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ETHIOPIAN FOOD & DRUG AUTHORITY

EFDA VOICES

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IN THIS ISSUE

EFDA is Building The First Of Its Kind Food, Medicine, And Medical Equipment Quality Control Center Of Excellence

Dr. Lia Tadesse, Minister of Health, officially launched the first food, medicine, and medical device quality control center in the nation, which will be built in Addis Ababa's Aqaki Kaliti sub-city, with funding from the World Bank.

The first quality control center for food, medicine, and medical devices in our nation will feature 257 quality inspection rooms, 400 spaces for parking, and a contemporary sewage disposal. The World Bank will cover the whole 1.5 Billion ETB cost of the center's development, which will be finished within two years.

During her opening remarks, the Honorable Minister stated that the facility would be built to an international standard of excellence and will serve to expand access to comprehensive and high-quality medical care. Additionally, her Excellency remarked that it will play a crucial role in safeguarding public health and preventing illnesses and deaths brought on by a lack of quality and safety.

According to Dr. Lia, one of the main goals the government has set for the health sector in the upcoming years is to update the safety and quality control system across all sectors to an international standard, making this center vital to achieving this goal.

During her opening remarks, the Authority's Director General, Mrs. Heran Gerba, thanked the Addis Ababa city Administration, Aqaki Qaliti sub-city, the Ministry of Health, in particular Dr. Lia Tadesse, the World Bank and the Authority's staff for supporting the construction effort.

She added that the quality control center will greatly benefit Ethiopia and East Africa and contribute to the Authority's goal of making Africa a center of excellence by realizing the vision set forth in the ten-year strategic plan.

Dr. Abera Beru, the Chief Executive Officer of Akaqi Kaliti Sub-city, reaffirmed his sub- cities fully commitment to providing all essential support for the quick construction and operation of the center of excellence.

> **"The facility would be built to an international standard of excellence and will serve to expand access to comprehensive and high-quality medical care."**
>
> **Dr. Lia Tadesse, Minister of Health**

IMPORTANT MESSAGE

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EFDA VISION

To be a center of excellence in food and health products regulation in Africa

EFDA MISSION

To protect and promote public health by ensuring the safety, effectiveness, quality and proper use of regulated products through licensing, inspection, registration, laboratory testing, post-marketing surveillance, community participation, and provision of up-to-date regulatory information.

EFDA OBJECTIVE

To protect and promote public health through realization of the following objectives:

1. Protect the public from unsafe food
2. Safeguard the public from falsified, substandard and ineffective health products
3. Protect the public from tobacco and alcohol related health risks
4. Attain public confidence on food and health product regulation

Strategic Directions

1. Strengthen food safety regulation.
2. Strengthen detection, prevention and response to food adulteration and illegal trade
3. Improve regulation of safety, efficacy, quality and proper use of medicines
4. Strengthen safety, quality and performance regulation of medical devices
5. Improve regulation of safety of cosmetic products
6. Strengthen tobacco and alcohol control system
7. Enhance public ownership
8. Improve efficiency and effectiveness
9. Enhance partnership and collaboration
10. Enhance good governance
11. Improve human resource development and Management
12. Improve evidence-based decision making
13. Strengthen Food and health products regulatory infrastructures
14. Improve quality management system
15. Improve formulation and implementation of legal frameworks

2015 Outstanding Leadership Award in the Health Sector, Ms. Heran Gerba

Ms. Heran Gerba, Director General of the Ethiopian Food and Drug Authority (EFDA) received the 2015 Outstanding Leadership in the Health Sector Award, at the 24th Annual Review Meeting of the Health Sector, on October 20, 2022,in Hawassa city.

Ms. Heran has shown has demonstrated excellent leadership skills, demonstrated in her efforts in ensuring effective control of health resources and improving the various aspects of the institution.

In her acceptance speech, Ms. Heran expressed that the award is not only for her, but also for the leadership and staff of the Authority at all levels.

Ms. Heran is a pharmacist by profession and received her Bachelor's degree in pharmacy from Addis Ababa University School of Pharmacy and her Master's degree in Drug Analysis and Quality Assurance.

She started working in the Authority in 2011, assuming various positions, then later advancing to the position of General Director. Through this journey, she strengthened her learned skills. In addition to this, she has been fulfilling her responsibilities as a steering committee board member and chairperson in various governmental institutions.

Ms. Heran has received awards and recognition from the World Health Organization, as well as from Judewell Kenfeld International Award Organization for her strong participation in the prevention of cigarette smoking, and she is known for her strong participation on various platforms.

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COVID-19 Vaccine Safety Monitoring System Dissemination Workshop

The Ethiopian Food and Drug Authority organized a dissemination workshop to discuss the results of the country's COVID-19 vaccine safety monitoring system.

The goal of the one-day workshop was to improve the involvement of key stakeholders and partners in vaccine safety monitoring while also communicating the results of the assessment on Ethiopia's national AEFI monitoring system, and the findings of COVID-19 vaccine safety surveillance monitoring.

During the workshop, the State Minister of Health, His Excellency Dr. Dereje Duguma, communicated: 'Our nation, Ethiopia, is one of the top in Africa in terms of COVID-19 vaccine coverage, thanks to the extensive efforts of the government and collaborative organizations in the health sector.'


We need to continue to promote the types of vaccines that are suitable for our country and that our society can easily take," His Excellency continued. Additionally, he urged medical facilities to keep improving the mechanism for informing the relevant authorities of any negative consequences related to the use of drugs and vaccines.

According to Ms. Heran Gereba, General Director of the Authority, four of the five COVID-19 vaccine types that the EFDA granted pre-licensing to, have been implemented. A safety monitoring surveillance is presently being conducted on the two vaccines produced by Pfizer and Janssen. She added that one vaccine type had previously undergone comparable surveillance.

Ms. Heran further explained that the study's findings demonstrate how crucial it is to encourage immunization since it prevents the disease from inflicting significant harm, life-threatening sickness, and even death. Finally, she expressed her sincere appreciation for the unreserved contributions made to the study's success by the regional health bureaus, regional regulatory agencies, EFDA regional branches, and partner organizations.

EFDA's Yearly Forum For Partner Organizations

Inter Luxury Hotel on October 7, 2022

The EFDA hosted a yearly forum for partner organization, to review the implementation and difficulties of the 2014 fiscal year plan. The Authority's high-level strategic direction, and Health regulatory center of excellence project progress and gaps, and the forum's objectives were discussed.

The director general of the Authority, Ms. Heran Gerba, stated that thanks to the cooperation and partnership of various government institutions, partners, and other sector actors, our country was able to prevent the epidemic in an effective manner considering the impact that was thought have been caused the COVID-19 epidemic.


All Stakeholders Are Urged To Cooperate To Ensure The Proper Use Of Tramadol Hydrochloride.

The Ethiopian Food and Drug Authority held a press conference for journalists on November 1 2022, to discuss the initiatives it has been working on for the past five years to ensure proper Tramadol use.

The Deputy Director General of the medicine sector of the Authority, Seyoum Wolde, who gave the press conference, said that, based on the research conducted by the authority over the past five years regarding Tramadol and the suggestions received from the society, the Authority is closely monitoring those who are aware of the drug's addictive nature and the harm it causes to the health of students. He recalled that Tramadol was included in the lists of narcotic and psychotropic drugs.

The Authority is closely monitoring those who are aware of the drug's addictive nature and the harm it causes to the health of students.

The office has issued a directive to be executed for the relevant stakeholders after the deputy director noted that Tramadol is listed in the list of narcotic and psychotropic substances and should only be sold with a special prescription.

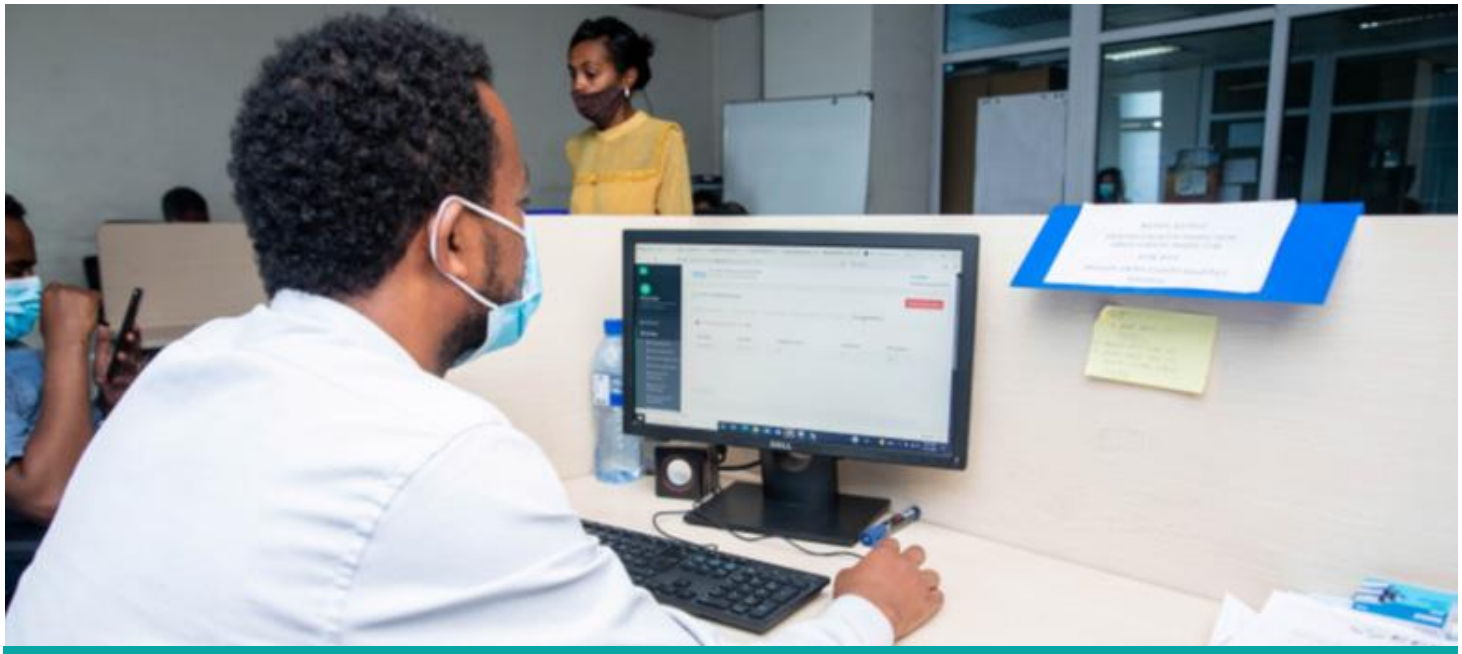
Ato. Seyoum finally asked drug retailers to follow the instructions and only dispense the drug with a special prescription, pointing out that we still receive reports that young people are using Tramadol inappropriately. He also urged the public, in particular young people, to avoid putting themselves in danger by using Tramadol improperly.

In other news, the Director-General, who mentioned the recent deaths of children who took cough syrup in Gambia and Indonesia, confirmed that these drugs have not been registered in our country and if they have been imported illegally, the Authority is working in coordination with the relevant regional regulatory bodies to ensure strict monitoring.

New Era of Digitalization on health and health related products control: Electronic Regulatory Information System (eRIS)

It has been three years since the Ethiopian Food and Drug Authority (EFDA) digitalized the manual control system of the health resources that it controls, including medicine, medical equipment, cosmetics and food.

Before any health and health related products are delivered to the public, manufacturers, importers and distributors must go through a one-stop electronic regulatory information system implemented by the Authority. The system begins with taking a qualification certificate, then registering the product, getting an import license and distributing it to the market.



In this modern control system, it is a prerequisite for any manufacturer, importer and distributor of health resources to obtain a certificate of qualification called through the "iLicense" component of the system. It allows clients to register a product after obtaining a certificate of qualification. This product registration component of the system is called "iRegistration". The next component is called "iImport", this is used to accept, review, and authorize applicants import request applications for import. "iImport" has two components: One for registered drugs, where the registrant starts the process of obtaining an Import Permit electronically from his/her location.

The second is a special Pre-Import Permit, which is given when there is a shortage of health resources or for emergency services.

The iRegister component allows importers to apply for market authorization and certification, and helps user's access information about their application process.

The three licensing systems mentioned above, "iLicense", "iRegistration" and "iImport" were previously provided separately, but now they have been integrated. This eliminates the need for multiple usernames and passwords to use the three services.

Developed by a local software development firm, the system allows data to flow seamlessly, and allows new features to be added and improved over time. This system is expected to play an important role in ensuring the quality of the regulatory body, including the certification of qualifications, product registration and licensing, by updating and updating it.

In this regard, the Authority will create an opportunity for the office to easily track the status of drugs and medical equipment from international and local suppliers, starting from the port of entry, to the warehouse of the EFDA and to every clinic across the country.

The system also allows service requesters to easily obtain qualification, product registration and purchase license online without having to physically come to the facility. Using technology, service requesters save time, energy and resources that they had to spend before having to come to the facility.

In terms of making improvements to the system, the Authority has regularly provided capacity building training to professionals at all levels and provided the necessary resources to successfully make the system stand on its two legs.

In addition to this, according to the national transformation plan set by the health sector, the Authority office will update the control system by implementing new procedures supported by digital technology.

The Authority, in collaboration with USAID DHA has recently developed a mobile application called iVerify, used to monitor the movement of medicine from manufacturers to the point of issue; to track, trace, and verify each product throughout the supply chain and health import process. iVerify literally means "I will verify the correctness of the medicine in my hand".

This mobile application, designed to help control the supply chain of drugs, provides a significant benefit to regulatory institutions and drug suppliers as it allows monitoring the movement of drugs from the manufacturer to the user.

After any drug is put in the market, users can use their smartphone and install the iVerify application from the Google Store. The application will allow them to search and verify the drug's legality on their own.

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After users hit the search button and instruct the app to search for them, there are two types of answers they can get. One shows whether the drug is registered and states that whether the drug is approved. The other declares that the search has failed; next, the user will be asked for the location of the seller and other information, and if they want to inform the Authority about this. In addition, as soon as the user fills in the information and sends it to the Authority, the information will be received immediately.

Based on the customer's information provided by the official office using the iVerify mobile application, the information experts working on the electronic regulatory registration system will send the information directly to the relevant department, i.e. to the drug registration or drug control or to the branches.

As a result, the departments will carry out inspections. Investigative work will be paid attention to so that the society will not be harmed due to unregistered or infiltrated drugs.

To implement the iVerify mobile application, information was entered into the database of the electronic control information system, but the work of entering manual data from outside the database into the database is currently being done. This is being done by entering the drug information that the institution has already received, registered and authorized into the automation system before updating the control operations, and updating the application to show this.

In order to make this operational system fully functional and successful, the official office is working to make the system more efficient.

One of the main reasons that encouraged the institution to follow this modern system is to identify counterfeit and substandard drugs that are part of illegal drug trafficking, and to find the type and amount of drugs that are allowed in the market now, and the drugs that enter the market are approved and safe. The Authority is mandated to ensure the safety, quality and efficacy of medicines - and will continue to utilize this electronic system to ensure increased processing efficiency and transparency and facilitate one unbroken chain of information – from application to port.

This product registration component of the system is called "iRegistration". The next component is called "iImport", this is used to accept, review, and authorize applicants import request applications for import. "iImport" has two components: One for registered drugs, where the registrant starts the process of obtaining an Import Permit electronically from his/her location.

Addis Ababa Tobacco Smoke Free Initiative

On June 23, 2014, Ethiopia ratified the WHO is Framework Convention on Tobacco Control. The ratified Food and Medicine Administration Proclamation No. 1112/2019 is the primary piece of federal tobacco control legislation, which governs, among other things, smoke free environments, tobacco advertising, promotion and sponsorship, tobacco packaging and labeling, tobacco product regulation, protection against tobacco industry interference, and tobacco-related licensing and sales. Proclamation No. 533/2007 on Broadcasting Service, along with the Ethiopian Food and Drug Authority, empowers the Broadcast Authority to license broadcasters (TV and radio), print media, and advertising agencies, among other entities and enforces compliance with tobacco advertising violations.

The 2021 Tobacco Control Directive issued by EFMHACA governs, among other things, smoking restrictions, tobacco advertising, tobacco packaging and labeling, and product regulation, and repeals the 2015 Tobacco Control Directive.

The proclamation forbade the promotion or advertisement for tobacco in any way, whether indirect or direct. The rule does not, however, apply to legal forms of expression that are recognized by the FCTC Art. 13 Guidelines and that might be mistaken for advertising, including trade newsletters, legitimate journalistic or artistic expression, among others. Sponsorship of tobacco products in any way, including financially, is not allowed. Rotating text and visual health warnings must cover 70% of the front and back of the packaging for tobacco products. It is illegal to put deceptive phrases on packaging and labels, such as "light" and "low tar," among other things.

The law restricts certain components of cigarettes, including the prohibition of distinct flavors, components that give the impression of having health benefits, and components linked to vigor and energy. Manufacturers and importers are required by law to provide government agencies with information about the components and emissions of their products.

The sale of tobacco products online and within 100 meters of health care, educational, and youth-serving facilities is illegal. The law also forbids the sale of shisha, single cigarettes, and tiny packets of cigarettes. It is prohibited to sell tobacco products to anyone under the age of 21.Any interior public area, workplace, and any form of public transportation are off-limits to smoking and the use of any tobacco product. Additionally, smoking is not permitted in the outdoor areas of government buildings, youth facilities, amusement parks, and other places.

Anywhere that forbids smoking; it is illegal to create a designated smoking area. Smoke-free legislation may be passed by subnational jurisdictions that are stricter than the national law.

Based on this, last year, Mrs. Heran Gerba launched the campaign to rid Addis Abeba of tobacco smoke, and work with the relevant stakeholders got underway.

The primary importance of creating a smoke-free environment is to protect citizens from becoming secondhand smokers, to reduce morbidity and mortality from secondhand smoke, to encourage smokers to quit, and to decrease the number of new smokers.

In the initiative, workspaces, which are inward from doorways, in-door public gatherings, public utility vehicles, and other places of public assembly, are the main areas and it requires measures to protect people from tobacco smoke.

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Ms Heran Gerba, Director General of EFDA When awarding companies with certificates of recognition for going smoke-free in the workplace.

The reason why the initiative focused on Addis is because it is the capital of the country and the seat of diplomats, and this cooperation will have a positive impact on accelerating tobacco control at the national and regional levels in addition to identifying and correcting the gaps in the implementation of the tobacco control proclamation.

A task force consisting of the Ethiopian Food and Drug Control Authority, Addis Ababa Food and Drug Control, and civil society organizations (Mathews Wondu Ethiopian Cancer Society, Meqoamia Community Development Organization and HDAMA) has been established. Addis Ababa Food Medicine and Health Care administration and Control Authority is taking the coordination role.

Bole and Arada, two sub-cities, were selected as demonstrations. A baseline assessment was conducted in six selected woredas (districts) of Bole (2, 3 and 4) and Arada (1, 4 and 10) sub-cities woredas. Bars, restaurants, youth centers, government offices, health facilities and schools were included in this survey.

Inspection of the distribution of visual anti-smoking materials, day and night joint control to monitor the work progress bars, restaurants, and pubs was conducted twice in the sub-cities. Weekend night inspections of bars, restaurants and nightclubs have all been found to be in violation of the law. Awareness raising was also done during the control period and the districts/ cities continued to strengthen tobacco control in the remaining districts as well as various administrative penalties were imposed on those found violating the law (verbal warnings, written warnings, fines, temporary packing and some were prosecuted). The cooperation to make Addis Ababa city free from tobacco has been evaluated at different times, which was coordinated by the Ethiopian Food and Drug Control Authority.

Some selected hotels with three or more star ratings have been monitored day and night, and now 80% of the hotels have created a smoke-free hotel. Additionally, popular media and organizations have been involved in creating awareness about creating a tobacco-free environment.

Illegal tobacco products were collected and exhibitions were organized in the main public squares, awareness was given in a way that reflected the many health, social, economic and environmental impacts of tobacco.

Hundreds of smoke-free facilities were created that can serve as models for other facilities. In addition, tobacco control was carried out as part of the regular work of the school and the work of sharing good practices with other sub-cities.

A few months ago, the city administration launched a motto of "Smoke Free Addis Ababa" with the aim of making all public and work areas within the city 100% smoke free. As part of the Smoke Free Addis Ababa Initiative, which is coordinated and monitored by EFDA, additional other sub-cities were included as part of the initiative, which means the smoke free initiatives have been implemented in the whole city. During the pilot projects of the initiative, having strong legislation and enforcement mechanisms in place, the commitment of top management and wisely and properly using the limited resources are a good experience that was remarkably achieved. The challenges in the implementation include awareness of law enforcement officers and investors, the presence of chronic smoking conditions at night and weekends, hiding information during inspection, gaps in the implementation of law in all institutions, appearance of inspectors' misconduct, lack of resources and lack of multi-stakeholder cooperation are the major challenges the initiatives has been faced.

Meanwhile, the initiative tried to solve those problems by facilitating ongoing awareness forums, day and night time inspection strengthening. Proclamation 1112/11 will be implemented in a uniform manner in all public utilities, strengthening multi-stakeholder cooperation, conducting evaluation meetings attended by all stakeholders and encouraging stakeholders to include tobacco control in their annual work plans.

The following strategies helped the initiative excel the project:

- Expanding or enhancing the initiative to create a smoke-free environment that was started in two sub-cities (Arada and Bole) in the remaining 9 sub-cities, development or expansion in 3 districts of each sub-city, continue to the rest of the districts, identify civic associations working at the district level and involve them in tobacco control.
- Organizing awareness forums for law enforcement agencies, health extension workers, women's and youth associations, hotel and restaurant owners and managers, Health and Education Sectors on the harm of tobacco and incorporating the Proclamation in the curriculum and controlling tobacco advertisements and display at point of sale.

Among the tasks that must be done continuously include informing the city administration, sub-city and district leaders about the initiative to create a smoke-free environment, strengthening the coordination of tobacco control task force in Addis Ababa city administration, printing and distributing no-smoking stickers, brochures and posters, promoting the initiative by involving the media, controlling the wholesale and distribution of illegal tobacco and reporting and evaluating monthly performance.