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ETHIOPIAN FOOD & DRUG AUTHORITY

EFDA VOICES

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A MONTHLY NEWS LETTER PUBLISHED BY ETHIOPIAN FOOD AND DRUG CONTROL AUTHORITY

IN THIS ISSUE

EFDA Received ISO/IEC 17020 Accreditation on Medicine and Medicine Facility

The Ethiopian Food and Drug Authority (EFDA) has achieved ISO/IEC 17020:2021 accreditation from the Ethiopian National Accreditation Office (ENAO). The Authority commemorated the award event held on March 10, 2022 at the Capital Hotel, Addis Ababa

EFDA's Director General, Heran Gerba, received the accreditation certificate from Areya Fesseha the General Director of Ethiopia Accreditation Service.

Dr. Teshome Ayele, State Minister of Health, Ministry of Health, opened the event saying *'The recognition brings great pride to the health sector, and also inspires other health activities to achieve similar recognition which will have global acceptance.'*

Heran Gerba, addressed the audience reflecting that:

> **"The Authority has been working over the last one year by completing various documents, while conducting training, to pass different auditing procedures."**

According to her, the accreditation will provide different benefits, including: managing impartiality and conflicts of interest; providing global recognition and great staff momentum; certifying the technical competence of people, processes and equipment; ensuring reliable equipment and results; cost savings and risk mitigation as well as improving trust and customer satisfaction.

Areya Fesseha, said on the occasion that the accreditation will stay for five years, but every year the performance will be followed and audited thoroughly. In case the authority does not follow the accredited rules, the service will take the accreditation without mercy.

The scope of the accreditation process is the medicine inspection process, including inspection of large scale medicine manufacturing facility; inspection of small scale medicine manufacturing facility; Inspection of medicines, import, export and wholesale; sampling and post marketing quality surveillance.

Previously, EFDA has received two international accreditation on medicine and condom laboratory.

IMPORTANT MESSAGE

The Ethiopian Food and Drug Authority (EFDA) has achieved ISO/IEC 17020:2021 accreditation from the Ethiopian National Accreditation Office (ENAO).

EFDA VISION

Quality health services and products to all citizens

EFDA MISSION

To promote and protect the public health by ensuring safety and quality of products and health service through registration, licensing and inspection of health professionals, pharmaceuticals food establishments and health institutions and provision of up-to-date regulatory information while promoting rational medicine use.

EFDA OBJECTIVE

To promote and protect the public health by ensuring safety and quality of products and health service through registration, licensing and inspection of health professionals, pharmaceuticals food establishments and health institutions and provision of up-to-date regulatory information while promoting rational medicine use

To establish and maintain an effective and efficient quality assurance, market authorization, inspection and licensing system.

To ensure the safety, efficacy and quality of medicines including complementary and traditional medicines

To ensure that food consumed is safe, quality, sanitary and free of contaminants

To standardize health services and protect the public from unqualified and unethical professionals and substandard health institutions

To ensure an uninterrupted regulatory information provision and promote Rational Medicines use

Launch of the Addis Ababa Tobacco Smoke-Free Initiative

March 22, 2022 at Capital Hotel and Spa, Addis Ababa

After a successful smoke-free initiative in the two sub-cities Bole and Arada Woredas, the Addis Ababa Food and Drug Authority announced that they have been working on creating smoke-free areas and healthy citizens across the city. Based on the best practices and this experience, the Authority started to scale up the initiative through the other nine sub-cities.

During the launch of the initiative, Saharala Abdullahi, the State Minister of Health, stated that the goal of the initiative is to protect residents from becoming passive smokers and to protect them from numerous tobacco hazards, as well as to encourage smokers to quit smoking and to reduce the number of new smokers.

On the event, the EFDA Director General Heran Gerba recalled that the Addis Ababa tobacco-free initiatives took a year, and she stated that EFDA has been strictly assisting and following up on the project from the beginning. Finally, she expressed gratitude to all of the government and non-government organizations that contributed to the project's success.

According to Heran, the tobacco smoke-free initiative in Addis Ababa is not the duty of a single entity, thus she urged law enforcement agencies such as the police and 'Denbmaskber', as well as the general public, to actively participate in the project's implementation.

Finally, she stated that the media plays an important part in creating and raising knowledge about the dangers of tobacco smoking, and that the general public should confidently say,

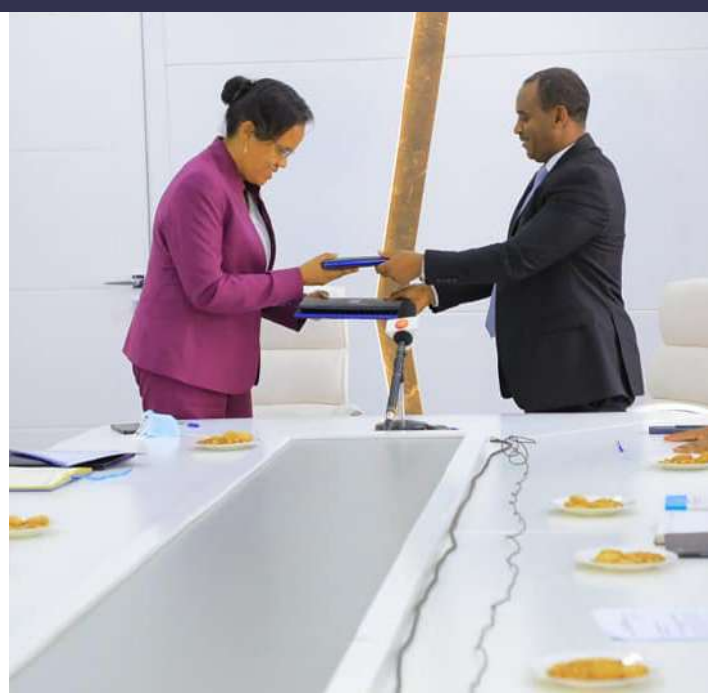
> **“Don’t smoke near me!”**

At the end of the half day event, Saharala Abdullahi and Heran presented a certificate to the four model hotels that have successfully restricted smoking-free areas.

MOU Signed Between EFDA and the Ethiopian Media Authority to Regulate Advertising on Health Regulatory Items

The event took place at the Ethiopian Media Authority office on March 23, 2022.

Heran Gerba, Director General of the Ethiopian Food and Drug Authority, and Mohammed Endires, Director General of the Ethiopian Media Authority, signed the agreement of understanding.



The purpose of the memorandum of agreement is to create a platform for authorities to execute their power, duties, and obligations through information exchange, lawmaking, awareness creation, and law enforcement.

In light of these considerations, the memorandum of agreement will ensure that the public's health is protected by preventing false or misleading advertisements on food, medication, and other regulatory product.

EFDA's Six Month Execution Plan of 2014 E.C Budget Year

Adama City, February 21-22, 2022.

In her introductory remarks, Heran Gerba, stated that the evaluation should be focused on the primary operations, which include the second-year strategic plan target, and that it would be used for the future track.

During the two-day meeting, personnel from the main office team, including team leaders, directors, the six branch heads, and the 17 port inspection coordinators, presented and discussed the authority's 2014 physical execution plan and each directorate's execution plan in detail.

Despite the fact that the authority faced numerous hurdles during the year, Heran asserts that the authority achieved amazing results in all health regulatory efforts.

During the meeting, the authority revealed that the regulatory body had awarded import permits for 18.7 billion Birr in medicine and 7.7 billion Birr in medical supplies in the previous six months. Similarly, after examination, 1.2 million tons of food and 3.6 billion birr worth of cosmetics and sanitary equipment were allowed to enter the country.

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The Authority also disposed of 6 billion birr in non-compliant pharmaceuticals and 25 million in medical supplies, as well as 648 thousand ton of food and 609 thousand birr in cosmetics, as well as illegally imported and sub-standard products that could potentially harm people.

Meanwhile the authority also has registered 1916 foods and provided market authorization for 519 medicines. While 176 new medicines which fulfilled the criteria have been given a certificate of competence regarding inspection, 457 medicine inspection and 720 food institutions Inspection also undertaken by the authority.

Media Professionals Received Training on the Regulation of Health Items

In his introductory remarks, Getu Bogale, East Ethiopia EFDA Branch Head, stated that the Eastern part of the country is especially vulnerable to illegal food trades due to the long boarder's lose control. As a result, in order to manage these unlawful food trades, media professionals should be aware of the issues and consequences of illegal foods that have an impact on public health. He also stated that in order to address the difficulties, we must collaborate with the media.

According to Remedan Eberahim, the Harari region's head of health and health-related regulation, media professionals will be trained on meals, pharmaceuticals, cosmetics, and cigarettes, allowing them to educate the public based on the information gained from the training.

Media professionals from the city administration of Dire Dawa, Harari, and Somali areas participated in the two-day training. The media's involvement in child food standards, iodized salt regulation and use, illegal food trade, media role, alcohol advertisement rules, food registration, food adulteration and tobacco control were all given and addressed in depth.

6th Ethiopian Health Exhibition and Congress

Ethiopian Skylight Hotel, 03-05 March 2022, Addis Ababa

Prana Events organized a three-day event on Ethiopia's top healthcare, medical, pharma, and wellness technology, inputs, and solutions trade exhibition, which attracted over 3000 participants. Ethiopia's largest multidisciplinary Professional Development (CPD) gathering, the Ethio Health Congress, provided a perfect platform for stakeholders operating in the country to debate diverse concerns across the whole health care value chain. The congress intended to provide practical solutions to the healthcare system in order to address the ever-increasing demand for clinical services and hospital resources as a result of the country's rapid economic development.

At the exhibition, the Authority promoted the Electronic regulatory information systems (eRIS) as well as other mobile applications such as i-verify and AEFI, which are critical in moving the health information system from manual to digital.

The event included the whole healthcare value chain, including medical, pharmaceutical, wellness, and cosmetics. This exhibition drew almost 80 exhibitors from ten different countries.

Ethiopia's Medicine and Medicine Facility Inspection Process Achieved ISO/IEC 17020:2012 Accreditation

The Ethiopian Food and Drug Authority is a national regulatory body established by the government through the Definition of Powers and Duties of the Executive Organs of the Federal Democratic Republic of Ethiopia Proclamation No. 1263/2021 and mandated to regulate medicines through the Food and Medicine Administration Proclamation No. 1112/2019.

In Ethiopia, there are currently 12 large-scale manufacturers, 80 small-scale manufacturers, 776 importers, and 738 wholesalers with licenses. Pharmaceutical establishments that manufacture, import, and distribute medicinal items in Ethiopia are licensed and inspected by the Authority. The Authority uses a variety of legal frameworks and science-based tools, such as standards, guidelines, and procedures, to carry out its inspection tasks. It also utilizes the Electronic Regulatory Information System (eRIS), a web-based application processing technology that allows the EFDA to manage and facilitate the licensing and inspection of importers, wholesalers, and manufacturers.

The Ethiopian National Accreditation Office (ENAO) has granted accreditation to EFDA to perform sampling and inspection in the field of medicines and medicine facility inspections in compliance with the requirements of ISO/IEC 17020:2012, Conformity assessment - General Requirements for the operation of various types of inspection bodies. The accreditation demonstrates the technical competence for the defined scope and operation of an inspection body's quality management system. While this certificate is valid, the authority's inspection reports and/or certificates will be accepted all over the world.

SCOPE OF THE ACCREDITATION

The scope of the accreditation process is medicine inspection process which includes:

- Inspection of large scale medicine manufacturing facility
- Inspection of small scale medicine manufacturing facility
- Inspection of medicines, import, export and wholesale
- Sampling and post marketing quality surveillance

MOTIVATION FOR ACCREDITATION

Accreditation is becoming more widely recognized around the world as the most transparent and non-discriminatory mechanism for ensuring an entity's operational competency. Regulation of medication is critical for all health systems and access to safe and quality medicines, including biologicals and vaccines. Regulatory bodies that work well provide trustworthiness, impartiality, consistency, and confidence in their inspection efforts in addition to assuring the quality, safety, and efficacy of medications. This necessitates adherence to international standards for inspection operations acceptability and recognition. In light of this, the EFDA has been trying to reach the maturity and functionality required by applicable international standards.

JOURNEY FOR THE ACCREDITATION

The Authority has been working over the past five years to standardize its medicine inspection methods in accordance with worldwide norms. In 2016, the initial steps toward implementing the ISO/IEC 17020:2012 requirements were taken. Since then, new procedures and documentation have developed. By 2020, a well-organized development and implementation of the ISO/IEC 17020:2012 quality management system had begun, and an application for accreditation had been submitted in March 2021. In October 2021, ENAO conducted an external audit. After correction of all the con-conformances identified, the medicine inspection process was accredited and awarded the accreditation certificate on February 21, 2022 by ENAO.

Because of excellent leadership, commitment, and buy-in from all employees, the EFDA was able to earn certification for its medicine inspection procedure.

KEY BENEFITS OF THE ACCREDITATION

- **Manage impartiality and conflicts of interest:** provides reliable and impartial basis for sound decision making.
- **Global recognition and momentum:** ensure quality inspection process and competition.
- **Technical competence of people, processes and equipment:** enables to build trust for the judgments of the authority during the inspection processes and results.
- **Reliable equipment and results:** provides better guidance and control for equipment maintenance and inspection records, which leads to unbiased, properly judged, and impartial inspections results.
- **Cost savings and risk mitigation:** reduces the need for re-work, thus reducing time and money during inspections.
- **Trust and customer satisfaction:** ensures impartiality and consistency in the inspection activities. It increases customer confidence on the inspection process, quality and safety of products and services, and the reliability of end results.

ACCREDITATION PROVIDER: ETHIOPIAN NATIONAL ACCREDITATION OFFICE (ENAO)

TYPE OF INSPECTION BODY: TYPE A

FACILITY ACCREDITATION NO: IB0013

EFFECTIVE DATA: 21 FEB 2022

EXPIRY DATE: 21 AUG 2026

THE LAST 6 MONTHS' PERFORMANCE REPORT

JULY 8, 2021- JANUARY, 8 2022

18.7
Billion Birr worth of medicine imported after inspection

Illegal medicines worth more than
6
Million Birr have been banned from usage

Imported more than
1.2
Million Tons of food, after inspection

Granted import license cosmetics worth
3.6 Billion Birr

Banned
609
Thousand Birr worth of illegal cosmetics unfit for human consumption

720
food institutions post-license inspection has been undertaken

7.7
Billion Birr worth of medical devices imported, after inspection

More than
25
million birr worth of illegal medical device banned from use

In a laboratory investigation of adulteration, 119 out of 225 sample food products were found to be unfit for human consumption

More than
648
Thousand Tons of illegal food been declared unfit for human consumption

374
after consignment quality tested (5 of them are not qualified)

Collected
382
reports on Adverse Drug Reaction

1,916
Registered Foods

519
Medicines licensed for the market

Post-licensing inspections have been completed for
457
medical institutions

176
new drugs have been approved and have received a certificate of competency