results in the control of quality, safety and effectiveness of products and services under its mandate.

TFDA has been carrying out its activities with the goal of protecting and promoting public health in line with its five-year strategic plans (2003 – 2008; 2008/09 –2012/13; 2012/13 – 2016/17; 2017/18-2021/22) and yearly business plans that provide for strategic ways of deploying institutional resources to realize its mission and vision.

The following are some of the outstanding milestones attained by TFDA during the 15 years of its existence:

Quality Management System

TFDA has managed to develop and implement Quality Management System (QMS) in order to deliver quality and consistent services to its customers. In view of implementing QMS, TFDA has been certified to ISO 9001: 2015 in areas of food, medicines, cosmetics, medical devices and diagnostics regulatory systems.

Conversely, TFDA has also managed to expand its Quality Control laboratory building and equip with a state of art modern analytical equipment and instruments. Such improvement has enabled the laboratory to be Prequalified by the World Health Organization (WHO) since January, 2011. The Microbiology and Food laboratories have been accredited by the Southern African Development Cooperation Accreditation System (SADCAS) to ISO/IEC 17025:2005 standards. This implies that analytical results obtained from the TFDA laboratories are internationally recognized and accepted.

Regulation of quality, safety and effectiveness of food, medicines, cosmetics,

medical devices and diagnostics was also strengthened.

• Registration of food, medicines, cosmetics, medical devices and diagnostics

The Authority registers products to ascertain their quality and safety before they are allowed to enter the market. Product registration has improved significantly, as the number of registered products has been increasing annually from 265 in 2003 to 15,361 in 2018. This trend signifies assurance of safety and quality products in the Tanzanian market.

• Registration and inspection of premises

Suitability of premises for intended use is important in controlling the safety and quality of products in the market. The law requires that any place intended for the sale, distribution, storage and manufacture of regulated products must be registered by TFDA. The number of inspected premises has increased from 11,021 in 2003 to 17,314 in 2018. Such phenomenal success is attributed to TFDA's investments in equipment and manpower.

• Import and export control

TFDA has put in place an electronic system for import/ export permit application, together with an all-the-time inspection system at the country's Ports of entries. This is to ensure that products imported or exported meet with the set quality and safety standards in the context of safeguarding public health. Through these systems, the number of import permits for food, medicines, cosmetics, medical devices and diagnostics has increased to 13,018 since 2003, while export permits currently stand at 2,553 from the 557 permits that were issued in 2003

• Destruction of substandard products

Since 2003, TFDA has been destroying food, medicines, cosmetics and medical devices that do not meet with the prescribed quality and safety standards. Thus, as a result of effective and efficient checks and controls installed at strategic points plus extensive public education by the Authority. Quantities of products that are destroyed for being unfit have been decreasing down the years.

To illustrate this, TFDA destroyed 664 tonnes of unsuitable products in 2018 compared to the 870.86 tonnes that were destroyed in 2016. This implies that the public is now generally aware of the laws and regulations governing the importation of regulated products.

• Post-Marketing Surveillance and clinical trials

'Post-Marketing Surveillance' is the system that is used to survey, identify and isolate products that do not meet quality, safety and efficacy standards, ready for controlled destruction.

TFDA's product surveillance systems have been strengthened and programmes intensified. Product samples have been clearly outlined in post-marketing surveillance programmes. Samples collected and analyzed yearly for their suitability increased from 130 in 2003 to 353 so far this year.

• Pharmacovigilance and food risk events

The Authority has introduced a follow up system to monitor the side-effects of food consumption, as well as of medicines, cosmetics, medical devices and diagnostics aimed at protecting public health.

To that end, TFDA established an 'Adverse Drug Reaction' (ADR) system for reporting all adverse impact cases caused by medicines, as well as for medical devices and diagnostics known as the 'Adverse Events in Medical Devices' (AEMD). The system facilitates following up on authorized products in the market. Detected cases are reported by

To illustrate this,TFDA destroyed 664 tonnes of unsuitable products in 2018 compared to the 870.86 tonnes that were destroyed in 2016.This implies that the public is now generally aware of the laws and regulations governing the importation of regulated products.

'primary contact users' to 'end users' of the products through filling in specially designed forms, through ADR android application tool and also through mobile phone text message system. TFDA is dedicatedly working hard to provide awareness and information on all the systems to the general public, always with the aim of protecting their health.

Additionally, TFDA works tirelessly on researches, measures and initiatives that are designed and intended to protect public health including protection from foodborne diseases such as aflatoxins, listeriosis, brucela, etc.

SMEs Promotion Strategy

TFDA has initiated various programmes that are aimed at empowering small and medium-size manufacturers of food and cosmetics. forexample in 2018 alone, the Authority trained 1,101 small

The Minister of Health, Community Development, Gender, Elderly and Children cutting the ribbon to officially launch the third batch Mini Lab Kits at TFDA Headquarters, on her right is Mr. Matthieu Kamwa the representative from WHO, Ms. Zainab Thabit the representative from the Ministerial Advisory Board to TFDA on her left and on the far left is Mr. Hiiti B. Sillo the Director General of TFDA.

and medium-scale food manufacturers on good manufacturing practices to enable them produce safe and quality products.

A review of the 'Fees and Charges Regulations, 2017' was done purposely to reduce the burden of charges and remove the inspection fee for premises and fee for importation of raw materials. In the same year, TFDA introduced a Regulation intended to ease identification and control of manufacturers, as well as subsequent follow-ups.

Also, TFDA signed a Memorandum of Understanding (MoU) with the Tanzania Bureau of Standards (TBS) and the Small Industries Development Organization (SIDO) geared at empowering small and medium manufacturers in Tanzania

• Sample analysis in TFDA Laboratory

The TFDA Laboratory is accredited to 'ISO/IEC 17025:2005 Certification' and is appropriately equipped with state-of-the-art equipment. It is also staffed with properly qualified, skilled experts who conduct analysis in a septic environment to assure safety, quality and efficiency of food, medicines, cosmetics, medical devices and diagnostics.

The analytical results enable the Authority to make scientific based regulatory decisions which are intended to safeguard public health at all times.

Since its inception fifteen years ago, TFDA has expanded its services in sample analyses for food, medicines, cosmetics, medical devices and diagnostics testing.

These services are available at the TFDA Sub Head office Laboratory located Off Mandela Road in Mabibo-External area in Dar es Salaam, as well as at its Lake Zone Laboratory in Mwanza city, which started operations in early 2018.

Indeed, there has been an increase in sample analysis, rising from 749 a few years ago to 7,160 in 2018.

• Communication and Public Education

In ensuring that the public get the right information in a proper manner on roles and responsibilities of TFDA in protecting and promoting Public health, TFDA has developed and implementing Communication and Public Education Strategy. Through this strategy different approaches have been identified such as outreach education campaigns have been conducted to reach specific stakeholders whereby in the period between 2015 and 2018, about 210,783 people from peripheral communities as well as students were reached in 23 regions across Tanzania Mainland.

Since its inception, the Authority has aired about 3,250 radio and TV spots, and participated in 1,990 live programmes. All these were geared to educate the public about safety, quality and effectiveness of regulated products.

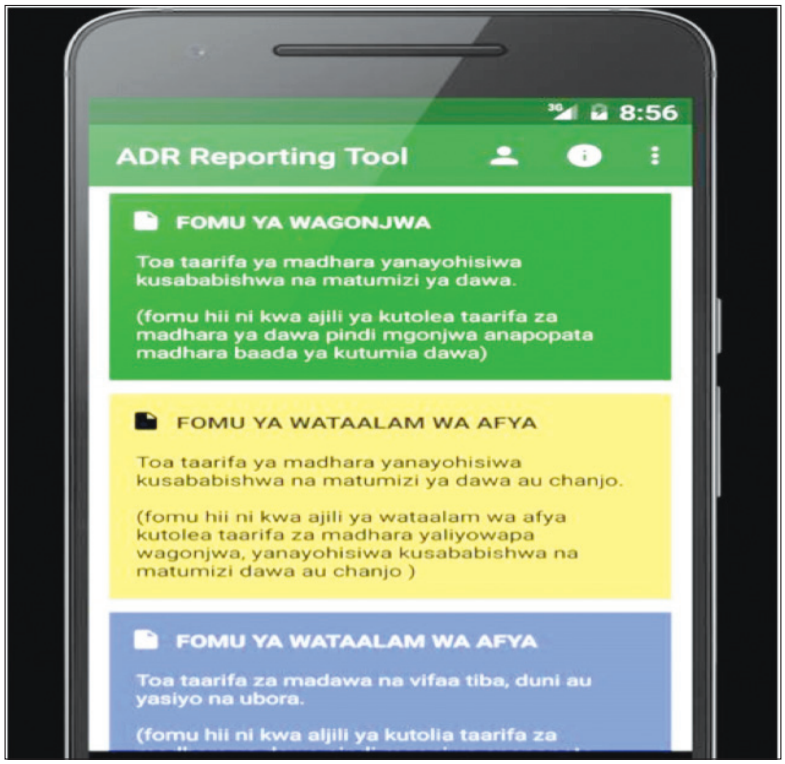
Establishment of the 'TFDA Clients Service Charter' was a remarkable event in its operations, as the Authority has been delivering quality services in accordance with approved service standards as specified in the Charter.

The Authority also has established a toll-free number 0800110084 to improve communication with its customers.

Management of resources

• Human resources

To carry out its activities effectively, TFDA had been recruiting staff members in line with its 'Human Resource Plan.' In that regard, the workforce increased from 62 in 2003 to 302 in 2018.



TFDA conducts short and long-term capacity building programmes for its staff, with the prime objective of equipping them with updated knowledge and skills and also boost their morale and productivity.

Establishment of the 'TFDA Workers Council,' coupled with the formulation of Internal Staff Regulations, served as a suitable platform for improving the working environment which also boosts workers' morale and productivity.

• Financial resources

For all of the Authority's 15 years of existence during which the Government Controller and Auditor-General (CAG) unfailingly audited TFDA books of accounts, the Authority was awarded an Unqualified Opinion Certificate for 14 years consecutively.

If nothing else, this is ample testimony that TFDA is fully committed to proper and effective management of its financial resources.

• Information and Communications Technologies

TFDA has automated a number of its functions to facilitate availability and ready accessibility at all times of information to its clients, staff and other stakeholders as approved from time to time.

The automated functions include the Human Resource Management Integrated System' (HR-MIS) which consists of all employees' public service information – the 'Financial Management System' (EPICOR); the 'Laboratory System' (LIMS) – which has all the information regarding samples and sample analysis conducted in the laboratory.

Morever, the Authority has put together a system that integrate all clients information known as Information Management Integrated System (IMIS) that serves as the self service portal which allows for Online submission of import/export applications, Product Retention Fee and a list of Registered products and premises.

• Construction of Head Offices building and Lake Zone laboratory

Construction of the Head offices building in the nation's commercial capital provides for sufficient space for TFDA's activities and other functional operations.

Expansion of the TFDA Laboratory at the Head offices premises, as well as construction of the Lake Zone Laboratory and the procure of state of art modern analytical equipment and instruments, expanded the scope of laboratory services provided by the Authority, thereby boosting its capacity to analyze samples.

• Establishment and expansion of Zonal Offices

Since 2003 to-date, TFDA has established seven zonal offices in Dar es Salaam, Arusha, Mwanza, Dodoma, Mbeya, Mtwara and Tabora.

The overriding objective for this was to bring TFDA's services closer to customers and stakeholders.

In the event, the Authority has also increased and empowered staff at the zonal offices, always recruiting the best of the breed and providing them with decent infrastructure and equipment.

• National and International Cooperation

TFDA works is close cooperation with National and International organizations in regulating food, medicines, cosmetics, medical devices and diagnostics business. Indeed, TFDA has been the leading regulatory Authority in harmonizing regulatory frameworks across sub-Saharan Africa, especially in the eastern, central and southern regions.

TFDA has been engaging in various regulatory frameworks under the United Nations and its institutions, as well as the African Union and other regional economic communities in Africa and beyond.

TFDA AT WHO MATURITY LEVEL 3:

Leading other countries in Africa

TANZANIANS have now reasons to trust medicines registered by the Tanzania Food and Drugs Authority (TFDA), which the World Health Organization (WHO) has assigned overall Maturity Level 3 for its regulatory system. TFDA becomes the first in Africa, attaining a status that only 30 percent of Regulatory Authorities worldwide have acquired.

"This elevation means that Tanzanians are assured of quality, safe and effaceable medicines that are registered by TFDA," Minister of Health, Community Development, Gender, Elderly and Children, Ms. Ummy Mwalimu said while receiving the officiating letter of TFDA for WHO-Maturity Level 3 in Dar es Salaam.

Ms. Mwalimu challenged TFDA to start working towards Maturity Level 4 which is the highest level in the WHO Global Benchmarking Tool. She explained that efforts to improve the Authority's medicine control system started over years back, and was put in place to ensure that Tanzanians only take medicines that are efficient in treating the diseases.

"It is the fact that if medicines don't cure due to inefficiency, Tanzanians will spend more on buying medicines, subjecting them to poverty," she urged.

WHO Country Representative Dr. Tigest Ketsela elaborated that the assessment of regulatory authorities is based on the WHO Benchmarking Tool (GBT) which is used for identification of strengths of national medicines regulatory systems, identify areas of improvements and then assist NRAs in development of Institutional Development Plans (IDPs).

In May, 2018 the Technical Team from WHO Headquaters and other countries in Africa visited The Tanzania Food and Drugs Authority (TFDA) for the benchmarking Programme so as to identify Strength and areas of improvement in the Authority and as well as establish Institutional Development Plan to address the areas of improvement and build on the strength identified. The 2018 benchmarking was part of the continuous monitoring and follow-up to evaluate the level of Institution Development Plans set up in the previous Benchmarking programmes in 2016 and the first done in 2011.

To be qualified for the Maturity Level three, the Tanzania Food and Drugs Authority has undergone level one of establishing an existing Regulatory system which was done back in 2003 when first TFDA became operational, and on to Maturity Level Two where TFDA has an evolving national Regulatory system-between 2004 and 2018 which partially performs essential Regulatory functions

As for at Maturity level three, TFDA has stable and a well-functioning and integrated regulatory system and moving on to operating at an advanced level of performance and continuous improvement.

"It is the fact that if medicines don't cure due to inefficiency, Tanzanians will spend more on buying medicines, subjecting them to poverty," she urged.

TFDA urges TAFFA members to abide to the rules and procedures

THE Tanzania Food and Drugs Authority (TFDA) recently met its stakeholders in Dar es Salaam in its move to remove all bottlenecks and unnecessary bureaucracy on the clearance of food and pharmaceutical products at the Dar es Salaam ports.

This, according to the then TFDA Acting Director General, Ms Agnes Kijo was yet another milestone sought to ease the burden of storage fees incurred by businesspeople at the country's main port.

Earlier on, TAFFA Secretary General, Mr. Tony Sway expressed his dismay over unnecessary bureaucracy businesspeople were encountering when clearing their cargo at the port something he said increased storage fees.

He punched holes to some government officials whom he accused of failing to comply with the regulation that provides for unconditional release of the products. "Unconditional release is a certificate issued to any importer of the product allowing the release of the goods after complying with all customs requirements,'' he said.

To achieve this, the Authority held a meeting with officials from the Tanzania Bureau of Standards (TBS), Government Chief Laboratory Authority (GCLA), Tanzania Revenue Authority (TRA), Tanzania Ports Authority (TPA) and Tanzania Freight Forwarders Association (TAFFA).

According to Ms. Kijo, the meeting aimed at facilitating an efficient business environment and creating awareness to TAFFA members who were complaining of unnecessary bureaucracy from competent authorities that were involved in cargo clearance at the port.

"Many of our clients have been coming to TFDA offices with incomplete documents thus making it difficult to issue a green light for clearance of their consignments,'' she said adding that TFDA decided to convene all stakeholders so as to take them through the procedures ought to be followed prior to clearance of food, medicines, medical devices, cosmetics and diagnostics.

For a person to be allowed to clear such consignments according to the legislation, he/she must have a registered premises, products and possess an import permit of a specified product.

Ms Kijo insisted at the meeting that TFDA was providing services to its customers for 24 hours daily and that with its Clients Service Charter more improvements on service delivery were being made.

As part of initiatives for improving the standard of service delivery, under the new charter, the process of issuing import and export permits for registered products now takes a single day, while it took between two up to five days previously.

The purpose of the charter is to openly show the responsibilities of TFDA to comply with the required quality standards in serving clients and this is in line with the National Development Vision 2025.

TFDA plans robust operation on illegal mass food catering services

TFDA is planning to embark on a countrywide operation to crack the whip on people and companies that fail to comply with the legislation on provision of mass food catering services.

In the preparation for the operation, the food and drugs watchdog has launched special awareness seminar to stakeholders countrywide so as to take them through the law and other regulations guiding mass food catering services in the country.

Speaking during the official launching of the seminar recently, the then TFDA Acting Managing Director, Agnes Kijo said apart from legal compliance issues, participants were equally equipped with additional skills on management of food safety and hygiene.

"Mass food catering regulations will be highly highlighted to remind participants of their obligations where as participants will have enough time for dialogue and at the end we will come up with resolutions and deliberations that will help in boosting the country's economy as well," she emphatically said.

Ms. Kijo further added that similar seminars are expected to be provided in all TFDA zones in the country and that at the end, both TFDA and stakeholders in the sector will agree on the period which the latter can go make all the required improvements.

"We intend to offer reasonable grace period to the businesspeople, after which we will launch a robust operation to crack the whip to service providers who will not abide by the law," she added.

However, since the provision of awareness seminars, many companies providing mass catering services have been coming up in bigger numbers for official registration of their business at TFDA offices.

The envisaged operation according to Ms Kijo will be done by TFDA in collaboration with Regional and Local Government Authorities through health officers in the respective areas.

Before the seminars, earlier statistics at TFDA indicated that there were 637 registered Mass Food Service Providers out of which 37 percent of that number was based in Dar es Salaam. However, according to Ms. Kijo, the number was at that time still small comparing to people who were providing similar services.

Following the seminar, she said many will be registered as some of them were unaware of the law. "We will take them through the procedures that they need to follow to have their business legally recognized through registration.

"We intend to offer reasonable grace period to the businesspeople, after which we will launch a robust operation to crack the whip to service providers who will not abide by the law," she added.

According to the World Health Organisation (WHO) statistics released in 2015, about 600 million people in the world were suffering from food borne disease and out of that number 420 people die as a result of those diseases.

In Africa, it is estimated that 91 million people suffer from unsafe food related disease out of which the deaths reported from the diseases are 137.

TFDA's Contribution To Implementing Tanzania's Industrialization Agenda

IN ADDITION to the efforts of TFDA in protecting and promoting health of Tanzanians at all times, the Authority has also been supportive of the development of domestic manufacturing of various products that include food, medicines, cosmetics, medical devices as well as diagnostic designed according to specific sartorial demands.

Doing all this is part and parcel of TFDA's mandate that is specifically intended to protect and promote public health by ensuring safety, quality and effectiveness of food, medicines, cosmetics, medical devices and diagnostics.

TFDA being a Regulatory Authority under the Ministry of Health, Community Development, Gender, Elderly and Children was officially established with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

If nothing else, this very much puts TFDA at the forefront in the drive to implement the Tanzania Government's industrialization agenda that is spearheaded by the fifth-phase Government of President John Pombe Joseph Magufuli (popular simply as 'JPM'), in power since November 5, 2015.

Tanzania's industrialization agenda is being implemented on the back of the Government's National Development Vision-2025, which envisages a semi-industrialized, middle-income Economy by Year-2025.

In that regard, the Vision in general and Industrialization in particular are being propelled by supportive strategies that include 5-Year Development Plans and other Programmes, Initiatives, etc., on pivotal sectors like Agriculture and, of course, Industrialization itself!

However, it is generally acknowledged that the envisaged Industrialization and poverty reduction goals noble as they admittedly cannot be attained in the absence of a healthy population as a result of the availability of affordable and safe food, medicines, cosmetics, medical devises and diagnostics.

This is wherein comes TFDA, the regulatory and executive organ whose primary mission is the protection and promotion of public health at all times ensuring the quality, safety and effectiveness of products.

Indeed, when the 5th Government prioritized Industrialization on the nation's socio-economic development agenda, the role of the TFDA assumed greater prominence.

As a Government instrument in areas that are central to general public health, the Authority is obliged to closely cooperate and support the government's efforts to achieve the country's industrialization agenda in every way that is humanly possible.

One way of doing that is for TFDA to help create a friendly business environment thus facilitating prospective foreign and local investors alike to substantially help grow a functional economy.

To that end, the Authority embarked upon the following activities:-

- It has created seven TFDA Zones across the 26 Administrative Regions on Tanzania-Mainland in efforts to bring its services closer to the people in the four corners of the sprawling country.
- It has upgraded its services delivery, having gone digital in electronically processing applications for various permits and licenses for clients.
- TFDA has strengthened and otherwise improved its laboratory services. This is considered crucial to invest in processing factories for food, medicines, cosmetics, medical devices and diagnostics.

In that regard, the Authority regularly conducts dialogues with, and training/guidance for, existing and prospective investors, giving them the requisite instructions, guidelines and inspection services.

- The Authority has reduced the time taken to process applications and other documentation. For instance, the time it takes for product registration by a local investor has been reduced from eight (8) months to a maximum of 120 days (4 months). Where full information has been received in time with the application, the registration period drops further, to two (2) months maximum.
- Also, it requires NOT more than twenty-four (24) hours to process import and export permits of products.
- TFDA has revoked various fees and charges that were previously levied on food export permits; food products labels; fees for food advertisements; fee for inspecting domestic industry, certified-true copies of food registration certificates, and inspection fees for small food indus-

tries.

• There is no fees and charges on imports of raw materials, packaging materials and machineries for domestic food-processing industries.

• The Authority has reduced the cost of registering premises approved by the Authority for food-processing activities to Tsh 50,000 only for processors registered with the Small Industries Development Organization (SIDO) and who are so-certified by the Organization.

• However, the fees for the registration of medical devices vary according to the type of device(s) involved.

• TFDA provides guidance on the best way to prepare for the registration of products immediately after completing all the processes of manufacturing. This is done free of charge.

• After a product manufacturing plant has been established and starts operations, the Authority routinely conducts supportive inspections designed to help investors to continue focusing on Good Manufacturing Practices, and do so according to the approved standards of quality and safety.

• TFDA regularly organizes various forums in order to share views and experiences relating to the performance of investors, and any challenges that may have arisen in due course of time and events. Both sides do their very best to provide solutions and, where necessary, doing so in collaboration with relevant government authorities and other institutions.

• TFDA also provides training on expertise relating to how best to prepare for product(s) evaluation before registration and quality training standards that are relevant to the manufacture of top-notch products.

• As it is, TFDA has provided relevant theoretical and practical training to 1,699 small-scale entrepreneurs in quality and safe food processing in 22 Administrative Regions on Mainland Tanzania that empowered them to be highly competitive.

Indeed, contribution of, and by, the TFDA to the Tanzania Government's industrialization efforts for the country has been in different forms in terms of activities and strategies.

One good example of these are the untiring efforts of the Authority's Food Inspection Section to make sure that Tanzania's industrial sector grows exponentially and does so on a sustainable basis.

To that end, TFDA regularly holds consultations with prospective investors in establishing food processing industries in Tanzania, guiding them on how best to go about starting a manufacturing business, including the best location; the right specification of the factory buildings; the processes of registering the factory as well as processed products.

Ditto for prospective investors both Tanzanian and foreign in the Manufacture of food, medicines, cosmetics, medical devices and diagnostics.

As it is, TFDA has taken upon itself the responsibility of being a committed coordinator of meetings and task forces for stakeholders which have been created under the Ministry of Industry and the Ministry of Health. These are tasked with dialoguing within the country and beyond its borders on mobilization of investments in the manufacture of pharmaceuticals, medical devices and cosmetics in Tanzania.

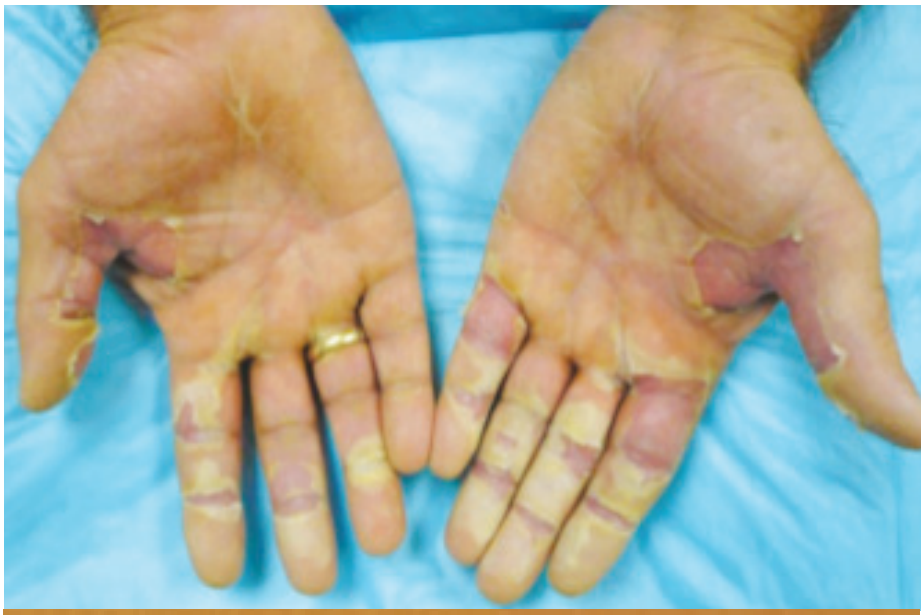
One such meeting was conducted at the JNICC Hall in Dar es Salaam on April 04 2018 and which was attended by 400 participants from different institutions, local and foreign. That meeting was principally intended to impart vital information on investment prospects in the country's health sector.

In August 2018, TFDA was also an active participant at meetings staged in China and South Korea that were organized to specifically encourage and promote the construction of plants for the manufacture of pharmaceuticals and medical devices in Tanzania.

All in all, TFDA is steadily but surely moving centre-stage in the President John Magufuli Government's rapidly unfolding industrialization agenda. This is with a view to propelling Tanzania to the envisaged semi-industrialized, middle-income country by Year 2025.

Vigilance system for medical devices and adverse events

THE medical devices vigilance system promotes a common approach in monitoring the safety and performance of medical devices by manufacturers, suppliers, importers and regulators with the aim of safeguarding consumers of the products.



Medical devices and in-vitro diagnostics should be continually assessed to critically determine their safety and performance when they are in use. This is due to the fact that information gathered during the pre-marketing phase is incomplete with regard to the adverse events that may occur while the devices are in use.

This is mainly because no amount of rigor in the pre-marketing review process can predict all possible device failures or events arising from their right use and misuse. It is through their actual use that unforeseen problems related to safety and performance can occur.

Monitoring of adverse events involves the two principles of 'adverse incident reporting' and 'post-marketing surveillance.'

Under 'post-marketing surveillance,' specific and structured data is required from the manufacturer as a condition for product approval, or to re-affirm product safety when a post-market adverse incident report suggests that pre-market safety claims are inconsistent with the actual use and result in unacceptable risks.

'Adverse incident reporting' requires the registration and investigation of adverse incidents relating to the use of a device – whereby the manufacturers are obliged to recall or modify any defective device.

Progressively, over the years so much attention was directed at reporting and recording of the ADR and, unlike AEMD, awareness between health employees and members of the public is widely known and thus the introduction of the Adverse Events in Medical Devices Vigilance System. Although the vigilance may have started as soon as the regulation of medical devices started, awareness is still lacking to majority of the people.

As the responsible body for regulating medical devices, TFDA is currently working on a sensitization programme for the reporting of adverse events caused by medical devices to members of the public. We are already implementing Phase One, which is sensitization of awareness programmes for health community workers throughout Tanzania.

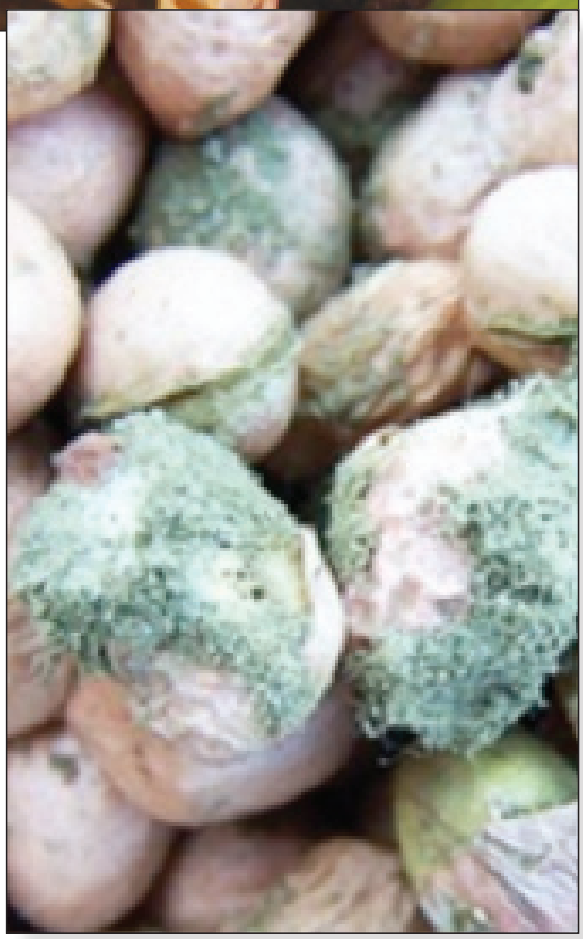
Adverse event/incident should be reported in a medical devices adverse event/incident reporting form for consumers and facilities available to all health centres, on the TFDA website and currently, in the text-message facilitation and will also be available soon to an application in Google Play store.

All these are efforts intended to make members of the public know that, in case of the adverse events caused by medical devices, reports can be forwarded to TFDA at any time, and from anywhere and help is available at all times to protect public health. All submitted reports will be treated as strictly confidential.

Members of the public are urged to report medical devices events to safeguard their health in particular, and protect public health in general. The feedback obtained in the reports will help TFDA to maintain the safety, quality and effectiveness of the medical devices and diagnostics circulating in the Tanzanian market.

Moreover, adverse events in medical devices vigilance system can be used for post-marketing surveillance programmes. This helps the government – working through TFDA – to continuously protect public health by withdrawing unfit medical devices and diagnostics that are already in the market, and also to ascertain that the medical devices already in the market are of good quality, effective, and safe for use.

TFDA sytrengtherns the war on fungal toxins in farm produce



THE recent reports on monitoring of maize and groundnuts produce in the market conducted by TFDA shows an increase in contamination of the products by mycotoxins which have negative effects on the health of consumers.

The increase of contamination of crops by mycotoxins compeled the Authority and its stakeholders to develop and redesign existing strategies for reducing fungal toxins in farm produce including maize, groundnuts and their products that are flour, peanut butter and complementary foods

Mycotoxins are toxins produced by fungus on agricultural products particularly maize and peanuts. Mycotoxins can grow during production, processing, storage and transportation and can affect human health. However, animals and products derived from animals exposed to mycotoxins like meat and milk threatens the health of the consumers. The reported types of mycotoxin are aflatoxin common in maize and fumonisins in peanuts

At different times the Authority has been providing education to various key players in the food chain including farmers, food manufactures and consumers to create an awareness of fungal activities, their health hazards and control methods in order to protect public health

Moreover, to combat the problem, TFDA has also strengthened surveillance of animal and crop produce in the market to assess the level of contamination of the products before reaching the public. This has enabled the Authority to safeguard the public and prevent effects associated with fungal activities

TFDA scientists in collaboration with others from various institutions have been conducting research on the heath impact of mycotoxins in the country.

It is the view of the scientists that exposure to fumonisins from maize complementary foods is associated with growth retardation, particularly in communities where maize is the main ingredient of complementary food.

Despite the effects of growth retardation, studies have shown other health impacts on the health of consumers.

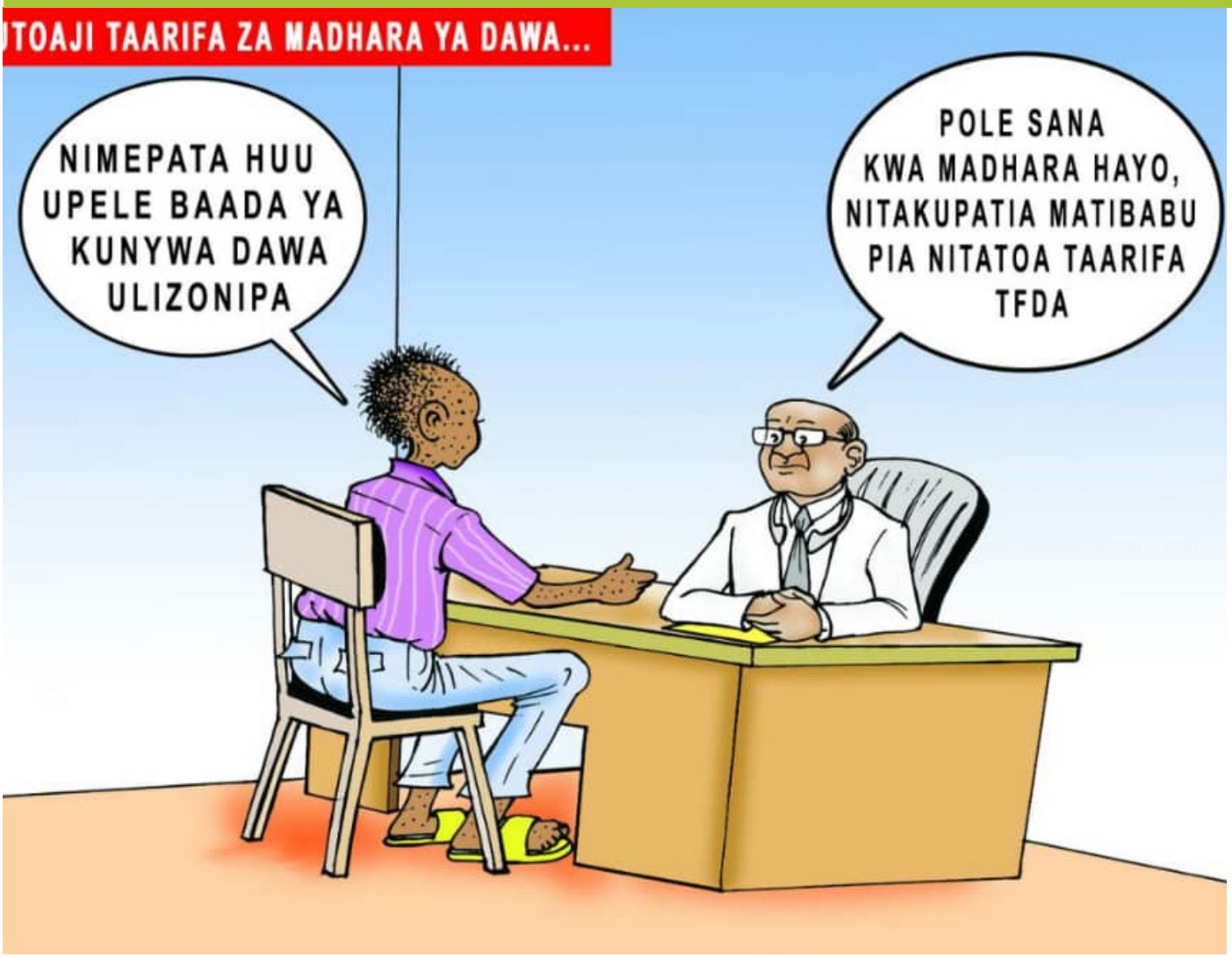
Different photors actions during TFDA's celebrations after being announced by WHO to be the 1st African Regulatory Authority to attain the Maturity Level 3 in regulating medical products. The ceremony was held at TFDA Sub Head Office in Dar es Salaam on 18th December, 2018.

ORBITUARY

Marry Mbwambo
15/12/1959-11/08/18

TFDA familly, with great love and sympathy shared the bitterness of loosing our fellow staff, mother and beloved sister Ms Mary Mbwambo on Friday 17th August, 2018. Mary died suddenly on her sleep at the age of 59 years and will be forever remembered for her cherishness, the precious moments we shared, hard work and caring heat.

MAY HER SOUL REST IN ETERNAL PEACE



Wataalum wa afya toeni taarifa kwa kujaza fomu maalum ya njano

" TAARIFA MOJA UTAKAYOTOA INAWEZA KUOKOA MAISHA YA WENGI "

IMETOLEWA NA:

MAMLAKA YA CHAKULA NA DAWA

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