JANUARY 2025

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.

Delegates from IGAD, ECSA, and the World Bank visited EFDA's Centre of Excellence

On November 21, 2024, delegates from IGAD, ECSA (East, Central, and Southern Africa Health Community), the World Bank, and the Ethiopian Ministry of Health visited the Centre of Excellence at the Ethiopian Food and Drug Authority (EFDA).

During the warm welcome, EFDA Director General Heran Gerba underscored Ethiopia's pivotal role as the cradle of humanity, stating, "Ethiopia is your home, and you are always welcome." She highlighted that once completed, the Centre of Excellence will not only benefit Ethiopia but also support neighboring countries and IGAD member states.

The facility, including 257 quality testing laboratories, marks a significant advancement in tackling the continent's diverse health challenges.

She expressed her appreciation for the organizations contributing to its development. Engineer Berhanu, representing the Ministry of Health, updated visitors on the project's progress, noting that construction has been completed on all three buildings, with finishing touches now underway.

Dr. Karim Wanga, speaking on behalf of IGAD, praised the initiative as "a crucial asset and a foundation for the healthcare systems in the region." Similarly, Dr. Julian Simon from ECSA commended the EFDA's leadership, stating that the Centre will position Ethiopia as a model for other African nations. This achievement underscores Ethiopia's commitment to advancing healthcare innovation and fostering regional collaboration.

Ethiopian Drug Quality Testing Laboratory Expands Services to African Countries

Addis Ababa, October 18, 2024 – The Ethiopian Food and Drug Authority (EFDA) announced that its drug quality testing laboratory is conducting quality testing for various African countries, alongside testing for locally produced and imported drug products.

The laboratory, recognized for its commitment to ensuring the safety, quality, and efficacy of medicines, holds an ISO 17025 accreditation certificate and has been audited by the World Health Organization (WHO) for Maturity Level 3, achieving a score exceeding 97 percent. As part of its efforts to safeguard public health, the laboratory is performing quality tests on drug samples from IGAD member countries, Mozambique, and Guinea.

These samples include medicines for HIV, family planning, and other therapeutic needs.

Atlaw Abate, EFDA's Head Executive, emphasized that ensuring the safety of medicines is a key mandate of the authority. He highlighted the laboratory's critical role in identifying harmful substances such as ethylene glycol, diethylene glycol, and nitrosamine impurities, which should not be present in medicines.

"Our mission is to protect society from the risks associated with unsafe medicines by conducting rigorous quality tests," Atlaw stated, reaffirming EFDA's dedication to upholding drug safety standards both nationally and regionally.

EFDA Evaluates Progress toward Achieving International Maturity Level-3 in Pharmaceutical Regulation

Addis Ababa, October 25, 2024 – The Ethiopian Food and Drug Authority (EFDA) conducted an evaluation of its efforts to achieve International Maturity Level-3 in pharmaceutical sector regulation, engaging regional regulatory bodies and health inspectors in the process.

Speaking at the opening of the evaluation forum, EFDA Director General Heran Gerba emphasized the importance of reaching Maturity Level-3 at the national level. She noted that following an audit conducted by the World Health Organization (WHO) on June 23, 2024, eight recommendations for improvement were identified.

Heran highlighted that the achievement of Maturity Level-3 requires a coordinated approach involving EFDA, regional regulatory bodies, and stakeholders.

. "This comprehensive audit system demands collaboration and planning from all parties. We must work together to complete the necessary adjustments," she stated.

The Director General commended the progress made in quality management by regional health regulatory offices, while urging them to diligently address the remaining tasks. She underscored that achieving Maturity Level-3 will ensure consistent access to safe, high-quality, and effective medicines for the Ethiopian population.

The forum marked a significant step in EFDA's commitment to strengthening its regulatory framework and aligning with international standards.

Stakeholders Discuss Revision of Food Importer, Exporter, and Distributor Control Guidelines

Addis Ababa, October 17, 2024 – A discussion forum was held to review and update the Food Exporter, Importer, and Distributor Control Guide No. 357_2021, which has been in effect since 2021.

Opening the forum, Girma Tefera, Head of the Food Sector Desk at the Southeast Addis Ababa Branch, highlighted the Ethiopian Food and Drug Authority's (EFDA) commitment to modernizing its guidelines to align with current needs and standards. He explained that the discussion was organized to gather feedback from stakeholders and ensure that the revised guidelines address the evolving demands of the sector.

During the session, Freselam Yosef from EFDA's Legal Services presented the draft revised guidelines. This was followed by an in-depth discussion, where participants shared their perspectives on critical issues they believe should be incorporated into the updated guidelines.

The forum provided a platform for exporters, importers, wholesalers, and other stakeholders to contribute valuable insights, ensuring the revised guidelines support both regulatory objectives and the needs of the food sector.

EFDA partners with Addis Ababa University Health Science College Black Lion Specialized Hospital to Enhance Tobacco Packaging Warnings.

The Ethiopian Food and Drug Authority Partners with Addis Ababa University Health Science College Black Lion Specialized Hospital to Enhance Tobacco Packaging Warnings.

The Ethiopian Food and Drug Authority (EFDA) has signed a memorandum of understanding with Addis Ababa University Health Sciences College Black Lion Specialized Hospital to develop public health warning texts and color pictograms for future tobacco packaging.

During the agreement signing on December 26, 2024, Dr. Sharmarke Sherif, Deputy Director General of the Medical Equipment Control Sector, highlighted the significance of Proclamation No. 1112/19.

This legislation mandates 70% color health warnings on cigarette packs, aiming to inform the public about the severe health risks associated with tobacco use and encourage smokers to quit. Dr. Sherif also noted that the current imported warnings have shown limited effectiveness, necessitating a new approach tailored to local needs.

Addis Ababa University Health Sciences College, Black Lion Specialized Hospital Clinical Services Director, Dr. Abdurazaq Ahmed, on his part, promised that his institution will make the necessary efforts to reach the target goal by increasing public awareness of the visual and written health warning messages on tobacco packaging.

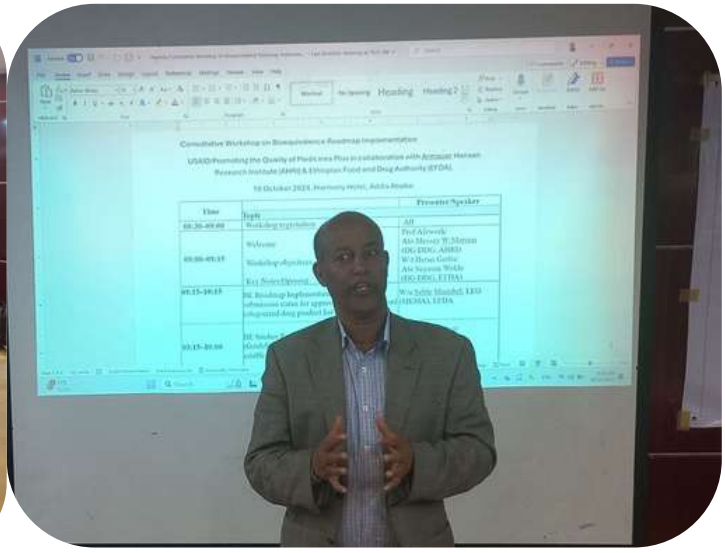
Wondu Bekele, Director General of the Mathiwos Wondu-YeEthiopia Cancer Society, urged that health warnings be continuously issued and designed in a way that informs not only current smokers but also those considering smoking.

This partnership represents a critical step toward strengthening tobacco control in Ethiopia by implementing impactful and locally relevant health warnings.

Local Drug Manufacturers Engage in Discussions on Bioequivalence Roadmap Implementation

Addis Ababa, October 16, 2024 – The Ethiopian Food and Drug Authority (EFDA), in collaboration with the Armauer Hansen Research Institute (AHRI), held a consultation forum with local pharmaceutical manufacturers to discuss the implementation of the National Bioequivalence Roadmap. The initiative aims to ensure the quality, safety, and efficacy of drugs in Ethiopia.

The forum, organized by EFDA in partnership with AHRI, was opened by Seyum Wolde, Deputy Director General of EFDA's Pharmaceutical Sector. In his remarks, Seyum emphasized the importance of local drug manufacturers submitting bioequivalence research findings for their products. He noted that incorporating these findings into market licensing processes would significantly enhance regulatory effectiveness.



Seyum also stressed the need for a standardized system to apply bioequivalence test results uniformly to both imported and locally produced drugs. He highlighted EFDA's alignment with recommendations from the World Health Organization (WHO) and the issuance of various guidelines to enforce bioequivalence research findings for domestically manufactured pharmaceuticals.

During the forum, local manufacturers presented action plans and implementation strategies. These efforts have been developed in collaboration with USP/PQM Plus, a program dedicated to strengthening pharmaceutical quality systems.

The consultation marks a key step in advancing Ethiopia's pharmaceutical sector, ensuring that local production meets international standards for drug quality and safety.

EFDA Opens Daycare Center to Support Employees' Children

Addis Ababa, October 21, 2024 – The Ethiopian Food and Drug Authority (EFDA) has inaugurated a new daycare center at its Southeast Addis Ababa branch to support employees by addressing childcare challenges during work hours.

During the inauguration ceremony, EFDA Director General Heran Gerba underscored the difficulties employees, especially mothers, faced in balancing work and childcare. Many had been forced to take extended leave or resign due to the lack of childcare options. She stated that the new daycare center is a significant step in solving these problems, providing much-needed support for health professionals and caregivers.

Heran also announced EFDA's ongoing construction of a Center of Excellence on government-allocated land in the Kaliti area. This facility will feature workspaces, a training center, and a permanent daycare center, offering a sustainable solution to employees' childcare needs.

Speaking at the event, Solomon Amede, Executive Director of Competence and Human Resources, noted that the Federal Government Workers' Proclamation No. 1064 mandates all federal offices to establish childcare facilities. He highlighted that the daycare center would benefit the 36 female and 11 male employees with children under the age of three, significantly easing their childcare concerns.

This initiative demonstrates EFDA's dedication to creating a supportive and inclusive workplace for its staff.

Assessment of Laboratories' Capacity for Trans Fatty Acids Testing Disclosed

A comprehensive evaluation of the capacity of nine laboratories to test industrially produced trans fatty acids has been conducted. This assessment aims to identify existing gaps in testing capabilities and strengthen regulatory measures to enhance food safety in Ethiopia.

The laboratories assessed include those at Addis Ababa University, Jimma University, Haramaya University, the Ethiopian Food and Drug Authority (EFDA), the Ethiopian Public Health Institute (EPHI), the Ethiopian Conformity Assessment Enterprise (ECAE), Bless, and JIJE LaboGlass.

The findings underscore the need to address identified gaps, foster stronger collaboration and coordination among stakeholders, and enhance support from development partners. These efforts are focused on equipping laboratories with the necessary resources and capabilities to perform trans fatty acids testing effectively, thereby upholding and improving food safety standards nationwide.

Study Report Paves the Way for Market Authorization of Traditional Medicines

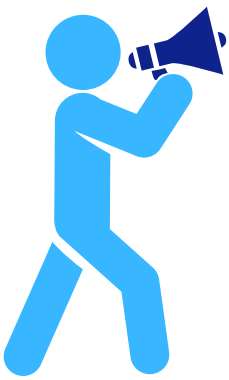
December 31, 2024, Ethiopia is home to a wealth of plants with the potential to serve as raw materials for traditional medicines. In light of this, the Ethiopian Food and Drug Authority (EFDA) has been conducting extensive research in collaboration with key stakeholders to facilitate the production and timely delivery of these medicines to patients.

At a discussion forum held in Adama city, the study findings were presented to relevant stakeholders. Speaking at the event, Ato Feyera Lejisa, from the Authority, emphasized the critical role of traditional medicines in strengthening Ethiopia's healthcare system. He highlighted the Authority's commitment to registering these medicines in line with rigorous criteria and announced plans for an official launch soon. He urged all stakeholders to actively support the initiative and leverage the sector to benefit society.

Presenting the study, Ato Dawit Dikasso shared that efforts are underway to align the production and registration of traditional medicines with EFDA's regulatory standards. The forum was designed to raise awareness among stakeholders before implementing the initiative.

During discussions held with stakeholders including representatives from the Regional Traditional Medicine Association, regional regulators, and drug manufacturers, a coordinated approach was proposed to enhance the availability and quality of traditional medicines. Participants agreed on the importance of collaboration and pledged their contributions to advancing this critical sector.

This initiative underscores EFDA's commitment to integrating traditional medicine into Ethiopia's healthcare framework, ensuring safety, efficacy, and accessibility for all.



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Public Alert

Tegretol Oral Suspension, Restriction of Use in Neonates

Novartis Phana Schweiz AG, the market authorization holder/manufacturer, has notified the Eihiopian Foed and Drug Authority (EFDA)) that TegretolD (carbamazepine) I00 mg/Sml Oral Suspension (Os), a product usually used for the management of generalized tonic-clonic and partial scizures, is no longcr recommended for neonates (below4 wecks of age for term babies or 44 wecks post-menstrual age for pre-term babies) due to the amount of propylene glycol (PG) in this formulation. Propylerne glycol one of the excipients in this product, is generally recognized as safe by the US Food and Drug Administration (FDA) for uses in food and tobacco products,phameceuticals, and cosmctics. However, the amount in this product is beyond the safety limnit for nconatcs mentioned in this alert letter. Therefore, the Authority (EFDA) requests all health professionals to avoid prescribing and dispensing the medicine for neonates since the risk of using this medicine in neonates outweigh its benefits.

The community was cautioned against using the medicine named RELIEF

The Ethiopian Food and Drug Authority has issued a warning to the public against using an unapproved drug known as RELIEF.

According to an official statement, the drug, circulating in the Ethiopian market, is believed to contain diclofenac, paracetamol, chlorpheniramine, and magnesium trisilicate.

The official emphasized that the quality, safety, and efficacy of this drug have not been legally registered or verified by the authority.It has been noted that the drug may cause side effects such as loss of appetite, diarrhea, stomach pain, nausea, vomiting, insomnia, fatigue, visual disturbances, dizziness, headache, skin rash, and elevated liver enzyme levels. Additionally, prolonged use of the drug could lead to kidney damage.

Research indicates that prolonged use of this drug can significantly increase the risk of severe liver and kidney damage, heart failure, and stroke. The public is urged to avoid using this drug and, if found in their area, to report it immediately by calling the toll-free number 8482 or contacting the Ethiopian Food and Drug Authority or regional health regulatory authorities.

Public Alert

The Ethiopia Food and Drug Authority mandated by article 38 Food and Medicine Administration Proclamation 1112/2019 to perform periodic monitoring of the safety, quality and efficacy of medicine through surveillance.

The Regulatory Authority is committed to safeguarding public health by ensuring the safety, efficacy, and quality of medicines available in the market. As part of the ongoing efforts, the authority has conducted post marketing surveillance on antimalaria medicines and found unregistered products circulating in Ethiopian market. Upon conducting quality control testing of the samples with accredited quality control laboratory, it was determined that they failed to meet the established specification standards which may lead to ineffective treatment or serious health risks.

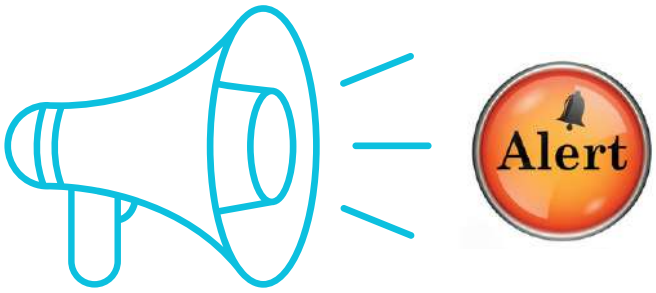
Therefore, the authority wishes to alert the public not to use the attached batches of Antimalaria medicines. If you have any of these antimalarial medicines from the affected batches, it's best to stop using them immediately and return to the facility of purchase or nearest healthcare facility.

The authority urges both health institutions and healthcare professionals to ensure that the antimalaria drugs whose batch numbers are listed below are not distributed to patients and that they are disposed of by following the necessary procedures.

Furthermore, it's essential for health facilities, retailers, and healthcare professionals to be vigilant in monitoring the supply chain to prevent the distribution and use of substandard and counterfeit pharmaceutical products. The Ethiopian Food and Drug Authority (EFDA) is urging everyone to report any suspicious, substandard, or falsified medicinal products through ADE reporting form, via email at pharmacovigilance@efda.gov.et , or by calling the toll-free number 8482.

The link provided below takes you to a list of health products that have been registered with the Ethiopian Food and Drug Authority.

eRIS - Electronic Regulatory Information System
https://eris.efda.gov.et/products



Public Alert

The list of Medicines that have failed Quality Control Testing

S/N	Name of Medicine		Batch no.	manufacturer	Product Registration Status in Ethiopia	Remark
	Generic Name	Brand Name				
1.	Artesunate 60mg/2ml powder for injection	Balsunate 60 mg	E22DP136	Bal pharma limited	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)
2.	Primaquine Phosphate IP 15 mg tablet	Primaquine Phosphate IP 15 mg tablet	PCQ-18	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
3.	Artesunate 120 mg injection	ZIFF ART-120	D0172313A	Unknown	Not Registered ያልተመዘገበ	The product did not comply labeling information with the manufacturer is not clearly described on the label
4.	Chloroquine phosphate 250 mg tablet	MALARIA-BEN	AMB-13	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter dissolution by UV
5.	Artesunate 60 mg powder for injection	ARNATE 60mg/vial	T and G DII2232068	T&G Medicare India	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)
6.	Chloroquine phosphate tablets 250mg	MALARIA-BEN	AMB-16	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
7.	primaquine Phosphate Tablets IP 15mg	Primaquine Phosphate Tablets IP 15mg	PCQ-16	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
8.	Artesunate 60 mg/mL	Malarbeat 60mg	MRE-01	Hanano India	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)