

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.

The Authority Gains International and National Accreditations, Boosting Africa’s Regulatory Leadership

The Ethiopian Food and Drug Authority (EFDA) has announced that the international and national accreditations it has obtained in 48 measurement standards have significantly enhanced its capacity to achieve its vision of becoming Africa’s Center of Excellence.

During an accreditation recognition ceremony held in Addis Ababa on July 2, 2025 the EFDA received accreditation from the Ethiopian Accreditation Service and the American ANSI National Accreditation Board (ANAB) in various areas, including food manufacturing, post-market surveillance, pharmaceuticals, and medical laboratory equipment.

Speaking at the event, Health Minister Dr. Mekdes Daba stated that the international accreditations secured by the authority mark a major step forward, significantly improving disease prevention and control efforts. She emphasized that this achievement will enhance the quality and scope of

regulatory work, bringing the country closer to its goal of global competitiveness in stringent regulatory oversight.

Deputy Health Minister Dr. Ferehiwot Abebe, who opened the ceremony, noted that the efforts to strengthen regulatory frameworks in both operations and organization have been successful. She congratulated all stakeholders, describing the new and renewed accreditations as a significant national achievement.

Dr. Dereje Duguma, another Deputy Health Minister, highlighted in his remarks that the success was not easily attained and stressed

the need for continued dedication to maintain and build upon these accomplishments.

EFDA Director-General Heran Gerba acknowledged that the success was not achieved alone but through the collaborative efforts of various stakeholders, including the strong support and follow-up from the Ministry of Health's leadership.

During the event, certificates of appreciation were awarded to institutions and individuals who contributed to securing the accreditations.

"Food Safety: Science in Action" – World Food Safety Day Celebrated in Ethiopia

World Food Safety Day was celebrated under the theme "Food Safety: Science in Action," with various events aimed at raising public awareness about food safety.

The Authority, in collaboration with the Ethiopian Agricultural Authority, the Ethiopian Standards Institute, and other international organizations, marked the occasion on June 7, 2025 by hosting a scientific symposium. The event featured research presentations and panel discussions on best practices in food safety.

Heran Gerba, Director-General of EFDA, emphasized that this year's theme highlights the critical role of science in ensuring food safety. He called on the government, businesses, and consumers to adopt science-based guidelines and practices to strengthen food safety measures.

"Science is at the heart of food safety," said Heran. "It helps us understand why food becomes unsafe, how to prevent foodborne illnesses, and guides us in making informed decisions."



She further noted that World Food Safety Day, observed annually on June 7, serves as a key platform to promote scientific knowledge in reducing disease risks, cutting economic losses, and improving lives.

Representatives from the Agricultural Authority and the World Food Programme also delivered remarks, stressing the importance of evidence-based policies and practices. This year marked the 7th global observance and the 6th national celebration in Ethiopia, featuring research presentations and interactive discussions.

The event reinforced Ethiopia's commitment to advancing food safety through science, policy, and public engagement.



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The Authority Marks 33rd World No Tobacco Day with Calls to Protect Youth from Industry Tactics

The Authority commemorated World No Tobacco Day on May 31, 2025, marking its 33rd national observance under the theme "Unmasking the Appeal: Exposing Industry Tactics on Tobacco and Nicotine Products." The event, organized by the Ethiopian Food and Drug Authority (EFDA) in collaboration with the Addis Ababa Food and Drug Administration, brought together health officials and civil society representatives to address the growing threat of tobacco use among youth.

During the commemoration, health authorities sounded the alarm on tobacco companies' aggressive marketing strategies targeting young people. Mr. Getachew Genetie, Head of Drug Inspection and Law Enforcement at EFDA, emphasized how the industry employs deceptive advertising, particularly through social media and school environments,

to lure new generations into nicotine addiction. "These tactics deliberately make tobacco products appear glamorous and harmless when they are anything but," he stated.

The event highlighted the severe health and economic consequences of tobacco use, which claims over 8 million lives globally each year. Mrs. Muluemebet Tadesse, Chief Executive Officer of the Addis Ababa Food and Drug Administration, presented alarming data showing rising tobacco use among Ethiopian adolescents. "We're seeing children as young as 13 experimenting with nicotine products due to these predatory marketing practices," she revealed.

This year's observance carried special significance as Ethiopia prepares to strengthen its tobacco control legislation. Health officials announced plans to introduce stricter regulations on tobacco advertising,



packaging, and sales, particularly near educational institutions. The government also pledged to expand public awareness campaigns about the dangers of tobacco use, with a special focus on digital platforms where youth are most vulnerable to industry influence.

As the event concluded, organizers called for a united front against the tobacco industry's tactics, urging parents, educators, and community leaders to play a more active role in protecting young people. The commemoration served as both a warning about the persistent threat of tobacco and a reaffirmation of Ethiopia's commitment to creating a tobacco-free generation.

In a separate development, on June 24, 2025, EFDA and members of the National Tobacco Control Coordinating Committee signed a Memorandum of Understanding (MoU) to boost enforcement of tobacco control regulations.

The MoU brings together government agencies and civil society organizations to improve coordination, enforce advertising bans, expand smoke-free public spaces, and raise public awareness.

EFDA Director General Heran Gerba stated that the agreement will support the implementation of both national tobacco laws and international obligations under the WHO Framework Convention on Tobacco Control.

“This collaboration marks a new phase in Ethiopia’s fight against tobacco and our commitment to protecting public health—especially among youth,” she said.

Ethiopia to Localize Health Warning Images on Tobacco Products.

June 30, 2025– The Ethiopian Food and Drug Authority (EFDA), in collaboration with the Black Lion Specialized Hospital at Addis Ababa University's College of Health science, has officially commenced the process of replacing generic health

warning images on tobacco products with nationally relevant imagery. This initiative follows a memorandum of understanding signed between the two institutions several months ago



Dr. Abdurazak Ahmed, CEO of Black Lion Specialized Hospital at Addis Ababa University's College of Health Sciences, emphasized the significance of making health warnings on tobacco products more nationally resonant. He stated that using images with psychological and environmental relevance will greatly contribute to the effectiveness of the messages, ensuring they achieve their intended goal. Dr. Ahmed affirmed his institution's unwavering commitment to the full implementation of this project.

During the launch ceremony, Ato Abera Deneke, Public Relations and Communication Executive at the EFDA, explained that efforts have been underway to ensure tobacco products carry health warning images and text, as mandated by Proclamation No. 1112/2011 and the tobacco control directive. He highlighted that these health warnings are known to be effective methods for encouraging public awareness of the dangers of tobacco products and promoting

behavioural change. Therefore, he added, the work to replace the health warning images on tobacco products with national imagery will enhance awareness creation and effective communication, thereby fostering behavioural change.

Professor Andualem Deneke, CEO of Addis Ababa University's College of Health Sciences, also delivered a message at the event, underscoring that no part of the human body remains unaffected by tobacco. He specifically urged law enforcement agencies, including the police and regulatory bodies, to further strengthen their control measures.

Staff Urged to Actively Participate in Completing and Handing Over the Excellence Center Project

On June 22, 2025, employees of the authority visited the under-construction Excellence Center in Addis Ababa.

During the visit, the Director-General of the authority, Heran Gerba, stated that the institution is working with strong focus and dedication to complete the construction of the Excellence Center,

which is currently 82% complete. The center is designed to fulfill the authority's vision of becoming a Center of Excellence for the regulation of food and health products in Africa.

The Director-General acknowledged that the project has faced numerous challenges to reach this stage.



However, thanks to the unwavering commitment of senior officials from the Ministry of Health, the consistent follow-up and support of the authority's staff, and financial backing from the World Bank, significant progress has been achieved. She emphasized that all employees must actively engage and take ownership to ensure the project's success, as it will serve as a key hub for capacity building in Ethiopia and across Africa.

Additionally, she expressed profound gratitude to the institutions and individuals contributing to the project's advancement. Some of the employees who toured the center shared their enthusiasm, noting that once operational, the facility will bring substantial benefits to the nation. They pledged their full support until the center is fully functional and begins delivering its intended services.

Monitoring and Reporting on Medicine and Vaccine Safety is Increasing, But Regions Urged to Strengthen System with Ownership and Commitment

Although monitoring and reporting on medicine and vaccine safety have been improving, regions have been called upon to work with greater ownership and commitment to further strengthen the system.

From July 28–30, 2025, the authority, in collaboration with stakeholders, conducted a review of the 2017 fiscal year's medicine and vaccine safety monitoring plan implementation and a discussion on the 2018 fiscal year plan in Adama city.

In his opening speech, Seyoum Woldie, Deputy Director General of the Medicine Sector at the authority, emphasized that efforts should continue to enhance patient and medicine user participation in medicine safety monitoring, building capa-

city by training health professionals at all levels, and strengthen supportive supervision and reporting systems. He stated that medicine safety monitoring should not be seen as an additional task but must be integrated as a core institutional function alongside regular service delivery.

Asnakech Alemu, the Executive Lead for Medicine Safety Monitoring and Clinical Trials at the authority, noted that while encouraging results have been achieved in medicine safety reports, vaccine safety monitoring, and product quality deficiency reports, institutions at all levels must work with greater focus and determination to further increase reporting.



During the forum, representatives from 12 regions and two city administrations presented their performance reports on medicine and vaccine safety monitoring and reporting activities carried out in the 2017 fiscal year, followed by extensive discussions.

The forum also highlighted the challenges regions faced, the solutions they implemented, and best practices in training and experience-sharing that could serve as models.

Additionally, the forum reviewed the current status of national medicine and vaccine safety monitoring and supportive supervision, as well as the sector's plan for the 2018 fiscal year, followed by in-depth discussions.

Participants included officials from the Ministry of Health, the Ethiopian Public Health Institute, regional food and medicine regulatory bodies, branch office heads of the authority, and representatives of associations and partner organizations.

Authority Leadership and Staff Conduct Fourth-Round Tree Planting Campaign Under the Motto: "Our Green Legacy is the Breath of Life: A Source of Food, Medicine, and Heritage for Generations"

In line with its annual winter volunteer month initiative, the leadership and staff of the Authority conducted a comprehensive three-phase tree planting campaign under the theme, "Our Green Legacy is the Breath of Life: A Source of Food, Medicine, and Heritage for Generations."

The first round took place on July 22, 2025, at the site of the Authority's under-construction Excellence Center.

During the event, Director General Heran Gerba announced that over 20,000 seedlings—including indigenous, medicinal, and edible species—would be planted by employees as part of the national Green Legacy initiative.

The second round was held on July 25, 2025, at Hawas Health Center in Adama City Administration, following the conclusion of the Authority's 2017 Ethiopian Fiscal Year Performance Evaluation Forum. Participants planted seedlings selected for their medicinal and nutritional value.



W/ro Semira Mohammed, Head of the Adama City Health Office, praised the initiative and affirmed that the planted seedlings would be carefully nurtured to maturity to maximize their environmental and health benefits.

In response, Director General Heran Gerba expressed appreciation for the health center’s collaboration and reiterated the Authority’s commitment to enhancing public health through sustained partnerships. She emphasized that all seedlings would be closely monitored to ensure successful growth and long-term impact.

The third round took place on June 28, 2025, in Gelan Sub-City, Sheger City, in collaboration with the Ethiopian Youth Federation.

Speaking at the event, Director General Heran Gerba highlighted the significance of planting trees that serve dual roles—both as sources of nutrition and medicine. She noted that the campaign’s collaborative nature offers a scalable model for other sectors, asserting that such united efforts can help propel Ethiopia from poverty toward prosperity

Honorable John Ahmed Aba Milik, representative of the Ethiopian Youth Federation, commended participants, stating: "By taking part in this tree planting campaign, you have contributed to a national legacy that will benefit future generations. Congratulations on this achievement. We encourage all participants to remain committed to nurturing these seedlings to ensure their sustainability."

Additionally, on July 31, 2025, under the slogan "Let’s Plant and Expand!", the Authority’s officials and employees participated in a national greening campaign in Gefersa, West Shewa Zone, Oromia Region, as part of the "One Jember" 700-million national tree planting initiative. The event was conducted in partnership with the Ethiopian Prosthetic and Orthotic Service and Burau Sub-City Administration.

This series of campaigns marks the fourth time the Authority has actively contributed to green development and afforestation efforts during the current rainy season, reaffirming its dedication to environmental sustainability and community health.

Media, Social Media Experts, and Public Relations Heads Urged to Promote Public Awareness and Responsibility on Food Safety



Two rounds of training were conducted in Adama from May 11–12 and May 15–16, 2025, targeting media, public relations, and social media professionals. The sessions emphasized the vital role of communication experts in promoting public awareness and fostering self-regulation regarding food and health product safety.

Organized by the Ethiopian Food and Drug Authority (EFDA) in collaboration with SNV, the training focused on the quality and safety control of milk and dairy products. It brought together public relations officers, media professionals, and social media influencers to deepen their understanding of food safety and their contributions to protecting public health.

Alemwork Eshete, Head of the Director General's Office at EFDA, underscored that disease prevention is a key component of the government's broader strategy to ensure a healthy and productive society. She urged social media professionals to play an active role in raising awareness and empowering communities to be self-regulating when it comes to food and health product safety.

Echoing this message, Heran Gerba, Director General of the Authority, emphasized the importance of leveraging media platforms and the communication skills gained from the training to promote food safety "from farm to fork." She noted that ensuring food quality and safety requires a mindset shift across all sectors and strengthened collaboration among stakeholders.

Negash Sime, Deputy Director General of the Food Sector, reiterated that preventing foodborne diseases and deaths demands a collective effort. He called on both social and traditional media outlets to scale up public education campaigns and contribute to combating food adulteration and the illegal trade of harmful food and health products.

He also stressed that regulatory efforts cannot be carried out by a single institution alone. A coordinated and inclusive approach involving regulatory bodies, the media, and the wider community is essential. He commended the Authority's Public Relations and Communications Executive Office for its continued public engagement initiatives and encouraged their further expansion.

Key topics covered during the training included Food and Medicine Administration Proclamation No. 1112/2019, Common legal violations and enforcement measures, Standards for food and milk quality and safety, The role of media and communication professionals in food safety and EFDA's nine-month performance report for the 2025 fiscal year.

Participants actively engaged in interactive discussions aimed at empowering the public to make informed decisions, advocate for safe food practices, and uphold community-level vigilance for better health outcomes.

Ethiopian Food and Drug Authority Strengthens Collaboration with stakeholders to Combat Illegal Trade of Food and Medicines



The Ethiopian Food and Drug Authority (EFDA) has launched a major nationwide initiative to crack down on the illegal trade of food and medical products. The regulatory body is working closely with regional authorities to strengthen enforcement and protect consumers from substandard and dangerous goods.

For the past three months, EFDA officials have held high-level meetings across several regions to coordinate efforts. The campaign comes amid growing concerns about counterfeit medicines and adulterated food products entering the market. Authorities warn these illegal products pose serious risks to public health and the economy.

The first major stakeholder meeting took place in Wolqite, where EFDA partnered with the Central Ethiopia Health Bureau. Regional health chief Samuel Darge reported significant progress in pharmaceutical and food safety regulation over the past year. "Our joint efforts with EFDA have yielded positive results, but we must remain vigilant," Samuel told attendees.

Fikadu Neman, head of EFDA's Hawassa branch, outlined the authority's ambitious vision to become Africa's excellence center food and drug regulator. The branch has been working closely with local inspectors to monitor product quality and safety standards.

In Mekelle, officials turned their attention to the growing problem of smuggled medicines. Deputy bureau head Yusuf Ibrahim revealed that fake and unregulated drugs continue to enter the region through porous borders. "These illegal products endanger lives and undermine our healthcare system," Yusuf warned during the forum.

The Tigray administration pledged to strengthen border checks and increase penalties for traffickers. Local authorities will work with customs officials to intercept suspicious shipments before they reach consumers.

The campaign moved to Hawassa, where EFDA Director-General Heran Gerba addressed regional health leaders. She emphasized that counterfeit goods not only harm health but also damage legitimate businesses. "When illegal products flood the market, everyone loses," Heran stated.

Meanwhile, in Bonga town, Southwest Ethiopia Opening the forum, Demelash Niguise, Deputy Administrator of the Keffa Zone and Head of the Revenue Office, highlighted the effective measures taken in the zone during the 2017 fiscal year, particularly in combating illegal malaria drug trafficking and food adulteration. His remarks underscored the importance of sustained regulatory enforcement at the local level.

Director-General of the Authority, Heran Gereba stressed the importance of sustained effort. "This is not a one-time operation but an ongoing commitment to protecting Ethiopian consumers," she said. The authority will provide additional training and resources to regional regulators in the months ahead.

Authorities are urging citizens to report suspicious products through EFDA's hotlines and mobile apps. "We all have a role to play in keeping dangerous goods off our shelves," Heran reminded the public.

SPECIAL EDITION

The Authority's Major Achievements in Strategic Actions and Key Activity Performance in the 2017 Ethiopian Budget Year

Enhancing Public Ownership of Regulation

The regulatory authority actively engaged the public through various media platforms to promote awareness and oversight of regulated products. During the fiscal year, it exceeded its target by conducting 91 live radio and TV discussions (>100%), focusing on critical issues such as milk product regulations, drug safety monitoring, medical device control, cosmetic product standards, and proper medicine usage. Additionally, it surpassed its goals for media outreach, achieving 189 news coverages (>100%) and 81 short messages/programs (94.19%), addressing topics like substandard malaria drugs, food adulteration, and illegal cosmetics. Public awareness campaigns were conducted in Amharic and Afan Oromo, covering antimicrobial resistance, rational drug use, adverse drug reactions, and cosmetic safety, with materials disseminated via print, electronic, and social media. A significant public alert was issued regarding a fake Artemether injection (Batch No. 231104SPF) from China, which lacked the active ingredient, ensuring its removal from circulation. The authority successfully reached its target of 50 million people (100%) through media campaigns, educating the public on good manufacturing practices, drug regulation, and food fortification. Furthermore, it collected 1,461 public complaints (24.48% of the 17,000 target), addressing issues such as non-compliant salt production, expired oil sales, illegal cosmetics, and unregulated drug use, while maintaining a 100% response rate for

verified concerns. These efforts strengthened public participation in regulatory oversight and ensured greater transparency in product safety.

Improving Efficiency and Effectiveness

The regulatory authority has taken significant steps to enhance operational efficiency and financial management. During the fiscal year, it exceeded its domestic revenue collection target, gathering 182.8 million Birr (>100%) against a planned 157.92 million Birr, while securing 450 million Birr (90%) from development partners against a 500 million Birr goal. To ensure timely budget execution and accountability, the authority prepared and submitted program-based budget performance reports, ensuring alignment between expenditures and outcomes. Additionally, it finalized and submitted budget requests for 2018 to the Ministry of Finance and Economic Cooperation, along with quarterly and monthly budget projections for 2017. Audit reports for Q4 of 2016 and Q1-Q3 of 2017 were also completed and submitted, covering payroll, contract payments, overtime compensations, and cash transfers. The authority addressed previous audit findings from the Federal Auditor General's 2015 report, demonstrating corrective actions in areas such as payable/receivable accounts and budget utilization, though some issues require continued attention. An interim audit for 2017 was conducted, with a full audit to follow upon fiscal year closure.

Strengthening Food Safety Control

To enhance food safety regulation, the authority implemented several key measures:

- **Product Registration & Market Approval:** Against a target of 3,656 food items, it approved 4,186 (>100%), including 93 supplementary foods, 10 infant/child foods, 508 specialized food products, and 3,575 pre-market notifications.
- **Competency Certification:** The authority issued competency certificates to 128 food manufacturers (96.97%) and 1,354 food distributors (>100%), surpassing initial goals of 132 producers and 998 distributors.
- **Post-License Audits:** It conducted audit inspections for 606 food producers (94.54%) and 1,303 distributors (59.07%) out of planned 641 manufacturers and 2,206 suppliers.
- **Quality Assurance Systems:** Efforts to enforce internal quality control systems succeeded in 90 factories (47.37%) and 418 distributors (79.62%), against targets of 190 producers and 525 suppliers.
- **Product Testing:** Consignment quality inspections were performed on 43 out of 55 selected food items (78.18%), with 385 samples tested overall. Of these, 292 met national standards, 19 failed, and 74 remain under review.
- **Import Control:** The authority ensured safety compliance for 1,624.44 tons (80.8%) of imported infant formula (against 2,010 tons planned), 2,184,797.13 tons (29.03%) of general food imports (target: 7,525,471.56 tons), 13,489.79 tons (100%) of food additives, and 316,709.4 tons of salt, issuing clearance approvals accordingly.

Strengthening the Identification, Prevention, and Response to Adulterated and Illegal Food Products

To enhance food safety and combat illegal food products, the regulatory authority conducted 81 market inspections (exceeding the target of 62 rounds) across various food distribution centers and retail outlets. Key enforcement actions included:

- **Seizure of Non-Compliant Products:**
- **Kombolcha, Afar (Semera, Logiya, Asaita, Dubti, Mile, Gewane, and Awash cities):** Products worth 1,814,899 ETB were seized due to lack of labeling, expired status, or substandard quality.
- **Jimma, Agaro, Metu, Bale, Mizan Aman, Bonga, Tarcha, Gambella, Saja, and Fofa:** Adulterated and expired food items valued at 4,243,093 ETB were confiscated.
- **Dire Dawa and Surroundings:** Products worth 11,025,750 ETB were removed from the market.
- **Mekele and Surroundings:** Contaminated water (313,800 ETB) and sugar (120,000 ETB) were intercepted, totaling 433,800 ETB.
- **Additional Seizures:**
- 458 kg of fake "Fafa" product (worth 458,000 ETB) intended for sale.
- 3,413,853 ETB worth of non-compliant products.
- 300 kg of spoiled Zalabera (105,000 ETB) in Dessie.
- 140 kg of spoiled Zalabera (49,000 ETB) in Kombolcha.
- 400 quintals of non-iodized salt and expired food-grade salt.
- **Crackdown on Counterfeit and Illegally Distributed Goods:**
- In Dessie, counterfeit oil (brand impersonation, no expiry date) worth 441,600 ETB was seized, and legal action was taken against three businesses.
- In Jimma Zone (Limukosa Woreda), 23 quintals of suspected adulterated pepper (1,035,000 ETB) were intercepted, with legal proceedings initiated.
- In Kombolcha, 35,000 ETB worth of unlabeled, spoiled powdered milk was confiscated in collaboration with trade and police offices.
- **Border Control and Interceptions:**
- 20 containers of illegal products were rejected at Bahir Dar port.
- 1,680 quintals of contraband salt (four trucks, 1,600,000 ETB) were returned to their origin.
- Illegal oil and aid-diverted powdered milk were seized from three distributors and retail shops.
- **Annual Totals:**
- 53,553,928 ETB, 381,126 tons, and 54,623,576 kg of unfit products were removed from the market.

- 16,422,927 ETB worth of products were ordered for collection.
- 77,977,513 ETB, 558 tons, and 557,637 kg of food items were repatriated to their origin countries.

Enhancing the Regulation of Drug Safety, Quality, Efficacy, and Rational Use

One of the key responsibilities of the authority is to ensure the safety, quality, and efficacy of medicines before they enter the market through pre-market evaluation and market authorization. During the reporting period, the authority planned to grant market authorization for 239 new drug applications (SRA), of which 70 (29.29%) were approved. Additionally, 6 (100%) new molecular entities, 30 (over 100%) new biological and vaccine products, 520 (45.41%) generic drugs out of 1,145, and 120 (37.74%) low-risk medicines out of 318 were authorized. In total, 746 (43.27%) new drug market authorizations were issued out of 1,724 planned for the fiscal year.

A major requirement for market authorization is compliance with Good Manufacturing Practice (GMP) certification. However, delays in foreign GMP inspections due to government travel restrictions have significantly impacted performance in this area.

Strengthening Pharmaceutical Quality Control

To ensure drug quality, pre-licensing inspections of manufacturers, distributors, and small-scale pharmaceutical producers are critical. During this period:

- 591 (100%) out of 516 planned manufacturer and distributor licenses were issued.
- 51 (82.26%) out of 62 small and medium-sized pharmaceutical producers received authorization.

- Audit inspections were conducted to monitor compliance:
- 100% (12/12) domestic manufacturers were inspected.
- 1,685 (100%) risk-based audits were conducted on manufacturers and distributors, exceeding the target of 1,584.
- 50 (69.4%) out of 72 small-scale producers were audited.
- Foreign GMP Inspections
- Only 18 (18.75%) out of 96 planned foreign GMP inspections were completed due to delays in government-approved international travel, affecting overall performance.
- Market Surveillance and Enforcement
- To combat drug diversion and illegal trade, the authority conducted:
- Intelligence-led operations, health facility audits, market surveys, and port controls in collaboration with customs.
- Inspections of 56 hospitals, clinics, and health posts, 78 pharmacies, and 49 other facilities, uncovering 47 batches of diverted medicines, 218 unregistered batches, 121 invoices lacking proper documentation, and 6 cases of overstocking.
- Confiscation of 45 tons (450 quintals) of illegal medicines at customs, including 0.9 tons (9 quintals) diverted from government institutions, valued at 313,906,382 ETB.
- Administrative actions against 56 health facilities, pharmacies, and drug stores, including 21 facing 3–6 month suspensions and fines ranging 10,000–60,000 ETB, while 60 received written warnings.
- Quality Testing and Post-Market Surveillance
- Malaria drug testing: 49 batches of Artemether-Lumefantrine tablets, 4 batches of Chloroquine Phosphate, 8 batches of Artesunate injections, and 9 batches of Artemether injections were tested. Out of 141 samples, 94 passed, 3 failed, and 35 are pending.
- Post-market surveillance: 134 samples were collected out of 308 planned.
- Regional Enforcement Operations
- Collaborations with regional health bureaus, police, and customs led to:
- Confiscation of 455,290 ETB worth of drugs in Somali, Harari, East & West Hararghe zones.

- Seizure of 1,213,491 ETB worth of illegal malaria drugs in Afar (Semera, Dubti, Asaita) and Northeast Kombolcha.
- 192,395 ETB worth of drugs seized in Dessie, Kombolcha, and Awash areas.
- 235,096 ETB worth of drugs intercepted in Debre Berhan, Harbu, and Kemise.
- 6,492,658 ETB worth of medicines seized around Hawassa, totaling 8,133,640 ETB for the year.

- 12,394,105.9 ETB worth of drugs withdrawn from the market for various violations.

Major Crackdowns on Illegal Trade

- Joint operations with federal police, customs, and Interpol in Konso, Jimma, and Addis Ababa led to the seizure of 31,872,000 ETB worth of illegal malaria drugs in Konso alone.
- 15 facilities in Hawassa were found holding over 3.5 million ETB in illegal medicines, totaling 39,341,200 ETB.
- 90 doping drugs intercepted during an individual smuggling attempt.
- 37,271,000 ETB worth of unregistered drugs seized in Karat (Konso) during a raid on three houses.

- 20,362,333.53 ETB worth of medicines removed from circulation in Addis Ababa.

Narcotics and Precursor Chemical Control

- 125 (>100%) narcotic and psychotropic drug licenses issued out of 80 planned.
- 110 (>100%) precursor chemical licenses issued out of 30 planned.

Overall Impact

- 1,098,180,644 ETB worth of unsafe medicines were removed from the market.
- 230,325,215 ETB worth of drugs were seized and collected.
- Quality-controlled drug exports worth 165,410,293,296.63 ETB, 3,938,412,194.54 ETB in medical supplies, and 198,648,822.61 ETB in NPS drugs were approved for release.

Strengthening the Quality, Safety, and Operational Control of Medical Devices

- To ensure the quality, safety, and efficacy of medical devices, the authority conducted evaluations and granted market authorizations for various categories. During the reporting period:
 - 302 (>100%) new Non-In Vitro Diagnostic (NIVD) medical devices were authorized against a target of 200.
 - 291 (58.2%) out of 500 planned new NIVD devices received market approval.
 - 334 (66.8%) out of 500 new In Vitro Diagnostic (IVD) devices were authorized.
 - Overall, 927 (77.25%) out of 1,200 planned medical device authorizations were approved.

Quality Testing and Inspections

- Microbiological quality testing was conducted on 26 (27.08%) out of 96 planned medical device samples.
- 19 types of medical devices underwent microbiological testing, with 5 (26.32%) completed.
- Pre-Licensing Inspections
 - Manufacturers & Distributors:
 - 2 (67%) out of 3 medical device manufacturers were inspected.
 - 40 (90.91%) out of 44 medical device importers/distributors were assessed.
 - 23 (85.19%) out of 27 low-risk medical device manufacturers were inspected.
- Post-Market Surveillance & Compliance
 - Foreign GMP Inspections: Planned inspections for 25 foreign manufacturers were not conducted due to travel restrictions.

Domestic Facility Audits:

- 17 (54.84%) out of 31 medical device manufacturers.
- 97 (>100%) out of 99 importers/distributors.
- 26 (83.87%) out of 31 low-risk manufacturers.
- Import Quality Control
 - 40,089,232,194.18 ETB worth of medical devices underwent quality checks before clearance.

Enhancing Cosmetic Product Safety Controls

- 170 (40.09%) out of 424 new cosmetic product notifications were approved.
- Pre-Licensing Inspections:
 - 16 (66%) out of 24 cosmetic manufacturers.
 - 104 (99.05%) out of 105 importers/distributors.
- Post-Market Inspections:
 - 81 (61.8%) out of 131 manufacturers.
 - 93 (53.76%) out of 173 importers/distributors.

Import Clearance:

- 75,587,490,642.12 ETB in cosmetics.
- 1,886,832,859.38 ETB in raw materials.
- 1,000,000 ETB worth of substandard cosmetics were removed from the market.

Strengthening Tobacco Control Measures

- Regional Tobacco Control Committees were established and reinforced.
- Illegal Tobacco Seizures:
 - 670 packs (worth 103,640 ETB) of unauthorized brands (Nyala, ORIS, Shamlan, etc.).
 - 16,348,864 ETB worth of illegal tobacco products confiscated.
 - 5.4 quintals of smuggled cigarettes seized.
- 100% Smoke-Free Public Spaces enforcement in Addis Ababa, Dire Dawa, Harar, and other cities.

Advancing Quality Management Systems

- WHO Maturity Level 3 recognition was pursued, with corrective action plans implemented.
- ISO 17020 Accreditation: Recommended after evaluation, pending minor corrections.
- Laboratory Upgrades:
 - Drug, medical device, and food testing labs maintained accreditation.
 - New IT systems (Shimadzu CDS, chemical inventory software) installed.
- ERIS System Transition: Migrated to Ethio Telecom Cloud for sustainability.

Strengthening Legal Frameworks

- 5 New Guidelines finalized (Traditional Medicine, Food Fortification, Medical Gas, etc.).
- 5 Suspended Directives reinstated (GMP, Administrative Sanctions, etc.).
- Crime Monitoring:
 - 1,011 criminal cases (2012-2016) analyzed, with 513 resolved.
 - 11 new cases referred to federal police.

Human Resource Development

- 554 staff trained across various fields.
- 201 inspectors and 166 healthcare workers received specialized training.

Partnerships & Regulatory Collaboration

- WHO Collaborative Registration: Achieved 100% for medicines and medical devices.
- IGAD & AUDA-NEPAD: Contributed to Africa Regulatory Reliance Framework.
- International Engagements: Participation in ICDRA (India) and continental dossier assessments.

Infrastructure Development

- Competence Center Construction: 82% completed.
- Clinical Trial System: New software developed for trial registration.



We encourage you to connect with the Ethiopian Food and Drug Authority (EFDA) through our official social media channels for the most accurate and verified information:

LinkedIn: (<https://www.linkedin.com/company/ethiopian-food-and-drug-authority>) for insights into our regulatory initiatives and professional updates.

Facebook: (<https://www.facebook.com/share/18c8cP82gT/>) to receive current news, events, and information about our community outreach efforts.

Telegram: (<http://t.me/ethiopianfoodanddrugauthority>) for timely updates and important announcements regarding food and drug safety.

Please be advised that any information not disseminated through these official channels has not been verified by EFDA. We emphasize the importance of relying on our official communications to ensure the reliability and integrity of the information you receive. Together, let us promote public health and safety in Ethiopia effectively!