TMDA

Tanzania Medicines and Medical Devices Authority

Newsletter

ISSUE NO. 10

The United Republic of Tanzania Signs the Treaty for Establishment of the African Medicines Agency (AMA)

CONTENT

1 The United Republic of Tanzania Signs the Treaty for Establishment of the African Medicines Agency (AMA)

3 MAB Visits pharmaceutical Indutries under Construction

4 Designation of TMDA as Regulator of TOBACCO Products

5 Innovation in Service Delivery: TMDA Recertified- Certified to ISO 9001 Status

6 Observe Ethical Conduct and Refrain from Corrupt Practices at Work Place: TMDA Employees urged

TMDA

Tanzania Medicines and Medical Devices Authoririty

Welcome Note From the Director General

Dear reader,

It is with great pleasure and honour, I present to you the 10th edition of our Newsletter which provides an insight of regulatory activities and events that had been undertaken by the Authority since the last edition.

Similar to the previous editions, this platform continues to communicate on milestones attained by the Authority in regulating the quality, safety and effectiveness of medicines, medical devices, diagnostics and more recently - tobacco products.

Amongst others, this edition covers a story on the signing of the Treaty for Establishment of the African Medicines Agency (AMA) at an event that took place on 10th August, 2021 at the African Union Headquarters in Addis Ababa, Ethiopia. The signed treaty is bound to be tabled before the Parliament for ratification.

Of more interest is also the assertion on change of mandate of TMDA after the Minister of Health, Community Development, Gender, Elderly and Children designated the Authority to assume the responsibilities of regulating tobacco products through Government Notice No. 360 which was issued on 30th April, 2021.

Due to the impending COVID-19 pandemic, the TMDA has strengthened its pharmacovigilance efforts by putting-up an active surveillance system of monitoring Adverse Events Following Immunization (AEFI's) for the sake of determining and assessing any risks associated with COVID-19 vaccines recently introduced.

The current edition further enlightens on other key regulatory events to include commitment of TMDA in facilitating investment in pharmaceutical and medical devices manufacturing, designation of Dodoma laboratory for analysis of tobacco products, TMDA School Clubs: Innovative Strategy to strengthen Public Education, completion of office and laboratory in Dodoma and re-certification of TMDA to ISO 9001-2015 Standard.

It is with no doubt that you will find this current edition useful, informative and that you will spare sometime to go through.

Enjoy your reading!

Adam M. Fimbo
Director General

TMDA
Tanzania Medicines & Medical Devices Authority

Editorial Note

Dear our Esteemed Reader,

The 10th edition of TMDA Newsletter has at last been finalized. This has happened due to commitment and dedication of time and efforts amongst TMDA experts who took their time to draft and finalize the same.

I would like to express my sincere gratitude to the Director General who is the Chief Editor for his dynamic leadership, tireless support and guidance throughout the drafting and approval of this edition.

This Newsletter has continued to be instrumental in disseminating information to the public on matters related to quality, safety and efficacy of medicines, medical devices and diagnostics.

We are still striving to educate the public through various means and approaches including reaching out to those residing in remote areas. The need for consumer awareness in these areas is critical to allow for wider information sharing which will result into voluntary compliance on regulatory matters.

Through this platform we believe the public we are mandated to protect will make appropriate decision when choosing products to consume and in case of any suspicion on product defects, substandard or falsified, they will communicate with us.

Constructive criticism, inputs and feedback will always be welcomed for improvement of the upcoming editions of this Newsletter.

Enjoy your reading!

Gaudensia Simwanza
Manager Communication &
Public Education

The United Republic of Tanzania Signs the Treaty for Establishment of the African Medicines Agency (AMA)

Her Excellency Ambassador Liberata Mulamula (MP), the Minister of Foreign Affairs and East African Cooperation signed the Treaty for Establishment of the African Medicines Agency (AMA) at the African Union Headquarters in Addis Ababa - Ethiopia on 10th August 2021.

On 10th August, 2021 at the African Union Headquarters in Addis Ababa, Ethiopia, Her Excellency Ambassador Liberata Mulamula (MP), the Minister of Foreign Affairs and East African Cooperation, officially signed the Treaty for the Establishment of the African Medicines Agency (AMA), aiming to regulate and facilitate access to quality, safe and effective medicines in Africa.

The event was witnessed by the Deputy Chairperson of the African Union Commission, H.E. Dr. Monique Nsanzabaganwa, Acting Ambassador of the United Republic of Tanzania in Ethiopia, Ms. Elizabeth Rwitunga, and Director of Africa Department in the Ministry of Foreign Affairs and East African Cooperation, H.E. Ambassador Naimi S. Azizi. Others were Director General of TMDA, Mr. Adam Fimbo, officials from the Ministry of Foreign Affairs and East African Cooperation and Mr. Merick Luvinga, Director of Legal Services from the Ministry of Health, Community Development, Gender, Elderly and Children.

Speaking during the event, H.E. Dr Monique Nsanzabaganwa noted that Tanzania has been a key leader in supporting the efforts of the Commission and the East African Community, in the harmonization of regulatory policies, under the African Medicines Harmonization Initiative, being led by the African Union Development Agency (AUDA-NEPAD).

"The current pandemic has reinforced the need for the continent to have very strong continental health institutions and the AMA working in tandem with the African CDC will be the key to collectively address the continental health challenges," H.E. Nsanzabaganwa added. She went on by encouraging Tanzania to move to the next step of ratifying the Treaty for the establishment of AMA.

On her side, H.E. Liberata Mulamula stated that the establishment of the AMA Agency is very timely particularly during the ongoing COVID-19 pandemic.

"The United Republic of Tanzania was determined to sign the Treaty establishing AMA in order to mitigate the challenge of combating falsified medical products at regional level," H.E Mulamula said. She further encouraged the other African Member States that have not signed the Treaty to do so at the earliest.

Speaking on regulatory perspectives

Members participated in the signing the Treaty for Establishment of the African Medicines Agency (AMA) poses in a group photo during the exit of the event which was held on 10th August 2021 in Addis Ababa, Ethiopia

soon after signing the Treaty, the Director General of TMDA, Mr. Adam Fimbo highlighted that, this step confirms how Tanzania has demonstrated her commitment to guarantee quality, safety and efficacy of medical products that are fundamental to the health and wellbeing of the people of Africa as a whole.

Moreover, Mr. Fimbo alluded to the expected benefits of AMA to include promotion of domestic pharmaceutical industry through creating enabling environment for marketing authorization of medicines in member countries as regulatory systems will be harmonized, facilitation of trade between member states in line with the African Continental Free Trade Area (ACFTA) and availability of medicines in case of public health emergencies.

The AMA Treaty was adopted by Heads of States and Government during their 32nd Ordinary Session of the Assembly which was held on 11 February 2019 in Addis Ababa, Ethiopia. The African Medicines Agency aspires to provide support for the improvement of weak regulatory systems. AMA shall build on the efforts of the African Medicines Regulatory Harmonization (AMRH) initiative, which is led by the Africa Union Development Agency - the New Partnership for Africa's Development (AUDA-NEPAD). The AMRH initiative provides guidance to AU recognized Regional Economic Communities (RECs) and Regional Health Organizations (RHOs), to facilitate harmonization of regulatory requirements and practice among the National Medicine Regulatory Authorities (NMRAs) of the AU Member States.

AMA will be the second specialized health agency of the African Union after the Africa Centres for Disease Control and Prevention (Africa CDC). The agency will among other functions coordinate and collaborate, where required and on a regular basis, the inspection of drug manufacturing sites, including the regulatory oversight and safety monitoring of medical products, as determined by State Parties and/or the AMA, and make reports available to the State Parties. AMA will also promote cooperation, partnership and recognition of regulatory decisions, in support of regional structures and NMRAs, that takes into account mobilization of financial and technical resources to ensure sustainability of AMA.

The Agency will further convene, in collaboration with the WHO, the African Medicines Regulators Conference (AMRC) and other bodies, meetings related to medical products regulation in Africa. In addition, AMA will provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics in the event of a public health emergency on the continent with cross border or regional implications where new medical products are to be deployed for investigations and clinical trials.

The AMA treaty is expected to be tabled to the Parliament of Tanzania for ratification and later depositing the instrument of ratification to the Commission. So far 22 countries have signed the Treaty and Seventeen (17) member states have ratified the Treaty and twelve (12) of these have deposited the instrument of ratification to the Commission.

According to the Charter on AU Treaties, the AMA Treaty will enter into Force 30 days upon the deposit of the 15th instrument of ratification at the Commission. The Commission expects to have the establishment and operationalization of the AMA in full progress in 2022.

Her Excellency Ambassador Liberata Mulamula (MP), the Minister for Foreign Affairs and East Africa Cooperation together with the Depute Chairperson of African Union, Dr. Monique Nsanzabaganwa, displaying the treat of establishment of AMA after signing on 10th August 2021 in Addis Ababa, Ethiopia

Establishment of the African Medicines Agency (AMA) at the African Union Headquarters in Addis Ababa - Ethiopia held on 10th August 2021.

MAB Visits pharmaceutical Indutries under Construction

The Chairman of Ministerial Advisory Board (MAB), Mr. Erick Shitindi, has assured investors of pharmaceutical manufacturing industries in the country on the Board's commitment and support towards realization of their investments as part of Government efforts in pushing forward the industrialization agenda.

Mr. Shitindi made the remarks during a visit paid by MAB members on 27th September 2021 at facilities located in Kibaha – Coast Region namely Kairuki Pharmaceutical Industry Ltd, Katwaza Pharmaceutical Industry Ltd and Hester Biosciences Africa Ltd.

The MAB Chairman alluded-to that, apart from overseeing the quality, safety and effectiveness of medicines, medical devices and diagnostics, the Authority is also responsible for providing technical support to industries to enable them meet good manufacturing practice (GMP) requirements.

"This is part and parcel of TMDA's mandate in its overall goal of protecting and promoting public health by ensuring accessibility to safe, good quality and effective medical products circulating in the country" Mr. Shitindi asserted.

The Chairman further enlightened that, MAB has been receiving updates on various stages and milestones on construction of industries in many parts of the country and today it has decided to come and see by itself.

Speaking on behalf of Director General of TMDA, the Director of Business Support, Mr. Chrispin Severe, assured owners of the new industries that TMDA has created a special desk to oversee the pharmaceutical industry with the aim of ensuring that services are provided promptly.

Mr. Severe went on by saying that, in improving services to our customers, there are no inspection fees charged for domestic factories and that before embarking into full fledged manufacturing, owners are required to submit their layouts for approval by the Authority.

Mr. Erick Shitindi

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

The Ministerial Advisory Board (MAB) in one of its regular meetings to oversee the Authority functions held on 15th September, 2021 in Dodoma

Designation of TMDA as Regulator of TOBACCO Products

In pursuant to Section 18 of the Tobacco Products (Regulations) Act, Cap 121, the Minister of Health, Community Development, Gender, Elderly and Children, Dr. Dorothy Gwajima (MP), has designated the Tanzania Medicines and Medical Devices Authority (TMDA) as the regulator of tobacco products since 30th April, 2021.

This decision has been made in an effort by the Ministry to protect and promote public health due to an increase in tobacco products consumption with a reciprocal increase in tobacco-related diseases.

In accordance with this designation, which has been delineated in the Tobacco Products (Regulations) (Designation of Inspectors) Notice, GN 360, the TMDA will now assume the roles of inspection, enforcement and regulation of tobacco products.

Speaking on regulatory approaches to be used in assuming this new obligation, the TMDA Director General, Mr. Adam Fimbo, said that TMDA will be regulating the manufacturing, importation, exportation, distribution, promotion, advertisement and sale of tobacco products. Since tobacco products have no reported health benefits, TMDA's stance on regulation of these products will differ in a certain respect from regulation of medical products.

"Tobacco products will be required to meet standards appropriate for the protection of public health to be granted marketing authorization" Mr. Fimbo alluded to. He added that, the context of such standards will consider all quality and safety parameters to protect and promote public health.

In line with regulating tobacco products in the country by considering the types of tobacco products to be regulated, TMDA will implement the following regulatory functions;

(a)Notification of all tobacco products circulating on the market.
(b)Product listing or registration for new tobacco products
(c)Premises registration and licensing
(d) Import and export control
(e)Tobacco product manufacturer inspections
(f) Inspection and enforcement
(g)Vigilance and surveillance of tobacco products
(h)Control of advertisement and promotion
(i) Recall and disposal
(j) Laboratory testing
(k) Public education and awareness

Director General of TMDA, Mr. Adam Fimbo, leads the Public Education team to sensitize the public on rational use of medicines and medical devices during the 45th DITF at Sabasaba grounds in Dar es Salaam held from 1st to 13th July, 2021

According to the Tobacco Products (Regulation) Act Cap, 121, tobacco products include tobacco leaves, extracts of tobacco leaves, cigarettes, cigars, cigarirus, hand-rolling tobacco and other smoking tobacco products such as, pipe tobacco, fine tobacco and any chewing tobacco which is manufactured wholly or partly from tobacco or any substance used as a substitute of tobacco. According to the same Act, and as provided for under regulations 3 and 9 of the Tobacco Products Regulations, 2014, smokeless tobacco products are prohibited to be manufactured or sold to the public. Such products include e-cigarettes, nicotine gels, dissolvable tobacco strips, orbs and pellets, chewing tobacco and any other related tobacco products and henceforth these will not be allowed to be used in Tanzania.

The goal of the TMDA is to protect and promote public health through creating a tobacco free society and to foster individual, community and government responsibility to prevent tobacco use by enabling multisectoral participation in tobacco control.

Public education on Tobacco Products control

Innovation in Service Delivery:

TMDA Recertified- Certified to ISO 9001 Status

After being subjected to a comprehensive external quality audit and found to comply with requirements, TMDA has been re-certified to ISO 9001:2015 standard in July 2021.

Since 2009, the TMDA quality management system had been serially audited by the auditing firm based in United Kingdom (ACM Company Ltd - UK) and certified to ISO requirements.

TMDA has been striving to provide quality regulatory services to its customers and stakeholders in the pursuit of promoting and protecting public health by ensuring quality, safety and effectiveness of medicines, medical devices and diagnostics.

The Authority has been introducing and implementing various programmes and initiatives by considering the needs and expectations of its customers. One of the major improvements in service delivery is the introduction and implementation of quality management system.

The commitment and innovation in improving and updating the service delivery system in-line with the changing needs and expectations of its esteemed customers has enabled the Authority to attain and maintain the certification status for four consecutive periods of every three years since its first certification in 2009.

Minister of Health, Community Development, Gender, Elderly and Children, Dr. Dorothy Gwajima (MP), addressing the media on outcome of special operation inspection of business premises dealing with medicine and medical devices which was conducted countrywide between 15th to 20th March,2021.

The ACM Company LTD, independently assessed and confirmed that the Authority is compliant with the requirements of ISO 9001:2015 whose scope covers the number of field of activities to include; regulatory body for inspection, enforcement, testing, analysis, evaluation and registration of medicines, medical devices and diagnostics; control of importation, distribution and manufacturing of medicines, medical devices and diagnostics and clinical trials control as well as vigilance of regulated products.

The attained ISO 9001:2015 certification will be valid for the next three years, from July 2021 to August 2024.

The chairman of Ministerial Advisory Board (MAB), Mr. Erick Shitindi, presenting his remark during the Press Conferee held on 5th May 2021 in Dodoma to reveal the findings on special operation inspection of premises dealing with medicines and Medical devices which was conducted countrywide between 15th to 20th March, 2021

Observe Ethical Conduct and Refrain from Corrupt Practices at Work Place: TMDA Employees urged

Awareness training on corruption, HIV/ AIDS and Non Communicable Diseases to TMDA staff as facilitated by PCCB and AMREF. The event was held on 19th August, 2021 at Dar es Salaam offices

TMDA employees have been urged to observe ethical conduct and good behavior when performing responsibilities of the Authority. The call was alluded to by the TMDA Director General, Mr. Adam Fimbo during an opening session of the awareness training on corruption to staff held on 19th August, 2021 at TMDA Sub-offices in Dar es Salaam.

Speaking during his inaugural speech, Mr. Fimbo said, the fight against corruption is the national agenda item and every employee should observe ethics, professionalism as well as rules and regulations on corruption. Responsibility and timely delivery of services is key in the fight against corruption.

"I once again remind you of the Authority's zero tolerance on corrupt practices and urge you to refrain from such unscrupulous behaviors, as legal and disciplinary measures will be taken against any culprit" reiterated Mr. Fimbo.

In addition, Mr. Fimbo stressed on the commitment of the Government to eliminate corruption and embezzlement of public funds and advised employees to observe rule of law in public service.

On her part, Ms. Bibie Msumi, who took center stage as a facilitator from the Prevention and Combating Corruption Bureau (PCCB) cautioned training attendees to discharge ethical conduct at highest level of degree and hate corruption by all means to uphold the credibility of the Government. She went on to express how civil servants are engaged in corrupt practices whether wittingly or to the contrary and how to avoid them.

The training was organized to educate TMDA staff on knowledge, practices and measures to avoid corruption. This is in tandem with TMDA's Strategic Plan and Government's efforts in the fight against this malpractice which is deleterious to national development. It is also in line with phase 3 of the National Anti-Corruption Strategy (2017-2022) which focuses on ensuring that corruption is eradicated from the country through new and enforceable approaches focusing on sectors with corrupt environments.

"I once again remind you of the Authority's zero tolerance on corrupt practices and urge you to refrain from such unscrupulous behaviors, as legal and disciplinary measures will be taken against any culprit" reiterated Mr. Fimbo.

TMDA Director General, Mr. Adam Fimbo, chaired the fifth Workers' Council meeting held on 2nd September, 2021 in Morogoro

The Ministerial Advisory Board (MAB) together with TMDA Management team are in a group photo immediately after visiting the ongoing construction of Central Zone office project in Dodoma. The project is expected to be completed on June 2021 under National Housing Cooperation as a main Contractor

TMDA Unveils new Office Building in Dodoma: What a milestone

TMDA always strive to improve service delivery to meet customer needs and expectations. In its efforts to bring regulatory services closer to the public and reduce unnecessary costs and inconveniences to customers in the central corridor, TMDA has completed the construction of office and laboratory in Dodoma capital city in June 2021.

The new office which adds up to the other buildings owned by TMDA which are located in Dar es Salaam and Mwanza regions, was constructed by the National Housing Corporation (NHC) (as the main contractor) and was officially handed over to TMDA on 30th June 2021.

The newly constructed office accomodates together with other amenities, the state of the art laboratory which has been designated to test herbal and tobacco products. The process of equipping the laboratory is currently ongoing to meet World Health Organization (WHO) standards in testing such products.

Apart from the laboratory, the office will also be used as the headquarters of TMDA and Central Zone office at the same time to serve customers residing in Dodoma, Morogoro, Singida and Iringa regions. The services to be offered will include inspection of regulated products and premises, registration and licensing of premises dealing with regulated products, safety monitoring, post marketing surveillance (PMS) and public education campaigns.

Plans are underway to officially open the building in tandem with existing government procedures.

All staff, Management and the Ministerial Advisory Board (MAB) are commended for accomplishing this task and registering this milestone. Congratulations to all who took part in this project and make it happen.

TMDA Central Zone building constraction

The Newly constructed TMDA Central Zone building in Dodoma

TMDA SCHOOL CLUBS:

INNOVATIVE STRATEGY TO STRENGTHEN PUBLIC EDUCATION

In the move to ensure that the public is always aware of TMDA functions in promoting and protecting public health, TMDA implements various educational programmes to reach specific audiences in line with its Communication and Customer Service Strategy.

Between 22nd and 27th August, 2021, TMDA arranged visits in various secondary schools with the intention of establishing school clubs in Morogoro municipality. Eleven (11) of them were established out of this initiative and the same are currently engaged in creating awareness, educating students and distributing promotional materials, publications, brochures and other Information, Education and Communication (IEC) materials.

Speaking during the briefing session, the Municipal Educational Officer, Mr Simbeye Vumilia, commended the efforts made by TMDA to reach out to such audience and cemented on the significance of such clubs in creating awareness on quality and safety of medical products.

On the flip side, the Morogoro District Executive Director, Ms. Rehema Bwasi, further alluded to the importance of the clubs in changing student's perception and how they would impact on rational use of medicines and medical devices. "The education that they would acquire will likewise reach to their families and henceforth protect the society at large" she stressed.

Secondary schools which were reached during the visit in Morogoro embraced Kolla Hill, Nanenane, Tubuyu, Uwanja wa Taifa, Kihonda, Kayenzi, Mwembesonga, Mgulasi, Mafiga, Sokoine University of Agriculture (SUA) and Sumaye.

On her side, Miss Sakina Said, the NaneNane secondary school teacher, who was appointed as the supervisor of the established school club, promised to engage students in activities as directed by TMDA so as the club can attain its goal of creating awareness among its members.

TMDA school club's programme has accrued a number of students in secondary schools who opted to join together as groups for the purpose of learning more about the Authority and are supervised by club teachers.

So far, there are a total of 50 school clubs which have established in three regions namely Dar es Salaam, Coast and Morogoro. Plans are underway to establish more in other parts of the country.

Public education

Establishment of TMDA School clubs in Morogoro Region

TMDA Central Zone Public education and customer service officer, Mr. Hussein Makame providing education on the role of TMDA, the proper use of medicines and how to report Adverse Drug Reactions to student and teachers of Kola Hill Secondary school in Morogoro on 10th May, 2021

TMDA Director of Laboratory Services, Dr. Danstan Hipolite (2nd left) and other laboratory officials in a group photo with WHO Inspectors, Dr. Elham Kossary (3rd left) and Ms Nateraz Simoes (2nd right) immediately after their exit meeting following the inspection to Quality Control Laboratory held on 28th May, 2021 in Dar es Salaam.

Tobacco Products to be Tested at Newly Constructed Dodoma Laboratory

Following the appointment of TMDA as the regulator of tobacco products, the Authority has decided to designate its recently constructed laboratory at the new office building in Dodoma capital, to test tobacco products.

This assertion has been revealed by the Director of Laboratory Services, Dr. Danstan Hipolite Shewiyo, when speaking on the Authority's initiatives and endeavors in improving laboratory services.

The Dodoma laboratory will serve customers residing in the central corridor comprising Dodoma, Singida, Morogoro and Iringa regions.

According to Dr. Shewiyo, the initial stages of designing, equipment acquisition, laboratory staff training, method development and validation are in progress and after finalization the laboratory will be officially launched.

The Director of Laboratory Services further highlighted that, together with tobacco products, herbal medicinal products will also be tested at the same laboratory. This will unequivocally allow the Authority to conduct post marketing surveillance (PMS) programmes smoothly and ensure speedy testing of the products for expedited regulatory action(s).

The Dodoma laboratory is expected to expand the scope and capacity of TMDA to analyze and test samples of products to enhance science-based decision making. Currently TMDA performs analysis of samples through its other established state of the art laboratories located in Dar es Salaam and Mwanza regions.

Unfit Medical Products Worth Tshs 7.7 Million Seized in Mbeya

Public Education on rational use of medicines, medical devices and diagnostics

In connection to TMDA's efforts in curbing illegal manufacturing and fraudulent mislabeling of medical products in Tanzania, a consignment of expired medicines and medical devices worth TZS 7.7 million had been captured in Mbeya city on 25th August 2021.

The unethical malpractice was discovered through a special operation which was conducted in the Southern Highlands regions of Tanzania which also observed unscrupulous deletion and stamping of fake labels with extended expiry dates.

The event was witnessed by a whistleblower who notified the Authority and measures were promptly taken to put perpetrators into custody. On the same location (Igawilo area in Mbeya municipality), other expired and government pharmaceutical products were found stored in a residential house of the suspect.

"The culprit was seen altering expiry dates on the products by using stamps and sell them to the public" the whistleblower asserted.

Speaking infront of the media who gathered during the confiscation exercise, Ms. Anitha Mshigati, Acting Manager – TMDA Southern Highlands Zone said, TMDA received information about the existence of unfaithful businessman who was seen selling expired medicines and medical devices, whose manufacturing and expiry dates were also tampered.

Ms. Mshigati clarified that the consignment included some expired antibiotics, anti-acids and anti-malarials of which some were government owned products whose labels had been altered and some were medical devices (i.e. surgical sutures and syringes).

The operation was on-going and involved all regions in the Southern Highlands Zone to include Mbeya, Songwe, Njombe and Sumbawanga. The Ports of Entry including Tunduma and Kasumulu were also involved. The operation intended to capture all expired, falsified and substandard products circulating in that part of the country.

TMDA oversees the implementation of the Whistleblowing Policy which sensitizes the public to report any wrong doing and information received from whistleblowers is treated with highest level of confidentiality including rewarding those who volunteer information.

The Authority urges the public to be more vigilant and submit any information whatsoever to allow for detection of culprits and regulatory actions to be taken against them.

"The culprit was seen altering expiry dates on the products by using stamps and sell them to the public" the whistleblower asserted.

Public Education on rational use of medicines, medical devices and diagnostics.

PICTORIAL

Annual Pharmacovigilance Stakeholders meeting held on 30th June 2021 at TMDA conference hall in Dar es Salaam

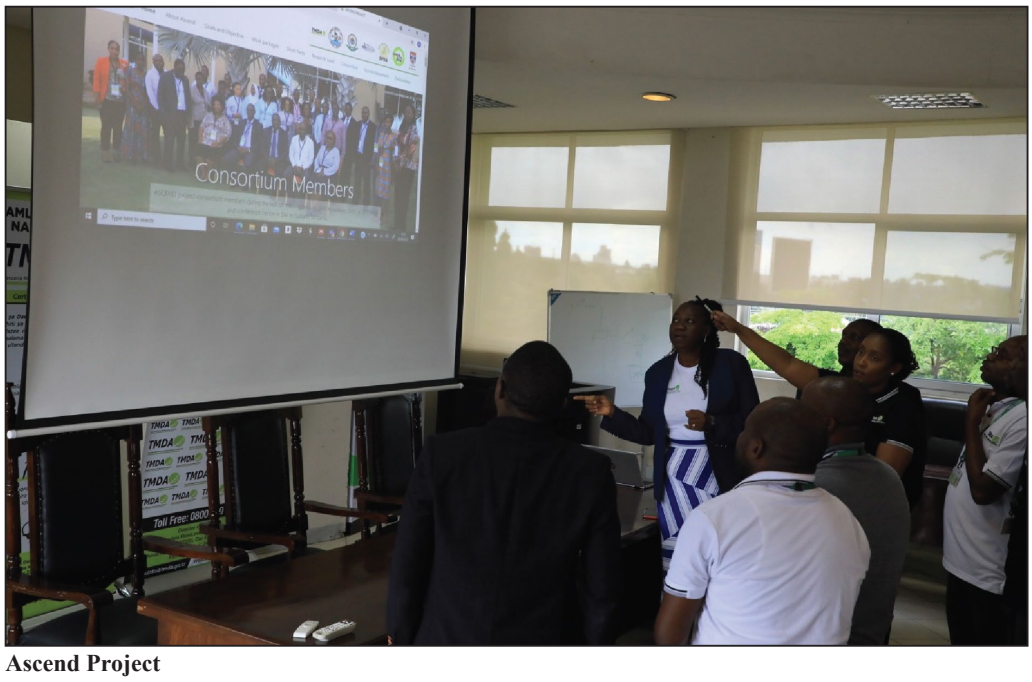
An official meeting between TMDA and Journalists of Arusha, Kilimanjaro and Manyara region held on 3rd June, 2021 in Arusha City.

Acting Director of Medical Products Control Dr. Yonah Hebron make a presentation during an official meeting with journalists of Arusha, Kilimanjaro and Manyara region held on 3rd June, 2021

PICTORIAL

Deputy Minister of Health, Community Development, Gender, Elderly and Children, Hon. Dr. Godwin Mollel (MP), giving directives to TMDA management during his official visit to TMDA laboratory located at in Dar es Salaam on 21st May, 2021.

Deputy Minister of Health, Community Development, Gender, Elderly and Children, Hon. Dr. Godwin Mollel (MP), witnessing how analysis of medical devices is done during his official visit to TMDA laboratory located in Dar es salaam on 21st May, 2021 to assess the performance of TMDA in implementing its role of protecting public health.



Ascend Project

Ascend Project

Deputy Minister of Health, Community Development, Gender, Elderly and Children, Hon. Dr. Godwin Mollel (MP), addressing TMDA employees during his official visit to TMDA Offices located in Dar es Salaam. The visit which was conducted on 21st May, 2021 aimed at assessing the performance of TMDA in implementing its role. Sited is the TMDA Director General Mr. Adam Mitangu Fimbo

Ascend Project

PICTORIAL

Annual Pharmacovigilance Stakeholders meeting held on 30th June 2021 at TMDA conference hall in Dar es Salaam

Director General of TMDA, Mr. Adam Fimbo, leads the Public Education team to sensitize the public on rational use of medicines and medical devices during the 45th DITF at Sabasaba grounds in Dar es Salaam held from 1st to 13th July, 2021

The TMDA Director General, Mr. Adam Fimbo and Registrar of Pharmacy Council, Ms. Elizabeth Shekhalage signed Memorandum of Understanding which defines areas of collaboration. The event took place on 3rd May, 2021 at PC conference hall in Dodoma

TUGHE election which took place on 25th July, 2021

Capacity Building to Inspectors

PICTORIAL

Deputy Minister of Health, Community Development, Gender, Elderly and Children, Hon. Dr. Godwin Mollel (MP), get wind of information on TMDA functions during his official visit to TMDA Offices located in Dar es Salaam on 21st May, 2021.

Director General of TMDA, Mr. Adam Fimbo, presenting certificate to MAB Chairman, Mr. Erick Shitindi after emerging Winner No. 2 amongst executive agencies category as recognition of outstanding Performance in Administration and Human Resource Management in the Public Service

TMDA provided education on the role of TMDA, the proper use of medicines and how to report Adverse Drug Reactions to social groups at kihonda ward in Morogoro district during the outreach campaign held from 23rd to 27th August, 2021

Together we protect and promote public healthy

TMDA donated 3192 packs of pads as part of Corporate Social Responsibility (CSR) to support Simiyu secondary schools female students who are in a special academic program organized by region as part of their preparation for the national exams

Capacity Building to Inspectors

JAMHURI YA MUUNGANO WA TANZANIA

WIZARA YA AFYA, MAENDELEO YA JAMII, JINSIA, WAZEE NA WATOTO

MAMLAKA YA DAWA NA VIFAA TIBA

IMETHIBITISHWA: ISO 9001: 2015

MASWALI NA MAJIBU KUHUSU CHANJO ZA UVIKO-19

1. Chanjo za UVIKO-19 ni nini?

Chanjo za UVIKO-19 ni bidhaa za kibaiolojia zilizotengenezwa ili kukinga mwili dhidi ya virusi vya ugonjwa wa homa kali inayoathiri mfumo wa upumuaji aina ya SARS-CoV-2, ambavyo husababisha ugonjwa wa virusi vya korona unaojulikana kama UVIKO-19.

2. Ni aina ngapi za chanjo za UVIKO-19 na zinafanyaje kazi?

Chanjo za UVIKO – 19 zimetengenezwa ili kuufundisha mwili kujikinga, kutambua na kuzuia maradhi yanayosababishwa na virusi vya UVIKO-19.

Hadi sasa kuna aina kuu nne (4) za chanjo za UVIKO-19 ambazo zimegundulika na kuanza kutumika duniani::

- Chanjo ambazo virusi vya korona vimeondolewa makali au kudhoofishwa – hizi hutumia virusi vya korona ambavyo vimedhoofishwa na kutosababisha magonjwa lakini zinaweka kinga kwa mtumiaji.
- Chanjo zitokanazo na protini – hizi hutumia vipande vya protini visivyo na madhara au ganda la protini ambalo hufanana na virusi vya UVIKO-19 ili kutoa kinga ya mwili.
- Chanjo za vekta za virusi - hutumia virusi salama ambavyo haviwezi kusababisha magonjwa lakini hutumika kama sehemu ya kutengenezea protini za virusi vya korona ili kutoa kinga.
- Chanjo zitokanazo na vinasaba (RNA na DNA) - hutumia RNA au DNA iliyoundwa na vinasaba kutoa protini ambayo husababisha kinga ya mwili.

3. Kuna chanjo ngapi za UVIKO-19 ambazo zimeidhinishwa kutumika hadi sasa?

Kuna chanjo 20 ambazo zimeidhinishwa na angalau Mamlaka moja ya udhibiti duniani kwa ajili ya matumizi kama ifuatavyo:

- Chanjo 2 za aina itokanayo na vinasaba (RNA) (Pfizer–BioNTech na Moderna).
- Chanjo 9 za virusi ambavyo vimeondolewa makali au kudhoofishwa (BBIBP-CorV, Chinese Academy of Medical Sciences, CoronaVac, Covaxin, CoviVac, COVIran Barakat, Minhai-Kangtai, QazVac, and WIBP-CorV).
- Chanjo 5 za aina ya vekta za virusi (Sputnik Light, Sputnik V, Oxford–AstraZeneca, Convidecia na Janssen).
- Chanjo 4 zitokanazo na protini (Abdala, EpiVacCorona, MVC-COV1901, Soberana 02 na ZF2001).

Kwa ujumla hadi sasa, kuna chanjo 330 ambazo ziko kwenye hatua mbalimbali za uvumbuzi ikiwa ni pamoja na 102 zilizo kwenye hatua ya utafiti, 30 kwenye majaribio ya awamu ya kwanza, 30 kwenye majaribio ya awamu ya pili, 25 kwenye majaribio ya awamu ya tatu na 8 kwenye majaribio ya awamu ya nne.

4. Aina gani za chanjo zimeorodheshwa na WHO kwa matumizi ya dharura?

Mpaka sasa Shirika la Afya Duniani (WHO) limeorodhesha aina 8 tofauti za chanjo kwa matumizi ya dharura (EUL) kama ifuatavyo:

Na.	Jina la chanjo	Mtengenezaji
1.	Pfizer/BioNtech - BNT162b2/COMIRNATY Tozinameran	Pfizer/BioNtech – US/Germany
2.	Astra Zeneca - AZD1222	AstraZeneca - UK
3.	Astra Zeneca - AZD1222	AstraZeneca (MFDS KOREA) – UK/Korea
4.	Covishield (ChAdOx1_nCoV-19)	Serum Institute of India Pvt. Ltd - India
5.	Janssen - Ad26.COV2.S	Janssen - subsidiary of Johnson & Johnson - US
6.	Moderna - mRNA-1273	Moderna - US
7.	Sinopharm - SARS-CoV-2 Vaccine (Vero cell), inactivated (InCoV)	Beijing Bio-Institute of Biological Products Co Ltd - subsidiary of China National Biotec Group (CNBG), China
8.	Sinovac - COVID-19 Vaccine (Vero Cell), Inactivated/ CoronavacTM	Sinovac - China

5. Ni chanjo zipi zimeidhinishwa na TMDA kwa matumizi nchini?

TMDA huidhinisha chanjo ambazo zimependekezwa na Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto kutumika nchini. Chanjo ambazo sasa zinaruhusiwa kutumika nchini Tanzania ni pamoja na:

Na.	Jina la chanjo	Mtengenezaji
1.	Janssen - Ad26.COV2.S	Janssen - subsidiary of Johnson & Johnson – US
2.	Pfizer/BioNtech - BNT162b2/COMIRNATY Tozinameran	Pfizer/BioNtech – US/Germany
3.	Moderna - mRNA-1273	Moderna – US
4.	Sinopharm - SARS-CoV-2 Vaccine (Vero cell), inactivated (InCoV)	Beijing Bio-Institute of Biological Products Co Ltd - subsidiary of China National Biotec Group (CNBG), China
5.	Sinovac - COVID-19 Vaccine (Vero Cell), Inactivated/ CoronavacTM	Sinovac - China

6. Idhini ya matumizi ya dharura (EUL) inamaanisha nini?

Idhini ya matumizi ya dharura (EUL) ni utaratibu uliowekwa na WHO wa kutathmini kama bidhaa mpya za afya zinafaa kwa matumizi wakati wa dharura. Lengo ni kufanya dawa, chanjo na vitendanishi vipatikane kwa haraka iwezekanavyo ili kushughulikia dharura iliyojitokeza bila kuathiri ubora, usalama na ufanisi wake. Tathmini hupima uzito wa tishio linalosababishwa na dharura na faida ambayo inaweza kupatikana kutokana na matumizi ya bidhaa hiyo dhidi ya athari zozote zinazoweza kujitokeza.

Njia ya EUL inajumuisha tathmini ya kina ya taarifa za majaribio ya bidhaa husika hasa katika hatua ya II na III na vile vile taarifa nyingine za ziada juu ya usalama, ufanisi, ubora na vihatarishi vyovyote kwa kuzingatia mahitaji ya nchi za kipato cha chini na cha kati. Takwimu hizi hupitiwa na wataalam wa WHO wasiofungamana na upande wowote wanaozingatia ushahidi wa sasa juu ya chanjo inayotathminiwa, mipango ya ufuatiliaji wa matumizi yake na mipango ya tafiti au uchunguzi zaidi.

Kama sehemu ya mchakato wa EUL, kampuni inayozalisha chanjo husika ni lazima ikubali kuendelea kutoa taarifa zaidi kuwezesha kupitishwa na WHO. Mchakato wa uthibitishaji wa WHO unatathmini pia taarifa za ziada zitokanazo na majaribio ya chanjo na msingi wake ili kuhakikisha chanjo husika inakidhi viwango muhimu vya ubora, usalama na ufanisi kwa watumiaji.

7. Kuna faida gani za kupata chanjo?

Chanjo za UVIKO-19 hutengeneza kinga dhidi ya virusi vya SARS-CoV-2 na hivyo kulinda mwili dhidi ya maradhi yanayosababishwa na ugonjwa wa UVIKO-19. Kutumia chanjo hii kunapunguza uwezekano wa kupata ugonjwa na kusaidia kupambana na virusi na madhara yanayoweza kusababishwa navyo. Kupata chanjo pia kunalinda watu walio karibu, kwa sababu ikiwa una kinga dhidi ya maambukizi kuna uwezekano mdogo wa kuambukiza mtu mwingine. Ni muhimu sana kulinda watu walio katika hatari kubwa ya kuugua ugonjwa wa UVIKO-19, kama watoa huduma za afya, watu wazima au wazee na watu wenye magonjwa sugu.

8. Mtu anaweza kupewa chanjo ikiwa ameshaambukizwa UVIKO- 19?

Hata ikiwa tayari uliwahi kuambukizwa UVIKO-19, unapaswa kuchanjwa kama chanjo inapatikana. Ulinzi ambao mtu anapata kutokana na kuwa na UVIKO-19 unatofautiana kati ya mtu na mtu, na pia bado haifahamiki kinga ya asili inaweza kudumu kwa muda gani.

9. Ufanisi wa chanjo maana yake nini?

Ufanisi maana yake ni uwezo wa chanjo kupunguza ugonjwa kwenye kundi la watu waliochanjwa ukilinganisha na kundi la wasiochanjwa. Ufanisi hupimwa kwa kutumia majaribio yaliyofanywa kisayansi na kusimamiwa kwa karibu. Ufanisi ni tofauti na uwezo wa chanjo kuzuia magonjwa baada ya majaribio kukamilika kwa kuwa katika kipindi hiki chanjo huonyesha inavyofanya kazi inapotumiwa na idadi kubwa zaidi ya watu. Ufanisi hupimwa tu wakati chanjo inafanya kazi katika hali fulani ambayo pia hudhibitiwa sana. Ufanisi hutumika pia kupima mashambulizi ya magonjwa, watu waliolazwa, idadi ya wanaoumwa na gharama za afya.

10. Chanjo za UVIKO-19 zimeharakishwa sana kuanza kutumika, je kuna hatua zilizorukwa wakati wa kutengeneza chanjo hizi?

Hakukuwa na njia fupi wala kuharakisha matumizi ya chanjo hizi. Tafiti za kisayansi kwa wanyama na binadamu zimefanyika ili kuthibitisha usalama na ufanisi wake. Kwa ujumla angalau awamu tatu za tafiti zinapaswa kufanyika kwa watu weusi na matokeo yanapaswa kuonesha usalama na ufanisi kabla chanjo haijaruhusiwa kutumika nchini Tanzania. Taarifa zilizowasilishwa na watengenezaji zimethibitisha kwamba tafiti hizo zilifanyika. Vile vile, TMDA ilishiriki katika tathmini ya pamoja ya chanjo hizi kupitia Muungano wa Mamlaka za Udhibiti wa Chanjo - Afrika (AVAREF) ambao uliandaa vikao kazi vya tathmini ya chanjo husika chini ya uratibu wa WHO.

11. Kuna haja ya kuchoma dozi zaidi ya moja na kwa nini?

Kwa mujibu wa matokeo ya tafiti yaliyopatikana hadi sasa, chanjo ya Janssen pekee ndio hutolewa kwa dozi moja wakati nyingine zinahitaji dozi mbili zinazotakiwa kutumika kati ya siku 21 au 28 kutegemeana na aina ya chanjo. Watafiti bado wanachunguza kama kinga inapungua baada ya kuchoma dozi zilizothibitishwa hadi sasa na kama kuna haja ya kuongeza tena. Mara tu tafiti zitakapokamilika, taarifa itatolewa kuhusu dozi ngapi zinatosha.

12. Mtu anaweza kupata tena UVIKO-19 baada ya kuchanjwa?

Mtu anaweza kupata tena UVIKO-19 baada ya kuchanjwa. Hii ni kwa sababu chanjo hizi hazina kinga ya asilimia 100 na bado utafiti unaendelea juu ya uwezo wa kuleta kinga ya muda mrefu na kupunguza maambukizi. Ndio maana tunapaswa kuendelea kujikinga na maambukizi sisi wenyewe na walio karibu yetu.

13. Kuna taarifa zimesambaa kwamba chanjo hizi zimewekewa sumaku na vifaa vya kuzuia mtu kupata mimba, je taarifa hizi ni za kweli?

Taarifa hizi si za kweli na ni uzushi ambao unaenezwa pasipokuwa na ushahidi wowote. Haiwezekani chanjo zikawekewa sumaku au kifaa chochote cha kuzuia mtu kupata mimba. Chanjo ni kemikali za majimaji ambazo zinaonekana kwa macho na

haiwezekani kufanya hivyo. Taarifa hizo zinapaswa kupuuzwa na kuzuiwa zisienee ili kuwezesha chanjo ziweze kutumika kwa walio wengi na hivyo kuleta kinga ya ugonjwa wa UVIKO-19.

14. Inawezekana mtu aliyepata chanjo kuweza kuambukizwa kwa mara nyingine tena?

Pamoja na kwamba chanjo za UVIKO-19 zimethibitika kuwa na usalama na ufanisi wa kuweza kuzuia watu kuugua sana na kulazwa hospitalini, bado hazijafikia 100% ya kinga. Hivyo basi, bado kuna asilimia ndogo ya watu waliopewa chanjo lakini wanaweza kupata UVIKO-19.

Hii inasababishwa na mambo mbalimbali kama vile tabia ya chanjo yenyewe, umri wa mtu, hali ya kiafya, kama aliwahi kuugua UVIKO-19, maambukizi mapya au aina ya virusi vilivyoko nchini. Bado haijulikani kinga ya muda mrefu ya chanjo tofauti za UVIKO-19 itadumu kwa muda gani. Kwa mantiki hii, hata kama chanjo za UVIKO-19 zinatolewa, lazima tuendelee kutumia mbinu zote za kiafya zinazofanya kazi kupunguza hatari ya maambukizi, kama vile kuzingatia umbali kati ya mtu na mtu, kuvaa barakoa na kunawa mikono na maji tiririka.

Kwa siku 14 za kwanza baada ya kupata chanjo, kinga ndio inaanza kuongezeka taratibu. Kwa chanjo ya dozi moja, ulinzi kwa kawaida hutokea wiki mbili baada ya chanjo. Kwa chanjo za dozi mbili, dozi zote zinahitajika kufikia kiwango cha juu cha kinga inayokusudiwa.

Pamoja na kwamba chanjo hizi zimeonesha ufanisi, bado TMDA inajifunza juu ya uwezo wa chanjo kuzuia maambukizi na kuleta kinga ya muda mrefu. Kusaidia kujiweka salama wewe na wengine, endelea kuzingatia kukaa umbali wa mita moja kutoka kwa wengine, kufunika kwa kiwiko wakati wa kukohoa au kupiga chafya, kusafisha mikono mara kwa mara kwa maji tiririka, kuvaa barakoa kwenye mikusanyiko ya watu wengi na kukaa eneo lenye mzunguko mzuri wa hewa. Hakikisha pia unasoma miongozo inayotolewa mara kwa mara na Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto.

15. Ninaweza kutumia chanjo tofauti kutoka kwa wazalishaji tofauti kwa wakati mmoja?

Bado hakuna taarifa za kutosha kupendekeza mchanganyiko huu. Tafiti zinaendelea kufanyika kuangalia kama mtu anaweza kuchomwa dozi ya chanjo moja na kisha kuchomwa dozi ya chanjo nyingine.

16. Chanjo hizi zinaweza kuwalinda watu dhidi ya aina zote za virusi vya korona?

Utafiti zaidi unahitajika kufanyika ili kutathmini ufanisi wa chanjo za sasa za UVIKO-19 dhidi ya mabadiliko ya virusi. Kwa taarifa zilizoko inaonekana

chanjo nyingi huleta kinga ya kutosha dhidi ya aina za virusi vilivyoko, hasa katika kupunguza makali ya ugonjwa, kulazwa hospitalini na vifo.

Tafiti bado zinaendelea kuangalia aina ya virusi na namna vinavyojibadilisha ili kufanya mabadiliko ya chanjo kuweza kuendelea kuleta kinga kwa watu wengi. Kwa hali ilivyo sasa idadi kubwa ya aina za virusi vilivyoko vinaweza kuzuiwa na chanjo zilizoko kusababisha ugonjwa mkali.

17. Baada ya kuchanjwa tunapaswa kuendelea kujitenga, kusafisha mikono na kuvaa barakoa tena, na kwanini?

Chanjo zimekuja kusaidia katika mapambano dhidi ya UVIKO-19. Pamoja na kwamba chanjo hizi zipo kwa sasa, tunapaswa kuendelea kuvaa barakoa, kunawa mikono mara kwa mara kwa maji tiririka, kukaa eneo lenye hewa nzuri, kuzingatia umbali na kujiepusha na mikusanyiko.

18. Kinga ni ya muda gani baada ya kuchanjwa?

Sio chanjo zitakazodhibiti ugonjwa bali uchanjaji. Wizara kupitia IVD inafanya kazi kuhakikisha upatikanaji wa chanjo kwa haki na usawa, na kuhakikisha kila mtu anapata kinga kwa kuanzia na walio hatarini zaidi. Hata hivyo, Ikumbukwe kuwa kupata chanjo sio lazima ni hiari kwa watu ambao wako tayari kuchanjwa.

Kwa sababu chanjo za UVIKO-19 zimetengenezwa hivi karibuni tu, ni mapema sana kujua muda wake wa kinga. Utafiti unaendelea kujibu swali hili. Hata hivyo inatia moyo kwamba taarifa zinazopatikana zinaonesha kuwa watu wengi wanaopona UVIKO-19 hutengeneza kinga ambayo hutoa angalau kipindi fulani cha ulinzi dhidi ya kuambukizwa tena - ingawa wanasayansi bado wanajifunza jinsi ulinzi huu ulivyo, nguvu yake, na inachukua muda gani.

19. Chanjo za UVIKO-19 ni salama kwa matumizi ya binadamu?

Kama chanjo yoyote ilivyo, chanjo za UVIKO-19 zinaweza kusababisha athari chache, za muda mfupi, kama vile homa ya kiwango cha chini, maumivu au ngozi kuwa nyekundu eneo ulipochomwa sindano. Athari hizi ni za kawaida na huisha baada ya siku chache. Madhara makubwa au ya kudumu ya chanjo yanawezekana lakini ni nadra sana kutokea. TMDA inaendelea kufuatilia usalama wa chanjo hizi ili kuangalia madhara yanayoweza kujitokeza baada ya matumizi ya muda mrefu kwa lengo la kulinda afya ya jamii.

Madhara yaliyoripotiwa hadi sasa ni ya wastani na yanajumuisha homa, uchovu, maumivu ya kichwa, maumivu ya misuli, baridi, kuhara, na maumivu kwenye sehemu palipochomwa sindano. Madhara haya yanatofautiana na aina ya chanjo.

Madhara haya yanatibika kwa kupumzika, kunywa maji mengi na kutumia dawa zenye paracetamol au acetaminophen. Ikiwa madhara yatazidi masaa 24, watumiaji wawaone wataalam wa afya kwa uchunguzi zaidi. Endapo mtu atapata shida ya kupumua, maumivu ya kifua, kuchanganyikiwa, kushindwa kuongea au kushindwa kutembea, ni vyema kuwahi kituo cha afya kilicho karibu kwa msaada zaidi.

20. Chanjo za mRNA ni salama? Ikiwa zinatengenezwa kwa teknolojia mpya, tunawezaje kuwa na uhakika?

Chanjo za UVIKO-19 za mRNA zimechunguzwa kwa teknolojia ya hali ya juu na kuthibitika kuwa na ufanisi wa kuzuia ugonjwa wa UVIKO-19. Teknolojia ya kutengeneza chanjo za mRNA imetumika miaka mingi na imehusisha pia uvumbuzi wa chanjo nyingine kama za ugonjwa wa zika, kichaa cha mbwa na mafua. Chanjo za mRNA hazina virusi vya korona na haziingiliani na DNA ya binadamu.

21. TMDA itafuatiliaje usalama wa chanjo hizi?

TMDA ina mifumo miwili ya ufuatiliaji wa bidhaa kwa ajili ya kuhakikisha usalama wake. Hii ni pamoja na ufuatiliaji wa hiari na ule wa karibu.

Mfumo wa ufuatiliaji usalama wa hiari

hutumia fomu za njano (kwa watoa huduma za afya) na fomu za kijani (kwa wagonjwa) kuripoti madhara ya dawa na chanjo (ADRs). Njia ya ufuatiliaji wa karibu (CEM) hutumia fomu maalum zilizoandaliwa kutegemeana na aina ya ugonjwa na dawa inayotumika. Njia ya CEM hutumiwa kwa dawa na chanjo mpya zilizoingizwa ikiwa ni pamoja na zile zinazotumika na watu wengi.
TMDA itatumia njia ya CEM kufuatilia usalama wa chanjo za UVIKO-19 ili kurekodi matukio yote pamoja na madhara ya muda mrefu ya chanjo.
Pamoja na hayo, mfumo wa kuripoti madhara kwa hiari pia utatumika ili kutambua madhara mengine yote yanayoweza kujitokeza wakati chanjo hizi zinatumika hapa nchini. Ufuatiliaji utafanywa kwa kushirikiana na Mpango wa Chanjo wa Taifa (IVD) ambao uko chini ya Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto.

22. Mtu anapaswa kuripoti madhara ya kiafya yanayotokea baada ya chanjo na nini kitatokea ikiwa tukio baya litaripotiwa?
Kama ilivyo kwa chanjo nyingine, TMDA inafuatilia kwa karibu usalama na ufanisi wa chanjo zote zinazotumika katika programu za chanjo. Ikiwa shida ya kiafya itaripotiwa kufuatia matumizi ya chanjo, uchunguzi wa kina hufanywa na TMDA kwa kushirikiana na IVD. Fomu za CEM za kukusanya taarifa za usalama wa chanjo za UVIKO-19 zitatumika (zinapatikana www.tmda.go.tz).
Hata hivyo, ni nadra kukuta shida za kiafya zinazotokea baada ya kuchanjwa kuthibitika kuwa kweli husababishwa na chanjo yenyewe. Shida za kiafya kufuatia chanjo mara nyingi hutokea kwa bahati mbaya na mara nyingi hazihusiani moja kwa moja na chanjo. Wakati mwingine zinahusiana na jinsi ambavyo chanjo husika imehifadhiwa, kusafirishwa au kusambazwa. Makosa yanayohusiana na utoaji wa chanjo yanapaswa kuzuiwa kwa kutoa mafunzo kwa wahudumu wa afya pamoja na kuimarisha mnyororo wa usambazaji.
Hata hivyo, endapo madhara ya chanjo yatatokea, TMDA itachukua hatua kwa mujibu wa sheria, kanuni na taratibu. Uchunguzi zaidi utafanyika pia ili kubaini ni nini haswa kilichosababisha madhara hayo na hatua za kurekebisha zitawekwa.

23. Kuna tahadhari zozote za kuchukua kabla ya kutumia chanjo hizi?
Chanjo za UVIKO-19 ziko salama kwa watu wengi wenye umri wa miaka 18 na zaidi, ikiwa ni pamoja na wenye magonjwa mengine kama vile shinikizo la damu, kisukari, pumu, mapafu, homa ya ini na ugonjwa wa figo.
Pamoja na hilo, mtumiaji atapaswa kuchukua tahadhari ikiwa:

- Ana upungufu wa kinga mwilini.
- Mtu ana ujauzito au kunyonyesha.
- Ana historia ya mzio haswa kwa chanjo

husika au viambata vyake.

- Ana udhoofu wa mwili.

24. Tunaweza kuacha kuchukua tahadhari baada ya chanjo?
Chanjo inatoa kinga dhidi ya kupata maambukizi makali na kifo. Kwa siku 14 za mwanzo baada ya kupata chanjo, mtu hatakuwa na kiwango kikubwa cha ulinzi, kwa kuwa huongezeka taratibu. Kwa chanjo za dozi moja, kinga kwa kawaida itatokea wiki mbili baada ya chanjo. Kwa chanjo za dozi mbili, dozi zote zitahitajika ili kufikia kiwango cha juu cha kinga inayotakiwa.
Wakati chanjo ya UVIKO-19 itakukinga na maambukizi makali na kifo, bado tunajifunza juu ya kiwango gani kitakuzuia kuambukizwa na kusambaza virusi kwa wengine. Takwimu kutoka nchi nyingine zinaonesha kuwa chanjo zinazotumika sasa zinalinda dhidi ya hali ya ugonjwa mkali na kulazwa hospitalini. Hata hivyo, hakuna chanjo yenye ufanisi wa 100%.
Wizara na TMDA bado tunaendelea kufuatilia mabadiliko ya aina ya virusi vilivyopo nchini na uwezo wa muda mrefu wa chanjo zilizovumbuliwa. Kwa sababu hizi, na kwa kuwa wengi katika jamii bado hawataweza kupata chanjo, kuendeleza hatua nyingine za kuzuia ni muhimu haswa katika jamii ambazo mzunguko wa virusi ni mkubwa. Ili kukusaidia wewe na wengine kuwa salama, na wakati juhudi zinaendelea kupunguza maambukizi ya virusi na kuongeza chanjo, unapaswa kuendelea kuzingatia kukaa umbali wa mita 1 kutoka kwa wengine, kukohoa au kupiga chafya kwenye kiwiko chako, kusafisha mikono yako mara kwa mara, kuvaa barakoa, kuepuka misongamano na kukaa maeneo yenye mzunguko mzuri wa hewa. Wakati wote fuata miongozo inayotolewa na Wizara na IVD kulingana na hali na hatari ya mahali unapoishi.

25. Chanjo ya UVIKO-19 inatolewa kwa watoto? wa umri gani?
Chanjo ya UVIKO-19 haitolewi kwa watoto bali kwa wenye umri unaoanzia miaka 16. Umri huu ndio imethibitika kuna maambukizi mengi ya ugonjwa wa UVIKO-19 na tafiti za usalama na ufanisi wake zimefanyika kuanzia kundi hili hadi miaka zaidi ya 60.

26. Mtu akiwa na UVIKO-19 anaweza kuchangia damu?
Mtu mwenye UVIKO-19 anayetaka kuchangia damu ni vyema kupata ushauri wa kitaalam kabla ya kufanya hivyo.

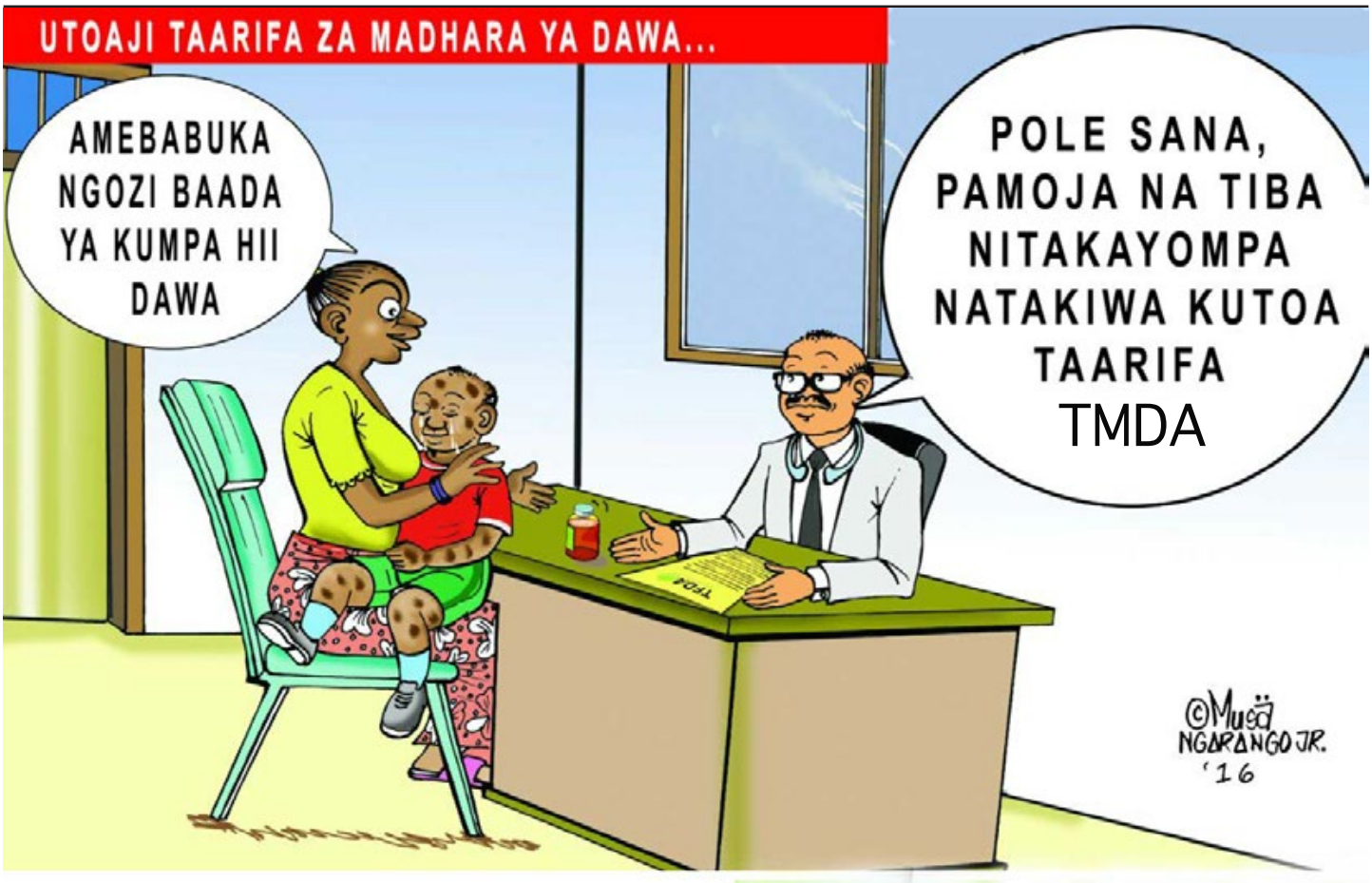
27. Watu wa vijijini watapataje chanjo?
Chanjo ya UVIKO-19 imeanza kutolewa kwenye vituo ambavyo vimeainishwa kupitia IVD iliyoko chini ya Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto. Ni vyema kufika vituo vya kutolea huduma za afya ili kufahamu mahali chanjo inapotolewa.

28. Chanjo ni njia inayotumiwa na mataifa makubwa kupunguza idadi ya watu na ilitengenezwa kwa ajili ya kupunguza watu duniani?
Chanjo ya UVIKO-19 imetengenezwa kwa lengo la kuleta kinga dhidi ya UVIKO-19 na sio kuangamiza watu. Kuna chanjo nyingi pia ambazo zimetengenezwa na mataifa hayo hayo makubwa na hadi leo haziuwi watu bali zinakinga watu dhidi ya magonjwa mbalimbali kama vile surua, tetekuwanga, polio, tetenasi, kichaa cha mbwa, saratani ya shingo ya kizazi, homa ya ini n.k. Huu ni uvumi ambao tunapaswa kuuacha ili tuweze kuwalinda watanzania wasipate maambukizi na ugonjwa mkali wa UVIKO-19.

29. Kama unatarajia kupata ujauzito bado unaweza kupata chanjo?
Kwa tafiti ambazo zimefanyika hadi sasa, chanjo ya UVIKO-19 haijaonekana kuleta madhara kwa mjamzito wala mtu anayetarajia kubeba ujauzito. Hata hivyo tafiti zinaendelea kufanyika kuona kama zinaleta madhara kwa wajawazito baada ya matumizi ya muda mrefu.

30. Nani anadhibiti chanjo Tanzania?
Sheria ya Dawa na Vifaa Tiba, Sura 219 imeipa mamlaka TMDA kudhibiti chanjo za binadamu na mifugo pamoja na chanjo za UVIKO-19. Udhibiti unahusisha usajili wa chanjo, udhibiti wa uingizaji nchini na usafirishaji nje ya nchi, ufuatiliaji ubora na usalama katika soko, ukaguzi, utoaji leseni za majengo yanayojihusisha na masuala ya chanjo, uchunguzi wa kimaabara na udhibiti wa majaribio ya chanjo.

Imetolewa na:
Mkurugenzi Mkuu,
Mamlaka ya Dawa na Vifaa Tiba (TMDA),
S.L.P 77150, Dar es Salaam au
S.L.P 1253 Dodoma
Simu: +255 222 450512/450751/452108
Simu ya Bure: 0800110084
Nukushi: +255 222 450793
Barua Pepe: info@tmda.go.tz Tovuti: www.tmda.go.tz



Wataalam wa afya toeni taarifa kwa kujaza fomu maalum ya njano

"TAARIFA MOJA UTAKAYOTOA INAWEZA KUOKOA MAISHA YA WENGI"

TMDA
Tanzania Medicines and Medical Devices Authority

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