EFDA's laboratories medical glove quality-testing receives ISO/IEC 17025: 2017 accreditation

The Ethiopian Food and Drug Authority's (EFDA) medical glove quality-testing laboratory and food quality and safety testing laboratory have received the ISO/IEC 17025: 2017 accreditation at the event held on August 16, 2023, and on June 27, 2023, respectively. Different initiatives have been undertaken to modernize the previous laboratories in terms of size and quality by providing the needed resources to organize the laboratory with cutting-edge laboratory equipment at different levels as well as building the capacity of the staff engaged in the process.

Speaking at the event, Minister of Health, H.E. Dr. Lia Tadesse, stated that building a laboratory to test the quality and safety of medical materials is one of the main tools that the Authority can use to ensure the quality, safety, and efficacy of medicines.

She also added that the Medical Glove Quality Testing Laboratory's ISO/IEC 17025:2017 accreditation would raise the prestige of the Authority's laboratory to an international level of acceptance.

H.E. Dr. Lia thanked the leaders and employees of the Authority as well as partners, USAID and Promoting the quality of medicines plus program, for their contribution in playing a significant role in raising the quality of service delivery in the health sector and safeguarding community health.

During the event, EFDA's Director General, Ms. Heran Gerba, said the Authority is focusing on becoming a center of excellence in Africa in the 10-year plan by strengthening the control by the duties and responsibilities given by Proclamation 1112/2019. She recalled that the medicine facility inspection had been accredited a year before by ISO/IEC.

At the end of the event, a certificate of recognition was given to the department heads, employees, partners, and others who contributed to the medical glove quality-testing laboratory's success.

IMPORTANT MESSAGE

The authority is focusing on becoming a center of excellence in Africa in the 10-year plan to strengthen the control sector in accordance with the duties and responsibilities given by the proclamation 1112/2019.

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

The EFDA's food quality and safety testing laboratory accreted under ISO/IEC 17025: 2017

The Ethiopian Food and Drug Authority's (EFDA) medical glove quality-testing laboratory and food quality and safety testing laboratory have received the ISO/IEC 17025: 2017 accreditation at the event held on August 16, 2023, and on June 27, 2023, respectively. Different initiatives have been undertaken to modernize the previous laboratories in terms of size and quality by providing the needed resources to organize the laboratory with cutting-edge laboratory equipment at different levels as well as building the capacity of the staff engaged in the process.

Close collaboration among stakeholders to ensure food safety

On June 27, 2023, World Food Safety Day was celebrated with the theme 'Food Standards Save Lives' at the event held in EIilly Hotel, Addis Ababa, which urged close collaboration among stakeholders to ensure food safety.

On the opening remark, EFDA's General Director, Ms. Heran Gerba, states that the food safety problem is becoming a health issue not less than malaria and HIV. She said that to address the problem, the food chain system from farm to shops should be given attention to ensure that the food reaches the consumer in a quality and safe way.

Ms. Heran pointed out that, the Authority is working on a food strategy to prevent health problems caused by food safety. She called upon the relevant stakeholders to work together to fulfill their responsibilities by following a quality production system and strengthening the control work to ensure food safety.

Unsafe and substandard foods harm people's health and well-being. During the event, it stated that we have to ensure that foods are not contaminated with pathogens, chemicals, drug residues, and foreign objects.

June 30 is Food Safety Day declared by the World Health Organization, which is celebrated this year for the 5th time internationally and the 4th time in Ethiopia. During the event, different research papers were presented and discussed among the participants.

EFDA annual meeting with regional health regulatory bodies

From August 31 to September 1, 2023, EFDA conducted an Annual Planning meeting with regional health bureaus in Adama. The meeting aimed to evaluate the performance of the 2015 EC and align the plan for the 2016 EC fiscal year implementation.

Oromia Health Bureau Head, Dr. Mengistu Bekele, in the opening said, that although there have been many successful actions to increase access to health services at the national level, it is important to coordinate for controlling the circulation of illegal health products caused by natural and man-made problems.

Dr. Mengistu said that the challenges facing to control of health products also relate to health professionals' ethical issues in being involved in illegal activities. However, the authority has provided a great deal of assistance to bureaus to control illegal health products, and measures has taken to detain the products, sealing companies and making them prosecuted.

During the event, EFDA's Director, Ms. Heran Gerba, urged all the regional health regulatory bodies to support the efforts of the Authority in moving to maturity level three of the World Health Organization.

Ms. Heran stressed different measures have been taken to dry the problem from the source and control of illegal food and health products. She also added that action should be taken against individuals and institutions involved in illegal food and health supplies trafficking through rapid information exchange and coordination efforts.

The Authority's Deputy Director General of the Food Sector, Mr. Negash Seme, on his part, urged the regional health regulatory bodies to work effectively to get support from the regional leaders in the regulatory system.

In addition, EFDA's Deputy Director General of the Pharmaceutical Sector, Mr. Seyum Wolde, said during the meeting that, a coordinated system between the regions and stakeholders is essential to make the regulatory work effective in routine activities.

Electronic Regulatory Information System (eRIS) implementation in Ethiopia: Its challenges and recommendations

By Abraham Kssaye

The Ethiopian Food and Drug Authority (EFDA) is responsible for regulating and controlling the safety, quality, and efficacy of food, drugs, medical devices, cosmetics, and other related products in Ethiopia. To improve its regulatory processes and enhance transparency, the EFDA has implemented an Electronic Regulatory Information System (e-RIS) which DHA supported its implementation.

The eRIS is an online platform designed to streamline the registration and licensing procedures as well as the monitoring and inspection activities of the EFDA. It allows stakeholders, such as manufacturers, importers, exporters, and healthcare professionals, to submit applications and requests electronically, eliminating the need for manual paperwork and reducing administrative burdens.

The main features of the e-RIS include:

Online application submission: Stakeholders can submit applications for product registration, licensing, and other regulatory approvals through the eRIS portal. The system provides a user-friendly interface for filling out application forms and attaching supporting documents.

Document management: The eRIS stores and manages all relevant documents electronically, including product dossiers, lab reports, and manufacturing certificates. This ensures easy access and retrieval of information when needed.

Review and approval process: The system enables EFDA officials to review applications and conduct necessary inspections and assessments. They can track and manage the progress of each application through an online workflow.

Communication and collaboration: The eRIS facilitates communication between EFDA and stakeholders through the portal. It allows stakeholders to ask questions, seek clarification, and receive updates regarding their applications without the need for physical meetings or telephone calls.

Monitoring and surveillance: The system also supports post-market surveillance activities, allowing the EFDA to track the safety and quality of registered products. Adverse event reporting, product recalls, and market surveillance activities can be managed through the eRIS platform.

Overall, the Ethiopian Food and Drug Authority's Electronic Regulatory Information System (e-RIS) aims to improve efficiency, reduce bureaucracy, and enhance transparency in the regulatory processes of food and drug products in Ethiopia. It facilitates easy and secure access to regulatory information and services, benefiting both the authority and stakeholders involved in the food and drug sector.

The Ethiopian Food and Drug Authority (EFDA) Electronic Regulatory Information System (eRIS) faces several challenges and gaps. Here are some of them:

Limited access to technology: The adoption of eRIS requires infrastructure such as internet connectivity, computers, and software. However, in Ethiopia, there is limited access to technology in some regions, hindering the successful implementation of eRIS.

Lack of digital literacy: Many regulatory stakeholders, including small-scale food and drug producers, lack the necessary digital literacy skills to effectively use eRIS. This poses a significant challenge in achieving widespread adoption and utilization of the system.

Insufficient training and awareness: Adequate training and awareness programs for the stakeholders are essential for the effective implementation of eRIS. However, there is a lack of comprehensive training programs targeting all stakeholders, resulting in limited understanding and utilization of the system.

Inadequate data management and quality control: eRIS relies on the collection, management, and analysis of large amounts of data. However, there are challenges in data management and quality control processes, leading to inaccuracies and gaps in information within the system.

Limited integration with other systems: eRIS should ideally be integrated with other

existing systems, such as drug registration and manufacturing systems, to ensure seamless flow of information. However, there are gaps in integration, resulting in duplication of efforts and inefficiencies.

Security and data privacy concerns: eRIS deals with sensitive information related to food and drug regulatory processes. Therefore, ensuring adequate security measures and data privacy provisions is critical. However, there may be gaps in security protocols and mechanisms to protect data from unauthorized access and breaches.

Limited stakeholder engagement: The successful implementation and utilization of eRIS require active engagement and participation from all stakeholders, including government agencies, food and drug producers, and consumers. However, there may be challenges in engaging all relevant stakeholders and obtaining their buy-in to effectively use the system.

Addressing these challenges and filling the gaps in the EFDA Electronic Regulatory Information System will promote efficiency, transparency, and effectiveness in food and drug regulatory processes in Ethiopia.

To address the challenges and gaps the following recommendations can be considered:

- **Improve technology infrastructure:** Efforts should be made to enhance internet connectivity and provide necessary hardware and software to ensure broader access to eRIS. This may involve opening of internet room at the head quarter of EFDA as well as in the branch offices.

- **Digital literacy training:** Conduct comprehensive training programs to enhance digital literacy among stakeholders. This can include workshops, seminars, and hands-on training sessions on how to effectively use eRIS. Customized training modules should be developed for different user groups, focusing on their specific needs and capabilities.

- **Increase awareness:** Launch targeted awareness campaigns to promote eRIS and its benefits among all relevant stakeholders. This can include advertisements, informational materials, and public forums to engage food and drug producers, government agencies, and consumers in understanding and utilizing the system.

- **Strengthen data management and quality control:** Implement robust data management practices and quality control mechanisms within eRIS. This can involve regular audits, validation checks, and data cleansing processes to ensure accuracy and reliability of information. Developing clear standard operating procedures for data management within eRIS is also essential.

- **Enhance integration with other systems:** Collaborate with other relevant agencies and organizations to integrate eRIS with existing systems, such as eTrade, electronic single window (ESW), custom's data base, and other systems which are operated by consumers associations. This will streamline processes, reduce redundancies, and ensure seamless flow of information between different systems.

- **Address security and data privacy concerns:** Establish stringent security protocols to protect data within eRIS from unauthorized access and breaches. This can involve encryption, access controls, regular security assessments, and compliance with data protection regulations. Implementing data privacy policies and obtaining informed consent from stakeholders for data sharing can also enhance trust in the system.

- **Foster stakeholder engagement:** Actively engage relevant stakeholders, including government agencies, food and drug producers, and consumers, in the development and implementation of eRIS. This can be achieved through regular communication channels, participation in decision-making processes, and soliciting feedback to continuously improve the system based on user Special attention should be also given for consumers to enable them directly access the information from the eRIS system. The eRIS system lacks this feature.

By implementing these recommendations, EFDA can overcome the existing challenges and gaps in eRIS, leading to a more efficient, transparent, and effective regulatory information system for food and drugs in Ethiopia.

Tobacco smoke free initiative in Ethiopia

Special Guest

The Addis Ababa Tobacco Smoke-Free Initiative since it started in 2021, is a campaign aimed at creating a smoke-free environment in Addis Ababa. The initiative focuses on raising awareness about the dangers of tobacco smoke and advocating for the implementation and enforcement of smoke-free policies.

The primary objective of the initiative is to protect the health and well-being of the residents of Addis Ababa by reducing exposure to secondhand smoke, promoting a healthier lifestyle, and preventing tobacco-related illnesses. It aims to create smoke-free public spaces, such as restaurants, bars, and government buildings, as well as public transportation and outdoor areas.

The initiative involves collaboration between various stakeholders, including government agencies, non-governmental organizations, health professionals, and the public. Key activities of the initiative include educational campaigns, community engagement, and policy advocacy.

Educational campaigns focus on raising awareness about the health risks associated with tobacco smoke, both for smokers and non-smokers. These campaigns use various communication channels, such as mass media, social media, and community events, to reach a wide audience and promote smoke-free behaviors.

Community engagement activities involve working closely with local communities to promote smoke-free policies and practices. This includes conducting workshops, training, and seminars to educate community members about the benefits of living in a smoke-free environment and empowering them to actively support the initiative.

Policy advocacy efforts aim to influence policymakers and lawmakers to implement and enforce smoke-free policies. This involves conducting research, providing evidence-based recommendations, and working with relevant authorities to develop and implement effective smoke-free regulations and laws.

Overall, the Addis Ababa Tobacco Smoke Free Initiative strives to create a healthier environment for the residents of Addis Ababa, protect them from the harmful effects of tobacco smoke, and reduce the overall prevalence of tobacco use in the city.

In this edition, we invited Ms. Heran Gerba, Director General of the EFDA, who is the creator and supporter of the initiative designed to make Addis Ababa smoke-free, as a special guest. She gave us a general explanation of the initiative.

Ms Heran Gerba, Director General of EFDA

EFDA Voice: How did the initiative started and being implemented to free Addis Ababa from tobacco smoke?

Ms. Heran: The origin of the initiative is proclamation 1112/19 issued in January 2019 which is a food and Drug Administration proclamation. It is a special proclamation in different ways. The proclamation has taken into consideration the articles or provisions of the framework convention for tobacco control which has strong restrictions It states different public places that must be 100% tobacco smoke-free and smoking is not allowed within 10 meters distance from the outside door of those public places. Before the implementation of the initiative, enclosed smoking areas used to be permitted, which are now prohibited. Seventy percent of tobacco labeling or packaging should contain health warnings, whereas before it had only 30% written warnings. Following the proclamation, 70 % of health images and warnings in the cigarette packages have been implemented. Provisions has conducted to control the sale of tobacco to youth and children under the age of 21. It is expected that the proclamation will be strong, but in terms of enforcement, subsequent strong legal frameworks should be issued. Since the regional regulatory bodies carry out the enforcement, their capacity should be strengthened in terms of human resources and budget. We monitor and evaluate regional performances regularly. Senior leaders also actively participate in the enforcement of the proclamation process.

Tobacco control is not the responsibility of one institution. One of the duties and responsibilities of our office is to coordinate tobacco control activities throughout the country. Many components contribute to the control outcome. For example, all government institutions should be free from tobacco smoke. The activities are a joint implementation and it is not satisfactory when we evaluate the implementation of the proclamation with the senior leaders of the relevant institutions. Even if there are reports submitted regularly it is challenging to reach every institution in the country at once. So, we work differently in Addis Ababa, to set it as an example for other regions. Addis Ababa is not only the capital of Ethiopia, but also the capital of Africa with various international institutions.

In addition, it is an initiative designed by the Authority in 2021 with the involvement of the Addis Ababa Food, Drug and Health Care Administration and Control Authority, aiming to build the image of the city. Since we are working in collaboration with other institutions including the civic associations to implement this initiative, , they have been making significant contributions in the process of approving the proclamation and its implementation. It started with the principle to start the implementation in some areas, and step by step expand it to create a huge revolution. When the implementation started in Addis Ababa, we focused on Bole and Arada sub-city which has many target places like health facilities, schools, bars and restaurants, hotels and cafeteria.

Following the selection of target places, a survey was conducted in randomly selected woredas and serves as a base for a strategy that has been set to be implemented by the government and private sectors. The initiative started with different awareness-raising programs and recognitions were also given to the institutions that committed to implementing the initiative and bringing change.

Currently, the Addis Ababa City administration is fully engaged and owned the implementation of the initiative in the Addis Ababa City. In addition, institutions such as schools, law enforcement, police, trade, health offices should take responsibility and play their own part for the implementation of this initiative

EFDA Voice: What are the actual results of the initiative? What efforts are being made to convey accurate information?

Heran: The results of this initiative should be monetized. However, the main harm of tobacco is that it is the cause of lung or respiratory organ cancer and other non-communicable diseases. What makes it costly is that it doesn't affect only smokers but also second-hand smokers. Studies show, one-third of tobacco-related deaths worldwide each year are related to second-hand smoke.

It has also economic costs for a country due to its effects. For example, cancer and other diseases related to tobacco require long-term treatments. Currently in Ethiopia, the spread of infectious diseases is mostly more than 50 %, which is a major health need of the growing society. Therefore, increasing the number of needs

will triple the pressure. Through reducing the spread of tobacco, we can also minimize its impact on people's health which also reduces a cost in the health sector. According to the Global Adult Tobacco Survey, the number of smokers has decreased in Ethiopia which is close to 5 % of the population which is still a large number when it compared to the total population.

This year, we received a report from each region that shows more than 64,000 institutions have been free from tobacco smoke. This is a huge success and we will consider continuous monitoring and evaluation systems on the effectiveness of the implementation.

EFDA Voice: What is being done to remind every citizen to ask for their right not to smoke tobacco through a social movement?

Heran: Despite changes in society's understanding of regulatory institutions, there is still a gap.

The awareness-raising platform was cost-effective since it was designed not only for tobacco smoke free initiatives but also for food and medicines safety packages. We have seen society collaborate with the Authority in law enforcement. For example, during some campaigns, there were cases where unsafe products were reported and action were taken. However, there is a gap in terms of informing society about the actions taken in illegal products.

Moreover, flavored and electronic cigarettes are illegal and banned from being sold in the country.

The illegals often smuggle sell these cigarettes to attract new smokers. We include all those details in the awareness program.

Continuous awareness-raising activities have to be done to create culture in a society to be curious about using different products by considering its health effects. Media and schools will also play significant roles and we will continue using them in the awareness program.

Especially, through using different platforms like mini media and social media, it is important to engage students in the effective implementation of Tobacco smoke-free initiative. Continuous activities should take place to involve different stakeholders and the community to create firm awareness about the effects of Tobacco.

EFDA Voice: Can you tell us about the results and best practices that have been obtained from the initiative?

Heran: In tobacco control, the World Health Organization (WHO) has given recognition to Ethiopia five times at the individual and institutional level. These recognitions show how the country has worked a lot which is also proven by the WHO evaluation. On the 2021 WHO's tobacco worldwide publication, it was mentioned that Ethiopia is making changes in Tobacco control. We have strong laws at the international level and need effective work and collaboration in its enforcement.

Areas that should be 100% free from tobacco smoke are actually 100% free. Ethiopia has passed a strong law that should be recognized and can be considered as an example to other countries.

Apart from that, when we started this initiative, one of the challenges of tobacco control was that many stakeholders had a role to play. Stakeholders have

formed an alliance and created a strong framework of cooperation. In terms of implementation, every institution has its own responsibility with a priority. Therefore, there were many challenges in putting this on the agenda. The effectiveness of bringing different stakeholders together for one agenda was the main lesson learned from the initiative.

Another thing that needs to be mentioned is the involvement and commitment of the management in general. Especially, the management of Addis Ababa City administration, from top to bottom, is handling this issue effectively and in a coordinated way. The first thing they did was to create their own institutions free from tobacco smoke as government and be an example to others.

Moreover, it was important to support sustainable solutions through public mobilization, starting from educating the community to involving the private sector in particular. It was important to provide training to the managers of the companies working around cafeterias and restaurants to create awareness and to involve them in the control system. However, appropriate and educational measures are being taken for those who do not obey the law. Therefore, I would say that if the regional states take this experience and implement it, good results will come in the future throughout the country.

> **Tobacco is the cause of general problems related to respiratory organs.**
> Ms. Heran Gerba, EFDA Director General,