OCTOBER 2024

NEWSLETTER
EFDA VOICE

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.

2016 Plan Implementation Evaluation Meeting of Food and Health Products Regulatory Sector Successfully Concludes

The Ethiopian Food and Drug Authority held its 2016 Plan Implementation Evaluation Annual Meeting for the Food and Health Products Regulatory Sector on August 29-30, 2024, in Diredawa City, setting key control plans to be implemented in the 2017 fiscal year.

During the event, Director General Heran Gerba highlighted significant progress in taking decisive action against offenders and improving the consistency of federal and state reporting methods, allowing for more effective handling of major issues. She emphasized the need for all regulatory bodies to work with greater focus and intensity, particularly in areas related to corruption, good governance, crime prevention, system development, and communication.

Heran also announced that the World Health Organization (WHO) would conduct another evaluation in November, aiming for the authority to reach WHO Maturity Level 3. She called on regional regulatory bodies to continue strengthening their efforts in preparation for the evaluation.

Dr. Sharmarkey Sharif, Deputy Director General of the Medical Devices Sector, noted plans to provide additional training in collaboration with regional bodies to prevent resource wastage and address safety concerns caused by malfunctioning medical devices through proper repair and use.

Ato Negash Semie, Deputy Director General of the Food Sector, stressed the importance of addressing gaps in good governance with accurate information and establishing accountability.

He also urged regulatory bodies to work closely with stakeholders and called for stricter oversight, particularly over establishments involved in packaging and selling unrefined edible oils at the village level.

Ethiopia is actively participating in a partnership and cooperation initiative with other countries to facilitate the operationalization of the African Medicines Agency (AMA) at the continental level.

To establish the African Medicines Control System (AMA), the Evaluation of Medicinal Products Technical Committee (EMP-TC) has been formed under the coordination of the African Union Development Agency (AUDA-NEPAD). This committee is working towards implementing effective systems for medicine regulation across Africa.

Mrs. Seble Shambel, lead executive officer of Drug Evaluation and Market Licensing at the Ethiopian Food and Drug Authority, announced that experts from Ethiopia participated in the First Continental Dossier Assessment Plenary Session held in Durban, South Africa, from July 22-26, 2024. During this international conference, crucial medications for the continent, including vaccines and cancer treatments, were evaluated and discussed, with plans for on-going assessments of additional drugs.

Five pharmaceutical experts from the authority represented Ethiopia at the event, where they exchanged knowledge and experiences. They reviewed evaluation reports provided by EMP-TC and emphasized that this initiative will bring significant change to the continent and lay the groundwork for the AMA.

Mrs. Seble highlighted that the conference aims to advance the vision of delivering quality, safe, and effective medicines at affordable prices across Africa. By harmonizing and improving the continental system, countries can share best practices, enhancing the quality and safety of medicines available to the public.

The conference head noted the importance of collaboratively reviewing complex drug documents to ensure safety, encouraging countries to create a network that strengthens the entire continental drug control sector.

The African Drug Control System Partnership and Cooperation Initiative promote regional development cooperation, with 28 countries, including Ethiopia, having signed on to it. This initiative serves as a precursor to the establishment of the African Medicines Agency.

The Ethiopian Food and Drug Authority has announced that capacity-building trainings are being provided to regional regulatory bodies in preparation for the 2017 fiscal year.

The Authority reported that training sessions were conducted for 436 food and health inspection inspectors from the regions and the two city administrations. Strengthening the capacity of health inspection bodies at all levels is crucial for effective implementation in the food and health inspection sector. The authority emphasized that the capacity-building efforts for regional inspectors will continue as planned.

In the current fiscal year, the goal is to enhance the capabilities of health resource inspectors, utilizing the experience and knowledge gained from the training. This will aid in preventing and controlling illegal food and health products that pose risks to public health.

At the end of the 2016 fiscal year, a training-of-trainers program was conducted, leading to training at the district level. As part of the training for regional supervisory bodies, 436 supervisors have received training in food and health resource control, with on-going training efforts planned for the preparation phase of the 2017 fiscal year.

The Authority has announced plans to develop a technology-driven system to monitor drugs imported from abroad until they reach the end user.

On August 8, 2024, the authority signed a memorandum of understanding with Medical Value Chain (MVC), a provider of drug distribution monitoring technology, to initiate this regulatory work.

Following the agreement, the authority's director general, Heran Gerba, shared that the agency has studied the experiences of other countries in implementing technology for drug distribution monitoring. She noted that there will be no costs incurred by the trainees, as expenses will be covered by the agreement between the technology supplier and the drug manufacturing companies.

The director general emphasized that the technology supplier must adhere to international standards. She also mentioned that the authority will closely monitor operations once the initiative begins.

Additionally, it was revealed that the drug distribution monitoring system has been installed at the authority and is currently under its control.

The Authority conducted practical training for food control experts following the implementation of compulsory standards for the development of edible oil and wheat flour at the national level.

On August 9, 2024, in Adama City, this capacity-building training aimed to address the significant lack of essential nutrients in food products nationwide. The training informed food manufacturers, importers, and distributors about the requirement to enrich edible oil with vitamins A and D and wheat flour with vitamin B complex and zinc.

Ato Wossenyeleh Ambaw, the executive officer of the authority's food quality and safety inspection division, opened the training by highlighting its importance. Participants learned about national legal frameworks for food fortification, food sampling methods, and the processes for fortifying edible oil at the factory level.

The training also included practical instruction on using the Eyecheck Chroma, a rapid diagnostic tool to ensure that cooking oil is fortified with vitamin A. This will facilitate the implementation of the Sri Tire system testing plan, a strategic initiative of the authority.Food inspectors from the headquarters, regional offices, and branch offices participated in this two-day training session.

African Traditional Medicine Day Celebrated in a Warm Atmosphere

On September 6, 2024, the Ethiopian Food and Drug Authority celebrated African Traditional Medicine Day in Addis Ababa under the theme "Providing Quality and Safe Traditional Medicine Treatment with Appropriate Control Methods."

Director General Heran Gerba addressed attendees, highlighting that the Authority has commemorated Traditional Medicine Day on August 31 every year since 2003. She noted that many African Union member countries have integrated traditional medicine into their education and health systems, leading to a significant increase in its use, which doubled between 2012 and 2020.

The Ethiopian Food and Drug Authority has established a legal framework and approved registration and technical guidelines for various traditional medicines in collaboration with stakeholders. Gerba announced plans to register six traditional medicines this year that meet quality, safety, and healing standards.

Ato Regasa Baissa from the Ministry of Health shared that efforts are underway to ensure that 10 percent of the seedlings planted in the country consist of medicinal plants, thereby enhancing their availability as part of the country's green development strategy.

Dr. Bijoy Nambiar, a representative of the World Health Organization, emphasized that Ethiopia is home to a rich diversity of traditional medicinal plants.

The management team of the Authority has initiated home renovation efforts as part of its winter charity service.

On July 25, 2024, Director General Ms. Heran Gerba, along with other government officials and the Authority's management team, participated in renovating homes for the underprivileged in Kirkos Sub-City, Woreda 2. This initiative is part of the on-going 2017 Winter charity service, with both the authority's staff and woreda executives collaborating to support the community.

In related news, the Authority provided essential medical support to those affected by the recent landslide in the Gofa Zone. On July 26, 2024, in Addis Ababa, Director General Heran Gerba delivered medicines and medical supplies worth over 500,000 Birr to Mrs. Aster Desalegn, CEO of Woreda 2, Kirkos Sub-City. Mr. Gerba expressed condolences to the victims and pledged ongoing support. Mrs. Aster thanked the authority for its prompt response and commitment to the community during this challenging time.

Under the motto "Green footprint is an action that will survive for generations!", a tree-planting event was held at Alert Comprehensive Specialized Hospital and Armauer Hansen Research Institute. Leaders and employees from the Ministry of Health, along with representatives from key institutions, participated in the program.

Additionally, on August 13, 2024, employees and leaders of the Authority participated in the annual tree-planting program at Danse Primary School in the Lafoto Keraniyo sub-city, Woreda 14.

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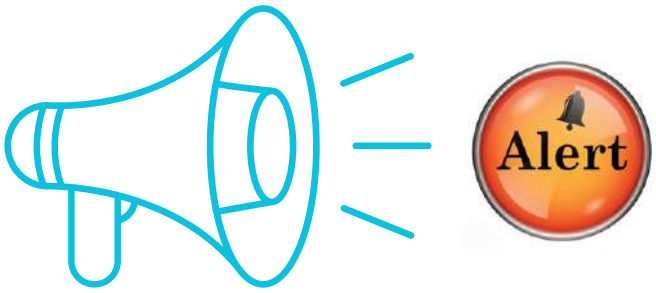

Public Alert

Misuse of Medicines and Unregistered Product Found in the Market

The Ethiopian Food and Drug Authority (EFDA) is issuing this combined alert to address two important issues: the misuse of medications due to misinformation on social media and the identification of an unregistered product in the market. The EFDA, under Proclamation No. 1112/2019, is committed to safeguarding public health by ensuring that medicines meet quality, safety, and efficacy standards, and by monitoring and regulating their use.

Misuse of Prednisolone on Social Media

Recently, the EFDA has observed a concerning trend on social media involving the inappropriate use of certain medications. Proper use of medicines is crucial for achieving desired therapeutic effects, but incorrect use—especially for conditions they are not meant to treat—can lead to significant harm. This is especially true for prescription drugs, which must be used under the careful supervision of healthcare professionals.

One such drug being misrepresented online is Prednisolone. This medication is intended for treating inflammation, allergies, asthma, and other medical conditions. However, false information is circulating, claiming that Prednisolone is effective for hip and general obesity, which is entirely incorrect. Such misinformation poses serious health risks.

The EFDA urges the public to be cautious. Taking Prednisolone without a doctor's prescription and supervision can result in severe health complications, potentially even death. The risks are scientifically proven, and the authority stresses the importance of using this medication only under medical guidance.

Unregistered Artemether 80 mg/ml Injection Found

During a recent market survey, the EFDA identified an unregistered product, Artemether 80 mg/ml injection, Batch No. 231104SPF, with a manufacture date of 11/2023, supplied by Shinepharm, China. Laboratory testing confirmed that the product did not contain Artemether, the active ingredient as labeled. This product is therefore ineffective and unsafe for use.

As a result, the EFDA advises health professionals not to use this medicine. Additionally, regional inspectors are directed to closely monitor their areas and take appropriate actions to prevent the distribution and use of this unregistered product.

Special Guest

Ato Abayneh Alemayehu, Chief Executive Officer (CEO) of the Ethiopian Food and Drug Authority (EFDA)

EFDA Voice: What is the rationale for establishing the Excellence Center?

Ato Abayneh: This Project (HRCoE) enhancing regulatory harmonization initiative and advance in pharmaceutical and food technology as well as national security issues in relation to food & bio terrorism are some of the points to give good reason for the significance of the complex building center.

Hence, it is proposed to establish the center which contains food, medicine and medical device laboratories, multipurpose training center, management offices, and conference halls. The design takes in to account the safety and chemical waste management advanced systems, with possible future expansions.

The above mentioned facts justify that the anticipated public satisfaction cannot be realized without achievement of the targets of such stretched objects of safety and quality assured health products; which are expected to contribute to better health sector outcome and economic growth of the country. Furthermore, the problem of safety and quality of food and health products results in public health hazard.

Therefore, strengthening the regulation of food and health products is one of the critical and contemporary issues.

The establishment of the center will have political, social and economic impact for the country. It will enable the country to cope up with the advancing science and technology, compete with the international market, and effectively protect the public from health risks emerging from adulterated, poisoned and/or poor quality food and medicine. Moreover; the success of this project undoubtedly provides best benchmark for the regulation sector nationally whereby other national & international regulatory authorities or similar firms, local food & pharmaceutical industries and higher teaching

institutions/universities can get services on fee basis and perform collaborative projects/researches that can strengthen national food, medical device, Vaccine & medicines quality assurance system and serve as income generating scheme for the country.

EFDA voice : What is the scope of the project?

Ato Abayneh : The main purpose of this project will primarily be to transform the public health protection system of the national regulatory sector through improved capacity and competency while serving as a training center for other regulatory authorities in the region. It will deliver the major functions:
Quality Assurance Testing Services

- Provide QC testing services (food, medicines, vaccine, in vitro diagnostic products, medical devices & traditional medicines)
- Participate on evaluation of investigation new drugs
- Prepare & distribute chemical working standards for domestic industries & neighboring countries
- Conduct accelerated stability tests (especially for food industries) on fee basis
- Serve as proficiency test scheme collaborating

EFDA Voice: What types of work will the center undertake in Research and Development?

Ato Abayneh : The center will play crucial role in designing and coordinating Food & health product regulatory system strengthening operational researches in collaboration with research institutes, Universities, industries and other relevant organs (at national & international level). Possible areas of such research are;

- Analytical method development especially for traditional medicine
- Evaluation of Investigation new drug
- Survey based research in relation to regulation of food & health products
- Research activities in clinical trials, Pharmco-genetics, biotechnology, bioethics, and nanotechnology, and other emerging new technologies
- Product development with domestic food and pharmaceuticals manufacturers
- Develop various regulatory model tools
- MSc and PhD researches in collaboration with universities with special emphasis given to regulatory staff development for practical application

EFDA: What types of training services will be provided by the center?

Ato Abayneh : The training packages designed in such an away to fill gaps between theoretical concepts and skills required by regulators in day to day operations. The proposed skill developments short term trainings for regulators and laboratory personnel include; but not limited to:

- Regulatory Sciences training
- GMP inspectors training
- HACCP Inspectors training
- Quality Management System(QMS) trainings
- Quality Control/Advanced Analytical/ techniques...etc

These training will be designed on modular basis in collaboration with domestic and overseas higher teaching institutions and the trainees might be staffs of federal, regional regulatory bodies, food industry, pharmaceuticals industry, universities. The training center will be designed and constructed in such a way to serve as multipurpose institution for accommodating national & international training, workshops and conferences for regulators, MoH, other national institutions & international organizations (WHO, USP etc). It may also provide catering and accommodation services for trainees, for trainers (invited domestic & overseas professors)

Therefore, the major focus of the center will be Food, medical device, vaccine and medicines quality control laboratories which are the backbone for proper functioning of regulatory authorities.

Since the establishments of laboratories requires considerable capital investment and by are expensive to maintain and operate, careful planning is necessary to achieve optimum results. These proposed roles of the center to be established, is in line with Ethiopian government policies & strategies with a great support of World Bank. For instance, the Health Policy clearly indicated the need for "Developing quality control capability to assure efficacy and quality of products" as one of the subsections of strategies.

The following National Drug policy 1993 also addresses that "Drug quality standards shall be set"; and "Government operated quality control laboratories will be established both centrally and regionally". Proclamation 1112/2019 Section 4 subsection 6 also mentioned organizing center of quality control laboratories as needed to carry out its duty; as one of the powers and duties of the executive organ. EFDA secured center of sited land before two years at Akakiy kality sub city, Addis Ababa and the number of the laboratories it will determine in relation to the objectives of the system and the volume of work.

EFDA Voice: Who are the beneficiaries of the project?

Ato Abayneh : This project will have a substantial benefit for national and regional (Eastern Africa) citizens, food, medical device, cosmetics and medicine manufacturers, importers and exporters, foreign manufacturers sending their product to the country, and other national, regional and international stakeholders are direct project beneficiaries mentioned in the stakeholders analysis part.

EFDA Voice: What inputs are required for the project?

This project is intended to strengthen the regulatory sector through multi- dimension of capacity building activities for the coming three years to make a regulatory sector in order to build the regulatory confidence for safeguarding the citizens and to take part its roll for fulfillment regulation activities and to take part its roll for fulfillment of the SGTP and FHRSTP II. Therefore, the project encompasses the elements of the constriction buildings , regulatory capacity training & education as well as the development different research outputs and procurement of office materials and vehicles. The summery of inputs required are annexed (Annex 1).

EFDA Voice: What are the Project Outcomes?

Ato Abayneh : The Project outcome will be:

- Strengthened the country capacity to protect citizines and the region from food and medicine related health problems
- A center that gives solution to all national issues related to food, medical device, vaccine & medicines quality assurance as well as emerging public health risks.
- Strengthened ability of Regulatory professionlas on product testing, analysis, data management and inventery management system
- Increment of types of food and medicine analysis
- Fully acredetated food and medicine laboratory
- Strengthened confidence of consumers, food and medicine traders
- Foreign currency savings as a result of decrease of patients from food and medicine quality and safety problems
- Improves the psycological costs of citizines encoured as a result of health problems that will come from using unsafe food and medicine products
- Public protection against unsafe and poor quality products (food and medicine)
- Satisfied Quality Assurance need of the country
- Self-sufficient and model center of Excellence that can serve as food & medicines quality assurance related research ,training & testing services provider the country and the region (Africa)
- A center that produces national regulatory expert pool
- Motivated international investment flow into the country
- Strong collaborative network among neighboring countries and meeting the future African Medicine Agency (AMA) laboratory testing need

EFDA Voice: What is the project budget breakdown plan for the years 2016 to 2018 E.C.?

Ato Abayneh : The construction will be constructed on phase based in this regard the 1st phase Construction of building HRCoE laboratory budget were funded by world bank which is under construction and Procurement of laboratories equipment's and supplies office Furniture, Utilities Purchase under progress of the tender the Constriction of Building of HRCoE Training Center will continued