EFDA
የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን
ETHIOPIAN FOOD & DRUG AUTHORITY

# EFDA VOICES

EFDA NEWSLETTER • AUGUST 2022 •

A MONTHLY NEWS LETTER PUBLISHED BY ETHIOPIAN FOOD AND DRUG AUTHORITY

## IN THIS ISSUE

**Article ·1·**
Ethiopia Food and Drug Authority celebrated the formal launch of the institution's new brand

(PAGE 1)

**Article ·2·**
The authority reported that throughout the 2014 fiscal year, their efforts to keep illegal food and medical supplies under control were encouraging.
(PAGE 2)

**Art icle ·3·**
EFDA operational heads and employees tree planting in various area of Addis Ababa
(PAGE 3)

**Article ·4·**
The Authority donated medicine, sanitary products, and medical equipment totaling nearly 12 million Birr to a number of NGOs
(PAGE 3)

**Article ·5·**
Journalists are urged to do their share to safeguard society against unregulated food trade and unsafe foods
(PAGE 4)

**Article ·6·**
World No Tobacco Day was celebrated for the 30th time in our country and the 35th time in the world with the motto "Tobacco is a big threat to us and our earth"
(PAGE 4)

**SUCCESS STORIES**
(PAGE 5)

# The Ethiopian Food and Drug Authority celebrated thelaunch of its institutional new brand

State Minister of Health his excellency Dr. Dereje Duguma delivered his message at the launching ceremony on July 7,2022, held at the Skylight Hotel, stating that the new brand prduced by the Authority will allow it to advance to the desired level and foster public ownership of the rules governing food and health products.

The state minister also urged the public to follow the different directions given by the authority and to help promote and create a fresh image of the Authority, in addition to reporting on regulation activities.


Ms. Heran Gereba, General Director of the EFDA, during her introductory remarks stated that the major objective of developing the new brand is to uphold the Agency's proclamation by creating a new logo, names, and identity to maintain the institution in the minds and hearts of the community.

In this regard, the authority has created a brand using a research-based, scientific process, through a consulting firm, which is now being publicly introduced. She emphasized the authority's vision of becoming an African center of excellence for food and health product regulation would be realized with the support of the new brand.

Dr. Dereje and Ms. Heren presented certificates of appreciation at the conclusion of the ceremony to those who contributed ideas, knowledge, and funds, either directly or indirectly, to the branding effort.

> "The **Authority's vision of** becoming an African center of excellence for food and health product regulation would be realized with the support of the new brand."
>
> **Ms. Heran Gereba**, General Director of the EFDA

## IMPORTANT MESSAGE

The new Brand produced by the Authority will allow it to advance to the desired level and foster public ownership of the rules governing health and health products.

## 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 Authority reported that throughout the 2014 fiscal year, its efforts to keep illegal food and medical supplies under control were encouraging.

The safety monitoring and control of medications, including the COVID vaccine, reorganizing the food laboratory to begin various tests, overseeing food safety and implementing corrective measures, launching a smoke-free project at the Addis Ababa level, and integrating the community in cooperation with stakeholders were accomplished in the aforementioned year. The Authority has taken over and begun working with all city administrations, managing illicit food and health items, and making illegals to be legally responsible, according to the Authority's Director General, Ms. Heran Gerba, said the Authority has been taken over and started working by all city administrations, control over illegal food and health products and holding illegals accountable by law.



Director General added that communication work is being done, the institution is being digitized, social responsibility is being prioritized.

At the end of the evaluation program, presented the results that came from a market survey of food, medicine, medical devices, cosmetics, and tobacco using the existing laws and protocols to punish the illegals; which showed remarkable results, however this is insufficient. Ms. Heran urged the participants in the upcoming fiscal year to coordinate their efforts and strengthen the focus placed on prosecuting and punishing entities and people involved in the circulation of illegal food andmedical supplies.

The evaluation of the execution of the Authority's 2014 fiscal year plan, which lasted two days, was successfully completed by strengthening coordination procedures, creating effective controls around food, health products, and other controlled products that cause health harm, and reminding them to take responsibility for preventing health issues that may happen to the public in advance.

In her closing remarks, said that the next fiscal year, 2015, goals will be achieved by strengthening institutional development, working in accordance with strategic plans, basing operations on savings; establishing waste-free and continuous operations with excellence; continuing to and resolutely combating theft and corrupt practices. She made it clear that should work assiduously to create an institution that is outstanding.

**Communication work is being done, the institution is being digitized, social responsibility is being prioritized.**

# EFDA operational heads and employees planted trees ṅvarious areas of Addis Ababa.

The EFDA management team and employees contributed to the green legacy campaign by implementing an organization -wide planting campaign. The event was hosted on July 13,2022 at Abebech Gobena Maternal and Children's Hospital in Ayat, as well as the Woreda,2 thirty-five field and youth center in Kirkos sub-city.


Approximately 2,000 fruit-bearing seedling trees were planted during the occasion, and the employees agreed to care for them until they produced the desired fruits.

Since the campaign's inception four years ago, the authority's staff members have contributed to the green legacy initiative by planting seedling trees each year.

## The Authority donated medicine, sanitary products, and medical equipment totaling nearly 12 million Birr to a number of institutions

In accordance with its social responsibility, the authority has donated food, clothing, medical supplies, and other materials five times this year to the Ministry of Defense, hospitals, NGOs, and war victims.

and distributors of food, medication, medical supplies, and

Cosmetics. At various times throughout the year, the Authority's highest officials presented the donation to the group representatives.

The organizations also expressed their gratitude for the assistance theyreceived and noted that it arrived at the right time.

# Journalists are urged to do their share to safeguard society against illegal food trade and unsafe foods

A training was organized in Adama on June 24 and 25, 2022, addressing guidelines for food advertising, illegal food trade, mixing food with foreign substances, infant food and iodized salt control guidelines and precautions, as well as the role of media.

On June 24, 2022, Ato Negash Sime, the Deputy Director General of the EFDA, officially opened the training, stating that in order to effectively control the distribution of unsafe food and illegal food; it needs for a coordinated action. In particular, journalists should use their creative skills to inform the public about the risks associated with using unregistered foods.

**In order to effectively control the distribution of unsafe food and illegal food, there should be a need for coordinated action.**

The speaker went on to say that, we want the media to have a stronger role in safeguarding the country's future generations by collaborating with the government to inform the public about the problems relating to the quality andsafety of infant food.

Ato Negash says that some food advertisements exaggerate and imply that a product contains components that it does not, which poses a risk to the public.

In order to reinforce the authority's control system for maintaining public health, Dr.Tegene Regassa, Director of Public Relations and Communications for the Ministry of Health, urged the media professionals to help raise public awareness. Additionally, Dr. Tegene emphasized the need for media experts to concentrate on the job of informing the public about illegal food trafficking and unsafe foods.

## World No Tobacco Day was celebrated for the 30th time in our country and the 35th time in the world with the motto "Tobacco is a big threat to us and our earth"

The World Health Organization stated that tobacco use not only damages one's health but also ruins 3.5 million hectares of forest, releases 84 million megatons of carbon dioxide into the atmosphere, and significantly contributes to global warming in its information about this year's No Tobacco Day theme.

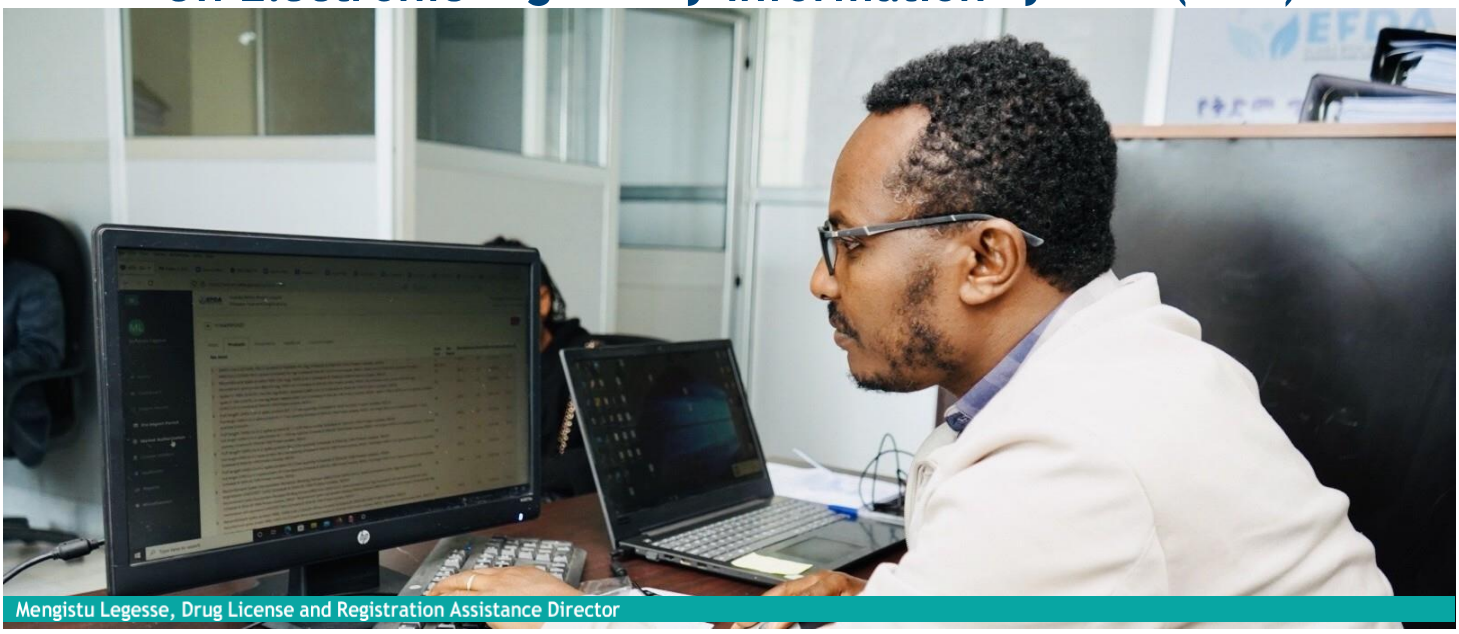
When the day was commemorated with a panel discussion, EFDA Deputy General Director Negash Seme noted that the majority of tobacco production currently takes place in developing countries. He asserted that it is preventing the expansion of agriculture. Various tobacco-related educational papers were also presented and discussed throughout the panel discussion.



According to the World Health Organization, smoking causes the deaths of 1.2 million passive smokers each year and 8 million individuals annually. In order to hold producers accountable for the costs associated with the effects of tobacco products on the environment, the economy, and people's health, Mr. Negash urged the government, policymakers, and other institutions to strengthen the law, including the implementation and strengthening of current guidelines, regulations, procedures, and plans.

# SUCCESS STORIES

## On Electronic regulatory information system (eRIS)



Mengistu Legesse, Drug License and Registration Assistance Director

**EFDA Voice:** Could you please clarify the difference between the old paper-based drug licensing and registration process and the new digital approach?

**Mengistu:** The two are exceedingly challenging to compare. I really appreciate the professionals working with hard copy documents, because it is impossible to forecast how long it will take to find a document and a document could even be lost. It is very difficult to even to put the documents in order. Therefore, the system has brought us significant development. Clients can now receive a queue number from the system itself, and the system will adhere to that number. We can also accurately determine who did which tasks, see who is overworked, and divide responsibilities accordingly.

Currently, we do our entire job digitally, which has simplified things and given us more time to enjoy our work. We have suggestions for improvements in a few areas, but overall it is an excellent system. Our customers can use the systems while relaxing at home. Whether a case is filed for approval or further information is needed, the system assists in tracking and responding to those requests. Moreover, I believe that the system has undergone a significant transformation.

**EFDA Voice:** How can the new digital online registration and licensing system help to boost customer numbers in addition to elevating consumer satisfaction?

**Mengistu:** The distinction is plain to see. With the manual system, you must perform everything from the office. The system is accessible from anywhere, online. If you like, you can work from home, this flexibility significantly boosts effectiveness. It also saves customer's time, as they will not need to travel to visit our offices. With data from the system, we are able to redistribute responsibilities from those with workloads to those without them, maximizing the use of time and skills. Operational effectiveness and efficiency result from this. This has a significant impact.

**EFDA Voice:** What conditions must be met before a client can access your services directory?

**Mengistu:** A client who seeks out our services must, primarily, have a legal personality. You must possess a Certificate of Competency. They must set up a warehouse and an expert for this, and the expert goes to the inspection department to checkit against the qualification certificate. After that, they sign an agreement with a third- party business to register a drug or product. We will get in touch with the absent local agency and foreign company after the deal is signed. The agent will then submit the technical quality document using the username and password provided, whether they are in this country or elsewhere. This document provides comprehensive information that traces the life cycle of a drug or food product. As soon as the document is delivered to us, we will screen it. Instead of closely examining the paper throughout this phase, it is reviewed to see if all the required documents have been submitted. The client will next be prompted to pay the screening and document evaluation. The document's eligibility for examination will then be confirmed, and experts can begin their evaluation if payment has been received. After that, the first assessor will pass it to the second assessor to see what the first assessor did not observe. Thegroup leader will be notified if something qualifies. If the document is qualified, the team leader makes his own judgment and delivers it to the director. However, if it does not meet the requirements, it will be sent back to the appraisers or the applicant. Finally, the director will approve it and the customer will receive a five-year market license from the authority.

**EFDA Voice:** How well equipped are the Agency's document reviewers?

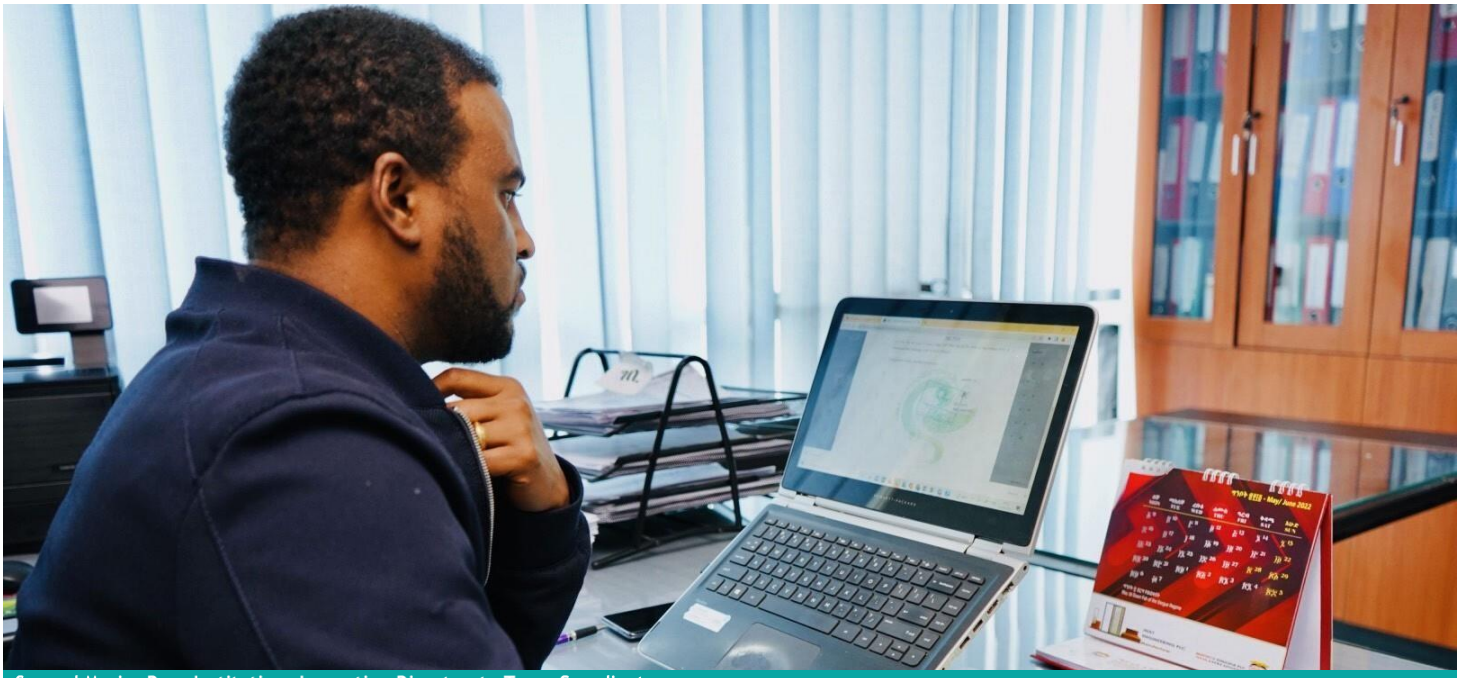
**Mengistu:** Human potential is growing and developing. There is no limit. The potential of our experts differ from expert to expert. We have experienced or senior professionals, there are also beginner professionals. We regularly organize meetings and provide capacity building training together with partner organizations. When we assign new experts to the first document, we are creating a situation where second evaluatorscan gain experience by assigning those with work experience. As we know, science constantly brings new things. There will be new things that come that we have never seen before, like the COVID-19 vaccine. As a result, new training and a new perspective are required. We are collaborating on this with partner organizations including the World Health Organization.

**EFDA Voice:** The drug license and registration takes place over the internet. How will you offer the service if the internet goes out?

**Mengistu:** All of us are concerned about this. We will fail if our stakeholders abruptly stop supporting us. It should be taken into account because we do not know what will take place. Our stakeholders have been helpful. Their employees are highly disciplined, and have a lot of talent, particularly the JSI staff. We willnot be able to maintain this level if they do not assist us. Because this system requires the Internet to function, it should not be stopped. The paper-based system is tedious and impractical and so we advise that the internet connectivity issue be given special focus, as an Institution.

**EFDA Voice:** What new or additional service would you recommend the system should provide?

**Mengistu:** There are things that have not been added to the system. For example, cosmetic notificationsare still done on paper. Sanitizers, disinfectants, low-risk medicine, etc. are not included in this system. For example, how many new molecules registered this year should be published separately/Sometimes the top management should issue the reports we need. These are easy features, which Ibelieve they will add soon.



Samuel Marie, Drug Institutions Inspection Directorate Team Coordinator

**EFDA Voice:** How do you see the prior and present inspections in the process of verifying the quality, safety, and effectiveness of medications?

**Samuel:** A significant disparity exists. The professional, the customer, office, and the nationall place a high value on it. Because it was quite challenging to go back and review when it was manual and most documents would be lost, whichcaused numerous issues. Beyond that, it was too difficult to enforce our regulatory framework because exercising control begins with giving permission and giving a group legitimacy. This implies that in order to grant licenses, a functioning licensing system must be in place. When it was manual, thelevel of difficulty was high. Only the viewer of thehandbook could see it at the time it was created,which also created a transparency issue. However, it is a system now. Many bodies, not just one, aregranted the right. There are other factors at play.When an inspection is necessary, it is presented tothe inspector, who approves it. It means it has many actors. In actuality, several authorized bodies arealso involved in this besides the directorate. This indicates that the licensing process is largely openand transparent. Documentation is a further vital component, as scans from the registry, legacy data is present. Therefore, even from the perspective of documentation, there is a significant difference.

**EFDA Voice:** What do you think about the new online system's effectiveness in terms of quality and efficiency?

**Samuel:** Although there is a delay in terms of speed, the applicants must submit supporting documentation. Due to the nature of the electronic format, it is occasionally possible for fake papers to be entered. It is more possible for inaccurate documents to be submitted remotely rather than in person. As a result, you can get documents that were not altered yet still did not fit the bill. The applicants' perspective is that the response is quite positive because they are able to apply remotely and obtain their license at any time and from any location. They come here to take their license. Occasionally, the inspection may be delayed because the inspection work is done by this directorate, which goes beyond merely granting consent. When there is a lot of work, there are often extra jobs and delays. Moreover, I would not say that it moves very quickly, since there are many elements. However, our system for certifying quality is open and responsible as it keeps track of when it was edited, screened, displayed, the date and time, and other details, it entirely widens accountability.I think that quality rather than speed of control is more important. As a result, the system has given us tremendous importance in terms of quality.

**EFDA Voice:** How does a client get started with the drug licensing application process?

**Samuel:** In the beginning, we tried to put the entire step by step system interface for the applicants on a printed paper, and use that to guide them. JSI staff here also provide support in food and drug inspection. Applicants create usernames and passwords to access their own systems. They fill the requirements on the system that forms the basis of our guide. The application will then be delivered to the team leader. The team leader gives the documents to the screeners. Thus, as a base office, an expert evaluates the sending of the completed and attached documents according to the requirements, and at the same time, an expert is assigned to perform inspection work at the institutions. The screeners report a fail or pass. If they say it is good, it will go to the applicant. The applicant will correct and send based on the comments given. If the screeners send a pass, the team leader will confirm. Then the team leader sends inspectors, but before the inspectors do an inspection, if they believe that the documents are not prepared according to the standards, then the team leader can return it. The team leader returns it to the expert who first screened it. All the inspectors go to the site with past documents and conduct inspections, it is electronic based. This is because I License is integrated with an application called ODK. Therefore, there are no checklists to go with the manual. It is on the system. I will generate a license barcode before they leave. It is meant for that unique application. After you scan the barcode, you go there and do an on-site GPS track, so you can integrate the GPS track checklist with the application you scanned. Then when you add it, it will immediately follow the inspection report to the system. After entering, the inspection will be passed or failed. If it fails, the team leader must return to the applicant. Because the applicant is not required to fill another questionnaire. That application needs to be fixed. If it passes the inspection, the team leader approves it and proceeds to issue a certificate.

**EFDA Voice:** How many people are served in a day?

**Samuel:** There is a person who takes a certificate. There is someone taking application information. There is someone asking for screen information. Maybe up to 50 people to be certified.

**EFDA Voice:** What do you think if this is added to the electronic information system?

**Samuel:** We face many things when we are at work. For example, this system only works in this central office. Professionals work elsewhere. For example, they work from any office that we do not control. Therefore, there will be correspondence with regional regulatory bodies working on the pharmaceutical sector. If possible, if the system embraces them, it will help us to improve our work. Because there are things we can do together. It would be good to include drug retail establishments as well. It would be good if they embrace the country by expanding the system. It would be nice if this could be improved.

**EFDA Voice:** What steps should be taken, in your opinion, to make the system sustainable?

Samuel: This job is funded. If the partner that supports us stops supporting this, there will be problems that may occur. Therefore, it is good to proactively do some work before then. For example, while the participation of the authority's IT experts in the system is preserved, it should already be considered to replace the experts of the partner organization on the system admin with the authority's IT experts.

**EFDA Voice:** What are customers saying about the system?

It is good. However, there may be elements in between that the system is not optimized for because this is web based. There are many people whoare used to manual and have difficulty coming to electronic. However, about 95 percent of applicants are very happy with the system. Now the applicant who comes either has no information or comes to take a certificate. Now the applicants have avoided coming here.

**EFDA Voice:** Thank you so much

**Samuel:** Thank you.